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* The responses to the questionnaire in the original languages are available on the SCP electronic forum at: <http://www.wipo.int/scp/en/exceptions/>.

COMPILATION OF RESPONSES TO THE QUESTIONNAIRE ON EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

Country: ALBANIA
Office: General Directorate of Patents and Trademarks

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

According to Article 5 of our Law No 9947 date 07/07/2008 Patentable Inventions are:

- *Patents shall be granted for inventions, in all fields of technology, provided that they are:*
 - (a) *new;*
 - (b) *involve an inventive step; and*
 - (c) *are susceptible of industrial application.*

- *The subject-matter of an invention protected by a patent may be a product or a process.*

- *Biotechnological inventions shall also be patentable if they concern:*
 - (a) *biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;*
 - (b) *plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;*
 - (c) *microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety;*
 - (ç) *an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.*

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

According to Article 6 of our Law No 9947 date 07/07/2008 Patents shall not be granted in respect of:

- *Inventions the commercial exploitation of which would be contrary to public order, morality or public health and human life; such exploitation may be deemed to be so contrary even if it is not prohibited by law or regulation. On this basis, the following, in particular, shall be considered unpatentable:*
 - (a) *processes for cloning human beings;*
 - (b) *processes for modifying the germ line genetic identity of human beings;*

- (c) *uses of human embryos for industrial or commercial purposes;*
- (ç) *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

- Plant or animal varieties or essentially biological processes for the production of plants or animals, without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process;

- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene

- Methods for treatment of the human body or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

- Substances obtained through internal nuclear transformations for military purposes.

- The following in particular shall not be regarded as inventions within the meaning of paragraph 1 Article 6 of Law No 9947 date 07/07/2008:

- (a) *discoveries, scientific theories and mathematical methods;*
- (b) *aesthetic creations;*
- (c) *schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;*
- (ç) *presentations of information.*

- The above paragraph shall exclude patentability of the subject-matter or activities referred to therein only to the extent to which a patent application or a patent relates to such subject-matter or activities as such.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

According to Article 36 of our Law No 9947 date 07/07/2008 the rights conferred by a patent are:

1. When a patent is related to a product, the owner of the patent shall have the exclusive right to prohibit any third party from performing the following actions without his authorization: making, using, offering for sale, selling, stocking or importing for these purposes that product.

2. When the patent is related to a process, the owner of the patent shall have the exclusive right to prohibit third parties from performing the following actions without his authorization:

- (a) *to use the process that constitutes the subject of the patent;*
- (b) *to use, offer for sale, sell, stock or import for these purposes at least the product obtained directly by that process.*

3. The owner of a patent has the right to assign and to transfer the patent to his successors in title, as well as to make license agreements on the patent.

Article 37. Prohibition of indirect use of the invention

1. *The owner of a patent shall have the right to impede third parties, other than those who have gained the right to use the invention for which the patent was granted, from supplying or offering to supply to a Person, other than one entitled to exploit the patented invention, means relating to an essential element of the invention, for putting it into effect therein, when the third party has knowledge, or when from the circumstances it becomes clear that those means are suitable and intended for putting that invention into effect.*
2. *This provision shall not apply if these means are staple commercial products, except when the third party induces the Person supplied to commit acts prohibited by article 36.*
3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 38 (a) Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

(a) Acts performed privately, not for commercial purposes;

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 7.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 38(b) Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

(b) acts performed merely for experimental purposes relating to the subject matter of the invention;

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 14.-16.

[Note from the Secretariat: response was not provided.]

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Please explain by citing legal provision(s) and/or decision(s):

Acts performed merely for experimental purposes relating to the subject matter of the invention (Article 38(b)).

18.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 38 (c) Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

(c) The extemporaneous individual preparation of a medicine in a pharmacy according to a medical prescription or with other processes that lead to its preparation.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Pharmacists

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 43. Prior Users

1. *The rights conferred by a patent shall have no effect on Persons who within the territory of the Republic of Albania, have used the invention or are in the process of serious and effective preparations for its use, before the filing date of the application, or, in cases when priority is claimed, before the priority date. These Persons shall have the right to continue use or preparations for use.*

2. *The right of prior use may be transferred, with the enterprise or company, or with that part of the enterprise or company where the use or the preparations for use have been made.*

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34.-35.

[Note from the Secretariat: response was not provided.]

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

[Note from the Secretariat: response was not provided.]

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 38 Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

*(c) the use on board **vessels** of other countries of the Paris Union of devices forming the subject of the patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter Albanian waters, provided that such devices are used there exclusively for the needs of the vessel;*

*(d) the use of devices forming the subject of the patent in the construction or operation of **aircraft or spacecraft or land vehicles** of other countries of the Paris Union, or of accessories of such aircraft or land vehicles, when those aircraft or spacecraft or land vehicles temporarily enter Albania;*

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

*The rights conferred by the patent shall not extend to the use on board vessels of other countries of the Paris Union of devices forming the subject of the patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels **temporarily or accidentally** enter Albanian waters, provided that such devices are used there exclusively for the needs of the vessel*

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for

example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Patent Act explicitly stipulates that the subject matter of the patented invention is used exclusively for the needs of the vessel. Article 38(ç).

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 38 Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

- (a) acts performed privately, not for commercial purposes;*
- (b) acts performed merely for experimental purposes relating to the subject matter of the invention;*
- (c) the extemporaneous individual preparation of a medicine in a pharmacy according to a medical prescription or with other processes that lead to its preparation.*
- (ç) the use on board vessels of other countries of the Paris Union of devices forming the subject of the patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter Albanian waters, provided that such devices are used there exclusively for the needs of the vessel;*
- (d) the use of devices forming the subject of the patent in the construction or operation of aircraft or spacecraft or land vehicles of other countries of the Paris Union, or of accessories of such aircraft or land vehicles, when those aircraft or spacecraft or land vehicles temporarily enter Albania;*
- (dh) biological material obtained from the propagation or multiplication of biological material placed in the market by the holder of the patent or with its consent, where multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.*
- (e) the use by a farmer of the product of his crop for propagation or multiplication on his own holding, provided that the reproductive vegetable material was sold or otherwise commercialized by the holder of the patent or with his consent to the farmer, for agricultural purposes.*
- (ë) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animals reproductive material was sold or otherwise commercialized to the farmer by the holder of the patent or with his consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his agricultural activity, but not the sale as part of or for the purpose of commercial reproductive activity.*

52.-54.

[Note from the Secretariat: response was not provided.]

55. The exception covers the regulatory approval of:

Any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Making
Using*

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

Article 39 Exhaustion of rights

The rights conferred by a patent shall not extend to acts committed in the Republic of Albania with regard to a product protected by the patent after the said product has been put on the market in the Republic of Albania by the patent's owner or with his consent.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 50 Compulsory Licenses

1. On request, the court is entitled to grant a compulsory license to any Person who can demonstrate the capability to exploit the invention which is the subject-matter of the granted patent in the Republic of Albania when he meets all the requirements defined in the implementing regulation of this Law, provided that:

(a) four years have expired from the filing of the application and three years have expired from the grant of the patent;

- (b) *the patent owner has not exploited the patent on reasonable terms or has not made effective and serious preparations to do so, unless he provides legitimate reasons to justify his inaction.*
- (c) *the Person requesting the compulsory license has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions, and if such efforts have not been successful within a reasonable period of time.*
2. *On request, the court is entitled to grant a compulsory license in respect of a first patent to the owner of a subsequent patent who cannot use his patent without infringing the first patent, provided that the invention in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. In the case of a compulsory license in respect of a dependent patent, the owner of the first patent shall be entitled to use the subsequent patented invention on reasonable terms.*
3. *On request, the court is entitled to grant a compulsory license in respect of patents and supplementary protection certificates relating to the manufacture and sell of pharmaceutical products, when such products are intended for export to importing countries in need of such products in order to address public health problems, subject to the implementing regulation.*
4. *The type of use covered and the conditions to be met shall be specified by the court. The following conditions shall apply:*
- (a) *The scope and duration of the exploitation shall be limited to the purpose for which it was authorized;*
- (b) *The exploitation shall be non-exclusive;*
- (c) *The exploitation shall be non-assignable. In the case of a compulsory license in respect of a dependent patent, the exploitation authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.*
- (ç) *The amount of products manufactured under the license shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of products manufactured under other compulsory licenses granted elsewhere.*
5. *The exploitation shall be authorized, above all, to supply the market of the Republic of Albania, except in the case provided in paragraph 3 of this article.*
6. *A compulsory license shall be valid until the end of the time period designated by the court or until the end of the term of the patent. However, the court may, on reasoned request, decide to cancel the authorization, subject to adequate protection of the legitimate interests of the Persons so authorized, if and when the circumstances which led to it cease to exist and are unlikely to recur.*
7. *Compulsory licenses shall be registered in the patent register.*
8. *The owner of the patent shall be entitled to adequate compensation for a compulsory license, taking into account the economic value of the authorization. When the parties do not agree, the amount of this compensation shall be set by the court.*
9. *The holder of a compulsory license may renounce at it at any time. If the holder does not begin exploitation within one year from the final grant of the compulsory license, the owner of the patent may claim for the compulsory license to be modified or annulled.*
10. *The requirements of paragraphs 1(c) and 5 of this article shall not be applicable when such use is permitted to remedy a practice determined after judicial or administrative process*

to be anti-competitive. The need to correct anti-competitive practices may be taken into account of in determining the amount of remuneration in such cases. The court shall have the authority to refuse termination of an authorization if the conditions that led to such authorization are likely to recur.

66.-72.

[Note from the Secretariat: response was not provided.]

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Article 50 Compulsory Licenses

1. *On request, the court is entitled to grant a compulsory license to any Person who can demonstrate the capability to exploit the invention which is the subject-matter of the granted patent in the Republic of Albania when he meets all the requirements defined in the implementing regulation of this Law, provided that:*

- (a) four years have expired from the filing of the application and three years have expired from the grant of the patent;*
- (b) the patent owner has not exploited the patent on reasonable terms or has not made effective and serious preparations to do so, unless he provides legitimate reasons to justify his inaction.*
- (c) the Person requesting the compulsory license has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions, and if such efforts have not been successful within a reasonable period of time.*

74.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 51 Exploitation by the Government or Third Parties Authorized by the Government

1. *When the interests of essential defense or national security require it, the Minister of Defense or the Minister of Health may, even without the approval of the owner of the patent or the applicant, by a notification in the GDPT Gazette, authorize a governmental agency or a specific Person to make, use or sell the invention for which the patent application was submitted, or the patent was granted, subject to payment of equitable remuneration to the owner of the patent or to the patent applicant. The owner of the patent or the patent applicant shall be notified as soon as possible.*

2. *An appeal to the court can be taken against the decision of the Minister of Defense or the Minister of Health.*

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Refusal to grant licenses on reasonable terms
Public health
National security*

84. (a) What are the public policy objectives for providing government use in your country?

To protect health and security interests

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 38. Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

(e) the use by a farmer of the product of his crop for propagation or multiplication on his own holding, provided that the reproductive vegetable material was sold or otherwise commercialized by the holder of the patent or with his consent to the farmer, for agricultural purposes.

(ë) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animals reproductive material was sold or otherwise commercialized to the farmer by the holder of the patent or with his consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his agricultural activity, but not the sale as part of or for the purpose of commercial reproductive activity.

90.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 38 Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

(ë) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animals reproductive material was sold or otherwise commercialized to the farmer by the holder of the patent or with his consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his agricultural activity, but not the sale as part of or for the purpose of commercial reproductive activity.

96.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

Please list any other exceptions and limitations that your applicable patent law provides:

[Note from the Secretariat: the applicable law of Albania does not provide other exceptions and limitations.]

Country: ALGERIA
Office: Algerian National Institute of Industrial Property (INAPI)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

*Ordinance No. 03-07 of July 19, 2003 on Patents.
(Section 1, Articles 3 to 9)*

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Article 8 of Ordinance 03-07 of July 19, 2003 on Patents.

- (1) Plant varieties or animal breeds and essentially biological methods of obtaining plants or animals;*
- (2) Inventions, the implementation of which on Algerian territory would be contrary to ordre public or morality;*
- (3) Inventions, the exploitation of which on Algerian territory would harm the health and lives of people and animals or the preservation of plants, or would seriously endanger the protection of the environment.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

*Article 11 of Ordinance 03-07 of July 19, 2003.
The patent shall confer on its owner the following exclusive rights:*

- (1) where the subject matter of the patent is a product, prevent third parties acting without his consent from manufacturing, using, selling, offering for sale or importing for such purposes this product;*
- (2) where the subject matter of the patent is a process, prevent third parties acting without his consent from using the process and the following acts: using, offering for sale, selling or importing for such purposes the product obtained directly by this process.*

The application is not published and publication is post grant.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;*

Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Ordinance No. 03-07 of July 19, 2003 on Patents.

Article 12: "The rights stemming from a patent shall extend only to the acts performed for industrial or commercial purposes.

Such rights shall not extend to:

- (1) acts performed solely for scientific research purposes;*
- (2) acts concerning the product covered by the patent after the product has been lawfully traded;*
- (3) the use of means patented on board foreign vessels, space craft or air or land locomotives which temporarily or accidentally enter the national waters, air space or territory".*

- 5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 12(1).

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

The promotion of scientific research and economic development.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

Algerian legislation does not provide for a distinction with regard to the nature of the organization.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

These terms are not defined in the applicable legislation.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

*Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
Research and/or experimentation must be conducted with or using the patented invention (“research with”)*

Please explain by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

The relevant Algerian legislation does not distinguish these two terms.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

No, Algerian legislation does not state other criteria.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered appropriate.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenge encountered in this area.

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Algeria does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Ordinance No. 03-07 of July 19, 2003 on Patents, Article 14.

32.-33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The scope of the use is that of good faith, as stipulated in Article 14(1).

No, no provision is made by Algerian legislation for quantitative or qualitative limitations in this respect.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No, no provision has been made for such remuneration.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

No

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework is considered appropriate.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No comments.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Ordinance No. 03-07 of July 19, 2003 on Patents, Article 12-3.

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign

transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The terms “temporarily” and “or accidentally” are used but not defined by the applicable legislation.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No comments.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

No, the legislation does not state any other criteria.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, the applicable legal framework of the exception is considered appropriate.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No comments.

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Algeria does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Uncertain, please explain: National legislation has not specified the place of exhaustion.

If the exception is contained in statutory law, please provide the relevant provision(s):

Ordinance No. 03-07 of July 19, 2003 on Patents, Article 12(2).

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

The applicable exhaustion of rights regime has not been deemed appropriate. We contemplate revising the law with a view to clarifying the exhaustion of the right (international).

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

No comments.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Ordinance No. 03-07 of July 19, 2003 on Patents, Articles 38 to 50.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
Dependent patents

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

These terms are not defined by the applicable legislation.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, the import of a patented product or a product manufactured using a patented process constitutes “working” of the patent, as stipulated by Article 11 of Ordinance 03-07 of July 19, 2003.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Following expiry of a period of four (4) years beginning from the date of filing of the patent application or three (3) years beginning from the date of grant of the patent.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

If the patentee provides evidence that the circumstances made it impossible to remedy the lack or insufficiency of exploitation of his patent.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

These terms are not defined by the applicable legislation.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

Article 49(2) of Ordinance 03-07 of July 19, 2003

Where public interest, in particular national security, nutrition, health or the development of other sectors of the national economy so requires, and inter alia where the fixing, for patented pharmaceutical products, of excessive or discriminatory prices in relation to average market prices”.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

The conditions are: – notable technical progress – and significant economic interest (Article 47(2) of Order 03-07 of July 19, 2003).

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Yes, the applicable legislation gives general guidelines as to the remuneration to be paid by the beneficiary of the compulsory license to the patent owner.

Article 41 of Order 03-07 of July 19, 2003.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

None.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, the legal framework applicable to the granting of compulsory licenses is considered appropriate.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

No comments.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 49, Ordinance 03-07 of July 19, 2003.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security*

84. (a) What are the public policy objectives for providing government use in your country?

The aim is the protection of citizens and the development of the national economy.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85.-86.

[Note from the Secretariat: response was not provided.]

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework applicable to the grant of licenses for use by the authorities is considered appropriate.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

No comments.

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Algeria does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Algeria does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Algeria does not provide other exceptions and limitations.]

Country: ARMENIA (REPUBLIC OF)
Office: Intellectual Property Agency of the Republic of Armenia

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

A technical solution in any field, relating to a product (in particular, a device, substance, biotechnological product) or process (process of affecting a material subject matter using material means), shall be protected as an invention. An invention shall be granted legal protection if it is new has an inventive step and is industrially applicable (conditions for patentability of invention).

(Article 9 of Law on Inventions, Utility models and Industrial designs)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

(1) *The following shall not be subject to legal protection:*

- (a) *scientific discoveries;*
- (b) *scientific theories, mathematical methods, provision of common information;*
- (c) *methods of organization and management of economy;*
- (d) *conventional signs, schedules and rules;*
- (e) *processes for performing mental acts;*
- (f) *algorithms for calculating machines;*
- (g) *projects and plans for constructions, buildings and site developing;*
- (h) *solutions concerning the outward appearance of the product having exclusively aesthetic value;*
- (i) *topographies of integrated microcircuits.*

(2) *Inventions, the exploitation of which contradicts the public interests, morality, philanthropy principles shall not be subject to legal protection.*

(3) *The following shall not constitute patentable inventions:*

- (a) *plant and animal varieties, as well as the natural biological processes of their raising;*
- (b) *processes for cloning of human beings;*
- (c) *use of human embryos for industrial or commercial purposes;*
- (d) *processes for modifying the genetic identity of human beings;*
- (e) *processes for modifying the genetic identity of animals, as well as animals resulting from such processes.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Patent on invention or utility model gives the exclusive right to patent owner to use the patented subject matter at his own discretion, if it does not infringe other patent owner's rights as well as to forbid third parties:

(a) where the subject matter of patent is a product, to prevent third parties without the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, importing, offering for sale, selling or putting into civil circulation the product developed directly by that process.

(Paragraph 1 of Article 16 of Law on Inventions, Utility models and Industrial designs)

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of patented invention, utility model shall not constitute an infringement of the exclusive rights of the patent owner if used:

*for personal needs with no purpose to make profit;
(Article 17(1) of Law on Inventions, Utility models and Industrial designs)*

5.-10.

N/A

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of patented invention, utility model shall not constitute an infringement of the exclusive rights of the patent owner if used:

*as a subject of scientific research or scientific experiment;
(Article 17 (2) of Law on Inventions, Utility models and Industrial designs)*

12.-22.

N/A

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of patented invention, utility model shall not constitute an infringement of the exclusive rights of the patent owner if used:

for single preparation of medicaments in pharmacies based on physicians' prescriptions;

(Article 17 (3) of Law on Inventions, Utility models and Industrial designs)

24.-26.

N/A

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No.

28.-30.

N/A

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Any person who, before the priority date of an invention, utility model, has used an identical solution created independently of the inventor and has used it bona fide in the territory of the Republic of Armenia or who has made the necessary preparatory works for it, shall retain the right to further non-compensated use, provided that the scope of such use is not extended (right on prior use).

(Paragraph 1 of Article 18 of Law on Inventions, Utility models and Industrial designs)

32.-33.

N/A

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

*A prior user must provide that the scope of such use is not extended.
(Paragraph 1 of Article 18 of Law on Inventions, Utility models and Industrial designs)*

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No, a prior user retains the right to further non-compensated use.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The right on prior use shall be permitted to be transferred to another natural or legal persons only together with the production unit in which the use of the identical solution has taken place or the necessary preparations for such a use have been made.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Any person, who starting from the date of lapse of legal protection right in invention or utility model till the date, the information on restoration of rights of validity of patent on invention or utility model is published in Official Bulletin bona fide started to use the protected invention or utility model or made necessary preparatory works, reserve the right to use it free of charge without scope extension of the use (right to later use).

39.-41.

N/A

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of patented invention, utility model shall not constitute an infringement of the exclusive rights of the patent owner if used:

*on any vehicle belonging to another State and being accidentally or temporarily on the territory of the Republic of Armenia, if it is determined exclusively by the needs of the vehicle and the latter belongs to citizens and (or) legal persons of a State providing the same rights to citizens and legal persons of the Republic of Armenia.
(Article 17 (4) of Law on Inventions, Utility models and Industrial designs)*

43.-44.

N/A

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

N/A

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

The use of patented invention, utility model shall not constitute an infringement of the exclusive rights of the patent owner if used:

*on any vehicle belonging to another State and being accidentally or temporarily on the territory of the Republic of Armenia, if it is determined exclusively by the needs of the vehicle.
(Article 17 (4) of Law on Inventions, Utility models and Industrial designs)*

48.-50.

N/A

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of the Republic of Armenia does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National
International

If the exception is contained in statutory law, please provide the relevant provision(s):

(1) The patent owner or the owner of exclusive license has no right to prevent to put into civil circulation in the Republic of Armenia a patented invention or utility model or product, developed by patented process, if this product or article has been legally put on the market in the Republic of Armenia by the patent owner or with his consent.

(2) Import of a patented product including an industrial property subject matter or developed by a patented process into the territory of the Republic of Armenia shall not be deemed as infringement of exclusive rights of the patent owner if it has been legally put on the market in a foreign country by the patent owner or with his consent.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

61.

N/A

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

N/A

63.-64.

N/A

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

(1) Any person or the Republic of Armenia may, without the consent of the patent owner (rightholder), use the protected invention, utility model or industrial design (compulsory license) by court decision where:

- (a) the public interest demands, in particular, national security, nutrition, health or the development of other vital sectors so requires;*
- (b) it is determined that the owner of the patent or his licensee abuses the patent rights, in particular where the manner of exploitation, contrary to the adopted regulations, restrains competition;*

(c) *the invention, utility model, industrial design has not been used or has been used unconscientiously during the period of 4 years from filing the application or 3 years from granting patent (certificate) (the later filing date shall be applied).*

(2) *The court shall grant compulsory licenses with regard to given circumstances and after hearing the rightholder.*

(3) *Compulsory licenses shall be granted provided that the person filing the request proves that he has made efforts to conclude a license contract with the rightholder on reasonable commercial terms and that such efforts failed to succeed within a reasonable period of time.*

(4) *Paragraph (3) of this Article shall not apply if a state of war or emergency has been declared.*

(Article 69 of Law on Inventions, Utility models and Industrial designs)

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68.-70.

N/A

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

The applicable law provides for 4 years from the filing date of the application or 3 years from granting of patent (certificate) (the later date will be applied).

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

The court shall grant compulsory licenses with regard to given circumstances and after hearing the rightholder.

(Paragraph 2 of Article 69 of Law on Inventions, Utility models and Industrial designs)

73.-74.

N/A

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

(1) *Compulsory licenses shall be granted under the following conditions:*

- (a) scope and duration shall be limited with regard to their purposes;*
- (b) they shall be only non-exclusive;*
- (c) they may not be transferred to third parties, with the exception of the licensee enterprise or business;*
- (d) they shall be granted primarily for the suffice of the internal market demand.*

(2) *Where a patent, hereinafter referred to as "the second patent", cannot be exploited without infringing another patent, hereinafter referred to as "the first patent", the following conditions, in addition to paragraph (1) above, for the grant of compulsory license in respect of the first patent it is necessary that:*

- (a) the invention protected by the second patent shall involve a technical advance of considerable economic significance compared to the invention protected by the first patent;*
- (b) the owner of the first patent shall, under reasonable conditions, be entitled to a cross-license to use the invention protected by the second patent;*
- (c) the use authorized in respect of the first patent shall be transferred by the person having the compulsory license only with the simultaneous transfer of the company's part, where the use of the mentioned subject matter is realized.*

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

(1) *A compulsory license shall be granted to the owners of patents against equitable remuneration.*

(2) *The amount of the remuneration shall be determined with regard to the circumstances of each case and taking into account the economic significance of such an authorization.*

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

N/A

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Compulsory licenses have not been ever issued in the Republic of Armenia.

79.-80.

N/A

Government use

81.-88.

[Note from the Secretariat: the applicable law of the Republic of Armenia does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

89.-100.

[Note from the Secretariat: the applicable law of the Republic of Armenia does not provide exceptions and limitations related to farmers' and/or breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Republic of Armenia does not provide other exceptions and limitations.]

Country: AUSTRALIA
Office: IP Australia

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

From Section 18 Patentable Inventions, of the Patents Act 1990.

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

- (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and*
- (b) when compared with the prior art base as it existed before the priority date of that claim:
 - (i) is novel; and*
 - (ii) involves an inventive step; and**
- (c) is useful; and*
- (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.*

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:

- (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and*
- (b) when compared with the prior art base as it existed before the priority date of that claim:
 - (i) is novel; and*
 - (ii) involves an innovative step; and**
- (c) is useful; and*
- (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention*

*The requirement that a patentable invention be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies, imports a number of threshold and subject matter limitations from common law. The most significant case in this regard is the High Court decision in *National Research and Development Corporation v Commissioner of Patents* [1959] HCA 67; [1959] 102 CLR 252. That decision is understood to require that patentable subject matter be for "a mode or manner of achieving an end result which is an artificially created state of affairs of utility in the fields of economic endeavour" (*CCOM Pty Ltd v Jiejing* [1994] FCA 1168 at [128]).*

Accordingly it is understood that a distinction lies between the fine and useful arts and that mere schemes, abstract ideas and mere intellectual information are not patentable.

The Advisory Council on Intellectual Property has recently concluded a study of patentable subject matter requirement in Australia, Patentable Subject Matter December 2010
(<http://www.acip.gov.au/library/ACIP%20PSM%20final%20report%204%20Feb%202011.pdf>)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

From Section 18 Patentable Inventions, of the Patents Act 1990.

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

From Section 13 of the Patents Act 1990.

Section 13. Exclusive rights given by patent

(1) Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.

(2) The exclusive rights are personal property and are capable of assignment and of devolution by law.

(3) A patent has effect throughout the patent area

From Section 57 of the Patents Act 1990

Section 57. Effect of publication of complete specification

(1) After a complete specification relating to an application for a standard patent has become open to public inspection and until a patent is granted on the application, the applicant has the same rights as he or she would have had if a patent for the invention had been granted on the day when the specification became open to public inspection.

(2) Subsection (1) does not give the applicant a right to start proceedings in respect of the doing of an act unless:

(a) a patent is granted on the application; and

(b) the act would, if done after the grant of the patent, have constituted an infringement of a claim of the specification.

From Schedule 1 – Definitions

Exploit, in relation to an invention, includes:

- (a) where the invention is a product-make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or*
- (b) where the invention is a method or process-use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use;*

It is clear however that the rights granted to a patentee are “negative” rights. That is, they prevent exploitation by others without authorisation of the patentee. They do not however amount to right to exploit and any such exploitation is subject to any other law that may regulate activities in the field of the patented invention. See Grain Pool of WA v Commonwealth [2000] HCA 14 [81]-[85].

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- ? *Private and/or non-commercial use;*
- ? *Experimental use and/or scientific research;*
- √ *Prior use;*
- √ *Use of articles on foreign vessels, aircrafts and land vehicles;*
- √ *Acts for obtaining regulatory approval from authorities;*
- √ *Exhaustion of patent rights;*
- √ *Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI “Other Exceptions”.

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

In Australia there is no statutory exclusion for private and/or non-commercial use.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

While not a matter yet determined by Australian Courts, it is considered that a non-commercial use defence may arise under common law - see the UK decision Frearson v Loe (18760 9 ChD 48. (Genes and Ingenuity, Chapter 13, Report 99, Australian Law Reform Commission, June 2004.)

6.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Currently in Australia there is no statutory provision clarifying researchers' freedom to conduct experiments.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The Australian courts have not tested any implicit exception for experimental research. It is however considered that a research exemption may exist under the non-commercial use defence referred to at question 5. Given this uncertainty a statutory research exemption is under consideration in Australia as discussed at question 21 below. .

13.-20.

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 is currently (July 2011) being considered by Parliament. The Bill amends the Patents Act to draw a line between research and commercial activities. The amendments are designed to clarify that research and experimental activities relating to patented inventions are exempt from infringement, whereas commercial activities are not. The intent is to give broad and clear protection to research and experimental activities in order to maximise the potential for research in Australia.

The Bill includes the following amendment, please note however that these amendments have not been approved by the Australian Government at the time of writing.

After section 119A (see answer to question 51)

Insert:

119C Infringement exemptions: acts for experimental purposes

(1) A person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention.

(2) For the purposes of this section, experimental purposes relating to the subject matter of the invention include, but are not limited to, the following:

- (a) determining the properties of the invention;*
- (b) determining the scope of a claim relating to the invention;*
- (c) improving or modifying the invention;*
- (d) determining the validity of the patent or of a claim relating to the invention;*
- (e) determining whether the patent for the invention would be, or has been, infringed by the doing of an act.*

The Explanatory Memorandum to the Bill

(http://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s837_ems_561ef790-9811-43d0-b14f-04c924723c94/upload_pdf/356916em.pdf) contains a discussion of the policy background and consideration relevant to the proposed provision.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Australia does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 119 (Patents Act 1990). Infringement exemptions: Prior use.

(1) A person may, without infringing a patent, do an act that exploits a product, method or process and would infringe the patent apart from this subsection, if immediately before the priority date of the relevant claim the person:

- (a) was exploiting the product, method or process in the patent area; or*
- (b) had taken definite steps (contractually or otherwise) to exploit the product, method or process in the patent area.*

(2) Subsection (1) does not apply if, before the priority date, the person:

- (a) had stopped (except temporarily) exploiting the product, method or process in the patent area; or*
- (b) had abandoned (except temporarily) the steps to exploit the product, method or process in the patent area.*

(3) Limit for product, method or process derived from patentee

Subsection (1) does not apply to a product, method or process the person derived from the patentee or the patentee's predecessor in title in the patented invention unless the person derived the product, method or process from information that was made publicly available:

- (a) by or with the consent of the patentee or the patentee's predecessor in title; and*
- (b) through any publication or use of the invention in the prescribed circumstances mentioned in paragraph 24(1)(a).*

(4) Exemption for successors in title

A person (the disposer) may dispose of the whole of the disposer's entitlement under subsection (1) to do an act without infringing a patent to another person (the recipient). If the disposer does so, this section applies in relation to the recipient as if the references in subsections (1), (2) and (3) to the person were references to:

- (a) the disposer; or*
- (b) if the disposer's entitlement arose because of one or more previous applications of this subsection--the first person:*
 - (i) who was entitled under subsection (1) (applying of its own force) to do an act without infringing the patent; and*
 - (ii) to whom the disposer's entitlement is directly or indirectly attributable.*

(5) *Definition*

In this section:

exploit includes:

(a) *in relation to a product:*

- (i) *make, hire, sell or otherwise dispose of the product; and*
- (ii) *offer to make, hire, sell or otherwise dispose of the product; and*
- (iii) *use or import the product; and*
- (iv) *keep the product for the purpose of doing an act described in subparagraph (i), (ii) or (iii); and*

(b) *in relation to a method or process:*

- (i) *use the method or process; and*
- (ii) *do an act described in subparagraph (a)(i), (ii), (iii) or (iv) with a product resulting from the use of the method or process.*

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

The grant of a patent should not deprive a party from continuing to do what they were doing before the patent was granted. On the other hand an inventor should not be deprived of patent protection by the secret acts of third parties, of which they can have no knowledge. Section 119 attempts to provide a balance between the rights of the patentee and those of the third party. It is intended to safeguard the rights of third parties who have independently used an invention before the priority date of an application for a patent.

It should also be noted that Australia has a grace period for prior public disclosure of the invention by the inventor or successors in title. The prior use exception is also seen as an important balancing provision such that a person who relies on an unfettered disclosure remains free to exploit the invention despite the grant of a patent. Subsection 119(3) has the effect of applying the prior use exemption to public disclosures by the patentee or predecessor in title which would be covered by the grace period provisions.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This provision was amended by the Intellectual Property Laws Amendment Act 2006. The amendments clarified the existing legislation in three key areas: whether the prior use had to be in Australia; whether the provision was limited to commercial use; or whether the right is limited to the actual user of whether it can be assigned or licensed.

The amendments ensured that the prior user right is limited to use in Australia, that the benefit of the right extends to assignees, but not licensees and that the use encompasses acts which would otherwise constitute an infringement of the patent, including commercial use.

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The scope of ‘use’ is defined in section 119 by referring to the definition of ‘exploit’. Exploit is defined for this section of the Act in section 119(5).

(5) *Definition*

In this section:

exploit includes:

(a) *in relation to a product:*

(i) *make, hire, sell or otherwise dispose of the product; and*

(ii) *offer to make, hire, sell or otherwise dispose of the product; and*

(iii) *use or import the product; and*

(iv) *keep the product for the purpose of doing an act described in subparagraph (i), (ii) or (iii); and*

(b) *in relation to a method or process:*

(i) *use the method or process; and*

(ii) *do an act described in subparagraph (a)(i), (ii), (iii) or (iv) with a product resulting from the use of the method or process.*

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No. The exception to infringement is absolute and not dependant on the payment of reasonable remuneration.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes (section 119(4) allows the person to assign. However prior users cannot licence their rights)

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

No

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No. However other provisions apply

If yes, please explain the conditions under which such use can continue to apply:

Where an application or patent ceases to have effect in certain circumstances but is restored, for example through the granting of an extension of time, special provisions apply to allow a third party to apply to the Commissioner of Patents for a licence to continue to exploit the invention. The person must show that they took definite steps to avail themselves of or exploit the invention as a result of the ceasing of the application or patent. See for example subsection 223(9) and regulation 22.21. The terms of such a licence are determined by the Commissioner (22.21(5)) taking into account the circumstance but the licence is royalty free (See HRC PROJECT DESIGN PTY LTD v. ORFORD PTY LTD [1997] APO 12.)

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to this section of the Patents Act 1990 are currently being considered.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 118 (Patents Act 1990). Infringement exemptions: use in or on foreign vessels, aircraft or vehicles

The rights of a patentee are not infringed:

(a) by using the patented invention on board a foreign vessel, in the body of the vessel, or in the machinery, tackle, apparatus or other accessories of the vessel, if the vessel comes into the patent area only temporarily or accidentally and the invention is used exclusively for the needs of the vessel; or

(b) by using the patented invention in the construction or working of a foreign aircraft or foreign land vehicle, or in the accessories of the aircraft or vehicle, if the aircraft or vehicle comes into the patent area only temporarily or accidentally.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Paris Convention

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The terms temporarily and accidentally are included in section 118 of the Patents Act 1990. These terms are not defined within the Act.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 118(a) relating to foreign vessels includes the restriction “the invention is used exclusively for the needs of the vessel”

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments are planned to this section of the Patents Act 1990.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 119A (Patents Act 1990). Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals

(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

(a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:

(i) are intended for therapeutic use; and

(ii) are not medical devices, or therapeutic devices, as defined in the Therapeutic Goods Act 1989; or

(b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

(2) Subsection (1) does not apply to the export from Australia of goods for purposes described in paragraph (1)(b) unless the term of the patent has been extended under Part 3 of Chapter 6 and the goods consist of or contain:

(a) a pharmaceutical substance per se that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete

specification of the patent and in substance falls within the scope of the claim or claims of that specification.

Note: Part 3 of Chapter 6 provides for the extension of the term of standard patents claiming pharmaceutical substances.

(3) In this section:

pharmaceutical patent means a patent claiming:

(a) a pharmaceutical substance; or

(b) a method, use or product relating to a pharmaceutical substance, including any of the following:

(i) a method for producing a raw material needed to produce the substance;

(ii) a product that is a raw material needed to produce the substance;

(iii) a product that is a pro-drug, metabolite or derivative of the substance.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

This exception seeks to prevent patentees having a de facto extension of the patent term. Without the exception alternative manufacturers could not gain regulatory approval until the term has expired. These processes would take some time and amount to an extended period of exclusivity for the original patentee.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This type of exception was first introduced in 1998 (Intellectual Property Laws Amendment Act 1998) along with provisions for pharmaceutical extensions of term. The exceptions for regulatory approval were amended in 2006 (Intellectual Property Laws Amendment Act 2006) to introduce section 119A (see above, answer to question 51).

54. Who is entitled to use the exception? Please explain:

Under Section 119A of the Patents Act 1990 (see answer to question 51) there are no restrictions as to who may use the exception.

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: Pharmaceutical Patents (see answer to question 51)

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: Any use for the purpose of obtaining regulatory approval as indicated above.

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods or for obtaining similar regulatory approval under the law of a foreign jurisdiction.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 introduces an exemption for activities solely for the purpose of gaining regulatory approval to market or manufacture a patented technology. This expands the existing exemption for pharmaceutical inventions to all technologies.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

The issue is not specifically dealt with in Australia Patents Act, however the Act states that a patent holder has exclusive rights to exploit their invention in Australia. Exploit is specially defined in the Act, this definition includes importation.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The situation for exhaustion and parallel importation in Australia is that national, rather than international, exhaustion applies. However, there is little Australian case law on this issue.

Exhaustion and parallel importation seems to apply to patents, unless the patent owner has placed contractual restrictions to the contrary. This principle is part of the existing Australian law, subject to a qualification that importation of the patented article put into circulation outside Australia by the Australian patentee will be an infringement if, at the time of first putting the article into circulation, that patentee attached an express stipulation against bringing it into Australia.

The general legal principle that applies in Australia is that it is not an infringement of a patent for a purchaser to use or dispose of as the purchaser pleases, assuming the purchase was by way of an authorised sale of the product. In general the sale of the product is the trigger for exhaustion.

Australia is also bound by international obligations under Free Trade Agreements. For example the Australia – United States FTA (Article 17.9.4) states that “Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent

owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.”

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

It is currently considered to provide an adequate balance between the interests of patentees and consumers.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain.

Please explain your answer by citing legal provision(s) and/or decision(s):

It is not clear and Australian courts have not considered the circumstances where a condition expressed as a notice on a product would be binding.

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 133 (Patents Act 1990). Compulsory licences

(1) Subject to subsection (1A), a person may apply to the Federal Court, after the end of the prescribed period, for an order requiring the patentee to grant the applicant a licence to work the patented invention.

(1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.

(2) After hearing the application, the court may make the order if satisfied that:

(a) all the following conditions exist:

- (i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;*
 - (ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;*
 - (iii) the patentee has given no satisfactory reason for failing to exploit the patent;*
- or*

(b) the patentee has contravened, or is contravening, Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.

(3) An order must direct that the licence:

- (a) is not to give the licensee, or a person authorised by the licensee, the exclusive right to work the patented invention; and*
- (b) is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;*

and may direct that the licence is to be granted on any other terms specified in the order.

(3A) [repealed]

(3B) If the patented invention cannot be worked by the applicant without his or her infringing another patent:

- (a) the court is to make the order only if the court is further satisfied that the patented invention involves an important technical advance of considerable economic significance on the invention (other invention) to which the other patent relates; and*
- (b) the court must further order that the patentee of the other invention:*
 - (i) must grant to the applicant a licence to work the other invention insofar as is necessary to work the patented invention; and*
 - (ii) is to be granted, if he or she so requires, a cross-licence on reasonable terms to work the patented invention; and*
- (c) the court must direct that the licence granted by the patentee of the other invention may be assigned by the applicant:*
 - (i) only if he or she assigns the licence granted in respect of the patented invention; and*
 - (ii) only to the assignee of that licence.*

(4) An order operates, without prejudice to any other method of enforcement, as if it were embodied in a deed granting a licence and executed by the patentee and all other necessary parties.

(5) The patentee is to be paid in respect of a licence granted to the applicant under an order:

- (a) such amount as is agreed between the patentee and the applicant; or*
- (b) if paragraph (a) does not apply—such amount as is determined by the Federal Court to be just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act).*

(6) The patentee or the Federal Court may revoke the licence if:

- (a) the patentee and the licensee are agreed, or the court on application made by either party finds, that the circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur; and*
- (b) the legitimate interests of the licensee are not likely to be adversely affected by the revocation.*

Section 134 (Patents Act 1990). Revocation of patents after grant of compulsory licence

(1) Where a compulsory licence relating to a patent is granted, an interested person may apply to the Federal Court, after the end of the prescribed period, for an order revoking the patent.

- (2) *After hearing the application, the court may make the order if satisfied that:*
- (a) *both:*
 - (i) *the reasonable requirements of the public with respect to the patented invention have not been satisfied; and*
 - (ii) *the patentee has given no satisfactory reason for failing to exploit the patent;*
 - or
 - (b) *the patentee is contravening Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.*

Section 135 (Patents Act 1990). Reasonable requirements of the public

- (1) *For the purposes of sections 133 and 134, the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:*
- (a) *an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:*
 - (i) *to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or*
 - (ii) *to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or*
 - (iii) *to carry on the patented process to a reasonable extent; or*
 - (iv) *to grant licences on reasonable terms; or*
 - (b) *a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or*
 - (c) *if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.*

(2) *If, where paragraph (1)(c) applies, the court is satisfied that the time that has elapsed since the patent was sealed has, because of the nature of the invention or some other cause, been insufficient to enable the invention to be worked in Australia on a commercial scale, the court may adjourn the hearing of the application for the period that the court thinks sufficient for that purpose.*

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Compulsory licensing provisions are provided to ensure the balance between the granted monopoly and the public interest.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

As stated in the answer to question 65, one of the ground that must be met for the grant of a compulsory licence is that the patentee has given no satisfactory reason for failing to exploit the patent.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, the patentee enjoys exclusive rights to exploit their invention. The definition of ‘exploit’ given in the Patents Act 1990 includes importation.

However, this question relates to the principle of exhaustion addressed in question 60. In Australia a product purchased in another jurisdiction legally and with no conditions attached can be imported by the purchaser.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

3 years after sealing (as specified by Regulation 12.1(1))

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

The reasons are not described in the Act and would be determined on a case-by-case basis.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Section 133(2) deals with the conditions require for the court order the patentee to grant a licence (see answer to question 65).

The “reasonable period” of section 133(2)(a)(i) has not been the subject of judicial interpretation in Australia.

Section 133(5) deals with payment to the patentee (also see answer 65).

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

Section 133(2)(b) is relevant.

“After hearing the application, the court may make the order if satisfied that:

...

(b) the patentee has contravened, or is contravening, Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.”

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Section 133(3B) deals with the circumstances where the patented invention cannot be worked without infringing another patent. The conditions associated with the grant of a licence in such cases are given in section 133(3B)(a-c). See answer to question 65.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Section 133(5)(b) provides such a general policy (see answer to question 65).

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

N/A

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

IP Australia is not aware of any instances any compulsory licences being granted by the courts in Australia.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Chapter 17 of the Patents Act 1990 relates to The Crown. Sections 163 – 172 are relevant to this question.

Section 163. Exploitation of inventions by Crown

(1) Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the

Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement:

- (a) if the application is pending-of the nominated person's rights in the invention; or*
- (b) if a patent has been granted for the invention-of the patent.*

(2) A person may be authorised for the purposes of subsection (1):

- (a) before or after any act for which the authorisation is given has been done; and*
- (b) before or after a patent has been granted for the invention; and*
- (c) even if the person is directly or indirectly authorised by the nominated person or patentee to exploit the invention.*

(3) Subject to section 168, an invention is taken for the purposes of this Part to be exploited for services of the Commonwealth or of a State if the exploitation of the invention is necessary for the proper provision of those services within Australia.

Section 164. Nominated person or patentee to be informed of exploitation

As soon as practicable after an invention has been exploited under subsection 163 (1), the relevant authority must inform the applicant and the nominated person, or the patentee, of the exploitation and give him or her any information about the exploitation that he or she from time to time reasonably requires, unless it appears to the relevant authority that it would be contrary to the public interest to do so.

Section 165. Remuneration and terms for exploitation

(1) [repealed]

(2) The terms for the exploitation of the invention (including terms concerning the remuneration payable to the nominated person or the patentee) are such terms as are agreed, or determined by a method agreed, between the relevant authority and the nominated person or the patentee or, in the absence of agreement, as are determined by a prescribed court on the application of either party.

(3) For the purposes of subsection (2), the terms, or the method, may be agreed before, during or after the exploitation.

(4) When fixing the terms, the court may take into account any compensation that a person interested in the invention or the patent has received, directly or indirectly, for the invention from the relevant authority.

Section 165A. Exploitation of invention to cease under court order

(1) A prescribed court may, on the application of the nominated person or the patentee, declare that the exploitation of the invention by the Commonwealth or the State is not, or is no longer, necessary for the proper provision of services of the Commonwealth or of the State if the court is satisfied that, in all the circumstances of the case, it is fair and reasonable to make the declaration.

(2) The court may further order that the Commonwealth or the State is to cease to exploit the invention:

- (a) on and from the day specified in the order; and*
- (b) subject to any conditions specified in the order. In making the order, the court is to ensure that the legitimate interests of the Commonwealth or of the State are not adversely affected by the order.*

Section 166. Previous agreements inoperative

An agreement or licence (whether made or given before or after the commencement of this Act) fixing the terms on which a person other than the Commonwealth or a State may exploit an invention is inoperative with respect to the exploitation, after the commencement of this Act, of the invention under subsection 163 (1), unless the agreement or licence has been approved:

- (a) if the relevant authority is the Commonwealth-by the Minister; or*
- (b) if the relevant authority is a State-by the Attorney-General of the State.*

Section 167. Sale of products

(1) The right to exploit an invention under subsection 163 (1) includes the right to sell products made in exercise of that right.

(2) Where under subsection 163 (1) the sale of products is not an infringement of:

- (a) a patent; or*
- (b) a nominated person's rights in the products;*

the buyer, and any person claiming through the buyer, is entitled to deal with the products as if the relevant authority were the patentee or the nominated person.

Section 168. Supply of products by Commonwealth to foreign countries

Where the Commonwealth has made an agreement with a foreign country to supply to that country products required for the defence of the country:

- (a) the use of a product or process by the Commonwealth, or by a person authorised in writing by the Commonwealth, for the supply of that product is to be taken, for the purposes of this Chapter, to be use of the product or process by the Commonwealth for the services of the Commonwealth; and*
- (b) the Commonwealth or the authorised person may sell those products to the country under the agreement; and*
- (c) the Commonwealth or the authorised person may sell to any person any of the products that are not required for the purpose for which they were made.*

Section 169. Declarations that inventions have been exploited

(1) Subject to subsection (4), a patentee who considers that the patented invention has been exploited under subsection 163 (1) may apply to a prescribed court for a declaration to that effect.

(2) In proceedings under subsection (1):

- (a) the alleged relevant authority is the defendant; and*
- (b) the alleged relevant authority may apply by way of counter-claim in the proceedings, for the revocation of the patent.*

(3) The provisions of this Act relating to the revocation of patents apply, with the necessary changes, to a counter-claim.

(4) An application under subsection (1) in respect of an innovation patent cannot be made unless the patent has been certified.

Section 170. Sale of forfeited articles

Nothing in this Chapter affects the right of the Commonwealth or a State, or of a person deriving title directly or indirectly from the Commonwealth or a State, to sell or use an article forfeited under a law of the Commonwealth or the State.

Section 171. Acquisition of inventions or patents by Commonwealth

- (1) The Governor-General may direct that a patent, or an invention that is the subject of a patent application, be acquired by the Commonwealth.*
- (2) When a direction is given, all rights in respect of the patent or the invention are, by force of this subsection, transferred to and vested in the Commonwealth.*
- (3) Notice of the acquisition must be:
 - (a) given to the applicant and the nominated person, or the patentee; and*
 - (b) published in the Official Journal and the Gazette unless, in the case of the acquisition of an invention that is the subject of an application for a patent, a prohibition order, or an order under section 152, is in force in respect of the application.**
- (4) The Commonwealth must pay a compensable person such compensation as is agreed between the Commonwealth and the person or, in the absence of agreement, as is determined by a prescribed court on the application of either of them.*

Section 172. Assignment of invention to Commonwealth

(1) An inventor, or an inventor's successor in title, may assign the invention, and any patent granted or to be granted for the invention, to the Commonwealth. (2) The assignment and all covenants and agreements in the assignment are valid and effectual, even if valuable consideration has not been given for the assignment, and may be enforced by proceedings in the name of the Minister.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Other, please specify:

The grounds stated in section 163 of the Patents Act 1990 are "for the services of the Commonwealth or the State"

84. (a) What are the public policy objectives for providing government use in your country?

Historically, the two main justifications for use of the Crown use provisions have been:

- (i) the Crown should not be impeded by patents (which are, in effect, Crown grants) from acting in the public interest, particularly in relation to matters of national defence; and*
- (ii) unlike private traders, the Crown, through its departments and authorities is ordinarily engaged in public services, rather than commercial activities, and therefore should be in a special position in regards to use of patented inventions.*

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In 1903, Crown use and acquisition provisions were included in Australian patents legislation. Barwick CJ described the purpose of the Crown use provisions in the Patents Act 1952 (Cth) as being to 'ensure that the governments of the Commonwealth and of the States have the invention available to them for the benefit of the services of the respective governments at once, rather than at the end of the term of the letters patents'

In Stack v Brisbane City Council (1994) 131 ALR 333, the Federal Court considered the reasoning of the House of Lords in Pfizer Corporation v Ministry of Health [1965] AC 512 (Pfizer), in which it was held that the use of a patented drug (tetracycline) in National Health Service hospitals for patients was 'for the services of the Crown'. The House of Lords held that the phrase was not to be limited to the internal activities of Crown authorities, but that the services at issue could ultimately benefit individual members of the public. The House of Lords held, by majority, that an act was done 'for the services of the Crown' if it was done for the purpose of performing a duty or exercising a power which was imposed upon or invested in the executive government by statute or by prerogative, including providing services to the general public.

The Advisory Council for Intellectual Property has considered Crown Use Provisions (<http://www.acip.gov.au/library/Review%20of%20Crown%20Use%20Discussion.PDF> and http://www.acip.gov.au/library/review_of_Crown_Use_provisions.pdf).

The Australian Law Reform Commission has also considered the issue in "ALRC Discussion Paper 68 Gene Patenting and Human Health" (<http://www.austlii.edu.au/au/other/alrc/publications/dp/68/>)

85. If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

N/A

86. Please indicate how many times and in which technological areas government use has been issued in your country:

If the Crown use provisions were invoked the case would be between the relevant instrumentality of the Crown and the patentee and would not involve any of the administrative bodies responsible. As such it is difficult to determine the frequency of use, though we expect this has been minimal.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to this section of the Patents Act are currently planned

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

The main difficulty that has been tested by the courts is in defining which bodies can be considered to fall within the scope of the Crown.

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Australia does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Australia does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Australia does not provide other exceptions and limitations.]

Country: AZERBAIJAN

Office: State Committee on Standardization, Metrology and Patents, Patent Department

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

An invention is a technical solution relating to a product or process in any field and is granted by a legal protection if it is new, involves an inventive step and is industrially applicable ("Law on Patent" of the Republic of Azerbaijan (1997, 2009, Article 7)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The following subject matter shall not be deemed inventions:

- *scientific theories;*
- *mathematical methods;*
- *outcome of the art-constructive performance (design);*
- *methods of organization and performing for intellectual activity and for business activity;*
- *rules and methods for playing games;*
- *algorithms and programs for computers;*
- *methods of presenting information;*
- *symbols, schedules and rules;*
- *projects and plans for structures and buildings and for land development;*
- *plant and animal varieties (except for microorganisms) and essentially biological processes for raising them (except for non-biological or microbiological processes*
- *layout designs of integrated circuits;*
- *methods for the diagnostic of illnesses, methods for therapeutic and surgical treatment of humans or animal organisms.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Exclusive right on use of subject matter of industrial property shall belong to the owner of the patent, if it does not infringe upon the rights of other patent owners and the present Law (Article 14 (1)).

According to article 14(2) patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing¹ for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of a product containing the patented invention in the non-commercial purposes without the income not recognized as an infringement of the exclusive rights of the patent (Article 23).

5.-10.

[Note from the Secretariat: response was not provided.]

¹ This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of protected object of the invention in the purposes of a scientific research, experimental study and its validation prior to the patent term expiration with providing of exclusion of the manufacture or storage of products in large volume not recognized as an infringement of the patent holder's exclusive rights. (Article 23).

12.-15.

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention
invent around the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

*Research and/or experimentation must be conducted on or relating to the patented invention
("research on")
Research and/or experimentation must be conducted with or using the patented invention
("research with")*

Please explain by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

*A non-commercial purpose
A commercial purpose*

19.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The occasional preparation of medicines prescribed by a physician is not recognized as an infringement of the patent holder's exclusive rights. (Article 23, Acts not constituting infringement of the exclusive rights of patent owners).

24.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Any legal entity or natural person who, before the priority date of subject matter of invention protected by a patent and independently of the author, has devised and used in good faith on the territory of the Republic of Azerbaijan an identical subject matter of invention or has up until that date been making the necessary preparations for such use, has the right, without hindrance and without paying any compensation to the patent owner, to continue independently using the subject matter, provided that the scope of the use of the subject matter is not expanded (Article 16(1)).

32.-35.

[Note from the Secretariat: response was not provided.]

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The right of prior use may only be transferred to successor, another legal entity or natural person together with the enterprise where the subject matters of invention is used or where the necessary preparations for such use had been made. Successor, legal entity or natural person might use this right in a scope given a prior user in accordance with item 1 of the Article 16. (Article 16(3))

38.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of devices forming the patented subject matter of industrial property in the construction or operation of means of transport of other countries when such means of transport, if the means of transport temporarily or accidentally enter the territory of the Republic of Azerbaijan, provided that such devices are used there exclusively for the needs of the means of transport, if the means of transport belong to legal entity or natural persons of countries affording the same rights to owners of means of transport of the Republic of Azerbaijan, Law on Patent, Article 23

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes, "temporarily" or "accidentally", (Article 23 Acts not constituting infringement of the exclusive rights of patent owners).

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, provided that such devices are used there exclusively for the needs of the means of transport, if the means of transport belong to legal entity or natural persons of countries affording the same rights to owners of means of transport of the Republic of Azerbaijan, (Article 23, Acts not constituting infringement of the exclusive rights of patent owners).

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Azerbaijan does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

The placing on the market of any product in which a patented a subject matter of invention has been used or the application process protected by a patent shall be deemed to have been used of a subject matter of invention if they contain all of the essential features a patented of subject matter of industrial property. (Article 15(1))

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Law on Patent, Article 20

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

*Where the owner of a patent or his right successor does not use the subject matter of invention property within 3 years time from the date a patent is granted without any valid reason and does not made serious preparation to use or suspend more than 3 years and refuses from grant the license after termination of this period, any legal entity or natural person may appeal to the Court with a request for the grant compulsory license on use the subject matter of invention. Compulsory license shall be of non-exclusive character.
Article 20(1)*

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Within 3 years time from the date a patent is granted.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

[Note from the Secretariat: response was not provided.]

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

See 69.

74.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

With the objectives of safeguarding the interests of national security respective body of executive power has the right of giving his consent on use of the subject matter of industrial property without the consent of patent owner. In this case remuneration compensation is paid

to patent owner. In the case when patent owner is not satisfied with the amount of compensation, he may appeal to the Court in an order established by legislation of the Republic of Azerbaijan, Law on Patent, Article 18.

82.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Azerbaijan does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Azerbaijan does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Azerbaijan does not provide other exceptions and limitations.]

Country: BHUTAN
Office: Intellectual Property Division, Ministry of Economic Affairs

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Industrial Property Act of the Kingdom of Bhutan, 2001, Section 5 on Patentable Invention states that;

- (1) An invention is patentable if it is new, involves an inventive step and is industrially applicable.*
- (2) (a) an invention is new if it is not anticipated by prior art.*
 - (b) Prior art shall consist of everything disclosed to the public, anywhere in the world, by publication in tangible form or by oral disclosure, by use or in any other way, prior to filing or, where appropriate, the priority date, of the application claiming the invention.*
 - (c) for the purposes of paragraph(b), disclosure to the public of the invention shall not be taken into consideration if it occurred within twelve months preceding the filing date or, where applicable, the priority date of the application, and if it was by reason or in consequence of acts committed by the applicant or his predecessor in title or of an abuse committed by a third party with regard to the applicant or his predecessor in title.*
- (3) An invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the application claiming the invention and as defined in subsection (2)(b), it would not have been obvious to a person having ordinary skill in the art.*
- (4) An invention shall be considered industrially applicable if it can be made or used in any kind of industry. "Industry" shall be understood in its broadest sense; it shall cover, in particular, handicraft, agriculture, fishery and services.*
- (5) Inventions, the commercial exploitation of which would be contrary to public order or morality, shall not be patentable.*

Since the patent registry is not in place, the interpretation of standards of patentability conditions for different technology did not arise.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Industrial Property Act of Kingdom of Bhutan, 2001, Section 4 on Definitions states that;

- (3) The following, even if they inventions within the meaning subsection (2), shall be excluded from patent protection:*

- (i) *discoveries, scientific theories and mathematical methods;*
- (ii) *schemes, rules or methods for doing business, performing purely mental acts or playing games;*
- (iii) *methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body; this provision shall not apply to products for use in any of those methods.*

There is no other source for such exclusion.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Industrial Property Act of the Kingdom of Bhutan, 2001, Section 13, Rights Conferred by Patent states that;

13.(1) The exploitation of the patented invention in Bhutan by persons other than the owner of the patent shall required the latter's agreement.

(2) For the purposes of this Acts, "exploitation" of a patented invention means any of the following acts:

- (a) when the patent has been granted in respect of a product:*
 - (i) making, using, offering for sale, selling or importing for these purposes that product;*
 - (ii) stocking such product for the purposes of offering for sale, selling or using;*
- (b) when the patent has been granted in respect of a process:*
 - (i) using the process;*
 - (ii) doing any of the acts referred to in paragraph (a) in respect of a product obtained directly by means of the process.*

The second part of the question is not applicable as the Industrial Property Act of the Kingdom of Bhutan has publication only after the grant.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4.-10.

[Note from the Secretariat: the applicable law of the Kingdom of Bhutan does not provide exceptions for private and/or non-commercial use.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;

(4) (a) The rights under the patent shall not extend:

(iii) to acts done only for experimental purposes relating to a patented invention; or

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

NA

13. (a) What are the public policy objectives for providing the exception?

Promotion of R&D

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No, the applicable law does not make a distinction concerning the nature of the organization conducting the experimentation or research.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The applicable law does not define the concepts “experimental use” and/or “scientific research.”

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Not specified in the applicable law.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

Please explain by citing legal provision(s) and/or decision(s):

Section 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;

(4) (a) The rights under the patent shall not extend:

(iii) to acts done only for experimental purposes relating to a patented invention;

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

Not specified in the applicable law.

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

Not specified in the applicable law.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Our law does not provide for other criteria to be applied in determining the scope of the exception.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

[Note from the Secretariat: response not provided.]

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Since we don't have a Patent Registration System, most of the exceptions have not been implemented in our country.

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of the Kingdom of Bhutan does not provide exceptions for the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;

(4)(a) *The rights under the patent shall not extend:*

(iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Bhutan.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

NA

33. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

No, the applicable law does not define the scope of “use” and does not provide for any quantitative or qualitative limitations on the application of the “use” by prior user.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No, the applicable law does not provide for a remuneration to be paid to the patentee for the exercise of the exception.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

No.

Section 13(4)(b) of the Industrial Property Act of the Kingdom of Bhutan provides that “The right of prior user referred to in paragraph (a)(iv) may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made”.

The above provision in the applicable law does not address the conditions under which the transfer or licensing of the prior user’s right is allowed. This has not been addressed in other provisions of the applicable law and its rules.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

It has not been specified in our applicable law.

If yes, please explain the conditions under which such use can continue to apply:

N/A

39.-41.

[Note from the Secretariat: response not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 13(4) of the Industrial Property Act of the Kingdom of Bhutan states;

(4)(a) The rights under the patent shall not extend:

(ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Bhutan;

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

NA

44.

[Note from the Secretariat: response not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law does not provide any definition of the terms "temporarily" and "accidentally".

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No, the applicable law does not provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft).

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

NA

49.-50.

[Note from the Secretariat: response not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of the Kingdom of Bhutan does not provide exceptions for acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

Section 13(4) of the Industrial Property Act of the Kingdom of Bhutan states;

(4)(a) The rights under the patent shall not extend:

(i) to acts in respect of articles which have been put on the market in Bhutan by the owner of the patent or with his consent;

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

NA

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

The applicable law does not permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country.

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

[Note from the Secretariat: response was not provided.]

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

Patent Registration System has not started yet. Therefore, the exceptions available in our law have not been implemented.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

*Section 15, Industrial Property Act of the Kingdom of Bhutan, 2001:
Exploitation by Government or Person thereby Authorized*

15. (1) Where

(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or

(ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice:

the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subjected to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said decision, and, where a decision has been taken under paragraph (ii), the need to correct anti-competitive practices.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

NA

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Anti-competitive practices and/or unfair competition.
Public interest
National emergency and/or extreme urgency including government use
Refusal to grant licenses on reasonable terms*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Not specified in the applicable law.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Not specified in the applicable law.

71.-72.

NA

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

*Section 15, Industrial Property Act of the Kingdom of Bhutan, 2001:
Exploitation by Government or Person thereby Authorized*

15. (6) A request for the Minister’s authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

*Section 15, Industrial Property Act of the Kingdom of Bhutan, 2001:
Exploitation by Government or Person thereby Authorized*

15. (1) Where

(ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice:

the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was authorized

and shall be subjected to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said decision, and, where a decision has been taken under paragraph (ii), the need to correct anti-competitive practices.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

NA

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

No, the applicable law does not provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Yes, the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency.” However, their concepts and scope of application have not been specified.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

None

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

*Section 15, Industrial Property Act of the Kingdom of Bhutan, 2001:
Exploitation by Government or Person thereby Authorized*

15. (1) Where

(ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice:

the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subjected to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said

decision, and, where a decision has been taken under paragraph (ii), the need to correct anti-competitive practices.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

NA

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Anti-competitive practices and/or unfair competition.
Public interest
National emergency and/or extreme urgency including government use
Refusal to grant licenses on reasonable terms*

84.

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The applicable law does not define these two concepts and their scope of application.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

None

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

[Note from the Secretariat: response was not provided.]

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

NA

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

89.-100.

[Note from the Secretariat: the applicable law of the Kingdom of Bhutan does not provide exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Kingdom of Bhutan does not provide other exceptions and limitations.]

Country: BRAZIL
Office: Ministry of External Relations

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

According to Law n. 9.279 of 14 May 1996, an invention is patentable if it satisfies the requirements of novelty, inventive step, and industrial application. Moreover, the applicant shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and shall also indicate the best mode for carrying out the invention.

Those standards are applicable to all fields of technology.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Article 10 of Law n. 9.279 of 14 May 1996 establishes that the following are not considered to be inventions or utility models:

- I - discoveries, scientific theories, and mathematical methods;*
- II - purely abstract conceptions;*
- III - commercial, accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles or methods;*
- IV - literary, architectural, artistic and scientific works, or any aesthetic creation;*
- V - computer programs per se;*
- VI - presentation of information;*
- VII - rules of games;*
- VIII - surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animal body; and*
- IX - all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.*

Besides that, Article 18 of the Law also establishes that the following are not patentable:

- I - anything contrary to morals, standards of respectability and public security, order and health;*
- II - substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus; and*
- III - all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability - novelty, inventive step and industrial application - and which are not mere discoveries.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

According to Article 42 of Law n. 9.279 of 14 May 1996, a patent confers to its rightholder the right to prevent a third party from, without his consent, producing, using, offering for sale, selling or importing for these purposes:

I - a product that is the object of the patent;

II - a process or a product directly obtained by a patented process.

The publication of a patent application does not grant a right to the applicant, since it is a right contingent on the grant of the patent by the National Institute of Industrial Property. Nonetheless, Article 44 of Law n. 9.279 provides to the rightholder the right to obtain compensation for the unauthorized exploitation of the subject matter of the patent, including exploitation that occurred between the date of publication of the application and that of the grant of the patent.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Experimental use and/or scientific research;

Preparation of medicines;

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

Acts for obtaining regulatory approval from authorities;

Exhaustion of patent rights;

Compulsory licensing and/or government use;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions". Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 43, Paragraph I, of Law n. 9.279.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

The exception intends to establish a reasonable balance of interests between right holders and society at large. The Brazilian Legislation provides for an exception which does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties, in order to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

There is no such definition.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

There is no other criterion.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The Brazilian Government is carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 43, Paragraph II, of Law n. 9.279 of 14 May 1996.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

The patent system aims at stimulating research and innovation by providing a framework which ensures that the benefits of inventions accrue to society as a whole. In light of this fact,

the purpose of this exception is to limit the rights granted by a patent in order to allow the development of scientific or technological research, thereby striking the right balance between rightholders` and third parties` interests while fostering the advancement of the society.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

There is no such definition.

15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

There are no such definitions.

16.-17.

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant.

19. If the applicable law makes a distinction between "commercial" and "non-commercial" purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There is no other criterion.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The Brazilian Government is carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 43, Paragraph III, of Law n. 9.279 of 14 May 1996.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

It is fundamental to establish the right balance of interests between rightholders and users of intellectual property rights as well as to protect public interests by setting limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with its normal exploitation and do not unreasonably harm the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Therefore, the exception is considered to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Law n. 9.279 establishes that the preparation is to be carried out by a qualified professional.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There are no other criteria.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 45 of Law n. 9.279 of 14 May 1996.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

The prior use exception relates to the principle of acquired rights, which aims at avoiding unnecessary burden on good faith users who had been exploiting the invention before the date of deposit or priority of the patent application. Furthermore, this principle is found in the Brazilian Constitution under Article 5, which establishes the fundamental rights.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

There is no such definition and the law does not provide for quantitative or qualitative limitations.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No, it does not.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

Article 45, Paragraph 2, of Law n. 9.279 provides that the right thus conferred may be assigned only by transfer or leasing, together with the business of the undertaking or the part thereof that has direct relation with the exploitation of the subject matter of the patent.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Article 45 of Law n° 9.279 provides that a person who, in good faith, prior to the date of filing or of priority of a patent application, had been exploiting its object in Brazil will be guaranteed the right to continue the exploitation, without charge, in the previous form and conditions.

40.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The Paris Convention, revised in Stockholm in 1967, was ratified in Brazil by the Decree n. 635/1992, which provides that, among others, Article 5ter of the Convention is to be duly executed as provided therein, therefore being part of the Brazilian statutory law.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

The Paris Convention already provides that such an exception shall not affect negatively the rightholder.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

By analogy, one might consider that the exception also applies to spacecrafts.

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

There are no such definitions.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No, it does not.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There is no other criterion.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 43, Paragraph VII, of Law n. 9.279 of 14 May 1996.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

The legislation aims at avoiding the extension of patent terms beyond twenty years from the filling date, as pointed by the World Trade Organization panel "Canada - Patent Protection of Pharmaceutical Products" (DS114), thus establishing a reasonable balance of interests between rightholders and users of intellectual property rights, as well as protecting public interests.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

Non-authorized third parties regarding patented inventions whose acts aim exclusively at producing information, data and test results to obtain regulatory approval to market, in Brazil or any other country, in order to exploit and commercialize the patented product after its term of protection has expired in Brazil.

55. The exception covers the regulatory approval of:

Any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Making

Using

Other: Acts performed by non-authorized third parties regarding patented inventions which aim exclusively at the production of information, data and test results to seek approval to market, in Brazil or any other country, in order to exploit and commercialize the patented product after its term of protection has expired.

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

See answers to questions 54 to 56.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The Brazilian Government is carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

Article 43, Paragraph IV, of Law n. 9.279 of 14 May 1996.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Yes

Please explain your answer by citing legal provision(s) and/or decision(s):

Article 42 of Law n. 9.279 also establishes the rightholder's right to prevent a third party from, without his consent, importing a product that is object of the patent, or a process or a product directly obtained by a patented process.

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Decree n. 3.201 of 6 October 1999 and Articles 68 to 74 of Law n. 9.279 of 14 May 1996.

66.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Decree n. 3.201 of 6 October 1999 and Articles 68 to 74 of Law n. 9.279 of 14 May 1996.

82.-85.

[Note from the Secretariat: response was not provided.]

86. Please indicate how many times and in which technological areas government use has been issued in your country.

Since the enactment of Law n. 9.279, one compulsory license in the pharmaceutical area was issued.

87.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers` and/or breeders` use of patented inventions

Farmers` use of patented inventions

89.-94.

There is no such exception.

Breeders` use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 43, Paragraph V, of Law N. 9.279 of 14 May 1996.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

97. (a) What are the public policy objectives for providing the exception related to breeders` use of patented inventions? Please explain:

It is fundamental to stimulate the research and development of new plant varieties in order to establish a reasonable balance of interests between rightholders and users of intellectual property rights, as well as to protect public interests.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The non-commercial use of the subject matter of a patent related to living material by third parties is allowed as an initial source of variation or propagation to obtain other products.

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Article 43, Paragraph VI, of Law n. 9.279 of 14 May 1996.

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

Article 43, Paragraph VI, of Law n° 9.279 provides that rights conferred by a patent do not apply to third parties who, in the case of patents related to living matter, use, place in circulation or commercialize a patented product that has been introduced lawfully onto the market by the patentee or his licensee, provided that the patented product is not used for commercial multiplication or propagation of the living matter in question.

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

Yes.

(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

[Note from the Secretariat: response was not provided.]

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

The Brazilian Competition Law (Law n. 8.884 of 11 June 1994), in Article 24, Paragraph IV, Item a, provides for the possibility of recommending the compulsory license of a patent to the competent authorities as a penalty for the infraction against the economic order. Furthermore, Articles 20 and 21 of the Law establish several acts that may be considered violation to the economic order.

Country: CHILE
Office: National Institute of Industrial Property (INAPI)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard which establishes the requirements for determining whether an invention is patentable is Law No. 19.039 on Industrial Property of 1991, amended by Law No. 19.996 of 2005 and Law No. 20.160 of 2007.

Articles 33, 35 and 36 of Law No. 19.039 state that the requirements of patentability are novelty, inventive step and industrial applicability respectively.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

1. *Articles 37 and 38 of Law No. 19.039 establish the exclusions from patentability and non-patentable subject matter.*

“Article 37. The following shall not be considered an invention and shall be excluded from the patent protection provided by this Law:

(a) discoveries, scientific theories and mathematical methods.

(b) plants and animals, except for microorganisms which satisfy the general requirements of patentability. Plant varieties shall enjoy protection only in accordance with Law No. 19.342 on Rights of Breeders of New Varieties of Plants. Also not patentable are essentially biological procedures for the production of plants and animals, except for microbiological procedures. For these purposes, an essentially biological procedure is that which consists entirely of natural phenomena such as crossing and selection.

(c) Economic, financial, commercial, business or simple monitoring and supervision systems, methods, principles or plans; and those referring to purely mental or intellectual activities, or games.

(d) Methods of surgical or therapeutic treatment for the human or animal body, as well as methods of diagnosis applied to the human or animal body, apart from products intended to put one of these methods into practice.

(e) The new use, change of form, change of dimensions, change of proportions or change of materials for articles, objects or elements known and used for specific purposes. Without prejudice to the above, an invention eligible for protection may be constituted by the new use of known articles, objects or elements, provided that said new use resolves a technical problem without a previous equivalent solution, meets the requirements referred to in Article 32 and requires a change in the dimensions,

proportions or materials of the known article, object or element in order to obtain the above solution to said technical problem. The new claimed use shall be proven by means of experimental evidence in the patent application.

(f) Part of living beings as they are found in nature, natural biological processes, the biological material existing in nature or that which may be isolated, including a genome or germoplasm. However, the procedures which use one or more of the above biological materials and the products directly obtained thereby may be eligible for protection, provided that they satisfy the requirements established in Article 32 of this Law, that the biological material is appropriately described and that the industrial application thereof is explicitly included in the patent application.”

“Article 38. Inventions whose commercial working shall necessarily be prevented in order to protect ordre public, State security, morality and good customs, the health or life of persons or animals, or in order to preserve plants or the environment, shall not be patentable, provided that such an exclusion is not made merely because a legal or administrative provision exists, which prohibits or regulates said working.”

2. *Article 8 of Law No. 20.120 on Scientific Research on Human Beings, their Genomes, and Prohibiting Human Cloning also establishes non-patentable material.*

“Article 8. Knowledge of the human genome shall be the common property of humanity. Consequently, no person may acquire or establish ownership thereof or of part thereof. Knowledge of the structure of a gene and complete or partial DNA sequences shall not be patentable.

The biotechnology processes derived from knowledge of the human genome, as well as the products obtained directly therefrom, and diagnostic or therapeutic processes, shall be patentable according to the general rules.”

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

1. *Article 49 of Law No. 19.039 establishes the exclusive rights conferred by a patent.*

“Article 49. The owner of a patent shall enjoy exclusivity in producing, selling or marketing, in any form, the product or subject matter of the invention and, in general, carrying out any other type of commercial working thereof.

In process patents, the protection covers the products obtained directly by said process.

The scope of the protection granted by the patent or the patent application shall be determined by the content of the claims. The patent specification and the drawings shall be used to interpret the claims.

The patent right shall extend to the whole of the national territory up to the day when the period for grant of the patent expires.

The patent shall not confer the right to prevent third parties from marketing the product protected by the patent, whether they have been acquired lawfully after that product has been legally introduced into the trade of any country by the patent owner or by a third party, with the consent of that owner.

The patent shall not confer the right to prevent third parties from importing, exporting, manufacturing or producing the subject matter protected by a patent for the purpose of obtaining the registration or health authorization of a pharmaceutical product. The above shall not entitle said products to be marketed without the patent owner's authorization."

2. *Article 4 of Law No. 19.039 establishes the publication of an extract of the application in the Official Gazette, following acceptance for processing.*

"Article 4. Once an application for registration has been filed and accepted for processing, the publication of an extract thereof in the Official Gazette shall be compulsory, in the form and within the time periods determined by the regulations. Publication errors which, in the view of the Head of the Department, are not substantive, may be corrected by means of a decision laid down in the respective file. In case of substantive errors, the Head of the Department shall order a new publication, which shall be made within the period of 10 days, beginning from the date of the relevant decision."

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4.-10.

[Note from the Secretariat: the applicable law of Chile does not provide exceptions related to private and/or non-commercial use.]

Section III: Experimental use and/or scientific research

11.-22.

[Note from the Secretariat: the applicable law of Chile does not provide exceptions related to experimental use and/or scientific research.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Chile does not provide exceptions related to the preparation of medicines..]

Section V: Prior use

31.-41.

[Note from the Secretariat: the applicable law of Chile does not provide exceptions related to prior use.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Law No. 19.039 does not establish this exception. However, Chile is party to the Paris Convention and Chicago Convention on International Civil Aviation, which envisage these exceptions.

Paris Convention: Article 5ter

*Patents: Patented Devices Forming Part of Vessels, Aircraft, or Land Vehicles
In any country of the Union the following shall not be considered as infringements of the rights of a patentee:*

- (i) the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel;*
- (ii) the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country.*

Chicago Convention: Article 27

Exemption from seizure on patent claims

- (a) While engaged in international air navigation, any authorized entry of aircraft of a contracting State into the territory of another contracting State or authorized transit across the territory of such State with or without landings shall not entail any seizure or detention of the aircraft or any claim against the owner or operator thereof or any other interference therewith by or on behalf of such State or any person therein, on the ground that the construction, mechanism, parts, accessories or operation of the aircraft is an infringement of any patent, design, or model duly granted or registered in the State whose territory is entered by the aircraft, it being agreed that no deposit of security in connection with the foregoing exemption from seizure or detention of the aircraft shall in any case be required in the State entered by such aircraft.*

The provisions of paragraph (a) of this Article shall also be applicable to the storage of spare parts and spare equipment for the aircraft and the right to use and install the same in the

repair of an aircraft of a contracting State in the territory of any other contracting State, provided that any patented part or equipment so stored shall not be sold or distributed internally in or exported commercially from the contracting State entered by the aircraft.

The benefits of this Article shall apply only to such States, parties to this Convention, as either (1) are parties to the International Convention for the Protection of Industrial Property and to any amendments thereof; or (2) have enacted patent laws which recognize and give adequate protection to inventions made by the nationals of the other States parties to this Convention.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

The basis of this exception is the same as for the treaties where it is established. This exception seeks not to limit the transfer of goods and services that are not intended for trade in the country in question.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 45.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

The final paragraph of Article 49 of Law No. 19.039 establishes this exception.

“The patent shall not confer the right to prevent third parties from importing, exporting, manufacturing or producing the subject matter protected by a patent for the purpose of obtaining the registration or health authorization for a pharmaceutical product. The above shall not entitle those products to be marketed without the authorization of the patent owner.”

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

The aim of this rule, which has its source in the international treaties negotiated by Chile, is to incorporate flexibilities in the patent regime and to avoid the time for protection thereof being extended owing to the procedures necessary to obtain the health registration of a drug.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

The third importer, exporter, manufacturer or producer of the subject matter protected by a patent, with the aim of obtaining the registration or health authorization for a pharmaceutical product.

55. The exception covers the regulatory approval of:

*Certain products. Please describe which products: Pharmaceutical products
The final paragraph of Article 49 of Law No. 19.039 refers expressly only to "pharmaceutical products."*

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Making

Using in order to obtain registration or health authorization for a pharmaceutical product

Selling With the patent owner's authorization

Import

Export

Other. Please specify: Production of the invention patented in order to obtain the registration or health authorization for a pharmaceutical product.

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

National legislation does not envisage other criteria.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To date, the exception has been considered to meet the objective. Without prejudice thereto, this Article, together with all IP legislation, is being revised with a view to possible reform.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

International

If the exception is contained in statutory law, please provide the relevant provision(s):

Article 49(5) of Law No. 19.039 establishes the international exhaustion:

“Article 49. The patent shall not confer the right to prevent third parties from marketing the patent protected product, which such parties have acquired lawfully after that product has been lawfully introduced into the market of any country by the right owner or by a third party with the owner’s consent.”

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

This exception is based originally on the rulings concerning anti-trust commissions, which have now been replaced by the Court of Free Competition. There was a period in which the anti-monopoly bodies assumed powers to deal with such cases. Since said bodies are responsible for ensuring compliance with the standards designed to avoid conduct that harms free competition, they applied reasoning specific to the problems of parallel imports, and systematically sanctioned those industrial property rights holders who exercised the exclusive rights stemming therefrom in an abusive manner.

One example is the 1993 Ruling No. 886 of the Central Prevention Commission, which refers rather to marks, but is fully applicable to patents, which states that “the owner of a trademark that refers to articles or products of a certain manufacture may not lawfully oppose the trade of another person in genuine or authentic articles of the same origin, since the Law on Industrial Property prohibits trade in articles protected by a mark, that do not correspond to those that are lawful. The exclusive distributor of a foreign product may not prevent importers that acquire the same product also abroad from marketing it in the country.”

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

The aim of the rule was to establish the limits on the exercise of the industrial property rights with the aim of achieving balance in the system and promoting competition.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In legislative debates, it has been stated that parallel imports provide a balance between the industrial property right holders and, on the other hand, the rights of citizens, which are safeguarded before industrial property rights by the parallel imports mechanism, thus avoiding possible rights abuse.

The exhaustion of the right may be national or international according to the geographical scope which it covers. In making use of the freedom of choice which the TRIPS Agreement provides in this respect, Chile opted for the second formula, and so the intellectual property right owner which has disposed of it in different territories, at different prices, may not prevent any person from importing from where the product is cheapest and introducing it into a market where its value is higher.

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

There is no express rule on the matter within industrial property legislation.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

To date, the exception has been considered to meet the objective. Without prejudice thereto, this article, together with all IP legislation, is being revised with a view to possible reform.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Compulsory (non-voluntary) licenses are enshrined in Articles 51 to 51bis D of Law No. 19.039.

Article 51. A decision shall be taken on a non-voluntary license application in the following cases:

(1) Where the patent owner has engaged in conduct or practices declared contrary to free competition, in direct relation to the use or working of the patent in question, according to a firm or final decision of the Court of Free Competition.

(2) Where, for reasons of public health, national security, non-commercial public use, or national emergency or others of extreme urgency, declared by the competent authority, the grant of said licenses is justified.

(3) Where the aim of the non-voluntary license is to work a later patent that cannot be worked without infringing a previous patent. The grant of non-voluntary licenses for dependent patents shall be subject to the following rules:

(a) The invention claimed in the later patent shall include a technical advance of considerable economic significance with respect to the invention claimed in the first patent.

(b) The non-voluntary license for working the previous patent may be transferred only with the later patent.

(c) The owner of the earlier patent may, in the same circumstances, obtain a non-voluntary license on reasonable terms and conditions for working the invention claimed in the later patent.

As regards semi-conductor technology, the license may be granted only for non-commercial public purposes or to rectify the practice declared contrary to competition."

“Article 51 bis A. A person who requests a non-voluntary license shall provide proof that he requested previously from the patent owner a contractual license, and that he could not obtain such a license on reasonable terms and conditions, and within a reasonable period of time. This requirement shall not be imposed with respect to the clause contained in Article 51(2) of this Law. Nor shall this requirement be imposed where the aim of the non-voluntary license is to put an end to practices considered contrary to competition.”

“Article 51 bis B. The application for the grant of a non-voluntary license shall constitute a request and shall contain all the requirements of Article 254 of the Code of Civil Procedure. The following shall deal with such an application:

(1) In the case of Article 51(1), the Court of Free Competition, in accordance with the procedure provided for in Law No. 19.911.

(2) In the case of Article 51(2), the Head of the Industrial Property Department, in accordance with the procedure for nullity of patents established in this Law. In addition, on the basis of a reasoned decision, for the purposes of settling a particular incident, the Head may have temporary access to the request. This decision shall remain in force as long as the facts which substantiated it persist or until a final ruling is handed down.

(3) In the case of Article 51(3), the civil judge, according to the rules of competition of the Code of Civil Procedure and in accordance with the summary procedure.”

“Article 51 bis C. The competent authority shall take a decision on the application for a non-voluntary license, depending on the circumstances specific thereto.

Where said ruling is positive, the Court of Free Competition, the Head of the Department or the civil judge, as the case may be according to Article 51(1), (2) or (3), shall, on the one hand, fix the duration and scope of the license, limiting it for the purposes for which it was granted and, on the other, the amount of the remuneration that the licensee shall pay periodically to the patent owner. The license granted by this procedure shall be non-exclusive and may not be assigned, other than with that part of the firm that owns the patent.”

“Article 51 bis D. The non-voluntary license may be left without effect, either total or partial, subject to the licensee’s legitimate interests, if the circumstances which gave rise thereto have disappeared and are not likely to recur. The Court of Free Competition, the Head of the Department or the civil judge shall, according to the case and subject to consultation with the competent authority as appropriate, be authorized to examine, on the basis of a reasoned request, whether such circumstances continue to exist.

An application for withdrawal of a non-voluntary license shall not be accepted if the circumstances which gave rise to the issue thereof are likely to be repeated. Similarly, the Court of Free Competition, the Head of the Department or the civil judge may, as the case may be, at the request of an interested party, amend a non-voluntary license where new facts or circumstances so justify, in particular when the patent owner has issued contractual licenses on more favorable conditions than those granted for the beneficiary of the non-voluntary license.

In the non-voluntary license application proceedings, in the cases provided for in Article 51(1) and (3), the Department shall be heard before a ruling is handed down.”

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

The aim behind this rule is to provide the industrial property system with balance, by providing tools that limit the right where committed higher interests exist.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69.-73.

[Note from the Secretariat: response was not provided.]

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

In accordance with the provisions of Articles 51(1), 51 bis B(1) and 51 bis of Law No. 19.039, the competent entity for issuing a compulsory license based on anti-competitive practices is the Court of Free Competition, in accordance with the procedure established in Law No. 19.911.

It is the responsibility of the Court of Free Competition to determine in which cases a compulsory license should be granted owing to anti-competitive practices.

Article 51 bis C states: "The competent authority shall take a decision on the non-voluntary license application based on the circumstances specific thereto."

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Article 51(3) of Law No. 19.039 establishes the possibility of compulsory licenses for "dependent patents".

Article 51. A decision shall be taken on a non-voluntary license application in the following cases:

(3) Where the aim of the non-voluntary license is to work a later patent that may not be worked without infringing an earlier patent. The grant of non-voluntary licenses for dependent patents shall be subject to the following rules:

(a) *The invention claimed in the later patent shall include a technical advance of considerable economic significance with respect to the invention claimed in the first patent.*

(b) *The non-voluntary license for working the earlier patent may be transferred only with the later patent.*

(c) *The owner of the earlier patent may, in the same circumstances, obtain a non-voluntary license on reasonable conditions to work the invention claimed in the later patent.*

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

The second subparagraph of Article 51 bis C establishes that the authority competent to issue the license shall fix the amount of the remuneration to be paid periodically by the licensee to the patent owner. However, rules of general conduct for fixing the amount of the remuneration are not established.

“Article 51 bis C. The competent authority shall take a decision on the application for a non-voluntary license, depending on the circumstances specific thereto.

Where said ruling is positive, the Court of Free Competition, the Head of the Department or the civil judge, as the case may be according to Article 51(1), (2) or (3), shall, on the one hand, fix the duration and scope of the license, limiting it for the purposes for which it was granted and, on the other, the amount of the remuneration that the licensee shall pay periodically to the patent owner. The license granted by this procedure shall be non-exclusive and may not be assigned, other than with that part of the firm that owns the patent.”

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Article 51(2) of Law No. 19.039 does not define the concepts of “national emergency” or “circumstances of extreme urgency”. In Chile, compulsory licenses based on said cases have not been granted.

“Article 51. A decision may be taken on a non-voluntary license application in the following cases:

(2) Where for reasons of public health, national security, non-commercial public use, or national emergency or others of extreme urgency, declared by the competent authority, the grant of said licenses shall be justified.”

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Compulsory licenses have not been issued in Chile.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To date, the rule has been considered to meet the objective. Without prejudice thereto, this Article, together with all IP legislation, is being revised with a view to possible reform.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

To date, cases have not been submitted, for which reason practical problems in the implementation thereof cannot be identified.

Government use

81.-88.

[Note from the Secretariat: the applicable law of Chile does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Chile does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Chile does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Article 51(2) of Law No.19.039 establishes as a cause for the grant of a compulsory license "non-commercial public use".

"Article 51. A decision may be taken on a non-voluntary license application in the following cases:

(2) Where for reasons of public health, national security, non-commercial public use, or national emergency or others of extreme urgency, declared by the competent authority, the grant of said licenses shall be justified."

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

The legal source is Article 51(2) of the aforementioned Law No. 19.039

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The basis for this case of the grant of a compulsory license is the same as with respect to the earlier ones; providing the system with balance to allow the right to be limited in order to favor higher interests in the cases where this is necessary.

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

To date, the exception has been considered to meet the objective. Without prejudice thereto, this article, together with all IP legislation, is being revised with a view to possible reform.

(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

To date, there have been no cases allowing problems of practical implementation to be determined.

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

[Note from the Secretariat: response was not provided.]

Country: CONGO (REPUBLIC OF)
Office: Antenne Nationale de la Propriété Industrielle (National Industrial Property Unit)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

A new invention involving an inventive step and which is industrially applicable may be the subject of a patent (Article 2 of the Bangui Agreement of March 2, 1977).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The rights deriving from the patent shall not extend

- *to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;*
- *to acts in relation to subject matter brought on to the market on the territory of a member State by the owner of the patent or with his invention;*

or to the use of objects on board foreign aircraft, land vehicles or ships that temporarily or accidentally enter the airspace, territory or waters of a member State.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The patentee shall have the right to make changes, improvements to the invention. The owner of a patent may, by contract, grant to a person, whether natural person or legal entity, a license enabling him to test the patented invention.

Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

[Note from the Secretariat: response was not provided.]

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4.-10.

[Note from the Secretariat: the applicable law of the Republic of Congo does not provide exceptions related to private and/or non-commercial use.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights deriving from the patent shall not extend to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research.

12.-15].

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the scope of the patented invention
seek an improvement to the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”).

Please explain by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A commercial purpose

19.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-26.

[Note from the Secretariat: response was not provided.]

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No.

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31.-41.

[Note from the Secretariat: the applicable law of the Republic of Congo does not provide exceptions related to prior use.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42.-50.

[Note from the Secretariat: the applicable law of the Republic of Congo does not provide exceptions related to the use of articles on foreign vessels, aircrafts and land vehicles.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of the Republic of Congo does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60.-64.

[Note from the Secretariat: the applicable law of the Republic of Congo does not provide exceptions related to exhaustion of patent rights.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):
Non-voluntary license for non-export at the request of any person made after the expiry of a period of three years from the date of grant of the patent, whichever period expires last, a non-voluntary license may be granted where the patented invention is not being exported on the territory. On account of the refusal of the owner of the patent to grant licenses on reasonable commercial terms and procedures.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Notwithstanding the provisions of paragraph (1) above, a non-compulsory license may not be granted if the owner of the patent provides legitimate reasons for the non-working of the invention. (Bangui Agreement)

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Public health
National security
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Where certain patents are of vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the country's needs, they may be made subject, by an administrative enactment of the competent Ministry to the non-voluntary license regime.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of "non-working" or "insufficient working", please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

A non-voluntary license may be granted where the patented invention is not being worked on the territory or where the working of the patented invention on such territory does not meet the demand for the protected product on reasonable terms.

70. Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

No

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

[Note from the Secretariat: response was not provided.]

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Under national law, a non-voluntary license may be granted where, on account of the refusal of the owner of the patent to grant licenses on reasonable commercial terms and procedures, the establishment or development of industrial or commercial activities on the territory is unfairly and substantially prejudiced. (See Bangui Agreement).

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

The invention claimed in the later patent must represent substantial technical progress, of considerable economic interest, in relation to the invention claimed in the earlier patent
- the owner of the earlier patent has the right to a license on reasonable terms for the use of the invention claimed in the later patent;
- the use authorized in relation to the earlier patent shall be intransferable except where the later patent is also transferred.

76.-80.

[Note from the Secretariat: response was not provided.]

Government use

81.-82.

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention
Public health
National security
Dependent patents

84. (a) What are the public policy objectives for providing government use in your country?

Where certain patents are of vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the country's needs.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-92.

[Note from the Secretariat: response was not provided.]

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No, the applicable legal framework of the exception is not adequate to meet the objectives sought. Consequently, a process of revision is ongoing, the aim of which is to tackle the legislative gap through the addition to the Bangui Agreement of a number of provisions.

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of the Republic of Congo does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Republic of Congo does not provide other exceptions and limitations.]

Country: CYPRUS
Office: Department of Registrar of Companies and Official Receiver

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard used in our Patents Law, Law 16(I)98 (as amended) is that “an invention shall not be patentable unless it is novel, involves an inventive step and is industrially applicable”

The relevant provision in the Law is section 5(1).

The exclusions from patentability are stipulated as follows:

“The following, in particular, shall not be regarded as inventions within the meaning of subsection (1):

- (a) Discoveries, scientific theories and mathematical methods;*
- (b) Aesthetic creations;*
- (c) Schemes, rules and methods of performing mental acts, playing games or doing business and programs for computers and,*
- (d) Presentation of information*

A patent shall not be granted in respect of an invention exploitation of which would be contrary to public order or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by Law or Regulations.

The source of these exclusions from patentability is section 5(2) and (3).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

[Note from the Secretariat: response was not provided.]

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

“Where the patent concerns a product the owner of the patent shall have the right to prevent third parties from performing, without his authorization, the following acts:

- (i) The making of a product incorporating the protected invention*

- (ii) *The offering or the putting on the market of a product incorporating the protected invention, the using of such a product, or the importing or stocking of such a product for such offering or putting on the market or for such use.*
- (iii) *The inducing of third parties to perform any of the above acts.*

Where the patent concerns a process, the owner of the patent shall have the right to prevent third parties from performing, without his authorization, the following acts:

- (i) *The using of a process which is the subject matter of the patent.*
- (ii) *In respect of any product directly resulting from the use of the process, any of the acts referred to in paragraph (1) (ii) (of section 27), even where a patent cannot be obtained for the said product.*
- (iii) *Inducing third parties to perform any of the above acts.*

A patent shall also confer on its owner the right to prevent third parties from supplying or offering to supply a person, other than a party entitled to exploit the patented invention with means, relating to an element of that invention, exclusively for carrying out the invention, when the third party knows, or under the circumstances it is obvious, that those means are suitable and intended to be used for carrying out that invention.

This provision shall not apply when the means are commercial products and the circumstances of the supply of such products do not constitute inducement to infringe the patent”

The relevant statutory provisions are: section 27(1), (2) and (4) (a).

The rights conferred by a patent application after publication are prescribed by Section 28 as follows:

“28(1) A patent application shall, where published under Section 25 of this Law, provisionally confer upon the applicant from the date of such publication the same rights in respect of the subject-matter of the application as are conferred by Section 27 of this Law in respect of the subject-matter of a patent.

(2) The Court may decide to stay any proceedings brought before it in respect of unauthorized acts performed in relation to an invention that is the subject of a published application until a final decision has been made by the Registrar to grant or refuse a patent on the application.

(3) A patent application shall be deemed never to have had the effects set out in subsection (1) of this section if it is withdrawn, deemed to be withdrawn or finally refused.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The provision is contained in section 27(3)(i).

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

6. (a) What are the public policy objectives for providing the exception?

The public policy objectives for providing this exception are to encourage private initiative,

Principally learning, in colleges and universities and to avoid preventing use that is not commercial which means that such use is essentially for no profit and no harm will incur to the beneficiary/owner of the patent. Non-commercial use is basically a private use and a very restricted use.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

N/A

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

The Law provides expressly (Section 27(3)(ii)) "provided that it does not significantly prejudice the economic interests of the proprietor of the patent"

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

As things stand at the moment the current legal framework is considered adequate and no amendments to the legislation are under consideration.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section III: Experimental use and/or scientific research ²

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision in the Law is section 27(3) (iii).

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

13. (a) What are the public policy objectives for providing the exception?

The public policy criteria are to encourage inventiveness, educational promotion and scientific research in order to benefit mankind generally,

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The applicable Law does not make any such distinction.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

N/A

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

The act consist of making or using for purely experimental purposes.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

N/A

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

² Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

N/A

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There is a provision in section 27(3) (iii) which delineates the exception “in the making or using for purely experimental purposes or for scientific research”.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is considered adequate to meet the objectives sought. There are no amendments planned for the near future.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision is section 27(3)(iv) of the Law.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

25. (a) What are the public policy objectives for providing the exception? Please explain:

This exception is based on principles of the public benefit and the well being of mankind. If the preparation is limited to individual cases and for specific medical prescriptions there cannot be allegation of widespread infringement or at least infringement in a commercial scale. A case that such a medicine is required in a remote area or in a third world country, where the patent is not known or simply medicines under the patent have not been imported to pharmacies there, makes the exception soundly convincing.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Under our Law only pharmacists and medical doctors.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The exception must consist "of the extemporaneous preparation for individual cases of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared".

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework is considered adequate and no amendment(s) to the Law is(are) foreseen at present and in to the near future.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section V: Prior use

31.-41.

[Note from the Secretariat: the applicable law of Cyprus does not provide exceptions related to prior use.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42.-50.

[Note from the Secretariat: the applicable law of Cyprus does not provide exceptions related to the use of articles on foreign vessels, aircrafts and land vehicles.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Cyprus does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National
Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

The exception is provided in section 27(3) (i) of the Law.

If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

N/A

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

The public policy objective is the uninterrupted circulation of patented products in all the markets of Europe (European Union) after the product has been put in the market in Cyprus.

Another objective is the need to protect the patent against infringement in every country in the European Union and the patent if not protected specifically in a particular EU member state can be freely used/utilized by third parties.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

N/A

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

It has been considered adequate as far as I know.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

N/A

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

The exception is contained in sections 49 to 56 of the Law.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Refusal to grant licenses on reasonable terms

Dependent patents

Other, please specify: where the patented invention is a product, that a demand for the product in Cyprus: (i) is not being met, or (ii) is not being met on reasonable terms (anti-competitive practices).

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

The prime reasoning is the utilization of the patent and/or the patented product to the public benefit. It is also important to use the patent in order to encourage innovation and the further advancement of science and technology by other interested persons. Another objective is to promote trade and to boost the economy of our country by using patents as a source of potential income not only to the patentees but also to the whole of our country.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The terms that are mentioned in the question are not defined in our Law.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

No such legal provision exists in our Law.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period? *Four years*

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

No

If yes, what are "legitimate reasons"?

The provision in the Law does not specify "legitimate reasons". It merely says that an application for a compulsory license may be "opposed". However, Article 51(2) states that:

"[...] the Registrar shall, in determining whether to make an order or entry in pursuance of such an application, take account of the following matters, that is to say-

(a) the nature of the invention, the time which has elapsed since the publication in the Official Gazette of the Republic of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;

(b) the ability of any person to whom a license would be granted under the order concerned to work the invention to the public advantage; and

(c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted, but shall not be required to take account of matters subsequent to the making of the application."

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

In the Law there are no definitions of the quoted terms.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The legal provision required is found in section 49(2)(d) of the Law.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

By reason of the refusal of the proprietor of the patent to grant a license or licenses on reasonable terms, the working or efficient working in Cyprus of any other patented invention which makes a substantial contribution to the art is prevented or hindered (Article 49(2)(c)(ii))

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

In section 51(1)(b) is specified that the powers of the Registrar shall be exercised with a view to securing "that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention"

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

No such provision exists in the Law.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

No records of statistics exist at present.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is considered adequate. No amendments to the Law are foreseen in the near future.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

None is known.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant section is 49(1)(b) and relevant sections are also all sections from 49 to 56.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition*

84. (a) What are the public policy objectives for providing government use in your country?

Public policy objectives for the provision of government use in Cyprus are national emergency, national security, public health and the possible expertise of the government in a particular field of science and technology.

It can also be mentioned the necessity to work a patent or to produce a product when there is no response from the private sector.

The financial incentive cannot also be disregarded if money will go to the government's coffers from working itself a particular patent.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A.

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

These two concepts are not defined in the Cyprus Patent Law.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

N/A

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is considered adequate at present. No amendments are foreseen for the near future.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

N/A

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Cyprus does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Cyprus does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Cyprus does not provide other exceptions and limitations.]

Country: DENMARK
Office: Danish Patent and Trademark Office (DKPTO)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The Consolidate Patents Act (Act no. 91 of 28 January 2009)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The following is not considered as inventions:

- a) *discoveries, scientific theories and mathematical methods*
- b) *aesthetic creations*
- c) *schemes, rules or methods for performing mental acts, playing games or doing business or programs for computers*
- d) *presentation of information*

Patents shall not be granted in respect of:

- e) *methods for treatment of the human or animal body by surgery or therapy or diagnostic methods practiced on the human or animal body*
- f) *plant or animal varieties (plant variety as defined in EC regulation 2100/94, article 5)*
- g) *essential biological processes for the production of plants or animals*
- h) *the human body, at the various stages of its formation and development, and the simple discovery of one of its elements*
- i) *inventions contrary to ordre public or morality*
- j) *processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, also animals resulting from such processes*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 1(1):

“Any person who has made an invention which is susceptible of industrial application, or his successor in title, shall, in accordance with this Act, have the right on application to be granted a patent for the invention and thereby obtain an exclusive right to exploit the invention commercially. Inventions may be patented within all areas of technology.”

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3(3)(i)

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

6. (a) What are the public policy objectives for providing the exception?

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Alignment with Article 31a in Agreement relating to Community patents, 1989, signed by Denmark

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

No definition

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

None

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3(3)(iii).

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

13. (a) What are the public policy objectives for providing the exception?

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Alignment with Article 31b in Agreement relating to Community patents, 1989, signed by Denmark

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

None

16.

[Note from the Secretariat: response was not provided.]

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

Research and/or experimentation must be conducted with or using the patented invention (“research with”)

Please explain by citing legal provision(s) and/or decision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3(3)(iii)

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

No distinction

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3(3)(V)

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

25. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Alignment with Article 31b in Agreement relating to Community patents, 1989, signed by Denmark.

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Pharmacists making the preparation in a Pharmacy upon medical prescription

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, but it is hardly used since nearly no preparations take place at pharmacies any longer in our country

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 4(1)

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Qualitative limitation: "Use" must not constitute an evident abuse in relation to the applicant or his legal predecessor

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The "use" right provided for shall only be transferred to others together with the business in which it has arisen or in which the exploitation was intended.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

[Note from the Secretariat: response was not provided.]

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 5(1)

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

44. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of article 5 ter in the Paris Convention

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes, "temporarily" or "accidentally"

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

*Yes, devices used exclusively for the needs of the vessel, aircraft, or land vehicle.
The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 5(2)*

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3(3)(iv).

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

53. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of EU directives 2004/27 and 2004/28

54. Who is entitled to use the exception? Please explain:

Anyone

55. The exception covers the regulatory approval of:

Certain medicinal products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Acts necessary to obtain marketing clearance for medicinal product, e.g. studies, tests, examination or related procedures to the patented product.

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3(3)(ii).

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

A regional exhaustion regime has been determined by the EU Court of Justice and ensure the free trade between member states of the European Union.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

[Note from the Secretariat: response was not provided.]

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

None

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Sections 45-50.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 45(1)-(2).

“45.-(1) If a patented invention is not worked to a reasonable extent in this country when 3 years have elapsed from the grant of the patent and 4 years have elapsed from the filing of the patent application, any person wishing to work the invention in this country may obtain a compulsory licence to do so, unless there are legitimate reasons for the failure to work the invention.

(2) The Minister of Economic and Business Affairs may provide that for the purposes of the provision of subsection 1 working of the invention in another country shall be equivalent to working in this country. Such a provision may be made subject to reciprocity.”

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

See 69.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

3 yrs. from grant of patent and 4 yrs. from filing of patent

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

No

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

No

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

No

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Condition: The former invention constitutes a significant technical progress of considerable economic importance.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

“The proprietor of the patent for the invention or of the registered utility model for the exploitation of which a compulsory licence has been granted .. shall on reasonable terms be able to obtain a compulsory licence for the exploitation of the other invention.”

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 47 states, “When required by important public interest, any person who wishes to exploit an invention commercially for which another person holds a patent may obtain a compulsory license to do so.”

According to the preparatory remarks of the Act, such important public interests may concern (non-exhaustive list) national security, the population’s access to medical products and food, power supply, communication lines etc.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

[Note from the Secretariat: response was not provided.]

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

None

Government use

81.-88. If the exception is contained in statutory law, please provide the relevant provision(s):

No exceptions. Hence, questions nos. 82-88 not answered

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3b

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of EU directive 98/44 for the Legal Protection of Biotechnological Inventions.

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3b (2):

"3b-(2) Notwithstanding the provisions of section 3a(1) to (3), the sale or any other form of commercialisation of breeding stock or other animal reproductive material by the proprietor of the patent or with his consent to a farmer shall imply an authorisation for the farmer to use the animal or other animal reproductive material for the purposes of pursuing his own agricultural activity, but not to sell it within the framework or for the purpose of a commercial reproduction activity. The Minister of Economic and Business Affairs shall lay down provisions concerning the extent and the conditions of the farmer's exploitation of such patents for the purposes of pursuing his own agricultural activity."

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

None

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3b.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of EU directive 98/44 for the Legal Protection of Biotechnological Inventions.

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3b (1):

"3b.-(1) Notwithstanding the provisions of section 3a(1) to (3), the sale or any other form of commercialisation of plant propagating material by the proprietor of the patent or with his consent to a farmer for agricultural use shall imply an authorisation for the farmer to use the product of his harvest for multiplication or propagation by him on his own farm, the extent and conditions thereof being laid down in Article 14 of Council Regulation (EC) No. 2100/94 on Community plant variety rights."

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

None

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

None – questions nos. 101-103 not relevant.

Country: DOMINICAN REPUBLIC
Office: National Office of Industrial Property (ONAPI)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard or legal framework in force used to determine the patentability of a patent application is Law No. 20-00 on Industrial Property.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The exclusions from patentability contained in Law No. 20-00 are envisaged in Article 2 (repealed and replaced by Article 1 of Law No. 424-06 of November 20, 2006, the text of which is as follows):

Article 1 – Subject matter excluded from patent protection

(1) The subject matter which does not fit the definition of Article 1 of this Law shall not be considered an invention and shall therefore be excluded from patent protection. In particular, the following are not considered inventions:

- (a) Discoveries which consist in making known something which already exists in nature, scientific theories and mathematical methods;*
- (b) Exclusively aesthetic creations;*
- (c) Economic or business plans, principles or methods, and those referring to purely mental or industrial activities or games;*
- (d) Information presentations;*
- (e) Computer programs;*
- (f) Therapeutic or surgical methods for human or animal treatment, and also diagnostic methods;*
- (g) Any class of live material and substances pre-existing in nature, provided that the invention is directed toward the live material or substance in the form in which it exists in nature;*
- (h) The juxtaposition of known inventions or mixtures of known products, their variation in form, dimensions or materials, apart from in the case of a combination or merger thereof, such that they cannot function separately or that the characteristic features or functions thereof are modified in order to obtain an industrial result not obvious to a person skilled in the art;*

- (i) *Products already patented since a use distinct from that included in the original patent is attributed thereto;*
- (2) *The following inventions shall not be patentable and shall not be published:*
 - (a) *Those whose working would be contrary to ordre public or morality;*
 - (b) *Those which are obviously contrary to the health or life of people or animals, or may cause serious harm to the environment;*
 - (c) *Plants and animals, except for microorganisms, and essentially biological procedures for the production of plants or animals, that are not non-biological or microbiological procedures. Plant varieties shall be regulated by a special law, in accordance with Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

According to Article 29 of Law No. 20-00, the rights and protection conferred by a patent are as follows:

- (1) *The patent shall confer on its owner the right to exclude third persons from working the patented invention. With the limitations provided for in this Law, the patent owner shall therefore have the right to act against any person who, without his authorization, performs any of the following acts:*
 - (a) *where the patent has been granted for a product;*
 - (b) *manufacturing the product;*
 - (c) *offering for sale, selling or using the product; importing it or storing it for any of these purposes;*
 - (d) *where the patent has been granted for a process;*
 - (e) *using the process;*
 - (f) *performing any of the acts indicated in (a) with regard to a product obtained directly from the use of the process;*
- (2) *The scope of the protection conferred by the patent shall be determined by the claims. The claims shall be interpreted in the light of the description and the drawings and, where appropriate, such biological material as has been deposited.*

In relation to the second part of this question, the publication of an application does not confer exclusive rights on the applicant owing to the fact that the fundamental aim of the publication is to disclose to the public the information contained in the application so that the interested parties may make any observation they consider relevant.

The submission of observations shall not suspend the processing of the application. The observation may be submitted within 60 days following the publication date. See Article 21 of Law No. 20-00 on Industrial Property.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

(Article 30) of Law No. 20-00. The patent shall not give the right to prevent:

(a) acts performed in the private sphere and for non-commercial purposes;

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject.

6. (a) What are the public policy objectives for providing the exception?

To date, the Dominican Republic has no defined public policy objective for providing this exception; such an exception was included in the legislation, with TRIPS as a reference.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

There is no relevant case history.

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

These concepts are not defined in legislation.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

Law No. 20-00 (Article 30) establishes the following condition. "The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal

working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties”.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

With regard to exceptions, no changes to our legislation have been envisaged.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

For the time being no challenges have arisen.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 30. The patent shall not give the right to prevent:

- (b) Acts performed exclusively for the purposes of experimentation with respect to the patented invention;*
- (c) acts performed exclusively for the purposes of teaching or scientific or academic research.*

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject.

13. (a) What are the public policy objectives for providing the exception?

To date, the Dominican Republic has no defined public policy objectives for providing this exception; such an exception was included in the legislation, with TRIPS as a reference.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

There is no relevant legislative case history.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No, legislation does not specify differences as regards the nature of the organization that conducts experiments or research.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

These concepts are not defined in our legislation.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

Other, please specify: Law No. 20-00 (Article 30(b)) of the legislation specifies that the experimentation is with respect to the patented invention.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Please explain by citing legal provision(s) and/or decision(s):

Law No. 20-00 (Article 30(b)) of the legislation specifies that the experimentation is with respect to the patented invention.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose

19. If the applicable law makes a distinction between "commercial" and "non-commercial" purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

No distinction is made between these two terms.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The legislation (Article 30) establishes the following condition "The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties".

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

With respect to this exception, no changes to our legislation have been envisaged.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges to date.

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of the Dominican Republic does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 31. Right of the prior user of the invention.

(1) The rights conferred by a patent may not be enforced against a person who, in good faith and prior to the filing date, or where appropriate priority date, of the corresponding patent application, was already in the country producing the product or using the process which constitutes the invention, or had made effective and serious preparations for such production or use.

(2) That person shall have the right to continue producing the product or using the process as he had been doing, or to initiate the production or use that he had planned. This right may be assigned or transferred only with the firm or establishment in which such production or use was being carried out or had been planned.

(3) The exception provided for in this Article shall not apply if the person wishing to make use of it has acquired knowledge of the invention by means of an unlawful act.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

There is no source in case law.

33. (a) What are the public policy objectives for providing the exception? Please explain:

To date, the Dominican Republic has no defined public policy objective for providing this exception.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 31(1) of Law No. 20-00 specifies the following "producing the product or using the process which constitutes the invention, or had made effective and serious preparations for such production or use."

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The legislation does not envisage payment of remuneration to the patent owner.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

Article 31(2) states the following: "This right may be assigned or transferred only with the firm or establishment in which such production or use was being carried out or had been planned".

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The legislation (Article 30) establishes the following condition: "The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties".

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

With respect to this exception, no changes to our legislation have been envisaged.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges to date.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42.-50.

[Note from the Secretariat: the applicable law of the Dominican Republic does not provide exceptions related to the use of articles on foreign vessels, aircrafts and land vehicles.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 30(g) states "Those uses necessary to obtain health approval and to market a product following the expiry of the patent that protects it."

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

It has no basis in case law.

53. (a) What are the public policy objectives for providing the exception? Please explain:

To date, the Dominican Republic has no defined public policy objective for providing this exception.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not possible.

54. Who is entitled to use the exception? Please explain:

Any third party; Article 30 of the legislation does not specify who may or may not use this exception.

55. The exception covers the regulatory approval of:

Any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: The legislation does not specify the acts authorized, it only specifies "uses necessary to obtain the health approval and to market a product."

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Legislation (Article 30) establishes the following condition: "The actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties".

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

With respect to this exception, no changes to our legislation have been envisaged.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges have arisen to date.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

Article 30(d) "The sale, hire, use, usufruct, import or any form of marketing of a product protected by the patent or obtained by the patented process, once said product has been placed on the market of any country, with the consent of the owner or of a licensee, or in any other lawful manner. The products or processes which infringe industrial property rights shall not be considered lawfully marketed".

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

To date, the Dominican Republic has no defined public policy objectives providing for this exception; such an exception was included in the legislation, with TRIPS as a reference.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not possible.

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

N/A

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

There are no public policy objectives on this subject.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

No problems have arisen to date.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 40 envisages the following on Compulsory licenses:

(1) Where a potential user has tried to obtain the grant of a license from the owner of the patent on reasonable commercial terms and conditions, and such attempts have had no effect at the end of a period of two hundred and ten (210) days, beginning from the date on which the respective license was requested, the National Office of Industrial Property, subject to a hearing with the owner, may issue compulsory licenses in relation to that patent.

PARAGRAPH. In all the following cases, the National Office of Industrial Property shall grant compulsory licenses where the interested party shows that:

(a) it possesses technical and economic capacity to deal with the working in question. Technical capacity shall be evaluated by the competent authority, in accordance with the specific standards in force in the country, which exist in each branch of activity. Economic capacity means the possibility to fulfill the obligations stemming from the working to be performed;

(b) where the patent refers to a raw material from which an attempt is made to develop a final product, the applicant may develop the final product by himself or have third parties develop it in the country, apart from the cases where production on the national territory is impossible.

(2) In order to determine what the meaning of reasonable commercial terms and conditions is, the particular circumstances of each case and the economic value of the authorization shall be taken into account, bearing in mind the rate of average royalties for the sector in question, in relation to commercial license contracts between independent parties.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

This exception is provided through TRIPS; to date, the Dominican Republic has no case law on this subject.

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

To date, the Dominican Republic has no defined public policy objectives for providing this exception; such an exception was included in the legislation, with TRIPS as a reference.

(b) here possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

There is no case history.

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Legislation does not define as such the terms “non-working” or “insufficient working”, but Article 39 thereof defines what is meant by working of a patent.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

In accordance with Article 39 of the legislation, working of a patent means the following:

(a) here the patent has been granted for a product or a process to obtain a product, the supply of the internal market in terms of reasonable quantity, quality and price, through production in the country and import;

(b) here the patent has been granted for a process not covered by (a), the use of the process on a commercial scale in the country.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Article 41(1) of the legislation states that three (3) years must have passed from the grant of the patent or four (4) from the filing of the application, the period which expires later being applied, if the invention has not been worked or where the working thereof has been interrupted for more than one (1) year without due cause.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”? Article 41(2) states the following:

“A compulsory license shall not be granted where it is demonstrated that the non-working or insufficient working is due to chance or force majeure, or circumstances independent of the will or beyond the control of the patent owner and which justify the non-working or insufficient working. The lack of economic resources or the lack of economic viability of the working shall not be considered mitigating circumstances.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable

period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Article 40(2) of Law No. 20-00 states that: “In order to determine the meaning of reasonable commercial terms and conditions, the particular circumstances of each case and the economic value of the authorization shall be taken into account, bearing in mind the rate of average royalties for the sector in question, in relation to commercial license contracts between independent parties.”

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

In Article 42 of the legislation, the following shall inter alia be considered anti-competitive practices:

- (a) The fixing of excessive or discriminatory prices for patented products. In particular, where offers of market supply exist at prices significantly lower than those offered by the owner of the patent for the same product;*
- (b) The lack of market supply on reasonable commercial conditions;*
- (c) The obstruction of commercial or production activities;*
- (d) Any other act which national legislation characterizes as anti-competitive, limiting or restrictive of competition.*

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

In accordance with Article 44(c), Compulsory licenses shall extend to patents relating to the components and processes allowing them to be worked.

In addition, Article 45 on compulsory licenses in the case of dependent patents states the following:

(1) Where an invention claimed in a later patent cannot be worked in the country without infringing an earlier patent, the National Office of Industrial Property, at the request of the owner of that patent or his licensee, or of the beneficiary of a compulsory license for that patent, may grant a compulsory license with respect to the earlier patent, insofar as it is necessary to avoid the infringement.

(2) The compulsory license shall be granted only where the invention claimed in the later patent involves an important technical advance of considerable economic significance with respect to the invention claimed in the earlier patent.

(3) Where a compulsory license is granted in accordance with (1), in the same circumstances a compulsory license may be granted with respect to the later patent, if the owner of the earlier patent, his licensee, or the beneficiary of a compulsory license for said earlier patent, so requests.

(4) A compulsory license from among those provided for in this Article may not be granted exclusively. This compulsory license may only be the subject of a transfer where simultaneously the dependent patent, whose industrial working requires the license, is also

transferred. The transfer of the compulsory license shall be subject to the provisions of Article 32(2), as appropriate.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

In accordance with Article 44(g) of Law No. 20-00, “the patent owner shall receive reasonable remuneration according to the specific circumstances of each case, taking into account the economic value of the authorization. When determining the amount of the remuneration, in the cases in which the compulsory licenses have been granted to remedy anti-competitive practices, the need to correct said practices shall be taken into account and the revocation of the grant may be refused if it is considered that the conditions which gave rise to that grant are likely to recur”.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

These two concepts are not defined in the legislation.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

To date, the Dominican Republic has not granted any compulsory licenses.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

We consider the content of the legislation to be adequate and we do not plan to make any changes in this regard.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

No challenges have arisen to date.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

For reasons of public interest, and in particular for reasons of emergency or national security declared by the Executive Authority, the National Office of Industrial Property shall, at the request of any interested person or competent authority, or ex officio, make provision at any time for the following:

(a) an invention which is the subject matter of a patent or a patent application being processed is worked by a State body or by one or more public or private law persons designated for the purpose; or

(b) an invention which is the subject matter of a patent or a patent application being processed is open to the grant of licenses of public interest, in which case the National Office of Industrial Property shall grant a working license to any person that so requests and has the capacity to carry out such working in the country.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*National security
National emergency and/or extreme urgency*

84. (a) What are the public policy objectives for providing government use in your country?

To date, the Dominican Republic has no defined public policy objectives providing for this exception; such an exception was included in the legislation, with TRIPS as a reference.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not possible.

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

These two concepts are not defined in the legislation.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

To date working by the government has never been authorized in the Dominican Republic.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

We consider the content of the legislation to be adequate and we do not plan to make any changes in this regard.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

No challenges have arisen to date.

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of the Dominican Republic does not provide exceptions related to farmers’ use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of the Dominican Republic does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

They have been expressed.

102.

[Note from the Secretariat: response was not provided.]

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

No other mechanisms exist for the limitation of patent rights.

Country: EL SALVADOR
Office: National Center of Registries (CNR)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard used is the Law on Intellectual Property.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

[Note from the Secretariat: response was not provided.]

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

[Note from the Secretariat: response was not provided.]

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 116(b) of the Law on Intellectual Property

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

The Law does not make such provision, but it must be ensured that the normal working of the invention by the owner is not harmed.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

These concepts are not defined in the Law.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

No other criteria exist.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

There is provision for the possibility of revising current legislation in the medium term.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 116(c) of the Law on Intellectual Property.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

Generating research from patented inventions and allowing experimentation on the subject matter of the patented invention.

(b) here possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No, no distinctions exist.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

Those concepts are not defined.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention
invent around the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

[Note from the Secretariat: response was not provided.]

Please explain by citing legal provision(s) and/or decision(s):

There are no relevant legal provisions.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

There is no distinction in the Law.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is planned to revise the current Law in the medium term.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No problems have been encountered.

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of El Salvador does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 116(2) of the Law on Intellectual Property.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

The Law does not make such provision, although recognition of the right acquired for a previous use of the patent may be considered.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The Law does not contain any kind of definition.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No such provision is made.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The transfer of the enterprise with the establishment where production is carried out.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There are no other criteria.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is planned to revise the Law in the medium term.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges have been encountered.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 116(a) of the Law on Intellectual Property.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

The Law does not make such provision but it should be considered that the free transfer of the subject matter which the patented elements contain cannot be obstructed.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

No such definitions exist.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

In this case, Article 5ter of the Paris Convention applies, with reference to Article 116(a) of the Law on Intellectual Property.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There are no other criteria.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is planned to revise the Law in the medium term.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There have been no challenges.

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 116(e) of the Law on Intellectual Property.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

The Law does not make such provision, although the generation of information necessary to support the production of a health register should be allowed.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

Any third party.

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: Pharmaceutical and agricultural chemicals.

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Using

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There are no other criteria.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is planned to revise the Law in the medium term.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges encountered.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

Article 116(d) of the Law on Intellectual Property.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

There is no basis in the Law, but the owner may not exercise the right in the invention indefinitely.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

No express legal provision exists.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Currently the subject is being discussed by different national authorities and sectors.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

Mainly in the area of health a restriction on parallel imports is being considered.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 133 ff. of the Law on Intellectual Property.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*National security
National emergency and/or extreme urgency*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

The balance between private interest and the interest of society (basic needs of the population).

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69.-75.

[Note from the Secretariat: response was not provided.]

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

This should be established by the judge, in accordance with Article 134(b) of the Law on Intellectual Property.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The Law does not define the concepts.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

None.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

It is planned to revise the Law in the medium term.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

None.

Government use

81.-88.

[Note from the Secretariat: the applicable law of El Salvador does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of El Salvador does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of El Salvador does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of El Salvador does not provide other exceptions and limitations.]

Country: FINLAND
Office: National Board of Patents and Registrations of Finland

Note: Below the "Patents Act" refers to the Finnish Patents Act No. 550/67 of 15 December 1967, as last amended by Act No. 954/2010 of 12 November 2010
<http://www.prh.fi/en/patentit/lainsaadantoa/patenttilaki.html>

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

*Section 2(1) of the Finnish Patents Act:
Patents may only be granted for inventions which are new in relation to what was known before the date of filing of the patent application and which also differ essentially from them.*

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Section 1 of the Patents Act:

- Discoveries, scientific theories and mathematical methods;
- Aesthetic creations;
- Schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- Presentations of information.
- Methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals,
- Plant or animal varieties.
- Essentially biological processes for the production of plants or animals.

Section 1 a of the Patents Act:

- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Section 1 b of the Patents Act:

- Inventions the commercial exploitation of which would be contrary to ordre public or morality. The following inventions, in particular, shall be considered unpatentable:

- (1) processes for cloning human beings;
- (2) processes for modifying the germ line genetic identity of human beings;
- (3) uses of human embryos for industrial or commercial purposes;

(4) *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Section 1 of the Patents Act:

Anyone who has, in any field of technology, made an invention which is susceptible of industrial application, or his or her successor in title, is entitled, on application, to a patent and thereby to the exclusive right to exploit the invention commercially).

Section 3(1) and section 3(2) of the Patents Act):

The exclusive right conferred by a patent shall imply, with the exceptions stated below, that no one may exploit an invention, without the proprietor's consent, by:

(1) making, offering, putting on the market or using a product protected by the patent, or importing or possessing such product for these purposes;

(2) using a process protected by the patent, or offering such process for use in this country if he knows or if it is evident from the circumstances that the use of the process is prohibited without the consent of the proprietor of the patent;

(3) offering, putting on the market or using a product obtained by a process protected by the patent or importing or possessing such product for these purposes.

A patent shall also confer on its proprietor the exclusive right to prevent any person not having his consent from supplying or offering to supply any person not entitled to exploit the invention with the means of working the invention in this country in relation to an essential element of the invention where such other person knows, or where it is evident from the circumstances, that the means are suitable and intended for working the invention. This provision shall not apply where the means are staple commercial products, except where such other person attempts to induce the receiver to commit any of the acts referred to in the first subsection of this section. For the purposes of this subsection, any person using the invention in a manner referred to in subsection (3), item (1), (2) or (4), shall not be regarded as entitled to exploit the invention.

Rights conferred by public patent application (Section 60 of the Patents Act): *Where any person commercially exploits an invention which is the subject of a patent application after the application documents have been made available under Section 22, the provisions on patent infringement shall apply mutatis mutandis, if the application results in a patent. However, until a patent has been granted under Section 20, protection shall extend only to the subject matter disclosed both in the claims as worded when the application became available to the public and in the claims according to the patent. There shall be no liability to punishment, and damages arising from exploitation prior to the granting of the patent may be assessed only on the basis of Section 58 (2).*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Experimental use and/or scientific research;

Preparation of medicines;

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

*Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

*Section 3(3)(1) of the Patents Act:
Use which is not commercial*

5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

*Section 3(3)(3) of the Patents Act:
Use in experiments relating to the invention as such;*

12.-16.

[Note from the Secretariat: response was not provided.]

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

*Research and/or experimentation must be conducted on or relating to the patented invention
("research on")
Research and/or experimentation must be conducted with or using the patented invention
("research with")*

Please explain by citing legal provision(s) and/or decision(s):

*Section 3(3)(3) of the Patents Act:
Use in experiments relating to the invention as such;*

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 3(3)5 of the Patents Act:

Preparation in a pharmacy of a medicine prescribed by a physician in individual cases or treatment given with the aid of a medicine so prepared.

24.-25.

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Section 3(3)5 of the Patents Act:

Preparation in a pharmacy of a medicine prescribed by a physician in individual cases or treatment given with the aid of a medicine so prepared.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

Section 3(3)5 of the Patents Act:

*Preparation in a pharmacy of a medicine prescribed by a physician in **individual** cases or treatment given with the aid of a medicine so prepared.*

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 4 of the Patents Act:

Any person who, at the time the patent application was filed, was commercially exploiting the invention in this country may continue to do so, notwithstanding the grant of a patent, provided that the general nature of such previous exploitation is maintained and that the exploitation does not constitute an evident abuse in relation to the applicant or his predecessor in title. Such right of exploitation shall also be afforded, subject to the same conditions, to any person who has made substantial preparations for commercial exploitation of the invention in this country.

The right afforded under subsection (1) above can only be transferred to other parties together with the business in which it originated or in which exploitation was intended to take place.

32.-35.

[Note from the Secretariat: response was not provided.]

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

Section 4(2) of the Patents Act:

The right afforded under subsection (1) above can only be transferred to other parties together with the business in which it originated or in which exploitation was intended to take place.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Section 71 c of the Patents Act:

If a request under Section 71a or 71b is granted and if, as a result, the examination of a patent application that has been dismissed or rejected after becoming available to the public under Section 22 is resumed or a lapsed patent is reinstated, an announcement to that effect shall be made.

Any person who in good faith has begun to exploit an invention commercially in this country after expiration of the time limit for reinstating a dismissed application or after a rejection has become final or a patent has lapsed, but before such announcement is made, may nevertheless continue to exploit the invention provided he maintains the general nature of the exploitation. The right to exploit an invention shall be granted, on the same conditions, to anyone who has made substantial preparations for such exploitation in this country.

The right under subsection (2) above may only be transferred to another person together with the business in which it originated or in which exploitation of the invention was intended.

39.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 5 and 5(1) of the Patents Act:

Notwithstanding the patent, an invention may be exploited on foreign vessels, aircraft or other means of transport for their own needs when temporarily entering Finland in regular traffic or otherwise.

The Government may decree that, notwithstanding the grant of a patent, spare parts and accessories for aircraft may be imported into the country and used here for the repair of aircraft belonging to a foreign State in which corresponding privileges are granted in respect of Finnish aircraft.

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

See question 42.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

See question 42.

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 3(3)(4) of the Patents Act:

Examinations or experiments or measures arising from practical demands which are needed for an application to obtain a marketing authorisation for a medicinal product and which relate to the invention concerning that medicinal product.

52.-54.

[Note from the Secretariat: response was not provided.]

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: See question 51

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: See question 51.

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

Section 3(3)(2) of the Patents Act:

The exclusive right shall not apply to:

Use of a patented product that has been put on the market within the European Economic Area by the proprietor of the patent or with his consent;

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 45 – 50 of the Patents Act:

Section 45: *Where three years have elapsed since the grant of the patent and four years have elapsed from the filing of the application, and if the invention is not worked or brought into use to a reasonable extent in Finland, any person who wishes to work the invention in Finland may obtain a compulsory licence to do so unless legitimate grounds for failing to work the invention may be shown. (22.12.1995/1695)*

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

Section 46: *The proprietor of a patent for an invention whose exploitation is dependent on a patent held by another person may obtain a compulsory licence to exploit the invention protected by such patent if deemed reasonable in view of the importance of the first-mentioned invention or for other special reasons.*

The proprietor of a patent in respect of which a compulsory licence is granted under subsection (1) of this Section may obtain a compulsory licence to exploit the other invention unless there are special reasons to the contrary.

Section 46 a: *Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.*

Applicants for the licence referred to in subsection 1 above must demonstrate that they have applied unsuccessfully to the holder of the patent to obtain a contractual licence and that the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent.

Provisions concerning the right of a patent holder to obtain a compulsory licence for the exploitation of a plant variety protected by plant breeder's right are laid down by the Act on Plant Breeders' Rights (No. 789/1992).

Section 47: *In the event of considerable public interest, a person who wishes to exploit commercially an invention for which another person holds a patent may obtain a compulsory licence to do so.*

Section 48: *Any person who was commercially exploiting in this country an invention which is the subject of a patent application, at the time the application documents were made available under Section 22, shall, if the application results in a patent, be entitled to a compulsory licence for such exploitation, provided there are special reasons for this and also provided that he had no knowledge of the application and could not reasonably have obtained such knowledge. Such a right shall also be enjoyed, under corresponding conditions, by any person who has made substantial preparations for commercial exploitation of the invention in this country. Compulsory licences may also relate to the period of time preceding the grant of the patent.*

Section 49: *A compulsory licence may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner and in accordance with the terms of the licence who, before filing a claim for a compulsory licence, has made a verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention. A compulsory licence shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. A compulsory licence may only be transferred to a third party together with the business in which it is exploited or was intended to be exploited.*

Section 50: *Compulsory licences shall be granted by a court of law, which shall also decide the extent to which the invention may be exploited and shall determine the remuneration to be paid and any other conditions under the licence. In the event of a substantial change in the circumstances, the court may, on request, revoke the licence or lay down new conditions.*

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Section 45: *Where three years have elapsed since the grant of the patent and four years have elapsed from the filing of the application, and if the invention is not worked or brought into use to a reasonable extent in Finland, any person who wishes to work the invention in Finland may obtain a compulsory licence to do so unless legitimate grounds for failing to work the invention may be shown. (22.12.1995/1695)*

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 45(2) of the Patents Act:

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

3 years from the grant of the patent and 4 years from the filing of the patent application.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

No definition.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Section 49: *A compulsory licence may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner and in accordance with the terms of the licence who, before filing a claim for a compulsory licence, has made a verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention. A compulsory licence shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. A compulsory licence may only be transferred to a third party together with the business in which it is exploited or was intended to be exploited.*

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Section 46: *The proprietor of a patent for an invention whose exploitation is dependent on a patent held by another person may obtain a compulsory licence to exploit the invention protected by such patent if deemed reasonable in view of the importance of the first-mentioned invention or for other special reasons.*

The proprietor of a patent in respect of which a compulsory licence is granted under subsection (1) of this Section may obtain a compulsory licence to exploit the other invention unless there are special reasons to the contrary.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Section 50: *Compulsory licences shall be granted by a court of law, which shall also decide the extent to which the invention may be exploited and shall determine the remuneration to be paid and any other conditions under the licence. In the event of a substantial change in the circumstances, the court may, on request, revoke the licence or lay down new conditions.*

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Section 47: *In the event of considerable public interest, a person who wishes to exploit commercially an invention for which another person holds a patent may obtain a compulsory licence to do so.*

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Not used.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 75 and 76 of the Patents Act:

Section 75: *If the country is at war or in danger of war, the Government may decree, where required by the public interest, that the right to a given invention shall be surrendered to the State or to another party designated by the Government. Reasonable compensation shall be paid for the right to the invention thus surrendered. If no agreement is reached on compensation with the party entitled to compensation, the court shall determine the compensation.*

Where a party other than the State has availed itself of the right to an invention pursuant to subsection (1) above and if such party does not fulfill its obligations with regard to compensation, the State shall pay the compensation without delay on request by the party entitled to compensation.

Section 76: *Special regulations shall apply to inventions of importance to the defense of the country.*

82.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 3b(1) of the Patents Act:

By way of derogation from the provisions of Section 3 a, subsections (1) to (3), the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Council Regulation (EC) No 2100/94 on Community plant variety rights.

90.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 3b(2) of the Patents Act:

By way of derogation from the provisions of Section 3 a, subsections (1) to (3), the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

96.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Finland does not provide other exceptions and limitations.]

Country: FRANCE
Office: National Institute of Industrial Property (INPI)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The French Intellectual Property Code specifies three conditions of patentability, which are the same for all fields of technology that are the subject of a patent application (novelty, inventive step and industrial applicability).

Article L611-10 of the Intellectual Property Code (CPI) specifies the conditions of patentability: “In all fields of technology, new inventions which involve an inventive step and are industrially applicable shall be patentable”.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

French law specifies what is not considered to be an invention and what is excluded from patentability.

Article L611-10(2) of the CPI states: “The following shall not be considered to be inventions: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) plans, principles and methods in the exercise of intellectual activities, games or the field of economic activities and computer programs; (d) presentations of information;”

Article L611-16 of the CPI states: “Methods of surgical or therapeutic treatment of the human or animal body and the diagnostic methods applied to the human or animal body shall not be patentable. This provision shall not apply to products, in particular substances or compositions, for the implementation of one of these methods”;

Article L611-17 of the CPI states: “Inventions, the commercial working of which would be contrary to the dignity of the human person, ordre public or good manners, whereby this contrary nature cannot result solely from the fact that such working is forbidden by a legislative or regulatory provision, shall not be patentable”.

Article L611-18 of the CPI states: “The human body, at the different stages of its constitution and its development, and also the simple discovery of one of its elements, including the total or partial sequence of a gene, may not constitute patentable inventions. Only an invention constituting the technical application of a function of an element of the human body may be patent-protected. This protection covers the element of the human body only to the extent necessary for carrying out and working this particular application. Such application must be detailed in specific and precise terms in the patent application. The following shall, inter alia, not be patentable: (a) processes for cloning of human beings; (b) processes for modifying the genetic identity of human beings; (c) the uses of human embryos for industrial or commercial purposes; (d) the total or partial sequences of a gene taken as such”.

Article L611-19 of the CPI states: "The following shall not be patentable (1) animal breeds; (2) plant varieties as defined in Article 5 of Council Regulation (EC) No 2100/94, of July 27, 1994, on Community plant variety rights; (3) essentially biological processes for obtaining plants and animals; processes which require exclusively natural phenomena such as crossing or selection shall be considered such; (4) processes for modifying the genetic identity of animals, such that they cause suffering in those animals without substantive medical usefulness for humanity or animals, and also animals produced by such processes".

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

According to Article L611-1 of the CPI, the patent shall confer on its owner or his successors in title a direct or indirect exclusive right of working. Article L613-1 of the CPI specifies that: "The exclusive right of working mentioned in Article L.611-1 shall take effect from the time the application is filed."

The exclusive right of working conferred by the patent allows its owner to prohibit a number of acts performed without his consent. Article L613-3 states, for this purpose, that: "In the absence of the consent of the patent owner, the following shall be forbidden: (a) the manufacture, offer, marketing, use or also the import or retention for the above purposes of the product which is the subject of the patent; (b) the use of a process which is the subject of the patent or, where the third party knows or where the circumstances make it obvious that the use of the process is forbidden without the consent of the patent owner, the offer of its use on French territory; (c) the offer, marketing or use, or also the import or retention for the above purposes of the product obtained directly by the process which is the subject of the patent".

Article L613-4 of the CPI also states that: "(1) In the absence of the consent of the patent owner, the delivery or offer of delivery, on French territory, to a person other than those entitled to work the patented invention, of the means of carrying out, on such territory, of the invention relating to an essential element thereof, shall also be forbidden, where the third party knows or where the circumstances make it obvious that these means are suitable and intended for such performance..."

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and non-commercial use;

Experimental use;

Preparation of medicines prescribed and acts concerning medicines;

Prior use by a person who, in good faith, was in possession of the invention, before the filing date (priority date);

Use of articles on foreign vessels, aircrafts and land vehicles;

Acts for obtaining regulatory approval from authorities;

Exhaustion of patent rights;

Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private ~~and/or~~ non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

*Article L613-5 of the CPI states that “The rights conferred by the patent shall not extend to:
(a) the acts performed in a private context **and** for non-commercial purposes...”*

- 5.-8.

[Note from the Secretariat: response was not provided.]

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. No changes to legislation are planned.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section III: Experimental use

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-5 states that: “The rights conferred by the patent shall not extend to...(b) the acts performed for experimental purposes, which relate to the subject matter of the patented invention”;

The exception for the purposes of scientific research does not exist in French legislation.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

In keeping with Article L613-5 of the CPI, the aim of acts performed for experimental purposes shall be to verify the technical interest of the invention, to measure the scope thereof or to improve it and not to seek the commercial impact of the product or process.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

French legislation does not make a distinction regarding the nature of the body conducting the experimentation or research.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation should aim to:

*determine how the patented invention works
determine the scope of the patented invention
seek an improvement to the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on the subject matter of the patented invention

Please explain by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant.

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

The exception given to the patent monopoly by Article L613-5(b) of the CPI shall be assessed strictly and may apply only to the experimental acts, the aim of which is to participate in the verification of the technical interest of the invention or its development in order to advance knowledge, and not to commercially-oriented acts.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No legislative changes planned.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

The Law of February 26, 2007 introduced a specific exception for the bioequivalence tests in the field of medicines with a view to promoting the generic medicines found in Article L613-5(d) of the CPI: "the rights conferred by patents shall not extend to: the studies and tests required with a view to obtaining marketing of a medicine, and also for the acts necessary for their production and obtaining the authorization". This provision shall allow exemption for the marketing authorization and the acts necessary for obtaining it from the range of acts constituting infringement of a patent.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-5 of the CPI states that: "The rights conferred by the patent shall not extend to: (c) the extemporaneous preparation of medicines or that done by unit in pharmacies, on medical prescription, or to the acts concerning the medicines thus prepared".

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

Exception in the interest of public health (specific preparations in pharmacies).

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Pharmacists and doctors who may continue to carry out their specific preparations (the article of the Law specifies that these are medicines prepared in pharmacies and on medical prescription).

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

Article L613-5 of the CPI specifies that this exception applies to the extemporaneous preparations of medicines and those by unit in pharmacies.

28.-29.

[Note from the Secretariat: response was not provided.]

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

As far as we are aware, there have been no challenges in the application of this exception.

Section V: Prior use personal possession

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-7 of the CPI states that: "Any person who, in good faith, on the filing or priority date of a patent, was, on the territory where this book applies, in possession of the invention which is the subject of the patent, shall have the right, in a personal capacity, to work the invention, despite the existence of the patent".

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

This exception stems from the first applicant system and allows the inventor of a non-patented invention which he has kept secret since a date prior to the filing of the application of a third party relating to the same invention, to be able to continue working the invention personally after the filing of the patent. The benefit of the prior personal possession shall prevent any infringement action on the part of the patent owner

The possession must relate to the technology even covered by the patent and the invention must be known completely. The earlier holder must act in good faith.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Article L613-7 of the CPO specifies that the holder of the invention shall have the possibility to work it freely or to assign it until the filing or priority date of the patent application and that, from that date, he shall retain only the right to work it personally;

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

There is no provision for the payment of such remuneration. The earlier holder of an invention which he has not patented shall retain only a right of personal working not subject to remuneration for the benefit of the patent owner.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

No

Article L613-7 of the CPI specifies that: "the right recognized by this Article may be transferred only with the goodwill of the firm or part of the firm to which it is attached".

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

[Note from the Secretariat: response was not provided.]

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The earlier holder must act in good faith and the possession must be certain, unambiguous and on French territory.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No changes to legislation are planned.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-5(e) of the CPI states that: "The rights conferred by the patent shall not extend to the objects intended to be launched in the extra-atmospheric space introduced onto French territory". Article 5ter of the Paris Convention shall also apply.

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

Vessels
Aircrafts
Land Vehicles
Spacecraft

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 5ter of the Paris Convention refers to the criteria "temporarily or accidentally".

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 5ter of the Paris Convention limits the exception to the use on board vessels of means which are the subject of the patent in the body of the vessel, and also to the use of the means that are the subject of the patent in the construction or operation of aircraft or land vehicles, or accessories of such vehicles.

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-5(d) of the CPI states: "The rights conferred by the patent shall not extend to the studies and tests required with a view to obtaining a marketing authorization for a medicine, or also to the acts necessary for them to be carried out or the authorization to be obtained.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

This exception aims to facilitate the marketing of generic medicines. This exception allows generic medicine industries to begin the procedure with a view to a marketing authorization involving, inter alia, clinical trials without waiting for the monopoly on the patented product to expire. However, the working of generic medicines may only occur once the period of patent protection has expired.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

The person requesting the marketing authorization.

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: Medicines

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: Studies and tests with a view to obtaining a marketing authorization and acts necessary for producing and obtaining the marketing authorization.

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

Regional (European Economic Area)

If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-6 of the CPI specifies that "the rights conferred by the patent shall not extend to the acts concerning the product covered by the patent, performed on French territory, after the product has been commercialized in France or on the territory of a State party to the Agreement on the European Economic Area by the patent owner or with his express consent".

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

The exercise of the right in patents is restricted for the sake of the free circulation of goods on the territory of the European Union (EU). Once the owner of a patent has placed in circulation the product patented on the territory of one of the EU countries, he can no longer oppose the circulation of this product on the territory of the other countries of the EU by invoking the rights he holds in such a patent.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-11 of the CPI states that: “any public or private legal person may, upon expiry of a period of three years following the grant of a patent, or four years from the application filing date, obtain a compulsory license for the patent, subject to the conditions provided in the following articles, if at the time of the request, and in the absence of legitimate reasons, the patent owner or his successor in title: (a) has not begun to work or make effective and serious preparations to work the invention which is the subject of the patent on the territory of a Member State of the European Economic Community or of another State party to the Agreement on the European Economic Area; (b) has not marketed the product which is the subject of the patent in sufficient quantity to satisfy the needs of the French market. The same is true when the working provided for in (a) above or the marketing provided for in (b) above has been abandoned for more than three years. For the application of this Article, the import of products that are the subject of patents manufactured in a State party to the Agreement Establishing the World Trade Organization shall be considered working of the patent”.

Article L613-15 of the CPI states that: “the owner of a patent infringing an earlier patent may not work his patent without the authorization of the owner of the earlier patent; that owner may not work the later patent without the authorization of the owner of the later patent. Where the owner of a patent may not work it without infringing an earlier patent owned by a third party, the Regional Court may grant him a license to work the earlier patent to the extent necessary for working the patent of which he is the owner and insofar as this invention represents, in relation to the earlier patent, significant technical progress and is of considerable economic interest. The license granted to the owner of the later patent may be transferred only with that patent”.

Article L613-16 of the CPI states that: “If the interest of public health so requires and in the absence of an amicable agreement with the patent owner, the Minister for Industrial Property may, at the request of the Minister for Public Health, subject, by decree, to the ex officio license regime, under the conditions specified in Article L613-17, any patent granted for: (a) a medicine, medical device, an in vitro medical diagnostic device, or a related therapeutic product; (b) the process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product; (c) an ex vivo diagnostic method. The patents for these products, processes or methods of diagnosis may be subject to the ex officio license regime in the interest of public health only when these products, or products resulting

from these processes, or these methods are made available to the public in an insufficient quantity or quality, or at abnormally high prices, or when the patent is worked in conditions contrary to the interest of public health, or constituting anti-competitive practices following an administrative or court decision made final. Where the license aims to remedy a practice declared anti-competitive or in case of emergency, the Minister for Industrial Property shall not be obliged to seek an amicable agreement”.

Article L613-19 of the CPI states that: “the State may obtain, ex officio, at any time, for the needs of national defense, a license to work an invention which is the subject of a patent application or of a patent, whether this working is done by the State itself or on its behalf.”

Article L613-19-1 specifies that: “If the subject of the patent is an invention in the field of semi-conductor technology, a compulsory or ex officio license may be granted only for a use for public non-commercial purposes or to remedy a practice declared anti-competitive following court or administrative proceedings”.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
Dependent patents
Other, please specify: needs of the national economy*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

The patentee’s monopoly may be restricted by economic or social imperatives of general interest, which are considered more important.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

No legal definition.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

In accordance with French legislation, the import of a patented product or a product manufactured using a patented process constitutes an act of “working” of the patent (see

Article L613-3 of the aforementioned CPI in question 2). As a result, the grant of compulsory licenses for “non-working” or “insufficient working” cannot be obtained in the case of import of a patented product or a product manufactured using a patented process.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three years after the grant of a patent, or four years from the application filing date.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

No legal definition.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

In French patent legislation, two provisions envisage the possibility of granting compulsory licenses to combat anti-competitive uses:

The first provision envisages ex officio licenses in the interest of national public health, declared by decree of the Minister for Intellectual Property for a number of patents (in particular medicines, medical equipment, production or manufacturing processes) on the assumption that the patent is worked in conditions considered to constitute anti-competitive practices. Article L613-16 of the CIP specifies that:

“If the interest of public health so requires and in the absence of an amicable agreement with the patent owner, the Minister for Industrial Property may, at the request of the Minister for Public Health, subject, by decree, to the ex officio license regime, under the conditions specified in Article L613-17, any patent granted for: (a) a medicine, medical device, an in vitro medical diagnostic device, or a related therapeutic product; (b) the process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product; (c) an ex vivo diagnostic method. The patents for these products, processes or methods of diagnosis may be subject to the ex officio license regime in the interest of public health only when these products, or products resulting from these processes, or these methods are made available to the public in an insufficient quantity or quality, or at abnormally high prices, or when the

patent is worked in conditions contrary to the interest of public health, or constituting anti-competitive practices following an administrative or court decision made final. Where the license aims to remedy a practice declared anti-competitive or in case of emergency, the Minister for Intellectual Property shall not be obliged to seek an amicable agreement”.

The second provision applies specifically to patents relating to an invention in the field of semi-conductor technology and states that an ex officio license may be granted to remedy practices declared to be anti-competitive following administrative or court proceedings. Article L613-19-1 states that “If the subject matter of the patent is an invention in the field of semi-conductor technology, a compulsory or ex officio license may be granted only for a use for public non-commercial purposes or to remedy a practice declared anti-competitive following court or administrative proceedings”.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Article L613-15 of the CPI states that: “the owner of a patent infringing an earlier patent may not work his patent without the authorization of the owner of the earlier patent; that owner may not work the later patent without the authorization of the owner of the later patent. Where the owner of a patent may not work it without infringing an earlier patent owned by a third party, the Regional Court may grant him a license to work the earlier patent to the extent necessary for working the patent of which he is the owner and insofar as this invention represents, in relation to the earlier patent, significant technical progress and is of considerable economic interest. The license granted to the owner of the later patent may be transferred only with that patent”.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

No.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

According to the information available, no case relating to public health has been recorded.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

In France, recourse is very rarely had to compulsory license mechanisms. The existing provisions appear to be satisfactory.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81.-82.

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Public health

Other, please specify: national defense

84. (a) What are the public policy objectives for providing government use in your country?

These provisions refer to cases where:

- the working of the patent would be contrary to the interest of public health (products which are not made available to the public in a reasonable quantity, prices too high);*
- the working of the patent would be contrary to the interest of the national economy.*

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85.-86.

[Note from the Secretariat: response was not provided.]

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to legislation are envisaged.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L613-5-1 of the CPI states that: "By way of exception to the provisions of Articles L613-2-2 and L613-2-3, the sale or any other act of marketing of plant reproduction material by the patent owner, or with his consent, to a farmer for agricultural working purposes implies

for the farmer authorization to use the product of his harvest for reproduction or propagation by himself on his own holding. The conditions of such use shall be those which are provided for in Article 14 of Council Regulation (EC) No 2100/94 of July 27, 1994 on Community plant variety rights”.

Article L613-5-2 of the CPI states that: “By way of exception to the provisions of Articles L613-2-2 and L-613-2-3, the sale or any other act of marketing of breeding animals or animal reproduction material by the patent owner, or with his consent, to a farmer, implies for the farmer authorization to use, where appropriate for remuneration, protected livestock for an agricultural use. This authorization shall involve making the animal or animal reproduction material available for the continuation of his agricultural activity, but shall exclude sale as part of a commercial reproduction activity”.

Article L613-5-3 of the CPI states that: “The rights conferred by Articles L613-2-2 and L613-2-3 shall not extend to the acts performed with a view to creating or discovering and developing other plant varieties”.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

Articles L613-5-1 and L613-5-2 of the CPI introduce into patent law the “farmer or breeder’s privilege”, which constitutes the rule linking the monopoly and the plant and animal reproduction laws. This provision allows farmers to re-use, on certain conditions, the product of the harvest from protected seeds, without infringing the right in a patent or in a plant breeder’s certificate.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 92.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Article L623-25(2) of the CPI states that: “Subject to the provisions of Article L623-4, the use of the variety protected as a source of initial variation with a view to obtaining a new variety shall not constitute an infringement of the rights of the owner of a breeder’s certificate”.

Article L623-4 of the CPI states that: “Any plant variety may be the subject of a title called “plant variety certificate”, which shall confer on its owner an exclusive right to produce, introduce into the territory where this chapter applies, sell or offer for sale any or part of the plant, or all elements of plant reproduction or propagation of the variety under consideration and the varieties resulting therefrom by means of hybridization where their reproduction requires the repeated use of the initial variety. State Council decrees shall make the provisions of the previous paragraph gradually applicable to the different plant species,

depending on the development of scientific knowledge and means of control. The same decrees shall determine, for each of the plant species, the elements of the plant to which the breeder's right relates".

Article L613-15-1 of the CPI states that "Where a breeder may not obtain or work a plant breeder's right without infringing an earlier patent, he may request the grant of a license for this patent to the extent that this license is required for working the plant variety to be protected and insofar as the variety constitutes, in relation to the invention claimed in this patent, significant technical progress and is of considerable economic interest. Where such a license is granted, the patent owner shall obtain, on equitable conditions, on a request submitted to the court, the grant of a reciprocal license for using the protected variety. The provisions of Articles L613-12 to L613-14 shall apply".

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

Article L613-15-1 introduces a compulsory license procedure, as an exception to the patent monopoly, with a view to encouraging patent owners to grant a license voluntarily.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

[Note from the Secretariat: response was not provided.]

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The implementation of the compulsory license provided for in Article L613-15-1 is exceptional.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-102.

[Note from the Secretariat: response was not provided.]

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

National and European competition law sanctions the misuse of IP rights, as soon as such use is likely to be covered by the provisions relating to anti-competitive practices, in particular as part of unlawful agreements and abuse of dominant position.

Country: THE GAMBIA
Office: Registrar General's Office

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Section 4 of the Industrial Property Act

An invention is patentable if it is new, involves an inventive step and is industrially applicable.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Section 3 (3) of the Industrial Property Act excludes the following from patentability-

- (a) Discoveries, scientific theories and mathematical methods;*
- (b) Plant and animal varieties or essentially biological processes for the production of plants or animals, other than microbiological processes and the products of such processes;*
- (c) Schemes, rules or methods for doing business, performing purely mental acts or playing games;*
- (d) Methods for treatment of human or animal body by surgery or therapy, as well as diagnostic methods practised on the human or animal body, and this provision shall not apply to products for use in any of those methods*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Section 12 of Industrial Property Act grants exclusive right to exploit the patent.

Section 12(2) defines "exploitation" of patented inventions as

- (a) when the patent has been granted in respect of a product-*
 - (i) making, importing, offering for sale, selling and using the product,*
 - (ii) stocking such product for the purposes of offering for sale, selling or using;*
- (b) when the patent has been granted in respect of a process-*
 - (i) using the process;*
 - (ii) doing any of the acts referred to in paragraph (a) of this subsection in respect of a product obtained directly by means of the process.*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

[Note from the Secretariat: response was not provided.]

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4.-10.

[Note from the Secretariat: the applicable law of Gambia does not provide exceptions related to private and/or non-commercial use.]

Section III: Experimental use and/or scientific research

11.-22.

[Note from the Secretariat: the applicable law of Gambia does not provide exceptions related to experimental use and/or scientific research.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Gambia does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31.-41.

[Note from the Secretariat: the applicable law of Gambia does not provide exceptions related to prior use.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 12 (4) (b) of the Industrial Property Act

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

To mitigate against the harsh application of patent rights against foreign vessels, aircraft or vehicles.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

[Note from the Secretariat: response was not provided.]

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The exception applies in cases where the entry is temporary or accidental

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 12 does not restrict the application of the exception

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments are planned

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Gambia does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

Section 12(4) of the Industrial Property Act

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 12(6) and 14 of the Industrial Property Act

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

[Note from the Secretariat: response was not provided.]

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Public interest considerations

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

4yrs from date of filing of the patent application or 3yrs from date of grant of the patent.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

[Note from the Secretariat: response was not provided.]

73.-75.

[Note from the Secretariat: response was not provided.]

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Section 14 (3) provides for the payment of an equitable remuneration to the patentee

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

None

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 12(6)

82.-83.

[Note from the Secretariat: response was not provided.]

84. (a) What are the public policy objectives for providing government use in your country?

Public interest

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

86. Please indicate how many times and in which technological areas government use has been issued in your country:

None

87.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Gambia does not provide exceptions related to farmers’ use of patented inventions.]

Breeders’ use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Gambia does not provide exceptions related to breeders’ use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Gambia does not provide other exceptions and limitations.]

Country: GEORGIA
Office: National Intellectual Property Center of Georgia Sakpatenti

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

According to the Art 12 par 1 of the patent law of Georgia An invention is patentable where it satisfies the criteria of patentability - novelty, inventive step and industrial applicability.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Article 16 of the Patent Law of Georgia lists objects that cannot be as an inventions

1. *The following shall not be regarded as an invention:*
 - (a) *discovery, scientific theory, or mathematical method;*
 - (b) *artistic creation;*
 - (c) *algorithm, computer program;*
 - (d) *educational or teaching method and system, language grammar system, methods for performance of mental acts, rules for games or gambling;*
 - (e) *methods of business and organizational management;*
 - (f) *plans and schemes of structures, buildings or territories;*
 - (g) *presentation of information.*
2. *Objects under paragraph 1 of this Article shall not be considered patentable only where these are an immediate object of application.*

Article 17 of the Patent Law of Georgia lists objects on which cannot be granted a patent

A patent is not granted for:

- (a) *inventions against public order;*
- (b) *inventions related to surgical, therapeutic and diagnostic methods of treatment of humans and animals. This rule does not apply to devices and substances used in such methods;*
- (c) *inventions related to plant varieties and breeds of animals, as well as primarily biological methods for plant and animal breed selection. This rule does not apply to micro-biological methods and products obtained through such methods;*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Article 48 of the patent law of Georgia determines the scope of exclusive rights of the patent owner.

1. *The patent owner uses invention at his/her discretion. The patent owner has the right to sell or dispose of the patent otherwise, issue private license on the use of patent in accordance with applicable rules or/and to lease the patent.*

2. *The patent vests its holder with the exclusive rights to prohibit others, without holder's permission, from:*

(a) production, sale, offer for sale, use, import or other market use of a product protected by patent;

(b) use or offer for sale of a patented method;

(c) sale, offer for sale, use, import or other market use of a product directly made by the use of a patented method.

According to the Art 51 of the patent law of Georgia „The applicant holds conditional entitlement to all rights accorded by the patent, from the day of publishing an application until he/she is granted a patent. In case a patent is not granted, these rights will not be considered established“.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

Acts for obtaining regulatory approval from authorities;

Exhaustion of patent rights;

Government use;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the article 52 par. b) The following shall not be considered a violation of exclusive rights: private use of invention for personal ends, unless such action is not intended for commercial purposes.

5.-10.

N/A

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Georgian patent law does not consider an exception connected with experimental use and/or scientific research.

12.-22.

N/A

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Georgian patent law does not consider an exception connected with Preparation of medicines.

24.-30.

N/A

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the art 53 of the Patent law of Georgia

1. *Right of prior use is a right of a person to use the patent regardless of its effect, where such person has been using invention in good faith or conducted preparatory works for its use prior to the date of filing patent application in Sakpatenti or the priority establishment date.*
2. *The right of prior use entitles third persons to use invention exclusively for purposes and in volume corresponding to its purposes and volume of its past use or preparatory works, up to the date of filing or establishment of priority.*
3. *The right of prior use shall not be licensed privately.*
4. *It is permitted to transfer the right of prior use only together with an enterprise where actions referred to in par. 2 of this Article were undertaken.*

32.-33.

N/A

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

According to the Art 53 par 2 of the patent law of Georgia - The right of prior use entitles third persons to use invention exclusively for purposes and in volume corresponding to its purposes and volume of its past use or preparatory works, up to the date of filing or establishment of priority.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No the Patent law of Georgia does not provide a possibility for a remuneration to be paid to the patentee for the exercise of the exception.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

According to the Art 53 par 3 of the Patent law of Georgia - The right of prior use shall not be licensed privately.

However, according to the Art 53 par 4 of the Patent law of Georgia - It is permitted to transfer the right of prior use only together with an enterprise where actions referred to in par. 2 of this Article (Art 53 par 2 - The right of prior use entitles third persons to use invention exclusively for purposes and in volume corresponding to its purposes and volume of its past use or preparatory works, up to the date of filing or establishment of priority.) were undertaken.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

According to the Art 55 of the Patent law of Georgia considers Right of further use Any person, who has utilized an invention protected by patent in good faith or conducted preparations for exploitation of such invention from the date of patent revocation on the territory of Georgia until its reinstatement has the right to continue its use for entrepreneurial purposes. Transfer of this right is permitted only together with the enterprise (right of further use).

39.-41.

N/A

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art 52 Sub. Par. C) of the Georgian patent law - The following shall not be considered a violation of exclusive rights: c) use of invention aboard of the foreign vessel, aircraft or land transport temporarily present on the territory of Georgia. In such cases, invention should be used exclusively aboard such transportation means and not for entrepreneurial purposes;

43.-44.

N/A

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes. According to the Art 52 Sub. Par. c) use of invention aboard of the foreign vessel, aircraft or land transport temporarily present on the territory of Georgia. In such cases, invention should be used exclusively aboard such transportation means and not for entrepreneurial purposes;

The term temporarily is not defined by the law.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes. According to the Art 52 Sub. Par. c) use of invention aboard of the foreign vessel, aircraft or land transport temporarily present on the territory of Georgia. In such cases, invention should be used exclusively aboard such transportation means and not for entrepreneurial purposes;

48.-50.

N/A

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Georgian Legislation provides limitations and exceptions in respect of patent rights in connection with Acts for obtaining regulatory approval from authorities. According to the Law of Georgia on Medicine and Pharmaceutical Activities for the registration of a medicine the Agency for State Regulation of Medical Activities conducts special studies and necessary tests.

By the Law of Georgia on Medicine and Pharmaceutical activities Art 4 Par. 3 - „Patent rights and copyright of the producer of pharmaceutical products are protected by Georgian legislation“.

52.-59.

N/A

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art. 52 sub. par. A of the Georgia Patent Law The following shall not be considered a violation of exclusive rights:

(a) further dissemination or other use of the product produced by the patent owner or under his/her permission and put on the market;

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

61.

N/A

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

N/A

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law of Georgia does not consider the possibility of granting compulsory licenses.

66.-80/

N/A

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art 52 sub. par. D) of the Patent Law of Georgia - The following shall not be considered a violation of exclusive rights: d) use of invention in cases of natural disaster, catastrophe, epidemic or other emergency situations.

82.-88.

N/A

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Georgian legislation does not consider limitations and exceptions related to farmers' and/or breeders' use of patented inventions.

90.-94.

N/A

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Georgian patent law does not consider the possibility of granting patents on new varieties of plants. In Georgia relations in connection with breeders' rights are regulated by the Law on protection of Animal Breedings and Plant Varieties. Therefore Georgian Patent Law does not consider limitations and exceptions in connection with breeders' use of patented inventions.

96.-100.

N/A

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Georgia does not provide other exceptions and limitations.]

Country: GERMANY
Office: German Patent and Trade Mark Office (DPMA)

Note: The following remarks are based on the applicable legal provisions and the relevant commentaries on the German Patent Act (Schulte, Patentgesetz, 8th edition; Benkard, Patentgesetz, 10th edition).

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

*Patents are granted for **inventions** in all fields of technology provided that they are **new**, involve an **inventive step** and are **susceptible of industrial application** (Sec. 1(1) Patent Act).*

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

- *Discoveries, scientific theories and mathematical methods (Sec. 1(3) no. 1 Patent Act).*
- *Aesthetic creations (Sec. 1(3) no. 2 Patent Act).*
- *Schemes, rules and methods for performing mental acts, playing games or doing business (Sec. 1(3) no. 3 Patent Act).*
- *Programs for computers as such (Sec. 1(3) no. 3 and (4) Patent Act).*
- *Presentations of information (Sec. 1(3) no. 4 Patent Act).*
- *The human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene (Sec. 1a(1) Patent Act).*
- *Inventions the industrial exploitation of which would be contrary to "ordre public" or morality (Sec. 2(1) Patent Act)*
- *Processes for cloning human beings and for modifying the germ line genetic identity of human beings (Sec. 2(2) no. 2 Patent Act).*
- *Uses of human embryos for industrial or commercial purposes (Sec. 2(2) no. 3 Patent Act).*
- *Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes (Sec. 2(2) no. 4 Patent Act).*
- *Plant and animal varieties as well as essentially biological processes for the production of plants and animals (Sec. 2a(1) no. 1 Patent Act)*
- *Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body (Sec. 2a(1) no. 2 Patent Act)*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The patent owner has the exclusive right to use the patented invention (Sec. 9, first sentence, Patent Act). Any other person is prohibited from directly or indirectly using the patented products or processes (Sec. 9, second sentence, Patent Act, Sec. 10 Patent Act).

Under Sec. 33(1) Patent Act, the applicant is entitled to claim compensation as from the publication of his application.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 11 no. 1 Patent Act: The effects of a patent shall not extend to acts done privately and for non-commercial purposes.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

Acts undertaken in the private sphere for non-commercial purposes are excluded from the effects of a patent, because patents are not intended for intervention in the private sphere.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 11 no. 2 Patent Act: The effects of a patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

Patents are meant to encourage technological progress. For this reason the effects of the patent do not extend to acts done for experimental purposes. The provision is intended to prevent patent protection from hindering research and technological development.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The limitation of the effects of the patent for acts done for experimental purposes applies to all experiments relating to the subject matter of the patented invention, irrespective of the aim of the experiment, and of the person or organisation conducting the experiment.

15.-16.

[Note from the Secretariat: response was not provided.]

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Please explain by citing legal provision(s) and/or decision(s):

*Sec. 11 no. 2 Patent Act: acts done for experimental purposes **relating to the subject matter of the patented invention.***

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 11 no. 3 Patent Act: The effects of a patent shall not extend to the extemporaneous preparation in pharmacies of medicines for individual cases in accordance with a medical prescription as well as acts concerning the medicines thus prepared.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

This provision is intended to facilitate the exercise of medical activities, since patents should not restrict the freedom of the doctor (physician) to prescribe medicines in the interest of health promotion. This is to allow doctors to prescribe medicines to their patients in the individual case, which are prepared in pharmacies, irrespective of possible patent rights. In addition, the provision is to supplement the prohibition of patent protection of methods for treatment of the human or animal body by surgery or therapy.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The above-mentioned objectives are mentioned in the explanatory statement to the draft law on the Community patent and on amending provisions in patent law (document of the Bundestag BT-Drucksache 8/2087; p. 25) and the memorandum on the Convention for the European Patent for the Common Market (official gazette BIPMZ 1979, p. 325, 333).

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

The provision is intended to facilitate the prescription of medicines by doctors by way of exempting persons from the effect of the patent, who are directly involved in preparing and processing medicines in the individual case. It therefore concerns the activities of pharmacists and doctors.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

Sec. 11 no. 3 Patent Act does not contain explicit requirements concerning the admissible amount of medicines. However, the exemption from the effect of the patent only covers the "extemporaneous preparation for individual cases" (Sec. 11 no. 3 Patent Act). This is the amount which is required in one concrete individual case. The preparation of larger quantities of medicines for several patients is not covered by this provision.

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 12 Patent Act:

(1) A patent shall have no effect against a person who, at the time of the filing of the application, had already begun to use the invention in Germany, or had made the necessary arrangements for so doing. Such person shall be entitled to use the invention for the needs of his own business in his own plant or workshops or the plant or workshops of others. This right can only be inherited or transferred together with the business. If the applicant or his predecessor in title has, before applying for a patent, disclosed the invention to other persons and reserved his rights in the event of a patent being granted, a person learning of the invention as a result of such disclosure cannot, under the provisions under the first sentence, invoke measures which he has taken within six months after the disclosure.

(2) If the patent owner is entitled to a right of priority, the date of the prior application shall be substituted for the date of the application referred to in subsection 1. However, this provision shall not apply to nationals of a foreign country which does not guarantee reciprocity in this respect, where they claim the priority of a foreign application.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

The purpose of the provision is to protect the economic status of possession of the prior user. It is intended to prevent the destruction of legitimately created values. Investments in existing facilities are not to be devalued by another person's later patent application.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The prior user can exploit the invention for his own enterprise. The Patent Act does not provide for explicit limitations of a quantitative or qualitative nature in respect of the admissible exercise of the right to continued use.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

[Note from the Secretariat: response was not provided.]

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes (The prior user's right can be assigned, but not licensed)

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The entitlement of the prior user to exploit the invention for the needs of his own business can only be inherited or transferred together with the business.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The effect of the patent shall not extend to:

- *the use on board vessels of another State party to the Paris Convention for the Protection of Industrial Property of the patented invention, in the body of the vessel, in the machinery, tackle, gear and other accessories, where such vessels temporarily or accidentally enter the waters to which the territory of this Act extends on condition that such use serves exclusively the needs of the vessel (Sec. 11 no. 4 Patent Act);*
- *the use of the patented invention in the construction or operation of aircraft or land vehicles of another State party to the Paris Convention for the Protection of Industrial*

Property or of accessories for such aircraft or land vehicles, where these temporarily or accidentally enter the territory to which this Act applies (Sec. 11 no. 5 Patent Act).

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

Sec. 11 no. 4 and no. 5 Patent Act correspond to the provision under Art. 5^{ter} of the Paris Convention for the Protection of Industrial Property. They are intended to protect international traffic from impairments which might result from claiming patent rights.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

*The effect of a patent does not extend to the use of the subject matter of the patented invention on condition that the vessels, aircrafts or land vehicles **temporarily** or **accidentally** enter the territory to which this Act applies (Sec. 11 no. 4 and no. 5 Patent Act).*

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

*Sec. 11 no. 4 Patent Act explicitly stipulates that the subject matter of the patented invention is used **exclusively** for the needs of the vessel.*

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 11 no. 2b Patent Act stipulates that the effect of the patent does not extend to studies, experiments and any related practical requirements that are necessary to obtain either a

marketing authorisation for medicinal products within the European Union or an authorisation for medicinal products within the member states of the European Union or third countries.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

The purpose of the provision under Sec. 11 no. 2b Patent Act is to privilege the manufacturers of generic medicines. These manufacturers are allowed to carry out the use of the patent even before the term of protection ends under the condition that the use is necessary to obtain an authorisation for medicinal products.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Sec. 11 no. 2b Patent Act implements Article 10(6) of the amended Directive 2001/83/EC and Article of the amended Directive 2001/82/EC into national law.

54. Who is entitled to use the exception? Please explain:

Manufactures of medicaments, especially of generic medicines.

55. The exception covers the regulatory approval of:

Certain products: Medicaments

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other: Studies, experiments and any resulting practical requirements, i.e. any use under the patent's scope of protection that is intended to meet the prerequisites of a privileged study or a privileged experiment (for example: production or importation of the still protected active substance intended to be used in the experiment).

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The scope of admissible use comprises studies, experiments and any action to execute them, under the condition, that they are necessary to obtain an authorisation for medicinal products or approval. Therefore, a direct relation is required between the study, the experiment or its execution, on the one hand, and the authorisation or approval sought, on the other hand.

58.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National and EU/EEA-wide (i.e. the goods protected by patent rights must have been marketed in the territory of a Member State of the European Union or a Contracting State to the Agreement on the European Economic Area)

If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 9b Patent Act contains a specific exhaustion provision applying to the propagation of biological material:

Where the patent owner or a third party with the owner's consent markets biological material having specific properties, due to the invention, in the territory of a Member State of the European Union or a Contracting State to the Agreement on the European Economic Area, and where further biological material is obtained from this biological material by way of generative or vegetative propagation, the effects of Sec. 9 shall not apply if propagation of the biological material constituted the marketing purpose. This does not apply where the material so obtained is subsequently used for further generative or vegetative propagation.

There are no legal provisions on exhaustion governing other cases.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

e.g. Federal Court of Justice [BGH], judgment of 14 December 1999, X ZR 61/98 – Karate, published in GRUR 2000, 299:

1. Exhaustion of the rights conferred by a patent granted with effect in the Federal Republic of Germany occurs at any rate on principle, if the protected product has been put on the market by the patent owner or with his consent in Germany, in a Member State of the European Community or a State party to the Agreement on the European Economic Area.

2. Exhaustion constitutes an exception to the exclusive rights of the patent owner. The party invoking exhaustion has, on principle, the burden of production and proof as to the preconditions.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

In the interest of the free movement of goods and trade, the patent should not give the owner the right to influence the trade with specific patent-protected objects forever, if these objects have been put on the market by the patent owner or a third party with the owner's consent within a certain territory (Germany, EU, EEA). Once the patent owner has exercised his patent right by putting the protected object on the market himself or through a third party with his consent, there is no reason to give him further possibilities to influence the future fate of the protected object. Rather, the exclusive right to dispose of the protected object lies with the lawful acquirer (in relation to the patent owner) (BGH, judgment of 14 December 1999, X ZR 61/98 – Karate, published in GRUR 2000, 299). In the event that the protected object is put on the market in another Member State of the European Union by the patent owner or a third party with the owner's consent, the exhaustion of the patent right arises from Art. 34 of the Treaty on the Functioning of European Union according to which all quantitative

restrictions on imports and all measures having equivalent effect are, on principle, prohibited between Member States.

The particular exhaustion rule of Sec. 9b Patent Act is to ensure that a person purchasing propagation material in the European Union or a Contracting State to the Agreement on the European Economic Area, may in fact grow it since the material was bought for this purpose. Patent protection does not preclude the growing and exploitation. It should be noted, however, that this provision does not cover the later use of harvested material as seed.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 24 Patent Act:

(1) A non-exclusive authorisation to commercially exploit an invention shall be granted by the Patent Court in individual cases in accordance with the following provisions (compulsory license) if

- 1. the applicant for a license has unsuccessfully endeavoured during a reasonable period of time to obtain from the patent owner consent to exploit the invention under reasonable conditions usual in trade; and*
- 2. public interest commands the grant of a compulsory license.*

(2) If the applicant for a license is unable to exploit an invention for which he holds protection under a patent of later date without infringing a patent of earlier date, he shall be entitled to request the grant of a compulsory license with respect to the owner of the patent of earlier date if

- 1. the requirements of subsection (1) no. 1 are met and*

2. *his own invention comprises, in comparison with that under the patent of earlier date, an important technical advance of considerable commercial significance.*

The patent owner may require the applicant for a license to grant him a counter license under reasonable conditions for the exploitation of the patented invention of later date.

(3) Subsection (2) shall apply mutatis mutandis if a plant breeder has not obtained a plant variety right or cannot exploit it without infringing an earlier patent.

(4) A compulsory license under subsection (1) may be granted for a patented invention in the field of semi-conductor technology only if such grant is necessary to remove an anti-competitive practice on the part of the patent owner that has been established in judicial or administrative proceedings.

(5) If the patent owner does not use the patented invention or does not use it predominantly in Germany, compulsory licenses under subsection (1) may be granted to ensure an adequate supply of the patented product to the domestic market. Importing shall be deemed to constitute use of the patent in Germany in such case.

(6) The grant of a compulsory license in a patent shall be permissible only after the grant of the patent. It may be granted subject to restrictions and made dependent upon conditions. The scope and duration of use shall be restricted to the purpose for which they have been permitted. The patent owner shall be entitled to remuneration from the holder of a compulsory license that shall be commensurate with the circumstances and shall take into consideration the commercial value of the compulsory license. In the event of a significant change, with respect to the repeated remuneration that will become due in future, in the circumstances on which the determination of the amount of the remuneration was based, each party shall be entitled to require a corresponding adjustment. If the circumstances on which the grant of a compulsory license was based no longer apply and if it is unlikely that they will reoccur, the patent owner may require the withdrawal of the compulsory license.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Compulsory licences may also arise from cartel law. In his decision of May 6, 2009, Case No. KZR 39/06 – Orange Book Standard, published in IIC 2010, 269, the Federal Supreme Court ruled on a possible defence on the basis of cartel law:

“a) A defendant against whom an action has been filed on the basis of a patent may, in reply to the plaintiff patent holder’s application for an injunction, raise the defence that the latter is abusing a market-dominant position by refusing to conclude a patent licence contract with the defendant on non-discriminatory and non-obstructive conditions. b) A patent holder, however, only act abusively if the defendant has made him an unconditional offer to conclude a licence contract to which he remains bound and that the patent holder cannot refuse without infringing the prohibition on discrimination or obstruction, and if the defendant, if and as long as he is already using the subject matter of the patent, complies with those obligations that the licence contract to be concluded imposes on the use of the licenced object. c) If the defendant regards the patent holder’s licence requirements as abusively excessive or if the patent holder refuses to quantify the licence fee, the requirement of an unconditional offer is satisfied by an offer to conclude a licence contract under which the licensor shall specify the amount of the licence fee at his fair discretion.”

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Refusal to grant licenses on reasonable terms. Note: in this case the **public interest** must, in addition, command the grant of a compulsory licence (Sec. 24(1) no. 2 Patent Act)*

Anti-competitive practices and/or unfair competition. Sec. 24(4) Patent Act contains a specific provision for compulsory licences in the area of semiconductor technology: in addition to the general requirements under subsection (1) (unsuccessful endeavour of the applicant for a licence and public interest) the compulsory licence must be required to remove an anti-competitive practice on the part of the patent owner that has been established in judicial or administrative proceedings.

Furthermore, there is, as stated above sub 66., an obligation to grant licences accruing from cartel law provisions (abuse of a dominant position - compare decisions of the Federal Supreme court of July 13, 2004, Case No. KZR 40/02 – Standard-Spundfass, published in GRUR 2004, 966 and of May 6, 2009, Case No. KZR 39/06 – Orange Book Standard, published in IIC 2010, 269).

Dependent patents (Sec. 24(2) and (3) Patent Act; see comments on question 75)

Other, please specify: Under Sec. 24(5) Patent Act, compulsory licences can be granted within the scope of subsection (1) to ensure an adequate supply of the patented product on the domestic market if the patent owner does not use the patented invention or does not use it predominantly in Germany.

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

The provision of Sec. 24 Patent Act is intended to protect the public from any abuse of the exclusive right to which the patent owner is entitled.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 69.-72.

[Note from the Secretariat: response was not provided.]

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Under Sec. 24(1) no. 1 Patent Act, a compulsory licence will only be granted if the patent owner refuses to allow another person to use the invention despite an offer for reasonable compensation.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

See above comments on questions 66 and 67.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Under Sec. 24(2) Patent Act the applicant for a licence is entitled to request the grant of a compulsory licence with respect to the owner of the patent if the following requirements are met:

- dependent invention, i.e. the applicant for a licence is unable to exploit his later patented invention without infringing the earlier patent,*
- the applicant for a licence has unsuccessfully endeavoured during a reasonable period of time to obtain from the patent owner consent to exploit the invention under reasonable conditions usual in trade, and*
- the invention of the applicant for a licence involves, in comparison with that under the patent of earlier date, an important technical advance of considerable commercial significance.*

Sec. 24(2) Patent Act applies mutatis mutandis if a plant breeder has not obtained a plant variety right or cannot exploit it without infringing an earlier patent (Sec. 24(3) Patent Act).

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Under Sec. 24(6), 4th sentence, Patent Act the patent owner is entitled to remuneration from the holder of a compulsory license that is commensurate with the circumstances and takes the commercial value of the compulsory license into consideration.

In the event of a significant change, with respect to the repeated remuneration that will become due in future, in the circumstances on which the determination of the amount of the remuneration was based, each party is entitled to require a corresponding adjustment (Sec. 24(6), 5th sentence, Patent Act).

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

As far as the DPMA knows, the Federal Patent Court (BPatG) has issued a compulsory licence in just one case in the period from 1961 to 2004 (compare BPatG, judgment of 7 June 1991, no. 3 Li 1/90, published in BPatGE 32, 184). This compulsory licence was revoked by the judgment of the Federal Court of Justice (BGH) of 5 December 1995 (case no. X ZR 26/92, published in BGHZ 131, 247 – Polyferon).

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81.-88.

This exception does not exist in German patent law.

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 9c Patent Act:

(1) Where plant propagation material is marketed to a farmer by the patent owner or by a third party with the owner's consent, for agricultural use, the farmer may use the product of his harvest for propagation or multiplication by him on his own farm, contrary to Sections 9, 9a and 9b, second sentence. Article 14 of the Council Regulation (EC) no. 2100/94 in the applicable version and the implementing rules established on the basis of this Article shall apply mutatis mutandis to the conditions and the extent of this authorisation. Any rights arising therefrom for the patent owner shall be claimed in accordance with the implementing rules established on the basis of Article 14(3) of the Council Regulation (EC) no. 2100/94.

(2) Where farm livestock or animal reproductive material is marketed to a farmer by the patent owner or by a third party with the owner's consent, the farmer may use the farm livestock or the animal reproductive material for agricultural purposes, contrary to Sections 9, 9a and 9b, second sentence. This authorisation includes making the animals or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale for the purpose or within the framework of a commercial reproduction activity.

(3) Sec. 9a(1) to (3) shall not apply to biological material whose production in agriculture was adventitious or technically unavoidable. Therefore, as a rule, no claims can be made against a farmer who has cultivated seeds or planting stock not protected by this patent.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

The objective is to allow the farmer to use a part of his harvest product again for planting even if the propagating material is patented, since the seeds are intended for agricultural use and were sold for this purpose. This applies mutatis mutandis to the reproduction of farm animals.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

- *Sec. 9c(1) Patent Act: This provision implements Article 11(1) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ EC L 213 p. 13).*

- *Sec. 9c(2) Patent Act: This provision implements Article 11(2) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ EC L 213 p. 13).*

92.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 11 no. 2a Patent Act: The effects of the patent do not extend to the use of biological material for the purpose of breeding, discovering and developing a new plant variety.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

Sec. 11 no. 2a Patent Act specifies the scope of the research exemption for breeding, discovering and developing new plant varieties on the basis of the declaration of the German delegation for the minutes in the Internal Market Council of 27 November 1997 (statement of reasons regarding the draft of an Act to implement the Directive on the legal protection of biotechnological inventions, document of the Bundestag BT-Drucksache 15/1709, p. 15).

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

*The provision establishes a research exemption for breeding, discovering and developing new plant varieties and includes any use of biological material for the indicated purposes. The terms "biological material" and "plant variety" are defined in Sec. 2a(3) nos. 1 and 4 Patent Act: Under **Sec. 2a(3) no. 1 Patent Act**, "biological material" means, for the purposes of this Act, any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. For the definition of the concept of "plant variety", **Sec. 2a(3) no. 4 Patent Act** refers to the Council Regulation (EC) no. 2100/94 of 27 July 1994 on Community plant variety rights in the applicable version (OJ EC L 227 p. 1).*

99.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Sec. 11 no. 6 Patent Act: The effects of a patent shall not extend to the acts specified in Article 27 of the Convention on International Civil Aviation of 7 December 1944, where such acts concern the aircraft of another State to which the provisions of that Article are applicable.

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

[Note from the Secretariat: response was not provided.]

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Sec. 11 no. 6 Patent Act takes account of the Convention on International Civil Aviation of 7 December 1944.

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

Art. 27 of the Convention on International Civil Aviation of 7 December 1944 provides for an exemption of seizure on the grounds of patent infringement if the construction, mechanism, parts, accessories or operation of the aircraft infringe a patent on occasion of an authorised entry or transit flight. This exemption also covers the storage of spare parts and spare equipment for the aircraft.

In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

[Note from the Secretariat: response was not provided.]

(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

[Note from the Secretariat: response was not provided.]

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

Please see the comments on questions 66 and 67 regarding the obligation to grant licences accruing from cartel law.

Country: GREECE
Office: Industrial Property Organization (OBI)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard used is that an invention:

- (a) has to be new,*
- (b) involve an inventive step and*
- (c) is susceptible of industrial application.*

Article 5 of Law No 1733/1987 on technology transfer, inventions and technological innovation is the applicable law.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

According to article 5 par. 2 of Law No 1733/1987 the following are not regarded as inventions:

- (a) discoveries, scientific theories, and mathematical methods;*
- (b) aesthetic creations;*
- (c) schemes, rules, and methods for performing mental acts, playing games or doing business, and programs for computers;*
- (d) presentation of information.*

According to article 5 par. 6 of Law No 1733/1987:

- (a) Methods for treatment of the human or animal body by surgery or therapy;*
- (b) Diagnostic methods practiced on the human or animal body*
- (c) are not considered as inventions susceptible of industrial application.*

According to article 5 par. 8 of Law No 1733/1987 patents are not granted in respect of:

- (a) inventions the publication or exploitation of which would be contrary to public order (“ordre publique”) or morality;*
- (b) plant or animal varieties or biological processes for the production of plants or animals except microbiological processes or the products thereof.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

According to article 10 par. 1 of Law No. 1733/1987 the right to exploit the invention such as in particular:

- (a) To produce, offer or make available in the market, to use and to possess for said purpose the products protected by the patent;
- (b) To apply, offer or make available in the market the process protected by the patent;
- (c) To produce, offer or make available in the market, to use and to possess for said purpose the product whose production results from the process protected by the patent;
- (d) To forbid each and every third party from productively exploiting the invention, within the meaning of the above passages, or to import, without prior consent of the owner, the products protected by the patent.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 10 par. 2 a of Law No. 1733/1987

5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 10 par 2 a of Law No. 1733/1987.

12.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 10 par 2 c of Law No. 1733/1987.

24.-25.

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Pharmacists preparing the medicine in a pharmacy in execution of a medical prescription.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 10 par 3 of Law No. 1733/1987.

32.-33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

There is no definition nor any limitation.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The right can only be assigned together with the business entity, which exploits the invention.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

39.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 10 par 2 b of Law No. 1733/1987.

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The term "temporarily" is used. There is no definition of the term.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

The invention has to be built in the vessel, aircraft or vehicle.

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 11 par. 6 of Ministerial Decision DYC 3 (a) 83657/2006.

52.-53.

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

Anyone performing studies and trials.

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: Medicinal

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: Studies and trials necessary for obtaining a marketing authorization.

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

Regional: EU/EEA

If the exception is contained in statutory law, please provide the relevant provision(s):

[Note from the Secretariat: response was not provided.]

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Articles 13 and 14 of Law No. 1733/1987.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Public health
National security
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Only “insufficient working” is defined as production insufficient to cover local demand.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

The law does not contain such a definition.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four years from the filing date or three years from the grant of a patent.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

There is no definition in the applicable law.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

There are no such requirements provided.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

- (1) *The invention relates to the invention of the earlier patent;*
- (2) *The exploitation of the invention is not possible without infringing the rights of the earlier patent;*
- (3) *The invention constitutes a significant progress in comparison to the previous invention.*

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

The amount of remuneration is determined by a court decision according to the extent of the industrial exploitation of the invention.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

There is no definition.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

No non-contractual or compulsory license has been granted since the enactment of the new patent law in 1987.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 14 of Law No. 1733/1987.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Public health
National security*

84.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 9 par. 1 of Presidential Decree 321/2001.

90.-91.

[Note from the Secretariat: response was not provided.]

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

Use of the harvested product is allowed for propagation of multiplication by a farmer for the purposes of pursuing his own agricultural activity.

93.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 9 par. 2 of Presidential Decree 321/2001.

96.-97.

[Note from the Secretariat: response was not provided.]

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

Use of breeding stock or protected animal reproductive material is allowed for propagation of multiplication by a farmer for the purposes of pursuing his own agricultural activity.

99.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Greece does not provide exceptions related to other exceptions and limitations.]

Country: HONDURAS
Office: Directorate General of Intellectual Property

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The applicable legal standard is the Law on Industrial Property, contained in Decree No. 12-99-E

ARTICLE 6. An invention shall be patentable where it is industrially applicable, novel and involves an inventive step, and where it is not included in what our legislation excludes from protection as an invention (Articles 5, 6 and 7 of the Law on Industrial Property).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

ARTICLE 5. The following shall not be considered inventions and shall therefore be excluded from patent protection.

- (a) Theoretical or scientific principles;*
- (b) Discoveries which consist in making known or disclosing something which already existed in nature, even though it was previously unknown to humanity;*
- (c) Diagrams, plans, rules and methods for performing mental acts, games or business;*
- (d) Computer programs;*
- (e) Forms of presentation of information;*
- (f) Aesthetic creations and artistic or literary works;*
- (g) Methods of surgical or therapeutic treatment, or diagnosis applicable to the human body and relating to animals; and,*
- (h) Juxtaposition of known inventions or mixtures of known products, their variation in form, dimensions or materials, except where in reality there is a combination or merger such that they cannot function separately or the characteristics or functions thereof are modified in order to obtain an industrial result not obvious to a person skilled in the art.*

ARTICLE 7. The following shall not be patentable:

- 1. Essentially biological processes for obtaining or reproducing plants, animals or varieties thereof, including genetic processes or those relating to material capable of conducting its own duplication, by itself or in any other indirect manner, where they consist in selecting or isolating available biological material and leaving it to act in natural conditions; and,*
- 2. Plant varieties and species and animal species and breeds.*

ARTICLE 3. Also, a patent shall not be granted where its contents or form are contrary to ordre public, morality and good customs, or contravene any legal provision.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

ARTICLE 17. The patent shall confer on its owner the right to exclude third parties from the working of the patented invention. Therefore, and with the limitations provided for in our Law, the patent owner shall have the right to act against any person who, without his consent, performs any of the following acts:

1. *Where the patent has been granted for a product:
(a) manufacture the product; and,
(b) offer for sale, sell or use the product, or import it or store it for one of these purposes.*
2. *Where the patent has been granted for a process:
(a) use the process; and
(b) perform any of the acts indicated in paragraph (1)(b) of this Article with respect to a product resulting directly from the use of the process.*

The scope of the protection granted by the patent shall be determined by the claims. The claims shall be interpreted in the light of the description and the drawings.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

ARTICLE 18. The rights conferred by the patent may only be enforced against acts performed by third parties for industrial or commercial purposes. In particular, such rights may not be enforced against acts performed exclusively in the private sphere and for non-commercial purposes, or for experimentation, scientific research or teaching purposes relating to the subject matter of the patented invention.

The rights conferred by the patent may not be enforced against any person who markets, acquires or uses the product patented or obtained through the patented process, immediately after said product has been introduced lawfully into national or international trade by the owner of the patent or by his licensees.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

Eliminating barriers to trade, protecting the strictly personal or family individual right of use and stimulating scientific research and teaching in Honduras.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Our Law on Industrial Property clearly states that such rights may not be enforced against acts performed exclusively in the private sphere and for non-commercial purposes, or for experimentation, scientific research or teaching purposes relating to the subject matter of the patented invention.

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

Those terms are interpreted in a general manner and so are not established in a conceptual sense in our Law on Industrial Property.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

The Law does not envisage other criteria for determining the scope of this exception.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

For the time being, no kind of amendment is being considered with regard to this subject.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We have not encountered any kind of problem in Honduras with the practice of this type of exception.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

In particular, such rights may not be enforced against acts performed exclusively in the private sphere and for non-commercial purposes, or for experimentation, scientific research or teaching purposes in relation to the subject matter of the patented invention.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

As regards this exception in Honduras, no kinds of problems have arisen with the owners of patents when the patents are used for research and teaching.

13. (a) What are the public policy objectives for providing the exception?

Promoting research.

Increasing the level of scientific research in Honduras.

Enhancing the level of teaching for the purposes of scientific research.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Our Law on Industrial Property, which states only when use may be made of a patent, provided that it is in the private sphere and for non-commercial purposes or for experimentation, scientific research or teaching purposes in relation to the subject matter of the patented invention.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The legislation of Honduras does not refer to the type or nature of the organization which may carry out experiments or research; this is described in the legislation in general terms.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The legislation of Honduras does not define concepts of use for experimental purposes.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention
invent around the patented invention

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

Research and/or experimentation must be conducted with or using the patented invention (“research with”)

Please explain by citing legal provision(s) and/or decision(s):

The rights conferred by the patent may only be enforced against acts performed by third parties for industrial or commercial purposes. In particular, such rights may not be enforced against acts performed exclusively in the private sphere and for non-commercial purposes, or for purposes of experimentation, scientific research or teaching in relation to the subject matter of the patented invention (Article 18 of the Law on Industrial Property).

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

The Law on Industrial Property of Honduras refers to such terms but does so in general with no distinction, in other words it does not mention said definitions in conceptual terms. We therefore interpret it according to the economic sphere; when we refer to “commercial”, there is a perception of a gain, something which is not permitted by our Law, and when economic remuneration is not received, we are referring to the “non-commercial” sphere.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There are no other criteria for determining the scope of the exception.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

For the time being, there are no plans to make any kind of amendment in relation to this subject.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No kind of problems have arisen in relation to the application of this exception in Honduras.

Section IV: Preparation of medicines

23.-26.

[Note from the Secretariat: response was not provided.]

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No.

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31.-35.

[Note from the Secretariat: response was not provided.]

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

No

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Aircrafts
Spacecraft*

46.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-54.

[Note from the Secretariat: response was not provided.]

55. The exception covers the regulatory approval of:

Certain products. [Note from the Secretariat: response was not provided.]

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Using
Selling
Offering for sale
Other. Please specify: [Note from the Secretariat: response was not provided.]*

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

International

If the exception is contained in statutory law, please provide the relevant provision(s):

[Note from the Secretariat: response was not provided.]

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

As to compulsory licenses and other measures relating to the exploitation of patents, our Law states that a compulsory license shall not be granted where it is shown that the non-working or insufficient working are fortuitous or are due to force majeure, or to circumstances that are independent of the will or beyond the control of the patent owner and which justify the non-working or insufficient industrial working of the patented invention. The absence of economic resources or of economic viability of the working shall not be considered mitigating circumstances.

Where the compulsory license is requested for a patent in which a particular semi-conductor technology is claimed, the license shall be granted only for a public non-commercial use for the benefit of a public authority or other person acting on behalf of that authority, or in order to rectify a practice declared contrary to competition, by means of the appropriate administrative or judicial procedure.

In addition, for reasons of public interest, and in particular in cases of emergency or for reasons of national security, nutrition or public health, in a general sense these would constitute other exceptions (Articles 65, 66, 67, 68, 69, 70 and 71 of the Law on Industrial Property).

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Reference should be made to the fact that they are exceptional and only in relation to patents, the Law establishes certain cases in which their aim is the use or working of an investment made without the consent of the patent owner, which will resolve situations of public interest and emergency motivated by considerations of public health, nutrition and national security.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

As regards this type of license in Honduras, no kind of experience has been acquired.

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

ARTICLES 65 and 66. At the request of any person who provides proof of his capacity to work the patented invention, filed after four (4) years following the patent application filing date or three (3) years from the date of grant of the patent, the later date being applied, the Industrial Property Registry may, following a hearing with the patent owner, grant a compulsory license for the working of the patent, where this is not being worked.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

ARTICLE 65 For the purposes of this Law, working of a patent means:

1. *where the patent has been granted for a product, the internal market supply corresponding to the demand for the product is via local production, import or both;*
2. *where the patent has been granted for a process not included under (3) of this Article, the use of that procedure on a commercial scale in Honduras; and,*
3. *where the patent has been granted for a procedure to obtain a product, the internal market supply corresponding to the demand for the product obtained by that system, through the use of the procedure in the country or abroad.*

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three (3) years from the date of grant of the patent.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

ARTICLE 66 (second paragraph). A compulsory license shall not be granted where the absence of or insufficient working is shown as being due to chance or force majeure, or to circumstances independent of the will or beyond the control of the patent owner and which justify the absence of or insufficient industrial working of the patented invention. The absence of economic resources or of economic viability of the working shall not be considered mitigating circumstances.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

ARTICLE 67. Any person who requests a compulsory license in accordance with our Law shall provide irrefutable proof of having previously requested from the owner of the patent a contractual license and that he has not been able to obtain such a license on reasonable conditions and within a reasonable period of time. The compulsory license request shall indicate the conditions under which the license is expected to be obtained.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The decision to grant the compulsory license shall establish:

1. *the scope or extension of the license, specifying in particular the period and the acts, which shall be mainly in order to supply the country's domestic market.*

2. *the amount and form of the payment that must be made by the licensee, said payment being determined on the basis of the scope of working of the invention that is the subject of the license, and the economic value of the license; and,*
3. *other conditions which the Industrial Property Registry considers necessary or appropriate for the best possible working of the patent.*

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Where an invention claimed in a patent may not be worked industrially in the country without infringing a previous patent, the Industrial Property Registry may, at the request of the owner of that patent or his licensee, or the beneficiary of a compulsory license for that patent, grant a compulsory license with respect to the previous patent, insofar as it is necessary to avoid the infringement of that previous patent.

Such a license may be granted only when the invention claimed in the later patent involves technical progress of considerable economic importance with respect to the invention that is the subject of the previous patent.

Where a compulsory license is granted in accordance with the previous paragraph, the Industrial Property Registry may, in the same circumstances, grant a compulsory license with respect to the later patent, if the owner of the previous patent, his licensee or the beneficiary of a compulsory license for said previous patent so requests. A compulsory license from among those provided for in this Article may not be granted exclusively. This compulsory license may only be subject to assignment, transfer or sub-licensing where the dependent patent whose industrial working requires the license is at the same time subject to assignment, transfer or license. The assignment, transfer or sub-licensing for the compulsory license shall be subject to the provisions of our Law on Industrial Property, as appropriate.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

ARTICLE 71. Any license of public interest shall give rise to the corresponding payment in favor of the patent owner.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

ARTICLE 70. For reasons of public interest, and in particular in cases of emergency or for reasons of national security, nutrition or public health, at the request of any natural person or legal entity, or State entity, or ex officio, provision may at any time be made that:

1. *an invention, which is the subject matter of a patent or patent application being processed, is worked by a State entity or by one or more public or private law persons designated for the purpose; or,*
2. *an invention, which is the subject matter of a patent or a patent application being processed, is open to the grant of licenses of public interest, in which case the Industrial Property Registry shall grant a working license to any person who so requests and has the capacity to carry out such working in the country.*

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

There is no previous history of compulsory licenses being granted in Honduras.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

In relation to this subject, there are currently no plans to make any amendments to the content of the law.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

For the time being, we do not have any kind of experience as regards granting compulsory licenses.

Government use

81.-82.

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security*

84.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Honduras does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Honduras does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Honduras does not provide other exceptions and limitations.]

Country: HONG KONG, CHINA
Office: Intellectual Property Department

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Under section 93 of the Patents Ordinance (Chapter 514, Laws of Hong Kong) ("PO"), ([http://www.legislation.gov.hk/blis_pdf.nsf/CurAllEngDoc/61E6148388730EF1482575EF0012A52E/\\$FILE/CAP_514_e_b5.pdf](http://www.legislation.gov.hk/blis_pdf.nsf/CurAllEngDoc/61E6148388730EF1482575EF0012A52E/$FILE/CAP_514_e_b5.pdf)) an invention is patentable if it is susceptible of industrial application, is new and involves an inventive step. An invention shall be considered (a) to be new if it does not form part of the state of the art (section 94 of PO), (b) as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (section 96 of PO), and (c) as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture (section 97 of PO).

The above standard of patentability applies to all inventions irrespective of the technology involved.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The following are not regarded as inventions and thus are not patentable :-

- (a) a discovery, scientific theory or mathematical method;*
- (b) an aesthetic creation;*
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;*
- (d) the presentation of information (section 93(2) of PO).*

A method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body are not regarded as inventions susceptible of industrial application. However, a product, and in particular a substance or composition, for use in the above method is patentable if it meets the standard for patentability set out in Question 1 above (section 93(4) of PO).

An invention the publication or working of which would be contrary to public order or morality shall not be a patentable invention (section 93(5) of PO).

A plant or animal variety or an essentially biological process for the production of plants or animals (other than a microbiological process or the products of such a process) are not patentable (section 93(6) of PO).

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

A. Exclusive rights granted to a patent

The proprietor of a patent has the right to prevent all third parties not having his consent from doing the following acts in Hong Kong, China:

- (a) (in relation to any product that is the subject matter of the patent) making, putting on the market, using or importing the product or stocking the product whether for putting it on the market (in Hong Kong China or elsewhere) or otherwise;*
 - (b) (in relation to a process which is the subject matter of the patent) using the process or offering the process for use in Hong Kong China when the third party knows or, or it is obvious to a reasonable person in the circumstances, that the use of the process without the consent of the proprietor of the patent is prohibited;*
 - (c) (in relation to any product obtained by means of any patented process) putting on the market, using or importing the product or stocking the product, whether for the purpose of putting it on the market (in Hong Kong China or elsewhere) or otherwise.*
- (Section 73 of PO)*

Furthermore, the proprietor also has the right to prevent all third parties not having his consent from supplying or offering to supply in Hong Kong, China a person with the means (relating to an essential element of the patented invention) for putting the invention into effect when the third party knows, or it is obvious in the circumstances to a reasonable person, that the said means are suitable and intended for putting that invention into effect in Hong Kong, China (section 74 of PO).

B. Exclusive rights granted by publication of a patent application

There are 2 types of patents in Hong Kong China – (i) standard patent with a term of 20 years and (ii) short-term patent with a term of 8 years. The following provisions regarding exclusive rights accorded by publication of a patent application applies only to standard patents.

Where an application for a standard patent is published, the applicant shall have, as from the date of publication and until the grant of the standard patent, the same right as he would have had, if the patent had been granted on the date of the publication of the application, to bring proceedings in the court for damages in respect of any act which would have infringed the patent. However, the applicant shall only be entitled to bring proceedings in respect of any act only-

- (a) after the standard patent is granted; and*
 - (b) (assuming that the patent had been granted on the date of publication of the request to record) if the act would have infringed not only the standard patent, but also the claims in the form in which they were contained in the published request to record.*
- (section 88 of PO)*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 75(a), PO.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

6. (a) What are the public policy objectives for providing the exception?

It was considered that acts that are both private (i.e. not carried out in public and merely for the person's own use and benefit) and non-commercial should be exempted from infringement.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 42 of the Irish Patents Act 1992.

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

Not defined in the PO.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

N/A.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, it has been working well so far.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We have not encountered any challenge so far.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 75(b), PO.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A.

13. (a) What are the public policy objectives for providing the exception?

It was considered that acts done for experimental purposes should be exempted if they relate to the subject-matter of an invention. This would include, for example, trials carried out in order to discover something unknown, or to test an hypothesis, or even in order to find out whether something which is known to work in specific conditions would work in different conditions.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 42 of the Irish Patents Act 1992.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

Not defined.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

Other, please specify: The purpose of the experiment is not specifically set out in section 75(b) of the PO. The court will determine whether a particular act comes within the scope of the exception based on the facts and circumstances of each case.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

Please explain by citing legal provision(s) and/or decision(s):

Section 75(b) of PO provides that the rights conferred by a patent shall not extend to acts done for experimental purposes relating to the subject matter of the relevant patented invention.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

N/A

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, it has been working well so far.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We have not encountered any challenge so far.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 75(c), PO.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

25. (a) What are the public policy objectives for providing the exception? Please explain:

It was considered that extemporaneous preparation of a medicine for individual cases in a pharmacy in accordance with specific medical prescriptions should be exempted from infringement.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 42 of the Irish Patents Act 1992.

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Pharmacists working in a pharmacy who prepare medicine as and when required based on specific prescriptions.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Section 75(c) of PO requires that the preparation of a medicine must be in accordance with a medical prescription issued by a registered medical practitioner or registered dentist.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, it has been working well so far.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We have not encountered any challenge so far.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 83, PO.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A.

33. (a) What are the public policy objectives for providing the exception? Please explain:

It was considered that, where there has been a prior secret use of the claimed invention by a third party, the exception should provide such party with a right to continue his prior acts unaffected by the grant of the patent. However, the right provided would serve as a personal defence to an allegation of infringement and cannot be licensed to others.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular, section 55 of the Irish Patents Act 1992.

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Pursuant to section 83 of PO, where a patent is granted for an invention, any person in Hong Kong China who, before the deemed date of filing of the application for the standard patent or the date of filing of the application for the short-term patent or, if priority was claimed, before the date of priority –

- (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or*
- (b) makes in good faith effective and serious preparations to do such an act shall have the right to continue to do the act above.*

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes (The right can be assigned but it cannot be licensed to others)

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

If the prior act (which would constitute an infringement of the patent if it were in force) was done or preparations had been made to do it in the course of a business, the prior right user shall have the following rights -

- (a) where the prior right user is an individual:*
 - (i) he could assign the right to do the act in question or transmit such right on death, or*
 - (ii) he could authorize the doing of that act by any of his partners for the time being in the business in the course of which the act was done or preparations had been made to do it.*
- (b) in the case of a body corporate, it would be entitled to assign the right to do the act or to transmit such right on the body’s dissolution.*

However, the prior right user does not have the right to grant a licence to any person to do the act in question (section 83(2) & (3) of PO).

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, it has been working well so far.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We have not encountered any challenge so far.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 75(d), (e) and (f) of PO.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

44. (a) What are the public policy objectives for providing the exception? Please explain:

It was considered that foreign vessels, aircraft, land vehicles and aircraft coming temporarily into Hong Kong should be exempted from claims of patent infringement.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In formulating the exception, we have made reference to the laws of other jurisdictions and in particular section 42 of the Irish Patents Act 1992.

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Exceptions involving vessels, aircraft and land vehicles are set out in three provisions under the PO. They are sections 75(d), (e) and (f).

Sections 75(d) and 75(e)

It is an expressly stipulated in section 75(d) (which applies to vessels) and section 75(e) (which applies to aircraft, hovercraft and land vehicles) that the exceptions would apply if the above transportation vehicles have “temporarily or accidentally” entered Hong Kong China.

The expression “temporarily or accidentally” is not defined in the PO. It should be construed based on its ordinary and natural meaning.

Section 75(f)

This provision applies to aircraft that has lawfully entered or is lawfully crossing Hong Kong. This provision is in line with the obligations under article 27 of the Chicago Convention of which China is a member.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 75(d) of PO provides that the right of a patent shall not extend to the use of the invention which is the subject of the patent-

- (i) on board vessels registered in any of the Paris Convention countries or WTO member countries, territories or areas, other than Hong Kong China; or*
 - (ii) in the body of such vessels, or in the machinery, tackle, gear or other accessories of such vessels,*
- when such vessels temporarily or accidentally enter the territorial waters of Hong Kong China, but only if the invention is used in such waters exclusively for the needs of the vessel.*

Section 75(e) of PO provides that the right of a patent shall not extend to the use of the invention which is the subject of the patent in the construction or operation of-

- (i) aircraft, hovercraft or land vehicles of Paris Convention countries or WTO member countries, territories or areas, other than Hong Kong China; or*
 - (ii) such aircraft, hovercraft or land vehicle accessories,*
- when such aircraft, hovercraft or land vehicles temporarily or accidentally enter Hong Kong China.*

Section 75(f) of PO provides that the right of a patent shall not extend to the use of an aircraft which has lawfully entered or is lawfully crossing Hong Kong China, or the importation into Hong Kong China or the storage thereof, of any part or accessory of such aircraft. This provision only applies where the Central People’s Government of China has made a declaration with a view to the fulfillment of the provisions in the Chicago Convention.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Please see answer to Q.47.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, it has been working well so far.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We have not encountered any challenge so far.

Section VII: Acts for obtaining regulatory approval from authorities

[Note from the Secretariat: the applicable law of Hong Kong, China does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

The rights conferred on the proprietor of a patent would not be exhausted as long as the patent remains in effect.

If the exception is contained in statutory law, please provide the relevant provision(s):

N/A

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

[Note from the Secretariat: response was not provided.]

Please explain your answer by citing legal provision(s) and/or decision(s):

N/A

63-64.

N/A

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

*Compulsory licences for standard patents (sections 64-67 of PO)
Import compulsory licences for patented pharmaceutical products (sections 72A-72J of PO)
Export compulsory licences for patented pharmaceutical products (sections 72K-72R of PO).*

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Public health
National emergency and/or extreme urgency
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Compulsory licences on grounds of non-working or insufficient working of patent etc.
The objective underlying the grant of compulsory licences is to prevent abuse of monopoly rights by patent proprietors and to encourage manufacture. They ensure that patented inventions are applied practically to their fullest extent and patent rights are exercised without prejudice to the development of industry.

Import and export compulsory licences for patented pharmaceuticals
The objective of the provisions on import compulsory licences was to enable Hong Kong China to make use of the system under the Protocol amending the TRIPs Agreement (adopted by the General Council of the WTO on 6 December 2005) to import medicine in situations of national emergency or other circumstances of extreme urgency. Regarding export compulsory licences, the objective is to allow manufacturers in Hong Kong China to make use of the Protocol to make and export pharmaceutical products to other WTO members who declare that it is under national emergency or other circumstances of extreme urgency.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Compulsory licences on grounds of non-working or insufficient working of patent etc.
In formulating the provisions on compulsory licences, we have made reference to the laws of other jurisdictions and in particular sections 48-50 and section 52 of the United Kingdom Patents Act 1977.

Import and export compulsory licences for patented pharmaceuticals
Please refer to Question 68(a) above.

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The concepts of “non-working” and “insufficient working” are reflected in section 64(2) of PO which sets out the grounds upon which a person may apply for the grant of compulsory licence from the court.

These grounds are:

- (a) where the patented invention is capable of being commercially worked in Hong Kong China, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable (section 64(2)(a) of PO);*
- (b) where the patented invention is a product, that a demand for the product in Hong Kong China is not being met on reasonable terms (section 64(2)(b));*
- (c) where the patented invention is capable of being commercially worked in Hong Kong by manufacture, that it is being prevented or hindered from being so worked-*
 - (i) in the case of a product, by the importation of the product; or*
 - (ii) in the case of a process, by the importation of a product obtained directly by means of the process or to which the process has been applied (section 64(2)(c));*
- (d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms-*
 - (i) the working or efficient working in Hong Kong China of any other patented invention which involves an important technical advance of considerable economic significance in relation to the patent is prevented or hindered; or*
 - (ii) the establishment or development of commercial or industrial activities in Hong Kong China is unfairly prejudiced (section 64(2)(d)); and*
- (e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent or the establishment or development of commercial or industrial activities in Hong Kong China, is unfairly prejudiced (section 64(2)(e)).*

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

No.

As set out in Question 69 above, one of the grounds for application of a compulsory licence is that the patented invention is prevented or hindered from being commercially worked in Hong Kong China by manufacture as a result of importation of the product (section 64(2)(c) of PO).

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

After the expiration of 3 years from the date of grant of a standard patent (section 64(1) of PO).

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

The patentee may provide reasons to support his argument that the time elapsed since the grant of the patent has been insufficient to enable the invention to be commercially worked (or worked to its fullest extent). The court may, if it is satisfied with the reason(s) given by the patentee, adjourn the hearing to allow sufficient time for the patentee to exploit the patent (section 64(4) of PO).

The PO does not contain an exhaustive list of legitimate reasons. However, the court will consider whether justifiable reasons are given by the patentee based on the facts and circumstances of each case.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Compulsory licences on grounds of non-working or insufficient working of patent etc.
Where an applicant applies for the grant of a compulsory licence from the court based on any of the grounds set out in Question 69, he has to satisfy the court that he has made reasonable efforts to obtain authorization from the proprietor on “reasonable commercial terms and conditions” and that such efforts have not been successful within “a reasonable period of time” (section 64(5) of PO).

The PO does not provide a definition for the above expressions. The court will decide whether the above condition is satisfied based on the facts and circumstances of each case.

Export compulsory licences for patented pharmaceuticals

Before an applicant makes an application to the Director of Health of Hong Kong China for an export compulsory licence, it should make reasonable efforts to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions. The Director of Health will only consider granting the licence if the applicant has failed to obtain authorization within 28 days. The above requirement would not apply if, at the time of application of the export licence by the applicant, the importing member has declared that it was under national emergency or other circumstances of extreme urgency (section 72L(4) of PO).

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

None.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

One of the grounds for application of a compulsory licence is that the proprietor of the patent has refused to grant a licence on reasonable terms and as a result, the working or efficient working of any other patented invention is prevented or hindered. However, the

dependent patent must involve an important technical advance of considerable economic significance in relation to the patent that is the subject matter of the compulsory licence (section 64(2)(d) of PO).

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory licence to the patentee? Please explain:

Compulsory licences on grounds of non-working or insufficient working of patent etc.
When exercising its power to grant compulsory licences, the court is required to ensure that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention (section 66(1)(b) of PO).

Import compulsory licences for patented pharmaceuticals

(a) No remuneration is payable to the proprietor of the patented pharmaceutical product in Hong Kong China for such a licence if remuneration has been paid to the proprietor of the patent in the exporting country for production and export of the product to Hong Kong China.

(b) Where remuneration mentioned in paragraph (a) above has not been paid and all legal remedies to recover the payment in the exporting country have been exhausted, the Government of the Hong Kong Special Administrative Region, China (HKSAR Government) shall pay such amount of remuneration:

- (i) as may be agreed by the Director of Health, HKSAR Government and the proprietor of the patent in Hong Kong China. The total amount of remuneration agreed shall not exceed 4% of the total purchase price for the product payable by the import compulsory licensee to the seller of the product in the exporting member; or*
- (ii) if the remuneration cannot be agreed under paragraph (i) above, either party may apply to court for determination of the amount payable. In determining the amount, the court will take into account all factors relevant to the circumstances, including*
 - the economic value to Hong Kong China of the use of the relevant patented pharmaceutical product;*
 - humanitarian or non-commercial factors relevant to the grant of the licence.*

*The amount determined by the court would not be subject to the maximum limit under paragraph (i) above.
(sections 72E and 72J of PO).*

Export compulsory licences for patented pharmaceuticals

(a) The amount of remuneration to be paid by the export compulsory licensee to the proprietor of the patent shall be determined by the Director of Health of HKSAR Government. Such amount shall not exceed 4% of the total purchase price for the product payable by the importing member to the export compulsory licensee.

(b) Any party aggrieved by the determination made by the Director of Health, HKSAR Government may apply to court for a review. In determining the appropriate amount of remuneration, the court will take into account all factors relevant to the circumstances including the factors relevant to import compulsory licences mentioned in paragraph (b)(ii) above.

(sections 72P and 72R of PO)

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

In relation to import compulsory licences, the Chief Executive in Council of the HKSAR Government may declare a period of extreme urgency if it is necessary or expedient in the

public interest to do so to address any public health problem or threatened public health problem in Hong Kong China. During such period, if the Director of Health of HKSAR Government considers that Hong Kong China has no capacity to manufacture a patented pharmaceutical product to meet the needs for the product in Hong Kong China, the Director of Health may grant an import compulsory licence to any person to import, put on the market, stock or use the product in Hong Kong China (sections 72B and 72C of PO). In relation to export compulsory licences, these may be granted on the basis that the importing member has notified TRIPs Council that it is faced with a national emergency or other circumstances of extreme urgency. If the importing member has not so notified the TRIPs Council, the proposed compulsory licensee must make reasonable efforts to obtain authorization from the proprietor of the patent concerned prior to submitting his application for an export compulsory licence (section 72L of PO). "National emergency" or "circumstances of extreme urgency" are not defined in the PO and should be construed based on their ordinary meanings. Examples of such circumstances may include public health problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

None.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, it has been working well so far.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

We have not encountered any challenge so far.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 68-72, PO.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

National emergency and/or extreme urgency

84. (a) What are the public policy objectives for providing government use in your country?

The relevant sections confer powers on the HKSAR Government during a period of extreme urgency (declared by the Chief Executive in Council of HKSAR Government) to use patented inventions or an invention which is the subject of a published pending application, without the consent of the patent proprietor. The purpose was to allow immediate use of

these inventions to meet the urgent needs of the community during a period of extreme urgency.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In formulating the relevant provisions, we have made reference to the laws of other jurisdictions and in particular sections 55-59 of the United Kingdom Patents Act 1977.

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

A period of extreme urgency may be declared where it is necessary or expedient in the public interest for the maintenance of supplies and services essential to the life of the community or for securing sufficient supplies and services essential to the life of the community (section 68 of PO).

Examples of such extreme urgency may include massive health crisis.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

None.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, it has been working well so far.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

We have not encountered any challenge so far.

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Hong Kong does not provide exceptions related to farmers’ use of patented inventions.]

Breeders’ use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Hong Kong does not provide exceptions related to breeders’ use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Second or further medical uses of a known substance or composition.

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

The court in Hong Kong China affirmed in Abbott GMBH & Anor v Pharmareg Consulting Company Ltd & Anor [2009] 3 HKLRD 524] that second or further medical uses may be protected by patents using Swiss-type claims. This case relates to a standard patent granted in Hong Kong China for the use of a known chemical compound, Sibutramine, in the manufacture of medicaments for the treatment of obesity. Previously it was not known that the above compound could be used to treat obesity. In this case, the Court considered that there was novelty, not in the method of such use but in the new therapeutic purpose for which the substance was used and such second medical use could be protected by Swiss-type claims.

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

See Q102(i) above.

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

In the above case, the Court held that second medical use in Swiss-type claims must be for an end-purpose distinctively different from the first even though it was also for medical purposes.

In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

We believe that the courts in Hong Kong China will continue to acknowledge the validity of patents for second or further medical uses using Swiss-type claims. At this stage, we do not have any plans for legislative amendments on this issue.

(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

We have not encountered any practical problems so far.

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

N/A

Country: HUNGARY
Office: Hungarian Intellectual Property Office

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Article 1 of Act XXXIII of 1995 on the protection of inventions by patents (hereinafter referred to as "PA") provides for the criteria of patentability. In accordance with Paragraph (1) of Article 1, patents shall be granted for any inventions in any field of technology that are new, involve an inventive step and are susceptible of industrial application.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Pursuant to Paragraph (2) of Article 1 of PA the following in particular shall not be regarded as patentable inventions

- (a) discoveries, scientific theories and mathematical methods,*
- (b) aesthetic creations,*
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers,*
- (d) presentations of information.*

(3) Patentability of the subject matters referred above shall be excluded only to the extent to which a patent application or the patent relates to such subject matter as such.

In accordance with Paragraph (2) of Article 6 of PA no patent protection may be granted for an invention if the exploitation thereof within the framework of economic activity would be contrary to public policy or morality; such exploitation may not be regarded as contrary to public policy merely because it is prohibited by law or regulation. On the basis of this the following, in particular, shall not be granted patent protection:

- (a) processes for cloning human beings;*
- (b) processes for modifying the germ line genetic identity of human beings;*
- (c) uses of human embryos for industrial or commercial purposes;*
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal; and*
- (e) animals resulting from processes referred to in subparagraph (d).*

Pursuant to Paragraph (4) of Article 6 of PA plant varieties and animal breeds, as well as essentially biological processes for the production of plants or animals shall not be patentable. A process for the production of plants or animals is essentially biological if it consists entirely of crossing, selection or other natural phenomena. (Plant varieties may be granted plant variety protection under the provisions of Chapter XIII of PA.)

The above provisions are without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such process. Microbiological process means any process involving or performed upon or resulting in microbiological material.

Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety or animal breed.

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be granted patent protection. This provision however does not apply to products, in particular substances (compounds) and compositions, for use in such methods.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

In accordance with Article 19 of PA the holder of the patent (patentee) has the exclusive right to exploit the invention. On the basis of this exclusive right, the patentee shall be entitled to prevent any person not having his consent (a) from making, using, putting on the market or offering for sale a product which is the subject matter of the invention, or stocking or importing the product for such purposes; (b) from using a process which is the subject matter of the invention or, where such other person knows, or it is obvious from the circumstances, that the process cannot be used without the consent of the patentee, from offering the process for use; (c) from making, using, putting on the market, offering for sale or stocking or importing for such purposes a product obtained directly by a process which is the subject matter of the invention.

Pursuant to Article 18 of PA patent protection begins with the publication of the patent application with retroactively effect from the date of the application. The protection resulting from the publication is provisional and becomes definitive when the patent is granted.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

In accordance with Paragraph (6) (a) of Article 19 of PA the exclusive right of exploitation shall not extend to acts done privately or not involved in an economic/business activity.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

6. (a) What are the public policy objectives for providing the exception?

The private use does not prejudice the normal exploitation of the patented invention. The basic function of the patent system, i.e. the provision of an incentive to innovate is not endangered by the private use.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

The PA itself does not define the above concepts. A definition of “economic/business activity” can be found in Act CXXVII of 2007 on Value Added Tax (VAT Act) which can be taken as a basis in the course of the interpretation of the above provisions. In accordance with Paragraph (1) of Article 6 of VAT Act economic/business activity means the performance of an activity in a professional manner either permanently or on a regular basis, if it aims at, or results in, achieving any value, and it is delivered in an independent way.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

There are no other criteria.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered adequate; no amendments are foreseen.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

In accordance with Paragraph (6) b) of Article 19 of the PA the patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

13. (a) What are the public policy objectives for providing the exception?

The first objective is to provide for the possibility of performing further important research activities, as this is important for the society. It is also important to enable the generic entry into the market in due time, since this can provide patients with quality medicines at reasonable price, and decrease the costs related to the financing of medicines covered by the health scheme of the state.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

*The original wording of this provision was the following: The patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of **medicines**. This provision has been amended by Act XLVIII of 2001 in order to provide for a technology neutral terminology in conformity with Article 27 (1) of the TRIPS-Agreement. The amendment entered into force on 1.1.2002.*

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No.

15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

The applicable law does not define the above concepts.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

Other, please specify: The exception includes any experimental purposes, in particular tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

Research and/or experimentation must be conducted with or using the patented invention (“research with”)

Please explain by citing legal provision(s) and/or decision(s):

In accordance with Paragraph (6) b) of Article 19, the experimentation must be conducted “relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention.”

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

The applicable law does not make any distinction between “commercial” and “non-commercial” purpose.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There are no other criteria.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered adequate, there are no amendments foreseen.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

In accordance with Paragraph (6) c) of Article 19 of the PA, the exclusive right of exploitation does not extend to preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription, or acts concerning the medicine so prepared.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

25. (a) What are the public policy objectives for providing the exception? Please explain:

The policy objective is to provide patients with low cost quality medicines and to decrease the spending of the state health scheme. The use of the exception concerns minimal quantities, so this use is not prejudicial to the normal exploitation of the patent.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Those pharmacists, who are entitled to prepare medicines in a pharmacy in accordance with the relevant legal provisions.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

However, the legal provision states that medicines should be prepared on the basis of individual demand which indirectly determines the amount of the medicines prepared.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The medicines should be prescribed by a doctor and prepared for individual cases.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered adequate, there are no amendments foreseen.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

In accordance with Paragraph (1)-(3) of Article 21 of the PA a right of prior use belongs to any person who, in good faith, before the date of priority, in the territory of Hungary and within the framework of his economic activities, had begun to make or use the subject matter of the invention or had made serious preparations for that purpose. A prior user is

considered a bona fide user until it is proved that the prior use was based on the inventive activity that led to the patented product. Patent protection does not have effect against a prior user in respect of the making, using of the patented invention, or any preparation related thereto, to the extent that these activities were performed at the priority date.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

33. (a) What are the public policy objectives for providing the exception? Please explain:

Protection of investments that were performed in bona fide.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Pursuant to Paragraph (3) of Article 21 of the PA, the patent protection does not have effect against a prior user in relation to the extent of making, using or any preparation existing at the priority date. Te applicable law does not provide for any other limitations.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

In accordance with Paragraph (3) of Article 21 of the PA, the right of prior use may only be transferred together with the entitled business entity or with that part of the business entity in which such making, using or preparation has taken place.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

*Pursuant to Paragraph (4) of Article 21 of the PA, a **right of continued use** belongs to any person who, in the period between a declaration of lapse of patent protection and restoration thereof, in the territory of Hungary and within the framework of their economic activities, has started to make or use the subject matter of the invention or has made serious preparations for that purpose.*

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The subject matter of the invention should be used in the territory of the country and within the framework of the continued user's economic activities (Paragraph (4) of Article 21 of the PA)

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered adequate, there are no amendments foreseen.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

In accordance with Paragraph (5) of Article 21 of the PA – subject to reciprocity –, patent protection does not have effect with respect to means of communication and transport which are in transit in the territory of Hungary or to foreign goods which are not intended to be put on the market in the country.

The President of the Hungarian Intellectual Property gives a ruling on matters of reciprocity.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

44. (a) What are the public policy objectives for providing the exception? Please explain:

This exception is connected to the territoriality of patent rights. Those goods in transit that are not intended to be put on the market in Hungary do not enter the territory of Hungary. Valid patent rights are enforceable in the territory of Hungary.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

Vessels
Aircrafts
Land Vehicles
Spacecraft

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law applies the terms: "in transit" and "are not intended to be put on the market in the country".

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

See answers to question no. 42 and 46.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered adequate, there are no amendments foreseen.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

*Pursuant to Paragraph (6) b) of Article 19 of the PA, the patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, **including experiments and tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention.***

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

53. (a) What are the public policy objectives for providing the exception? Please explain:

See in point 13.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

*The original wording of this provision was the following: The patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, **including experiments and tests necessary for the marketing authorization of medicines**. This provision has been amended by Act XLVIII of 2001 in order to bring it into conformity with Article 27(1) of the TRIPS-Agreement and provide for technology neutral regulation. The amendment entered into force on 1.1.2002.*

54. Who is entitled to use the exception? Please explain:

No restriction is foreseen.

55. The exception covers the regulatory approval of:

Any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Making

Using

Other. Please specify: any activities related research

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

There are no other criteria.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered adequate, there are no amendments foreseen.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

*Pursuant to Article 20 of PA the exclusive right of exploitation conferred by patent protection shall not extend to acts concerning a product put on the market in the territory of the **European Economic Area** by the patentee or with his express consent, except where the patentee has legitimate interests in opposing the further marketing of the product.*

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

The adopted exhausting regime reflects that Hungary is member state of the European Union.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Yes

Please explain your answer by citing legal provision(s) and/or decision(s):

The patentee is entitled to oppose the further marketing of the product if he has legitimate interests in it.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Yes.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

None.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

In accordance with Article 31 of the PA, if within four years from the date of filing of the patent application or within three years from the grant of the patent, whichever period expires later, the patentee has not exploited the invention in the territory of the country to satisfy the domestic demand or if he has not undertaken serious preparations or has not granted a license for such purpose, a compulsory license shall be granted to the applicant for the license, unless the patentee justifies the lack of exploitation.

Pursuant to Paragraph (1) of Article 32 of the PA, if the patented invention cannot be exploited without infringing another patent (hereinafter referred to as "the dominant patent"), a compulsory license shall be granted, on request and to the extent necessary for the exploitation of the dominant patent, to the holder of the dependent patent, provided that the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the dominant patent.

Paragraph (1) of Article 33/A of the PA rules that the Hungarian Intellectual Property Office shall grant a compulsory license for the exploitation of an invention in the cases and on the terms laid down in Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2007 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (hereinafter referred to as "Regulation 816/2006/EC").

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Public health
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

The objective is to enable the exploitation of any useful patented inventions that are important for the development of the economy and the well-being of the society.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of "non-working" or "insufficient working", please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

If within four years from the date of filing of the patent application or within three years from the grant of the patent, whichever period expires last, the patentee has not exploited the invention in the territory of the country to satisfy the domestic demand or if he has not undertaken serious preparations or has not granted a license for such purpose, a

compulsory license shall be granted to the applicant for the license, unless the patentee justifies the lack of exploitation. (Article 31 of the PA)

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

*The importation per se does not constitute “working” of the patent, however, a legitimate import can mean that the patented invention is exploited **in the territory of the country in order to satisfy the domestic demand.***

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four years from the date of filing of the patent application or three years from the grant of the patent, whichever period expires last.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

The legitimate reasons are not listed by the applicable law. Legitimate reasons are taken into account in accordance with the circumstances of the given case.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

There is no definition in the applicable law. “Reasonable terms and conditions” and “reasonable period of time” are defined on a case by case basis.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

If the patented invention cannot be exploited without infringing another patent (hereinafter referred to as “the dominant patent”), a compulsory license shall be granted, on request and

to the extent necessary for the exploitation of the dominant patent, to the holder of the dependent patent, provided that the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the dominant patent. (Paragraph (1) of Article 32 of PA)

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Yes. In accordance with Paragraph (3) of Article 33 PA the patentee shall receive adequate compensation for the compulsory license, which shall be fixed, failing agreement between the parties, by the court. The compensation shall take into adequate account the economic value of the compulsory license. In particular, it shall be commensurate with the royalty the holder of the compulsory license would have paid on the basis of an exploitation contract concluded with the patentee, taking into account the licensing conditions in the technical field of the invention.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

No compulsory licenses have been issued so far.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The applicable legal framework is considered adequate, there are no amendments foreseen.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

None.

Government use

81.-88.

No such exception is provided for in the Hungarian law.

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

89.-100.

In the Hungarian law, exceptions and limitations related to farmers'/breeders' use exists in respect of the exclusive right of the holder of plant variety right.

Section XI: Other Exceptions and Limitations

101.-103.

No other exceptions and limitations are applicable in the Hungarian patent law.

Country: ITALY
Office: Italian Patent and Trade Mark Office

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

They can constitute object of patent for invention the inventions of all fields of technology that are new and involve an inventive step and are susceptible of industrial application. (1st paragraph of article 45 industrial property code.³ from now on lpc)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Not be regarded as invention within meaning above, namely: a) discoveries, scientific theories and mathematical methods; b) scheme, rules and methods for performing mental acts, playing games or doing business, end programs for computers; c) presentations of information. These subject-matter or activities shall exclude the patentability only to the extent to which a patent application or patent relates to such subject-matter or activities as such. (Paragraph 2, 3 article 45 lpc)

They can't constitute object of patent a) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; b) plant or animal varieties or essentially biological processes for the production of animals or plants, including new plant variety, with reference to which the invention consist entirely in genetic modification of other plant variety, even if the same modification, is the outcome of genetic engineering process. These provisions shall not apply to micro biological processes and to products obtained through these process, as well as to products, in particular to substances or compositions, for use in any of these cited methods. (Paragraphs 4, 5, of article 45 lpc)

They are not patentable the inventions the industrial whose exploitation would be contrary to "ordre public" and morality (article 50 lpc)

Namely with reference to biotechnological invention (paragraph 5bis article 45 lpc) are excluded from patentability a) The human body, from conception time and in the various stages of its formation and development, and the simple discovery of one of elements of body own, including the sequence or partial sequence of a gene, in order to guarantee that patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person end environment; b) inventions the commercial exploitation of which would be contrary to dignity of person, ordre public or morality; to protection of health, environment, and human and animal life, to conservation of plant and biodiversity and to prevention of serious prejudices to the environment, in compliance with principles contained in the article 27, paragraph 2 (TRIPS) . Such exclusion affect notably:

³ Decreto legislativo 10 febbraio 2005, n 30.

1. *all technological processes for cloning human beings, any is the used technique, the highest stage of projected development of conferred organism and purposes of cloning;*
2. *the processes for modifying the germ line genetic identity of human beings;*
3. *all uses of human embryos enclosed therein the lines of staminal embryonal human cells;*
4. *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;*
5. *the invention concerning protocols of genetic screening the exploitation of which conducts a discrimination or stigmatization of human person on the genetic, pathological, racial, ethnic, social and economic basis, or better having eugenic purposes and not diagnostic.*

(c) a mere DNA sequence, a partial sequence of a gene, used to produce a protein or part of a protein, unless indication and descriptions of a helpful function to valuation of industrial application requirement is provided and equivalent function is specifically claimed; each sequence is deemed as an independent sequence in patent law terms when sequences overlap only in parts which are not essential to the invention, (paragraph 1 article 81quinquies lpc.)

Anyway is excluded by patentability every technical process employing embryonal human cells. (Paragraph 2 article 81 quinquies lpc.)

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

In compliance with article 66 lpc the right granted with a patent consist of the exclusive faculty to carry out the invention and to profit from it in the State territory within and the provided conditions by the Code. Namely if the object of patent is a product, the patentee can forbid third, apart from his consent, to produce, to use, put on the market, to sell or to import the product to that purposes; if the object of patent is a process, the patentee can forbid third, apart from his consent, to apply process, as well as to use, put on the market, to sell or to import to that purpose the product, directly obtained with process.

With the publication of patent application the applicant can exercise the same rights of patent. (Paragraph 2nd article 53 lpc)

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other

parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions". Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The effects of a patent shall not extend to acts done privately and for non-commercial purposes. letter a), paragraph 1, article 68 lpc.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

Acts undertaken in the private sphere for non-commercial purposes are excluded from the effects of a patent, because patents are not intended for intervention in the private sphere

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception was introduced by 1979 reform to comply with Community Patent Convention.

7. -10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The effects of a patent shall not extend to acts done for experimental purposes letters a) paragraph 1, article 68 lpc.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

They want avoid that patent system thought up to stimulate innovation works as obstacle to innovation.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception (letter a) was introduced by 1979 reform to comply with Community Patent Convention.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

Not

15.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The effects of a patent shall not extend to extemporaneous preparation, for unit, of drugs in the chemists on medical prescription, and to drugs like made provided they do not use active ingredients realized in industrial mode (letter c, paragraph 1 article 68 lpc)

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

This provision is intended to facilitate the exercise of medical activities, since patents should not restrict the freedom of the doctor (physician) to prescribe drugs in the interest of health promotion. This is to allow doctors to prescribe drugs to their patients in the individual case, which are prepared in chemists, regardless of possible patent rights.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception, was introduced by 1979 reform to comply with Community Patent Convention. Attention! in Italy before the 1979 the drugs were considered unpatentable. The prohibition to use active ingredients realized in industrial mode has been introduced on 2005.

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

The law don't refer directly to who is reserved free use but it refers to preparation drug in the chemists on medical prescription

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

The letter c) paragraph 1 article 68 lpc does not explicit mention to admissible amount of drugs but only to "extemporaneous preparation, for unit, of drugs in the chemists by prescription", therefore this is the amount which is required in one concrete individual case

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

In the preparation of drugs they forbid to use active ingredients realized in industrial mode.

29.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Anyone, in the course of twelve prior months to filing date of patent application or priority date, have done use in own firm of invention can continue to use it within of prior use. This faculty, is assignable only along with the firm where the invention is used. (Paragraph 3 article 68 lpc)

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

It is to safeguard the prior user about his economic status of possession. It is essential to avoid the legitimately created values are ruined. A later patent application cannot endanger prior user's investments.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The law set out that prior user can continue use invention within prior use did by him in his firm.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The prior user don't have pay any remuneration for the exercise of the exception to patentee

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

No

The prior user can assign this right only with assignment of firm where the invention is used

37.

[Note from the Secretariat: response was not provided.]

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Anyone has made serious and effective preparations or has begun use the patented invention in bona fides can carry it out gratuitous within prior use or in so far as they result from preparations. (letter a paragraph 6 article 193 lpc)

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42.-50.

[Note from the Secretariat: the applicable law of Italy does not provide exceptions related to the use of articles on foreign vessels, aircrafts and land vehicles.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

The effect of the patent does not extend to studies and experiments aimed to obtainment, in the foreign country also, a marketing authorization of drugs and to consequent practical requirements therein enclosed preparation and usage of pharmacologically active raw materials, to that strictly necessary. (letter b, paragraph 1, article 68.)

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

The purpose of the provision is to privilege the manufacturers of generic drugs. These manufacturers are allowed to carry out the use of the patent even before the term of protection ends under the condition that the use is necessary to obtain an authorization for medicinal products.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation, Article 10(6) of the amended Directive 2001/83/EC and Article of the amended Directive 2001/82/EC into national law.

54. Who is entitled to use the exception? Please explain:

Manufactures of medicaments, especially of generic drugs are entitled to use this exception

55. The exception covers the regulatory approval of:
any products

Certain products. Please describe which products: Medicaments

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify

Studies, experiments and any resulting practical requirements, i.e. any use under the patent's scope protection that is intended to meet the prerequisites of a privileged study or a privileged experiment (for example: production or importation of the still protected active substance intended to be used in the experiment).

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The scope of admissible use comprises studies, experiments and any action to execute them, under the condition, that they are necessary to obtain an authorization for medicinal products or approval. Therefore, a direct relation is required between the study, the experiment or its execution, on the one hand, and the authorization or approval sought, on the other hand.

58.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

The exclusive faculties granted by this code to holder of industrial property right are exhausted when the protected products by an industrial property right have been putted on the market by the holder or with his consent in the State territory or in the territory of a member State of European community or European Economic Area. (Article 5 paragraph 1 lpc.)

This holder's powers limitation however is not applied when rightful motives subsist so as holder himself opposes to further marketing of products, namely when their condition is modified or altered after their putting in the market. (Article 5 paragraph 2 Ipc.)

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

They intend to avoid that monopoly can compromise certainty of trade, being used ad nutum by the holder to obstruct further marketing of protected product .

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. -64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Lapsed three years from the granting patent date or four years from filling application date, if this term expires later than prior in case Patentee or his successor, directly or through one or more licensees, has not carried out the patent invention producing in the territory of the State or importing objects, produced in a Member States of European Union or of European economic Area or in a State member of World-wide organization of the commerce, or rather he has carried out it in a measurement such to result in serious disproportion with the needs of Country, a compulsory license can be granted for not exclusive use of same invention in favour of every person concerned which applies for it. (Article 70, paragraph 1 Ipc)

The compulsory license can equally be granted in the event that implementation of invention have been for further three years, suspended or reduced in a measurement such to result in serious disproportion with the needs of Country, (Article 70, paragraph 2 Ipc)

Compulsory license is not granted if loss or insufficient implementation is due to grounds beyond patentee's will or of his successor. Lack of financial resources and in case the same product is diffused abroad, the lack of request in the internal market of patented product or obtained with patented process, not are encompassed among these grounds (Article 70 paragraph 3 Ipc) Granting of compulsory license does not relieve patentee or his successor from the burden of implementation. The patent lapsed if the invention is not carried on within two years from the granting date of the first compulsory license or it have been in a measurement such to result in serious disproportion with the needs of Country, (Article 70 paragraph 4 Ipc)

A compulsory license can be granted if the patent invention cannot be exploited without prejudice of rights relative to a patent granted on under prior application. In this case, license can be granted to later patent's holder in necessary measure as exploiting invention, provided that constitutes, with regard to of object earlier patent, an important technical progress of remarkable economic account. (Article 71 paragraph 1 lpc)

Compulsory license is assigned only jointly to patent on dependent invention. Patentee on primary invention have right granting of a compulsory license on reasonable terms on patent of dependent invention (Article 71 paragraph 2 lpc)

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

They will avoid that patentee can abuse of exclusive position vested to him by patent rights towards the public.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of "non-working" or "insufficient working", please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Patentee or his successor, directly or through one o more licensees, has not carried out the patent invention producing in the territory of the State or importing objects, produced in a Member States of European Union or of European economic Area or in a State member of World-wide organization of the commerce, or rather he has carried out it in a measurement such to result in serious disproportion with the needs of Country,

70. Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, if the imported patented products are realized in a Member States of European Union or of European economic Area or in a State member dell' World-wide organization of the commerce,

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three years from the granting date or four years from the filing date if this delay fall later the previous. Past three years in the case of suspension or reduction.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

The law affirms "Compulsory license is not granted if loss or insufficient implementation is due to grounds beyond patentee's will or of his successor". But it specifies "Lack of financial resources and in case the same product is diffused abroad, the lack of request in the internal market of patented product or obtained with patented process, not are encompassed among these grounds"

73.-74.

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Under the law compulsory licenses on the ground of dependent patents, can be granted to holder of posterior patent to the extent that is necessary exploiting invention, provided that constitutes, with regard to of object earlier patent a important technical progress of remarkable economic importance

76.-80.

[Note from the Secretariat: response was not provided.]

Government use

81.-88.

[Note from the Secretariat: the applicable law of Italy does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Italy does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Point 1. Breeder's Right

the breeder's authorization is required for following affected acts in respect of the propagating material of the protected variety: (a) production or reproduction (multiplication), (b) conditioning for the purpose of propagation, (c) offering for sale, selling or other marketing, (d) exporting or importing, (e) stocking for any of the purposes mentioned above. (see paragraph 1 article 107 lpc)

the breeder's authorization is required for this affected acts in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating materials of the protected variety unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material. (see paragraph 2 article 107 lpc)

Point 2. Breeder's Right extend

(a) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety, (b) varieties which are not clearly distinguishable from the protected variety in accordance with requirement of distinctness and (c) varieties whose production requires the repeated use of the protected variety. (see paragraph article 107)

The "Breeder's exemption"

Breeder's Right does not extend effected acts for the purpose to breeding other varieties as well as, where these not are variety listed in point 2 ,acts of which to point 1 affected in respect such other variety

96.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Italy does not provide other exceptions and limitations.]

Country: JAMAICA
Office: Jamaica Intellectual Property Office (JIPO)

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

An invention as described under Jamaica's a Patent act of 1857 includes any new and useful art, machine, manufacture or composition of matter not known or used within the Island, or some new improvement in any such invention or discovery.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The Legislation does not have any provision for exclusion.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The patentee is granted the full and exclusive right and liberty to make, construct, use and vend to others to use the invention.

Publication: A short notice is published in a daily newspaper and the Jamaica Gazette indicating the name of the applicant and the title of the invention. The Specification is not published. The Patentee is not accorded exclusive right until the Governor General of Jamaica signs the Letters Patent.

[...]

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Jamaica is currently preparing New Patent Legislation which will take us to the international standard that is required and where the questions on exceptions will be addressed.

[...]

[Note: The remaining questions are not applicable under the current Legislation.]

Country: JAPAN
Office: Japan Patent Office (JPO)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Under the Japanese Patent Act, an "Invention" is defined as a highly advanced creation of technical ideas utilizing the laws of nature (Article 2), and also required to be industrially applicable (main paragraph of Article 29). Moreover, the legal standard to determine patentability includes so called novelty and inventive step (Article 29 (1) and (2)).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Notwithstanding Article 29, any invention that is liable to injure public order, morality or public health shall not be patented (Article 32).

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Article 68 of the Japanese Patent Act stipulates that a patentee shall have the exclusive right to work the patented invention as a business.

Pursuant to Article 2(3) of the Japanese Patent Act, "working" of an invention means the following acts:

(i) in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof;

(ii) in the case of an invention of a process, the use thereof; and

(iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights; Compulsory licensing and/or government use;
Compulsory licensing and/or government use.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 68 of the Japanese Patent Act stipulates that A patentee shall have the exclusive right to work the patented invention as a business; provided, however, that where an exclusive license regarding the patent right is granted to a licensee, this shall not apply to the extent that the exclusive licensee is licensed to exclusively work the patented invention.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

Although it was presupposed in defunct Article that the effect of patent right was extended to, not only enforcement of the patented invention as business, but also to individual homely enforcement, that was considered to be excessive regarding the social actual condition.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 7.-8.

[Note from the Secretariat: response was not provided.]

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment for changing the legal framework of the exception has been scheduled.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 69(1) of the Japanese Patent Act stipulates that a patent right shall not be effective against the working of the patented invention for experimental or research purposes.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

It is intended to promote further inventive activities among the public.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The Japanese Patent Act does not make a distinction concerning the nature of the organization conducting the experimentation or research.

15.-20.

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment for changing the legal framework of the exception has been scheduled.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 69 (3) of the Japanese Patent Act stipulates that a patent right for the invention of a medicine (refers to a product used for the diagnosis, therapy, treatment or prevention of human diseases, hereinafter the same shall apply in this paragraph) to be manufactured by

mixing two or more medicines or for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

Taking into account an act of preparing medicine by a physician or a dentist has a social mission with a particular purpose of helping citizens, when becoming patients, recover their health, it is considered inappropriate for the effect of a patent right to extend to an act of preparing medicine. Yet, it is interpreted that medicine itself is generally deemed to be prepared by a medicine manufacturer with a patent license granted, and legally sold by a physician or a dentist.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Article 69 (3) of the Japanese Patent Act stipulates that a patent right for the invention of a medicine (refers to a product used for the diagnosis, therapy, treatment or prevention of human diseases, hereinafter the same shall apply in this paragraph) to be manufactured by mixing two or more medicines or for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment for changing the legal framework of the exception has been scheduled.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 79 of the Japanese Patent Act stipulates that a person who, without knowledge of the content of an invention claimed in a patent application, made an invention identical to the said invention, or a person who, without knowledge of the content of an invention claimed in a patent application, learned the invention from a person who made an invention identical to the said invention and has been working the invention or preparing for the working of the invention in Japan at the time of the filing of the patent application, shall have a non-exclusive license on the patent right, only to the extent of the invention and the purpose of such business worked or prepared.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

If the first-to-file system is strictly applied, it is not necessarily be fair that a party which had been working the same invention prior to the filing of a patent application by another party should be precluded from working the same invention of the patent right, just because the party was slightly behind in filing an application. Therefore, even if such a policy is applied, there remains a need to adjust the interests of the patent owner and any party already working the invention in question prior to the patent application.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 79 of the Japanese Patent Act stipulates that a person who, without knowledge of the content of an invention claimed in a patent application, made an invention identical to the said invention, or a person who, without knowledge of the content of an invention claimed in a patent application, learned the invention from a person who made an invention identical to the said invention and has been working the invention or preparing for the working of the invention in Japan at the time of the filing of the patent application, shall have a non-exclusive license on the patent right, only to the extent of the invention and the purpose of such business worked or prepared.

Pursuant to Article 2(3) of the Japanese Patent Act, "working" of an invention means the following acts:

- (i) *in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing*

through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof;

(ii) in the case of an invention of a process, the use thereof; and

(iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The Japanese Patent Act does not provide for a remuneration to be paid to the patentee for the exercise of the exception.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

Article 94(1) of the Japanese Patent Act stipulates that except for a non-exclusive license granted by an award under Article 83(2), 92(3), 92(4) or 93(2) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, a non-exclusive license may be transferred only where the business involving the working of the relevant invention is also transferred, where the consent of the patentee (or, in the case of non-exclusive license on the exclusive license, the patentee and the exclusive licensee) is obtained and where the transfer occurs as a result of general succession including inheritance.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Article 176 of the Japanese Patent Act stipulates that where a patent right pertaining to an invalidated patent or a patent right pertaining to the invalidated registration of an extension of the duration thereof has been restored through a retrial or where the establishment of a patent right or the extension of the duration of a patent right with respect to a patent application or an application for registration of an extension of the duration of a patent right refused by a trial decision has been registered through a retrial, and where a person has, without knowledge, been working the invention in Japan or has, without knowledge, been making preparations therefore, after the trial decision became final and binding but before the registration of the demand for a retrial, such person shall have a non-exclusive license on

the patent right, to the extent of the invention and the purpose of such business worked or prepared.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Article 80(1) of the Japanese Patent Act stipulates that a person falling under any of the following items, who is doing a business working an invention in Japan or preparing such business, before the registration of a request for a trial for patent invalidation, without knowledge that the patent falls under any of the paragraphs of Article 123(1), shall have a non-exclusive license regarding the invalidated patent right or the exclusive license existing at the time of the invalidation, only to the extent of the invention and the purpose of such business worked or prepared:

- (i) the original patentee in the case where one of two or more patents granted for the same invention has been invalidated;*
- (ii) the original patentee in the case where, after a patent has been invalidated, a patent is granted to the person who is entitled to obtain a patent for the same invention; and*
- (iii) in the case referred to in items (i) and (ii), a person that, at the time of the registration of the request for a trial for patent invalidation, has an exclusive license regarding the patent right to be invalidated, or a non-exclusive license effective under Article 99(1) regarding the patent right or an exclusive license on the patent right.*

Article 81 of the Japanese Patent Act stipulates that where a design right with regard to an application for a design registration filed on or before the date of filing of a patent application is in conflict with the patent right with regard to the patent application, the original holder of design right shall, upon expiration of the duration of the design right, have a non-exclusive license on the said patent right or on the exclusive license actually existing at the time of expiration of the duration of the design right, limited to the extent of the original design right.

Article 82(1) of the Japanese Patent Act stipulates that where a design right with regard to an application for a design registration filed on or before the date of filing of a patent application is in conflict with the patent right with regard to the patent application, a person who, at the time of expiration of the duration of the design right, actually owns the exclusive license on the design right, or a non-exclusive license having effect under Article 99(1) of the Patent Act as applied under Article 28(3) of the Design Act on the design right or on the exclusive license shall, upon expiration of the duration of the design right, have a non-exclusive license on the patent right or on the exclusive license actually existing at the time of expiration of the duration of the design right, limited to the extent of the original right.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment for changing the legal framework of the exception has been scheduled.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 69 (2) (i) of the Japanese Patent Act stipulates that A patent right shall not be effective against the following products:

(i) vessels or aircrafts merely passing through Japan, or machines, apparatus, equipment or other products used therefor

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

It is for substantial validity and correspondence with the Paris Convention.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 69 (2) (i) of the Japanese Patent Act stipulates that A patent right shall not be effective against the following products:

(i) vessels or aircrafts merely passing through Japan, or machines, apparatus, equipment or other products used therefor

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 69 (2) (i) of the Japanese Patent Act stipulates that A patent right shall not be effective against the following products:

(i) vessels or aircrafts merely passing through Japan, or machines, apparatus, equipment or other products used therefor

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment for changing the legal framework of the exception has been scheduled.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 69(1) of the Japanese Patent Act stipulates that a patent right shall not be effective against the working of the patented invention for experimental or research purposes.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

*Second Petty Bench of the Supreme Court
Decided on April 16, 1999 (Case No. 153(ju) of 1998) (Minshu 53 (4) 627)
<Summary of Decision>*

In a case where a person holds a patent right of a chemical substance or a medicine having said chemical substance as active ingredient, it is appropriate to interpret the following act falls into Article 69 (1) of the Japanese Patent Act, and thus is not deemed patent infringement; for the purpose of production and sale, to file an application prescribed in Article 14 of Pharmaceutical Affairs Act for an approval for its production, within the term of the patent right, the third party produces a chemical substance or medicine within the technical scope of patented invention, and by using it conducts a study required to obtain a material which should be attached to the above-mentioned application.

53. (a) What are the public policy objectives for providing the exception? Please explain:

If it is not allowed to conduct a clinical study required for an approval for production of generic medications within the term of the patent right, substantially speaking, the third party cannot use said patented invention freely even after the term of the patent right is expired. Moreover, a patent right holder can ensure financial benefit by an exclusive license of patented invention.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

[Note from the Secretariat: response was not provided.]

55. The exception covers the regulatory approval of:

Certain medicines and agrichemical products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Making
Using*

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment for changing the legal framework of the exception has been scheduled.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

*From Decision of Third Petty Bench Supreme Court on July 1, 1997
(BBS Supreme Court case)*

As for assignment of patented products in Japan, it was ruled that "in a case where a patent right holder or its licensee assigned to a patented product in Japan, it should be interpreted that the patent right of said patented product is exhausted since the purpose thereof is deemed to be achieved, and the effects of the patent right no longer extend to acts such as use, assignment, or lease of said patented product." As shown in this court decision, the national exhaustion doctrine is applied in Japan. In the meantime, as for assignment of patented products overseas, it was ruled that "in a case where a patent holder in Japan or a person deemed to be equal thereto assigned a patented product overseas, it should be interpreted that the patent right holder is not allowed to execute his/her patent right in Japan, except that for an assignee, an agreement was made between a patent holder and the assignee that the areas for sale or use of the patented product excludes Japan, and that for the third party to whom the patented product was assigned by the assignee and subsequent

acquirer, above-mentioned agreement was made between an assignee and said third party or acquirer, and it is explicitly indicated on the patented product. Therefore, the internationally applied exhaustion principle is not applied in Japan.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

It is to harmonize between protection of invention and public benefit, as well as to coordinate between product distribution in international trade and a right of patentee.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

At present, there is no court decision to overrule the above decision.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 83 of the Japanese Patent Act stipulates that, (1) Where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan, a person intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license; provided, however, that this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed.

(2) *here no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Commissioner of the Patent Office for an award.*

Article 92 of the Japanese Patent Act stipulates that, (1) Where a patented invention falls under any of the cases as provided in Article 72, the patentee or exclusive licensee may request the other person under the said Article to hold consultations to discuss granting a nonexclusive license to work the patented invention or a non-exclusive license on the utility model right or the design right.

(2) *he other person under Article 72 who is requested to hold consultations under the preceding paragraph may request the patentee or exclusive licensee requesting such consultations to hold consultations to discuss granting a nonexclusive license to the extent of the patented invention that the said patentee or exclusive licensee intend to work with a non-exclusive license on the patent right, on the utility model right or on the design right granted through consultations.*

(3) *Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (1), the patentee or the exclusive licensee may request the Commissioner of the Patent Office for an award.*

(4) *Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (2) and where a request for an award is filed under the preceding paragraph, the other person under Article 72 may request the Commissioner of the Patent Office for an award only within the time limit for the submission of a written answer by the said other person designated by the Commissioner of the Patent Office under Article 84 as applied mutatis mutandis under paragraph (7).*

(5) *In the case of paragraph (3) or (4), the Commissioner of the Patent Office shall not render an award to the effect that a non-exclusive license is to be granted where the granting of the non-exclusive license will be unreasonably prejudicial to interest of the other person under Article 72, the patentee or the exclusive licensee.*

(6) *In the case of paragraph (4), in addition to the case provided for in the preceding paragraph, the Commissioner of the Patent Office shall not render an award ordering a non-exclusive license to be granted if an award ordering a non-exclusive license to be granted is not rendered with respect to the request for an award under paragraph (3).*

(7) *Articles 84, 85(1) and 86 through 91-2 shall apply mutatis mutandis to the award under paragraph (3) or (4)*

Article 93 of the Japanese Patent Act stipulates that, (1) Where the working of a patented invention is particularly necessary for the public interest, a person(s) intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license.

(2) *Where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Minister of Economy, Trade and Industry for an award.*

(3) *Articles 84, 85(1) and 86 through 91-2 shall apply mutatis mutandis to the award under the preceding paragraph.*

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Dependent patents

Where the working of a patented invention is particularly necessary for the public interest (Article 93).

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

It is to balance the right of the patent holder and the purpose to the development of industry, or for the benefit of the public.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 83 of the Japanese Patent Act stipulates where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 83 of the Japanese Patent Act stipulates that, (1) Where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan, a person intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license; provided, however, that this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed.

Pursuant to Article 2(3) of the Japanese Patent Act, "working" of an invention means the following acts:

(i) in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof;

(ii) in the case of an invention of a process, the use thereof; and

(iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

3 years or longer (however, this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed).

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

Article 85 (2) of the Japanese Patent Act stipulates where there is a reasonable ground for failing to properly work the patented invention.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

There are no provisions to grant compulsory license simply due to refusal to grant license. However, as a condition to request for arbitrary license in Article 83 and 92 of the Japanese Patent Act, it is required that granting license is refused or licensing consultations cannot be initiated (Article 92 (3)(7)).

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

In a case where a person cannot work his/her own patented invention without working other's patented invention, the person can request the patent right holder or exclusive licensee to hold consultations on the grant of a non-exclusive license thereon. Yet, if no agreement is reached or no consultation is possible, the person can request for arbitration decision of Commissioner of the Japan Patent Office. Yet, in a case where the grant of a non-exclusive license would unduly injure the other person or the patent right holder, the Commissioner of the Patent Office cannot render an arbitration decision ordering a non-exclusive license to be granted.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

[Note from the Secretariat: response was not provided.]

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

There were some cases where arbitration decisions were requested. Yet, in any of these cases, the request was withdrawn before arbitration decision was made, and there have been no cases where non-exclusive license was granted by arbitration decision.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment for changing the legal framework of the exception has been scheduled.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81.-88.

[Note from the Secretariat: the applicable law of Japan does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Japan does not provide exceptions related to farmers’ use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Japan does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Japan does not provide other exceptions and limitations.]

Country: KYRGYZ REPUBLIC
Office: State Intellectual Property Service of the Kyrgyz Republic (Kyrgyzpatent)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

According to the Part 1 Article 5 of the Patent Law of the Kyrgyz Republic the conditions of any invention patentability are: novelty, inventive height and industrial applicability.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

In accordance with the Part 9 Article 5 of the Patent Law of the KR the following developments shall not be considered as inventions:

- 1) *scientific theories and methods of mathematics;*
- 2) *methods of organization and management of economy;*
- 3) *reference designations, schedules and rules;*
- 4) *methods of performance of mental activities;*
- 5) *algorithms and computer programs as such;*
- 6) *drafts and schemes for planned structures, buildings and territories;*
- 7) *decisions regarding only the appearance of articles aimed for satisfaction of aesthetic needs;*
- 8) *integrated circuits topography;*
- 9) *varieties of plants and breeds of animals;*
- 10) *decisions contradicting with public interests, principles of humanity and morals, hazardous to the environment.*

The presence of algorithm and software programs in the invention shall not be deemed as a fact influencing the patentability of an invention, if they are considered as a part of an invention.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

In accordance with the Part 1 Article 11 of the Patent Law of the KR the patent owner shall have the exclusive right to protected by the patent for Intellectual Property subject-matters, including the right to prohibit the use of these objects by other persons, except for the cases when such use does not infringe the exclusive right of the patent owner according to this Law.

In accordance with the Part 5 Article 11 of the Patent Law of the KR the manufacture, application, import, offer for sale, sale and any other introduction to the economic turnover or storage of a product for this purpose that contains objects of industrial property protected by

a patent as well as exploitation of the method protected by a patent for an invention shall be considered as the exploitation of an object of industrial property.

In addition, Article 14 of the Patent Law of KR provides that “the claimed invention since the date of publication of the information concerning application to the date of publication of the information concerning patent issue is provided by provisional legal protection in the scope of published formula but no more than the scope determined by the formula contained in the issued patent”

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those Parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other Parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI “Other Exceptions”.

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4.-10.

[Note from the Secretariat: the applicable law of the Kyrgyz Republic does not provide exceptions related to private and/or non-commercial use.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Part 2 Article 13 of the KR Patent Law conducting the scientific research or an experiment with an article containing an object of industrial property are not recognized as an infringement of the exclusive right of the patent owner.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

Observance of reasonable balance of interests between patent owners and community, as well as development and support of science and technology.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14.-15.

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Please explain by citing legal provision(s) and/or decision(s):

According to the Part 2 Article 13 of the KR Patent Law conducting of scientific research or an experiment on the article containing an object of industrial property are not recognized as an infringement of the exclusive right of the patent owner.

18.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of the Kyrgyz Republic does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Any natural person or a legal entity who before the date of priority of an object of industrial property, regardless from the author, has created and used on the territory of the Kyrgyz Republic a solution similar to the object of an industrial property or made the required preparations shall keep the right to use it free of charge without enlarging the scope of such use.

The right of prior use may be assigned to another natural person or legal entity but together with the production where the use of identical solution has taken place or the required

preparations has been made for that purpose (Patent Law of the KR, Part 1 and 2 of the Article 14).

32.-34.

[Note from the Secretariat: response was not provided.]

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The Patent Law of the Kyrgyz Republic does not provide for such remuneration. As stipulated in Article 14 "Any natural person or a legal entity who before the date of priority of an object of industrial property, regardless from the author, has created and used on the territory of the Kyrgyz Republic a solution similar to the object of an industrial property or made the required preparations shall keep the right to use it free of charge without enlarging the scope of such use."

36. According to the applicable law, can a prior user license or assign his prior user's right to a third Party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

As provided in Article 14 of the Patent Law of the Kyrgyz Republic "The right of prior use may be assigned to another natural person or legal entity but together with the production where the use of identical solution has taken place or the required preparations has been made for that purpose (Patent Law of the KR, Part 1 and 2 of the Article 14).

38.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The exception is contained in the Part 1 Article 13 of the KR Patent Law "Actions Not Considered as an Infringement of the Exclusive Right of the Patent Owner":

1) application of the means containing objects of industrial property protected by patents in the construction or during exploitation of transport facilities (sea-going, river, air, land and cosmic) of other countries under condition that said facilities temporarily or accidentally stay in the territory of the Kyrgyz Republic and are used for the needs of transport facility. Such actions shall not be considered as an infringement of the exclusive right of the patent owner if transport facilities belong to natural persons or legal entities of the countries that provide the same rights to the owners of transport facilities of the Kyrgyz Republic.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

On the bases of obligations of the Kyrgyz Republic resulting from signing of international agreements and observance of balance between the interests of patent owner and the whole community aiming at development.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

Part 1 Article 13 of the KR Patent Law "Actions Not Considered as an Infringement of the Exclusive Right of the Patent Owner"

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Part 1 Article 13 of the KR Patent Law "Actions Not Considered as an Infringement of the Exclusive Right of the Patent Owner"

1) application of the means containing objects of industrial property protected by patents in the construction or during exploitation of transport facilities (sea-going, river, air, land and cosmic) of other countries under condition that said facilities temporarily or accidentally stay in the territory of the Kyrgyz Republic and are used for the needs of transport facility. Such actions shall not be considered as an infringement of the exclusive right of the patent owner if transport facilities belong to natural persons or legal entities of the countries that provide the same rights to the owners of transport facilities of the Kyrgyz Republic.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

As provided in Article 13 of the Patent Law of KR, such protected by patent objects shall be used for the needs of transport facility.

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of the Kyrgyz Republic does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60.-64.

[Note from the Secretariat: the applicable law of the Kyrgyz Republic does not provide exceptions related to exhaustion of patent rights.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 12 of the Patent Law of the Kyrgyz Republic provides:

If the object of industrial property is not used or insufficiently used by the patent owner or persons to whom the rights for it has been transferred, within three years as of the date of granting a patent, that leads to insufficient supply of the appropriate goods or services at the market of goods and services, any person wishing and ready to use patent of an industrial property, in the event of refusal of the patent owner to conclude licensing agreement with this person on the conditions pursuant to the common practice, has the right to apply to court with an action to provide him a compulsory license for the use of this object.

If the patent owner fails to prove that the non-use or insufficient use of an object of industrial property is conditioned by excusable reasons, the court shall grant the indicated license specifying the scope of use, the amount, time limits and procedures of payment. The amount of payment must not be lower than the price of the license, which is determined in compliance with the established practice.

The patent owner that can not use an invention without infringing the rights of the other owner of a patent for an invention or for a utility model, who has refused to conclude a licensing agreement based on the conditions that are in compliance with the common practice, has the right to apply to court with an appeal to grant him a compulsory license for the exploitation of an invention or utility model under condition that his invention presents an important technological achievement of the significant economic value with respect to the invention or utility model patent for which belongs to the other person.

If the indicated license is provided, the court must establish the limits for the use of an invention or utility model, patent for which belongs to the other person, in the scope necessary to exploit an invention patented by the person requiring to provide him a compulsory license, as well as the amount, terms and payment order. The amount of payment must be established not less than the price for a license, which is determined in compliance with the common practice.

In the emergency situations (disasters, catastrophes, big accidents), as well as in the interests of the national security, the Government of the Kyrgyz Republic shall have the right

to grant a compulsory license coupled to payment of an applicable compensation to a patent owner, in this case the volume and time of exploitation of the patented object of industrial property shall be restricted by the purposes for which it was allowed. Disputes arising due to such exploitation shall be decided by court.

The compulsory license shall always be non-exclusive license; it cannot be reassigned to another person. (Article 12, Patent Law of the Kyrgyz Republic).

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
National security
National emergency and/or extreme urgency
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Observance of balance at protection providing to population; science and technology development.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

If the patent owner fails to prove that the non-use or insufficient use of an object of industrial property is conditioned by excusable reasons, the court shall grant the indicated license specifying the scope of use, the amount, time limits and procedures of payment. The amount of payment must not be lower than the price of the license, which is determined in compliance with the established practice (Article 12, Patent Law of the Kyrgyz Republic).

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

To be determined by the Court (Article 12, Patent Law of the Kyrgyz Republic).

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

To be determined by the Court (Article 12, Patent Law of the Kyrgyz Republic)

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Article 12 of the Patent Law of KR provides that: "[...] in the event of refusal of the patent owner to conclude licensing agreement with this person on the conditions pursuant to the common practice, has the right to apply to court with an action to provide him a compulsory license for the use of this object". Explanation of that statement is not provided in the Patent Law.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Article 12 of the Patent Law of the KR provides: "The patent owner that can not use an invention without infringing the rights of the other owner of a patent for an invention or for a utility model, who has refused to conclude a licensing agreement based on the conditions that are in compliance with the common practice, has the right to apply to court with an appeal to grant him a compulsory license for the exploitation of an invention or utility model under condition that his invention presents an important technological achievement of the significant economic value with respect to the invention or utility model patent for which belongs to the other person.

If the indicated license is provided, the court must establish the limits for the use of an invention or utility model, patent for which belongs to the other person, in the scope necessary to exploit an invention patented by the person requiring to provide him a compulsory license, as well as the amount, terms and payment order. The amount of payment must be established not less than the price for a license, which is determined in compliance with the common practice."

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

According to the Part 4 Article 12 of the Patent Law – “The amount of payment must be established not less than the price for a license, which is determined in compliance with the common practice”.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

According to the Part 5 Article 12 of the Patent Law the emergency situations are: disasters, catastrophes, big accidents.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

The compulsory licenses have not been issued.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

For purposes of national security (Article 12 of Patent law of KR).

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Public health
National security
National emergency and/or extreme urgency*

84. (a) What are the public policy objectives for providing government use in your country?

To allow the government to use invention at epidemic complicated emergency situations.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Article 1 of the Law of the Kyrgyz Republic “On Civil Protection” provides that:

“Emergency is a situation that developed in a certain area as a result of a dangerous natural or man-made phenomena, accidents, disasters, natural or other disasters that may cause or have caused casualties, damage to human health or the environment, significant financial loss and deterioration of conditions of life people.”

86.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of the Kyrgyz Republic does not provide exceptions related to farmers’ use of patented inventions.]

Breeders’ use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of the Kyrgyz Republic does not provide exceptions related to breeders’ use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Kyrgyz Republic does not provide other exceptions and limitations.]

Country: LATVIA
Office: Patent Office of the Republic of Latvia

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The requirements of patentability are set out in s. 4, 5, 7 and 8(1) of the Patent Law.⁴ These requirements are applicable to inventions in all technical fields.

Section 4. Patentability of an Invention

An invention shall be protected with a patent in any field of technology if the invention is new, it has an inventive step and it is susceptible of industrial utilization.

Section 5. Novelty

(1) An invention shall be considered as new if it is not a part of the state of the art.

(2) The state of the art shall include any knowledge which is publicly available in writing or orally, is used publicly or made public in any other way prior to the filing date of a patent in accordance with Section 28, Paragraph two of this Law or prior to the date of priority in accordance with Section 29 of this Law.

(3) As a part of the state of the art shall be considered also the national patent applications whose filing date in accordance with Section 29 of this Law is earlier than the date referred to in Paragraph two of this Section and which have been published on this date or following this date. This condition shall also be applied to the European patent applications with an earlier priority.

(4) The conditions of Paragraphs two and three of this Section shall not prohibit patentability to substances or the compositions thereof, known from the state of the art if the substances or the compositions thereof:

1) are intended to be used by utilising the methods referred to in Section 8, Paragraph two of this Law and this use is not a part of the state of the art; or

2) are intended for a specific use of the methods referred to in Clause 1 of this Paragraph in the cases when the specific use is not a part of the state of the art.

Section 7. Inventive Step

(1) An invention shall be considered as conforming with the inventive step if, taking into consideration the state of the art, the invention is not obvious to a person skilled in the relevant field of art.

⁴ The English version of the Patent Law may be found at the following address:
http://www.lrpv.lv/dl/pdf/pat_lik_en.pdf

(2) *If the state of the art is formed by the patent applications referred to in Section 5, Paragraph three of this Law, they shall not be taken into consideration when evaluating the inventive step.*

Section 8. Industrial Utilization

(1) *An invention shall be considered for industrial utilization if the subject thereof may be manufactured or used in any kind of industry, agriculture or other economic sector.*

The Section 6 provides for limitations to “absolute novelty”:

Section 6. Information Made Public which does not Cause Harm to Novelty

(1) *The conditions of Section 5 of this Law shall not be applied if an invention has been made public not sooner than six months prior to the filing date of a patent and if the communication to the public thereof is:*

1) *a fraudulent action against the applicant of the patent (hereinafter – applicant) or against the legal predecessor thereof; or*

2) *demonstration of the invention of the applicant or the legal predecessor thereof has taken place in an official international exhibition or an international exhibition equivalent to it organised in accordance with the Convention Relating to International Exhibitions signed at Paris on 22 November 1928 and as amended on 30 November 1972.*

(2) *The conditions of Paragraph one, Clause 2 of this Section shall be applied only if the applicant, when filing the patent application, declares that the invention has been demonstrated in such an exhibition and files a document certifying this fact within a time limit of four months from the filing date.*

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

- 1) *discoveries, scientific theories, mathematic methods;*
- 2) *aesthetic creations;*
- 3) *schemes, intellectual activities, rules and methods for commercial activities and games, as well as computer programs;*
- 4) *methods for presentation of information.*

In the field of medicine:

Patents can not be granted to methods for treatment of human or animal body by surgery or therapy and to diagnostic methods practised on human or animal body.

The s. 8(2) provides:

(2) *Therapeutic or surgical treatment methods and diagnostic methods, used in relation to human or animal body, shall not be considered for industrial utilization. This exception shall not apply to the devices and substances or the compositions thereof utilised when employing the referred to methods.*

In the field of biotechnology:

- 1) *human cloning;*
- 2) *modification of the genetic identity of human beings in germ cells;*

- 3) *utilisation of human embryos for industrial or commercial purposes;*
- 4) *methods for modifying the genetic identity of animals likely to cause them suffering without any substantial medical benefit to people or animals, as well as animals resulting from such methods.*
- 5) *A human body in different stages of formation and development and a simple discovery of one of its elements, including the sequence or partial sequence of a gene, may not be a patented invention.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

*Rights conferred by patent are set in Section 16:
Section 16. Exclusive Rights*

(1) A patent shall ensure the exclusive rights to the owner thereof. It is prohibited to third persons without the permission of the owner of the patent:

- 1) *to produce, to offer for sale, to distribute in another way on the market, to use, as well as to import, to export and to store for the referred to intentions the patented product;*
- 2) *to use the patented method;*
- 3) *to offer for sale, to distribute on the market in another way, to use, as well as to import, to export and to store for the referred to intentions a product directly acquired with the patented method; and*
- 4) *to supply or offer for supply essential elements of the patented product if third persons knew or they should have known in the relevant circumstances that such elements are suitable and intended for the implementation of the invention.*

(2) The conditions of Paragraph one, Clause 4 of this Section shall not be applied if the essential elements for the implementation of the invention are basic commercial products, except for the case when third person with such a supply motivates to carry out the activities referred to in Paragraph one of this Section.

Rights conferred by published patent application are set in Section 18.2:

“(2) Provisional legal protection shall be conferred to the invention for the time limit from the day when the patent application was made public according to the procedure specified in Section 35 of this Law until the day of the grant of the patent. If during this time limit third persons utilize the invention to be patented without the consent of the applicant, the owner of the patent is entitled to request a compensation.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 20.1

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

6. (a) What are the public policy objectives for providing the exception?

Obligations under Art. 30 of the TRIPS

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

n/a

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

There is no further explanation of these concepts

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

None

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no amendments are foreseen

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 20.2

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

13. (a) What are the public policy objectives for providing the exception?

Harmonization of national Patent Law with the laws of member states of the European Union

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

n/a

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

No further explanations are given

- 16.

[Note from the Secretariat: response was not provided.]

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

[Note from the Secretariat: response was not provided.]

Please explain by citing legal provision(s) and/or decision(s):

There is no further clarification of the exceptions provided.

- 18.

[Note from the Secretariat: response was not provided.]

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

No further explanations are given.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

No further criteria applied.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no further amendments are foreseen.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 20.4

"single preparation of medicinal products by a doctor's prescription in a pharmacy, as well as the actions with medicinal products prepared in such a way"

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

25. (a) What are the public policy objectives for providing the exception? Please explain:

Harmonization of national Patent Law with the laws of member states of the European Union

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

All three mentioned above

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no amendments are foreseen

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 22

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

33. (a) What are the public policy objectives for providing the exception? Please explain:

Harmonization of national Patent Law with the laws of member states of the European Union

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Sec. 22 says: "The person, who in good faith has utilised the invention for commercial purposes or carried out the necessary preparations for such a utilisation in the territory of Latvia prior to the filing date or the priority date of the patented invention, is entitled to utilise this invention further on for commercial purposes to the extent planned during the preparations without hindrance and without paying a remuneration to the owner of the patent"

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

Sec. 22.2 says: "The rights of prior use may be transferred to another person only together with the undertaking or a part of the undertaking in which the invention has been utilised within the meaning of Paragraph one of this Section".

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Sec. 46.6 says: "A person who, in the territory of Latvia following the making the patent application public within a time period between the loss of the right in accordance with Paragraph one of this Section and the day when the notification regarding the reestablishment of the right was published in the Official Gazette of the Patent Office, has utilised the invention in good faith for commercial purposes or carried out the necessary preparatory work for such a utilisation, is entitled to utilise such an invention further on for commercial purposes to the planned extent during the period of preparatory work, without hindrance and without paying the remuneration to the applicant or the owner of the patent."

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no amendments are foreseen

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 20.5

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

44. (a) What are the public policy objectives for providing the exception? Please explain:

Obligations under Paris Convention Art. 5ter

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

Spacecraft

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Sec. 20.5 of the Patent Law provides for:

"The exclusive rights resulting from a patent shall not be implemented in relation to:

5) utilisation of the invention in the construction or exploitation of such a foreign vehicle which temporarily or accidentally is located in the territory of Latvia if the invention is utilized only for the vehicle."

The terms "temporarily" and "accidentally" are not further explained

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No restrictions are provided for.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no amendments are foreseen

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec, 20.3

"The exclusive rights resulting from a patent shall not be implemented in relation to:

3) examination of the subject of a patented invention, as well as the research of medicinal products or plant protection products patented or protected with a supplementary protection certificate carried out in order to obtain a permission for distribution on the market thereof;"

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

53. (a) What are the public policy objectives for providing the exception? Please explain:

Compliance with Art. 10.6 of the EU directive 2004/27/EC

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

54. Who is entitled to use the exception? Please explain:

Supposed to be used by companies producing generic medicines

55. The exception covers the regulatory approval of:

Certain medicinal and plant protection products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Making

Using

Selling

Offering for sale

Import

Export

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no amendments are foreseen

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 21.1

“The right resulting from the patent shall not apply to the activities which have been carried out with the patented product in the European Economic Area if this product is included in the economic circulation in the European Economic Area by the owner of the patent himself or herself or another person with his or her consent, unless the owner of the patent has a legal basis to object to the further economic circulation of the product.”

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

The common policy of the EU

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Yes, no amendments are foreseen

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

None

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 54 deals with compulsory licences

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
National emergency and/or extreme urgency
Dependent patents
Overlapping rights of biotechnological patent owner and a plant variety owner

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Obligations under TRIPS and EU directives

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

No further explanation is given in law and no decisions on this matter

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Supposed to be. Sec. 16.1.1 (A patent shall ensure the exclusive rights to the owner thereof. It is prohibited to third persons without the permission of the owner of the patent:

1) to produce, to offer for sale, to distribute in another way on the market, to use, as well as to import, to export and to store for the referred to intentions the patented product;)

Sec. 16.1.3 (A patent shall ensure the exclusive rights to the owner thereof. It is prohibited to third persons without the permission of the owner of the patent:

3) to offer for sale, to distribute on the market in another way, to use, as well as to import, to export and to store for the referred to intentions a product directly acquired with the patented method;)

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four years following the filing date or within three years following the day when the notification regarding the grant of a patent was published.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

No further explanation is given

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

No further explanation is given

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

N/A

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Sec. 54.3.2: The compulsory licence of the patented invention may be obtained in conformity with Paragraphs one and two of this Section if:

2) an invention of a particular economic significance may not be utilised without the utilisation of another previously patented invention.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Sec. 54.9: “The owner of a compulsory licence shall pay to the owner of the patent a compensation, the amount of which shall be determined by the court, observing the economic value of the licence, the extent of utilisation of an invention and other circumstances.”

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

No further explanation is given

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

None

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no further amendments are foreseen

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

None

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 54.5 "If an emergency situation has been declared in the State, a compulsory licence may be granted by the Cabinet."

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

National emergency and/or extreme urgency

84. (a) What are the public policy objectives for providing government use in your country?

Obligations under Art. 31(b) of the TRIPS

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

85. If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

No further explanation is given

86. Please indicate how many times and in which technological areas government use has been issued in your country:

None

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no further amendments are foreseen

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

None

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 19.4

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

None

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

Obligations under the EU law

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

"If the owner of the patent or somebody else with his or her consent sells or markets otherwise a plant multiplication material to a farmer for agricultural purposes implying also a permission for the farmer to utilise the produced products for multiplication in the holding thereof, Paragraphs one, two and three of this Section shall not be applied to such an extent and on such conditions which conform with what is specified in Article 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights or Section 24 of the Plant Varieties Protection Law."

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no further amendments are foreseen

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

None

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Sec. 19.5

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

None

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

Obligations under the EU law

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

“Paragraphs one, two and three of this Section shall not be applied if the owner of the patent or somebody else with his or her consent sells or markets otherwise breeding animals or reproductive material of the animals to a farmer implying also a permission for the farmer to utilise the domestic animals protected by the patent for agricultural purposes. This permission shall include the offering of an animal or other reproductive material of animals for the performance of agricultural activities but not selling for commercial multiplication or to the purposes thereof.”

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, no further amendments are foreseen

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

None

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Latvia does not provide other exceptions and limitations.]

Country: LITHUANIA (REPUBLIC OF)
Office: The State Patent Bureau of the Republic of Lithuania

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

According to the Patent Law of the Republic of Lithuania (18 January 1994 No. I-372; as last amended on 10 May 2007 – No. X-1119; English version can be found on WIPO Lex database), patents shall be available for any inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (Art. 2).

Novelty of an Invention. An invention shall be considered new if it does not form part of the state of the art. The state of the art shall consist of everything which, before the filing date of patent application or where priority is claimed, before the priority date, has been published or was in public use in the Republic of Lithuania or abroad. An invention shall not be considered new if although unknown from the state of the art it had been described in an application for patent of a different applicant having an earlier filing date and published in the Official Bulletin of the State Patent Bureau later or on the same date, that the state of the art had been established (Art. 3).

Inventive Step. An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (Art. 4).

Industrial Applicability. An invention shall be considered industrially applicable if it can be made or used in industry, agriculture, health protection and other spheres (Art 5).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.¹

According to the Patent Law of the Republic of Lithuania (Art. 2), the following shall not be regarded as inventions:

- 1) discoveries, scientific theories and mathematical methods;*
- 2) design of products;*
- 3) schemes, rules and methods of games, intellectual or economic activities, as well as programmes for computers; and*
- 4) presentations of information;*
- 5) the human body or its element, including the sequence or partial sequence of a gene, at the various stages of its formation and development. This provision shall not apply to an element isolated from the human body or otherwise produced by means of a technical*

process, as well as to the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.

Patents shall not be granted for:

- 1) methods for treatment of the human or animal body by surgery or therapy, and diagnostic and prophylactic methods practised on the human or animal body. This provision shall not apply if an object of invention is equipment or materials utilised for such methods;*
- 2) plant or animal varieties or essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes for the production of plants or animals or the products thereof, as well as to plants or animals, if technical implementation of the invention is not restricted to a concrete plant or animal variety;*
- 3) inventions the commercial exploitation of which would be contrary to public interests, principles of morality and humanity. Decisions to refuse granting patents may not be adopted merely because the exploitation of such inventions is prohibited by laws or other legal acts. However, the following inter alia shall be considered unpatentable: a) processes for cloning human beings; b) processes for modifying the germ line genetic identity of human beings; c) uses of human embryos for industrial or commercial purposes; d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The Patent Law of the Republic of Lithuania (Art. 26) determines the rights of the owner of a patent. Where the subject matter of a patent is a product, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, importing or exporting that product. Where the subject matter of a patent is a process, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, importing or exporting a product obtained directly by that process.

Temporary legal protection shall be provided to a published patent application from the date of its publication until the date of patent grant (Art. 21, para. 3).

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;²
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law of the Republic of Lithuania (Art. 26) regulates that:

Where the subject matter of a patent is a product, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, importing or exporting that product.

Where the subject matter of a patent is a process, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, importing or exporting a product obtained directly by that process. The owner of the patent shall have no right to prevent third parties from performing acts referred to in paragraphs 1 and 2, provided that:

1) the act is done privately and for non-commercial purposes and it does not significantly prejudice the economic interests of the owner of the patent.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

6. (a) What are the public policy objectives for providing the exception?

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the first edition of the Patent Law of the Republic of Lithuania (1994).

- 7.-10.

N/A

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law of The Republic of Lithuania (Art. 26) regulates that:

Where the subject matter of a patent is a product, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, importing or exporting that product.

Where the subject matter of a patent is a process, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, importing or exporting a product obtained directly by that process.

The owner of the patent shall have no right to prevent third parties from performing acts referred to in paragraphs 1 and 2, provided that:

2) the act is done for experimental purposes or for scientific research, and this does not conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

N/A

13. (a) What are the public policy objectives for providing the exception?

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the first edition of the Patent Law of the Republic of Lithuania (1994).

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The applicable law does not make a distinction concerning the nature of the organization conducting the experimentation or research. It only regulates that the act should be done for experimental purposes or for scientific research, and this should not conflict with a normal exploitation of the patent and should not unreasonably prejudice the legitimate interests of the patent owner.

15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

N/A

- 16.-18.

[Note from the Secretariat: response was not provided.]

- 19.-22.

N/A

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law of The Republic of Lithuania (Art. 26) regulates that:

Where the subject matter of a patent is a product, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, importing or exporting that product.

Where the subject matter of a patent is a process, the owner of the patent shall have the exclusive right to prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, importing or exporting a product obtained directly by that process.

The owner of the patent shall have no right to prevent third parties from performing acts referred to in paragraphs 1 and 2, provided that:

3) the act consists of preparing medicines for individual cases in a pharmacy upon the prescription of a physician or if it is indicated how to use the medicines so prepared.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

25. (a) What are the public policy objectives for providing the exception? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the first edition of the Patent Law of the Republic of Lithuania (1994).

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

See question No. 23.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The applicable law provides that the act consists of preparing medicines for individual cases in a pharmacy upon the prescription of a physician or if it is indicated how to use the medicines so prepared.

29.-30.

N/A

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law (Art. 29) of the Republic of Lithuania determines the right of prior use. According to this article, natural and legal persons who in good faith were using or were making effective or serious preparations for such use before the filing date or, where priority is claimed, the priority date of a patent application, shall have the right to continue such use or to use the invention as envisaged in such preparations without taking into consideration the will of the owner of the patent. The right of the prior use may only be transferred together with the enterprise or its activities or with that part of the enterprise or its activities in which the use of an invention or preparations for such use have been made.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

33. (a) What are the public policy objectives for providing the exception? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the first edition of the Patent Law of the Republic of Lithuania (1994).

34.-35.

N/A

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The Patent Law of the Republic of Lithuania (Art. 29, para. 2):

The right of the prior use may only be transferred together with the enterprise or its activities or with that part of the enterprise or its activities in which the use of an invention or preparations for such use have been made.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

If yes, please explain the conditions under which such use can continue to apply:

The new edition of the Patent Law of the Republic of Lithuania (not entered into force yet) (Art. 33, part 4) states that a person who has in good faith used or made effective and serious preparations for using an invention which is the subject of a published patent application or a patent in the period between the loss of rights and re-establishment of those rights, may without payment continue such use in the course of his business or for the needs thereof.

39.-41.

N/A

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law of The Republic of Lithuania (Art. 30) regulates the rights of the owner of the patent with respect to foreign means of transport. According to this article, the following shall not be considered the violation of the rights of the owner of the patent: 1) the use of the means, which are the subjects of the patent, on any foreign vessel, temporarily or accidentally entering the waters of the Republic of Lithuania provided that such means shall be used exclusively for the needs of the vessel; 2) the use of the means which are the subjects of the patent in the construction of foreign air or land carriers or the exploitation of these means, as well as their use in supplementary constructions thereof, when such means of transport temporarily or accidentally enter the Republic of Lithuania.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

44. (a) What are the public policy objectives for providing the exception? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the first edition of the Patent Law of the Republic of Lithuania (1994) following the provisions of the Paris Convention.

45. The exception applies in relation to:

Vessels
Aircrafts
Land Vehicles

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The Patent Law of The Republic of Lithuania (Art. 30; cited answering question No. 42) provides for two terms: "temporarily" and "accidentally". However, the definitions of these terms are not defined in the law. There are no court decisions on this question as well.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

The Patent Law of The Republic of Lithuania (Art. 30) regulates the rights of the owner of the patent with respect to foreign means of transport. According to this article, the following shall not be considered the violation of the rights of the owner of the patent: 1) the use of the means, which are the subjects of the patent, on any foreign vessel, temporarily or accidentally entering the waters of the Republic of Lithuania provided that such means shall be used exclusively for the needs of the vessel; 2) the use of the means which are the subjects of the patent in the construction of foreign air or land carriers or the exploitation of these means, as well as their use in supplementary constructions thereof, when such means of transport temporarily or accidentally enter the Republic of Lithuania.

48.-50.

N/A

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

The Law on Pharmacy of the Republic of Lithuania (22 June 2006 No X-709; as last amended on 22 June 2011 No. XI-1506) regulates the application of this exception. It claims that: "the performance of necessary studies and trials in order to submit an application for the marketing authorisation in the Republic of Lithuania of a medicinal product according to paragraphs 5, 10 and 11 of this Article or in the Community Code of Medicinal Products according to the requirements laid down in Regulation (EC) No 726/2004 or in other states according to legal requirements of those states and the related practical needs shall be without prejudice to the rights granted by the medicinal product patent or by a supplementary protection certificate provided for in the Patent Law of the Republic of Lithuania and in other legal acts regulating the protection of industrial property" (Art. 11, part 13).

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

53. (a) What are the public policy objectives for providing the exception? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was included in the Law on Pharmacy of the Republic of Lithuania following the provisions of the Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

54. Who is entitled to use the exception? Please explain:

The aim is defined by the notion “[...] in order to submit an application for the marketing authorization [...]” (mentioned in question No. 51).

55. The exception covers the regulatory approval of:

Certain medicinal products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other: the necessary studies and tests, related practical needs

57.-59.

N/A

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

N/A

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Jurisprudence of the Court of Justice of the European Union is applicable.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The new edition of the Patent Law of the Republic of Lithuania (not entered into force yet) states that the owner of the patent shall have no right to prevent third parties from performing acts provided that they are related to patent owner's products, which have been put by the owner of the patent or with his consent on the European Economic Area market (Art. 35, part 3).

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

Generally, principle of free movement of goods within the EU does not allow controlling exhaustion of rights.

63.-64.

N/A

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Chapter 6 of the Patent Law of the Republic of Lithuania regulates the application of compulsory licences. These are: compulsory cross-licensing when an invention is related to the protected plant variety, compulsory licence for pharmaceutical products, exploitation of an invention with the authorisation of the Government of the Republic of Lithuania.

Compulsory cross-licensing when an invention is related to the protected plant variety. The Patent Law of the Republic of Lithuania (Art. 38):

Where a breeder cannot acquire or exploit a plant variety right without infringing the exclusive rights protected by a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the patent owner will be entitled to a cross-licence on reasonable terms to use the protected variety.

Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

Applicants for the licences referred to in paragraphs 1 and 2 of this Article must demonstrate that:

- 1) *they have applied unsuccessfully to the owner of the patent of a biological invention or the holder of the plant variety right to obtain a contractual licence;*
- 2) *the plant variety or the biological invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.*

The court shall make a decision regarding the granting of licences referred to in paragraphs 1 and 2 of this Article, the amount of royalty and other conditions and extent of a compulsory licence. If the conditions of granting of a compulsory licence change or disappear, at the request of the owner of the patent of a biological invention or the holder of the plant variety right, the court may revoke a compulsory licence or change its conditions.

Offices keeping a list of protectable plant varieties and the Patent Register of the Republic of Lithuania shall be responsible for the registration, in the manner prescribed by legal acts, of the licences referred to in paragraphs 1 and 2 of this Article.

Compulsory licence for pharmaceutical products. The Patent Law of the Republic of Lithuania (Ar. 38):

A competent institution authorised by the Government shall grant mandatory licences in compliance with Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Exploitation of an invention with the authorisation of the Government of the Republic of Lithuania. See questions No. 81 – 84.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Other, please specify: See question No. 65.

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

N/A

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Compulsory cross-licensing when an invention is related to the protected plant variety. The exception was involved in the Patent Law of the Republic of Lithuania (2005) after joining the European Union.

Compulsory licence for pharmaceutical products. The exception was involved in the Patent Law of the Republic of Lithuania in 2007 (in compliance with Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of

patents relating to the manufacture of pharmaceutical products for export to countries with public health problems).

Exploitation of an invention with the authorisation of the Government of the Republic of Lithuania. See question No. 84 (b)).

69.-73.

N/A

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The Law on Competition of the Republic of Lithuania (Art. 40):

1. Upon establishing that undertakings have performed actions prohibited under this Law or have otherwise infringed this Law, the Competition Council, following the principles of impartiality and proportionality, shall have the right:

1) to obligate the undertakings to discontinue illegal activity, to perform actions restoring the previous situation or eliminating the consequences of the infringement, including the obligation to terminate, amend or conclude contracts, also to set the time limits and conditions for meeting the above obligations.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

N/A

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Compulsory cross-licensing when an invention is related to the protected plant variety. The court shall make a decision regarding the granting of licences, the amount of royalty, other conditions and extent of a compulsory licence.

Compulsory licence for pharmaceutical products. The licensee shall be responsible for the payment of adequate remuneration to the rights-holder as determined by the Ministry of Economy of Lithuania.

Exploitation of an invention with the authorisation of the Government of the Republic of Lithuania. See question No. 81.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

N/A

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Compulsory licenses have not been issued in Lithuania.

79.-80.

N/A

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law of The Republic of Lithuania (Art. 39) regulates the exploitation of an invention with the authorisation of the Government of the Republic of Lithuania. According to this article:

The Government of the Republic of Lithuania may adopt a resolution to permit a State or municipal institution, natural or legal persons to market, without the consent of the owner of a patent, a patented invention within the territory of the Republic of Lithuania, if:

- 1) an invention protected by a patent is related to public needs, national security and public health protection, development of economically important sectors;*
- 2) the court determines that a method of the exploitation of an invention employed by the owner of a patent or licensee is anti-competitive.*

An invention may be exploited only for the purpose in respect of which the resolution has been adopted. The owner of a patent must, for the exploitation of the invention, be remunerated fairly, taking into consideration economic value of the invention.

If the owner of a patent or a person who has authorisation to use an invention, requests, the Government of the Republic of Lithuania may, taking into consideration their reasons, change the conditions of the use of a patented invention, and time limits of the validity of permission.

When authorisation to use a patented invention is issued to the owner of a patent which improves a previously patented invention (second invention) and that may infringe the exclusive rights of the owner of the first patent, the Government of the Republic of Lithuania shall, before the adoption of this resolution, take into consideration the following additional conditions:

- 1) the claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*
- 2) the owner of the first patent shall be entitled to a cross-licence (authorisation to each owner to use the patented inventions) to use the invention claimed in the second patent;*
- 3) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.*

The Government of the Republic of Lithuania may declare the resolution null and void, if the circumstances which led to the authorisation to use a patented invention cease to exist, or if a State or municipal institution, natural or legal persons use a patented invention for the purpose other than that in respect of which the resolution has been adopted.

Authorisation to exploit an invention must be non-exclusive, i.e. the owner of a patent shall not lose the right to use a patented invention himself, and it shall not prohibit the owner of a patent to conclude license agreements related to the use of a patented invention as well as to further exploit a patented invention or to implement his rights in other ways.

Authorisation to use a patented invention may not be transferred, except when the enterprise (or a part thereof) in which a patented invention is used, is transferred in a manner prescribed by law.

Attached to a request to permit the exploitation of a patented invention must be evidences confirming that the person seeking authorisation has requested, but has not received authorisation of the owner of a patent to use the patented invention. This provision shall not apply in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use of a patented invention. The owner of a patent must be informed in writing about a resolution, which is being drawn up, concerning the authorisation to use a patented invention, and about an intention to use a patented invention for the purposes provided for in subparagraph 1 of paragraph 1 of this Article.

Resolutions of the Government of the Republic of Lithuania concerning the authorisation to use a patented invention without the consent of the owner of a patent may be appealed against in court in a manner prescribed by law.

Upon the receipt of the resolution of the Government of the Republic of Lithuania concerning the authorisation to exploit an invention, the State Patent Bureau shall publish information on the authorisation in the next issue of its Official Bulletin.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Anti-competitive practices and/or unfair competition

Public health

National Security

Other, please specify: 1) when an invention protected by a patent is related to public needs, national security and public health protection, development of economically important sectors; 2) the court determines that a method of the exploitation of an invention employed by the owner of a patent or licensee is anti-competitive.

84. (a) What are the public policy objectives for providing government use in your country?

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the Patent Law of the Republic of Lithuania following the provisions of TRIPS Agreement.

85.-88.

N/A

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Patent Law of the Republic of Lithuania (Art. 26, para. 5, 6) the sale or other form of commercialisation of plant propagating material to a farmer by the patent owner or with his consent for agricultural use shall imply authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm. The extent and conditions of this derogation shall be laid down by Article 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights. The sale or any other form of commercialisation of a breeding stock or other animal reproductive material to a farmer by the patent owner or with his consent shall imply authorisation for the farmer to use the protected livestock for an agricultural purpose. This shall include making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the Patent Law of the Republic of Lithuania (2005) after joining the European Union.

92.-94.

N/A

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

The Patent Law of the Republic of Lithuania (Art. 38) regulates the compulsory cross-licensing when an invention is related to the protected plant variety. According to this article, where a breeder cannot acquire or exploit a plant variety right without infringing the exclusive rights protected by a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the patent owner will be entitled to a cross-licence on reasonable terms to use the protected variety.

Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

Applicants for the licences referred to mentioned above must demonstrate that:

1) they have applied unsuccessfully to the owner of the patent of a biological invention or the holder of the plant variety right to obtain a contractual licence;

2) the plant variety or the biological invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception was involved in the Patent Law of The Republic of Lithuania (2005) after joining the European Union.

98.-100.

N/A

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Republic of Lithuania does not provide other exceptions and limitations.]

Country: MADAGASCAR
Office: Madagascar Office of Industrial Property (OMAPI)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

ORDINANCE No. 89-019 of July 31, 1989 introducing a regime for the protection of industrial property in the Democratic Republic of Madagascar.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Article 8 of Ordinance No. 89-019: "1. Subject to the regulations specific to the items listed below, the following patent or invention author's certificate applications shall be irreceivable or shall be rejected for:

- (i) inventions contrary to ordre public, good morals and morality;*
- (ii) plant varieties or animal breeds or essentially biological processes for obtaining plants or animals;*
- (iii) software;*
- (iv) methods, systems, plans, scientific discoveries and theories as well as abstractions of pure form which do not resolve a specific problem or do not give a tangible technical solution, without prejudice to the protection of the practical applications which would incorporate them according to the requirements of Article 4;*
- (v) pharmaceutical, veterinary, cosmetic and food products.*

2. The patents and invention author's certificates obtained in contravention of paragraph 1 shall be null and void."

Article 9: "By decree of the President of the Republic, certain categories of inventions may be excluded from the field of patentability, temporarily or permanently, if an interest vital for education or teaching, public health, economy or national defense so requires."

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

"Article 27. Subject to the legislation in force, the patent shall confer on its owner the right to forbid third parties to carry out the following acts:

a. Where the patent has been granted for a product:

- (i) manufacture, import, offer for sale, sell and use the product;*
- (ii) keep this product for the purposes of offering it for sale, selling it or using it;*

b. Where the patent has been granted for a process:

- (i) use the process;*
- (ii) perform the acts mentioned above in relation to the product as it results directly from the use of the process, subject to the provisions of Article 8."*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

"Article 30. 1. The rights stemming from the patent or the invention author's certificate shall extend only to acts performed for industrial and commercial purposes."

5.-6/

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

Nil.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

Nil.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The current legal framework is considered to be appropriate.
"Article 140. The legal regime of protection for industrial property introduced by this Ordinance may be subject to revision."

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Nil.

12.-14.

[Note from the Secretariat: response was not provided.]

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

Nil.

16.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Madagascar does not provide exceptions related to the preparation of medicines..]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

“Article 31. Any person who, on the national territory, at the date of the filing of the patent or the invention author’s certificate application by another person, or at the priority date validly claimed for this application, in good faith, made the product or used the process, shall, despite the patent or the invention author’s certificate, have the right to continue these acts and, for the products thus obtained, to perform the other acts mentioned in Article 27.”

32.-33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Nil.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

[Note from the Secretariat: response was not provided.]

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

[Note from the Secretariat: response was not provided.]

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

[Note from the Secretariat: response was not provided.]

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Nil.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Nil.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

"Article 30.3. The rights stemming from the patent or the invention author's certificate shall not extend to the presence or use of products on board foreign vessels, spacecraft, aircraft or land vehicles which temporarily or accidentally enter the country's waters, airspace or territory."

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

Vessels
Aircrafts
Land Vehicles
Spacecraft

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Nil.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Nil.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Madagascar does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

"Article 30.2.: The rights stemming from the patent or the invention author's certificate shall not extend to the acts concerning the product covered by the patent or the invention author's certificate after this product has been lawfully sold in the country."

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Nil.

61.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

“Article 36. 1. Any natural person or legal entity may, following the expiry of a period of four years from the patent application filing date or three years from the date of grant of the patent, the period which expires later being applied, request from the competent court, in return for fair and equitable remuneration, the grant of a compulsory license for one or more of the following reasons:

- (i) the patented invention is not worked or is insufficiently worked in the country;*
- (ii) the patent owner refuses to grant licenses on reasonable conditions;*
- (iii) the working of the patented invention in the country does not satisfy, on reasonable conditions, demand for the product;*

2. For the application of paragraph 1, the compulsory license shall be granted only if the patent owner does not justify the absence of working or insufficient working in the country for legitimate reasons.

3. The compulsory license shall be non-exclusive and may be transmitted, even in the form of a grant of a sub-license, only with the establishment of the beneficiary of the license, or with the part of the establishment in which the patented invention is worked.

4. A compulsory license may be withdrawn only following a court decision.”

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms*

68.-69.

[Note from the Secretariat: response was not provided.]

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes. See question 2.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

See question 65: “Following the expiry of a period of four years from the application filing date or three years from the date of grant of the patent, the period which expires later being applied.”

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

Not specified.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

74.-77.

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Nil.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

Nil.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

“Article 37.2. The State may obtain, ex officio, at any time for the needs of public interest, a license for the working of an invention which is the subject of a patent application or a patent, whether such working is effected by itself or on its behalf. The royalties due under the ex officio license shall be determined by agreement between the State and the person filing the application or the patent owner or the successor in title of such applicant or owner. In the absence of an amicable agreement, the royalties shall be fixed by the competent court under Article 135.”

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Public health
National security
National emergency and/or extreme urgency*

84.-85.

[Note from the Secretariat: response was not provided.]

86. Please indicate how many times and in which technological areas government use has been issued in your country:

Nil.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Madagascar does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Madagascar does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Madagascar does not provide other exceptions and limitations.]

Country: MEXICO
Office: Mexican Institute of Industrial Property

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard used to determine whether an invention is patentable in Mexico is the Law on Industrial Property (LPI), published in the Federation Official Gazette on June 27, 1991, amended by different decrees published on August 2, 1994, October 25, 1996, December 26, 1997, May 17, 1999, January 26, 2004, June 16, 2005, January 25, 2006, May 6, 2009, January 6, 2010, June 18, 2010 and June 28, 2010.

The LPI does not incorporate provisions on patentability, which vary depending on the technology in question, it is simply limited to stating that "inventions that are new, involve an inventive step and are industrially applicable shall be patentable..."

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Article 16 of the LPI establishes the following exceptions to patentability:

- I. Essentially biological processes for the production, reproduction and propagation of plants and animals;*
- II. Biological and genetic material as found in nature;*
- III. Animal breeds;*
- IV. The human body and the living parts thereof, and*
- V. Plant varieties.*

There is no separate source which establishes exclusions to patentability and, to date, there is no relevant case law.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The LPI grants to the owner of a patent or his successors in title the following exclusive rights:

- a. right of exclusive working of the patented invention by himself or by a third party (Article 9, LPI);*

- b. *right to prevent other persons from manufacturing, using, selling, offering for sale or importing the patented product (Article 25(I) LPI);*
- c. *right to prevent other persons from using the patented process and from using, selling, offering for sale or importing the product obtained directly from that process (Article 25(II) LPI);*
- d. *right to request the administrative declaration of infringement of the rights conferred by the patent (Articles 187, 188 and 213 (II), (XI), (XII), (XIII) and (XXVII) LPI);*
- e. *right to institute a civil liability action for damages caused, through the infringement of patent rights, in which case, the corresponding compensation shall in no case be less than forty per cent of the public sale price of each product that involves an infringement of any of the industrial property rights regulated by the LPI (Article 24, 221, 221bis and 226 LPI);*
- f. *right to request the Mexican Industrial Property Office, in relation to the legal procedures relating to the infringement of any of the patent rights, to adopt provisional measures, such as ordering the withdrawal from circulation or preventing this, with respect to the goods that infringe patent rights; prohibit immediately the marketing or use of the products with which a patent right is infringed and ordering the seizure of property (Article 199bis, 199bis 1 LPI);*
- g. *right to grant voluntary or contractual licenses, be they exclusive or non-exclusive, for working the patented invention (Article 62 and 63, LPI);*
- h. *right to fix and collect royalties for the grant of voluntary or compulsory licenses (Article 15-B Federation Tax Code);*
- i. *right to request the nullity of a patent which has been granted for an invention that constitutes an invasion of what has already been patented (Articles 78 and 79, LPI);*
- j. *right to assign or transfer totally or partially the rights conferred by the patent (Article 62 LPI).*
- k. *right to pay the annuities for maintaining the patent in force, within the six-month grace period (Article 80 (II) LPI);*
- l. *right to request and obtain the restoration of the patent, within the six months following the grace period, for the late payment of the corresponding annuities (Article 81 LPI).*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- Private and/or non-commercial use;*
- Experimental use and/or scientific research;*
- Prior use;*
- Use of articles on foreign vessels, aircrafts and land vehicles;*
- Acts for obtaining regulatory approval from authorities;*
- Exhaustion of patent rights;*
- Compulsory licensing and/or government use;*
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

ARTICLE 22. The right conferred by a patent shall not produce any effect against:

I. a third party who, in the private or academic sphere and for non-commercial purposes, carries out purely experimental scientific or technological research, testing or teaching activities, and for that purpose manufactures or uses a product or uses a process equal to that patented;

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

6. (a) What are the public policy objectives for providing the exception?

Purely experimental scientific or technological research, testing or teaching activities, involving the manufacture or use of a product or a patented process, within the private or academic sphere and for non-commercial purposes, are activities which promote and foster inventive industrially applicable activity, the technical improvements and the dissemination of technological knowledge within the productive and academic sectors, as stated in Article 2(II) of the LPI.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

The industrial property legislation in force does not define what is meant by “non-commercial”, “commercial” or “private”.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

N/A

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Since there are no definitions which indicate clearly the scope and content of the exception, it would be advisable to amend the current legal framework.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 22(I) of the LPI states the following:

“Article 22. The right conferred by a patent shall not produce any effect against:

I. a third party who, in the private or academic sphere and for non-commercial purposes, carries out purely experimental scientific or technological research, testing or teaching activities, and for that purpose manufactures or uses a product or uses a process equal to that patented;...”

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

13. (a) What are the public policy objectives for providing the exception?

Purely experimental scientific or technological research, testing or teaching activities, involving the manufacture or use of a patented product or a process, within the private or academic sphere and for non-commercial purposes, are activities which promote and foster inventive industrially applicable activity, technical improvements and the dissemination of technological knowledge within the productive and academic sectors, as stated in Article 2(II) of the LPI.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

Article 22 of the LPI refers only to “a third party”, without specifying what the nature of that third party should be, but does state that such a party may carry out experimental, testing or teaching activities with a patented product or process, only in the “private or academic” sphere and for “non-commercial purposes”.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The industrial property legislation in force does not define what is meant by “use for experimental purposes”.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the validity of the claims
invent around the patented invention*

other, please specify: Academic or teaching

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Research and/or experimentation must be conducted with or using the patented invention ("research with")

Please explain by citing legal provision(s) and/or decision(s):

ARTICLE 22. The right conferred by a patent shall not produce any effect against:

I. a third party who, in the private or academic sphere and for non-commercial purposes, carries out purely experimental scientific or technological research, testing or teaching activities, and for that purpose manufactures or uses a product or uses a process equal to that patented;

V. a third party who, in the case of patents relating to live material, uses the patented product as an initial source of variation or propagation in order to obtain other products, apart from where said use is repeated, and

The performance of any activity envisaged in this Article shall not constitute an administrative infringement or offense in accordance with this Law.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose

19. If the applicable law makes a distinction between "commercial" and "non-commercial" purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

Article 22(I) of the LPI refers to "non-commercial purposes", although the LPI does not provide a definition of what is meant by that concept.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The normative case regulated by Article 22(I) of the LPI is sufficient to provide protection to third parties using a patented product or process in the private or academic sphere, for non-commercial and experimental, testing or teaching purposes, a situation for which there is no planned reform or addition to the Law on Industrial Property with respect to this item.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Mexico does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 22(III) of the LPI states the following:

“Article 22. The right conferred by a patent shall not produce any effect against:

...

III. any person who, prior to the patent application filing, or as appropriate recognized priority, date, uses the patented process, manufactures the patented product or has initiated the necessary preparations to carry out such use or manufacture;

...”

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

33. (a) What are the public policy objectives for providing the exception? Please explain:

The legislation in force seeks to protect users in good faith so that they may continue using their invention, although a third party not involved therein has obtained a patent for said invention, in order to achieve fairness between two holders of an invention, even though only one of them has patented it.

Similarly, it seeks to protect the user in good faith, provided that such a user may have invested economic, physical and intellectual resources in order to use the invention.

*On the other hand, the general legal principle may be considered as follows:
“first in time, first in right”.*

ARTICLE 10 BIS LPI

Article 10 BIS. The right to obtain a patent or a registration shall belong to the inventor or designer, as the case may be, without prejudice to the provisions of Article 14 of this Law. If the invention, utility model or industrial design has been produced by two or more persons jointly, the right to obtain the patent or the registration shall belong to them jointly.

Where different persons have made the same invention or utility model independently of each other, the person who first files the respective application or who claims the earliest

priority date shall have the best right to obtain the patent or the registration, provided that the application is not abandoned or refused.

The right to obtain a patent or registration may be transferred by acts intra vivos or by succession.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 22 (III) of the LPI establishes quantitative and qualitative limitations to the application of the use by the prior user.

With respect to the quantitative limitations, the Article states that the use must be “earlier” than the patent application filing, or where appropriate recognized priority, date.

In relation to the qualitative limitations, the Article mentions “uses”, “manufactures” or “has initiated the necessary preparations to carry out such use or manufacture”.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The LPI does not establish the obligation for payment of remuneration to the patent owner by the prior user.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

No

If yes, please explain what those conditions are:

N/A

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

No other criteria exist.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The normative hypothesis established by Article 22(III) of the LPI is sufficient to protect users in good faith of a patented product or process, and so there is no draft amendment or addition to the Law on Industrial Property in relation to this item.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 22(IV) of the LPI states:

“Article 22. The right conferred by a patent shall not produce any effect against:

...

IV. the use of the invention in question in vehicles of other countries that form part thereof, where such vehicles are in transit in the national territory;

...”

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

44. (a) What are the public policy objectives for providing the exception? Please explain:

The aim of the exception being considered is that the Mexican State guarantees the operation of international transport.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as “temporarily” and/or “accidentally” or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 22(IV) of the LPI uses the terms “in transit”. However, the legislation under discussion does not provide a definition of that term, and leaves it to the interpretation of the authority responsible for its application.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The exception is adequate and guarantees the operation of international transport; no amendments to the legislation in force are planned.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

With regard to this point, it should be noted that regulation of this type is covered by rules separate from the Law on Industrial Property, specifically in the Regulations on Materials for Health, Article 167bis (introductory part) of which refers to the so-called Bolar Clause, as a regulatory exception, and states:

“...Without prejudice to the provisions of the two previous paragraphs, the registration of a generic medicine may be requested, the active substance or ingredient of which is protected by a patent, in order to carry out the corresponding studies, tests and experimental production, within the three years prior to expiry of the patent. In this case, health registration shall be granted only when the validity of the patent ends.”

The information referred to in Articles 167 and 167bis of these Regulations, which is confidential or reserved in accordance with the provisions of the international treaties to which Mexico is a party and with the other applicable legal provisions, shall be protected against any disclosure to other individuals.”

This Article contains the express reference to the nature of the medicine for which registration is requested, i.e. it states that it is an “allopathic medicine”, as indicated in Article 224 of the General Health Law, under the classification heading “By their nature”, which is reproduced for quick reference:

“Article 224. Medicines are classified

...

B. By their nature:

1. Allopathic: Any substance or mixture of substances of natural or synthetic origin, that has a therapeutic, preventive or rehabilitatory effect, that is pharmaceutical in form and is identified as such by its pharmacological activity, physical, chemical and biological characteristics, and is registered in the Pharmacopeia of Mexico for allopathic medicines, ...”

Article 30 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is also included within the regulatory framework and states:

“Article 30

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The exception is not provided through case law.

53. (a) What are the public policy objectives for providing the exception? Please explain:

Authorizing the manufacturers of generic medicines who are beginning the studies, tests and experimental production of the medicines protected by a patent, close to entering the public domain, which will guarantee that, at the time the patent rights expire, the consumer public may opt to acquire the medicine from the firm which owned the patent, or through a third party laboratory at a more competitive price.

The possibility that at the end of the patent’s validity, the generic version of the medicine may enter the market and the validity of the patent may not be maintained artificially until such time as all the necessary tests are carried out in order to guarantee the bioequivalence, safety or effectiveness of the generic medicine.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

There are no such references.

54. Who is entitled to use the exception? Please explain:

Any person who meets the requirements of the Regulations on Materials for Health, established for obtaining a generic medication registration, and requests the registration of an allopathic medicine.

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: Allopathic medicines, whose active substance or active ingredient is protected by a patent, provided that it is within the three years prior to the expiry thereof.

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Making
Using
Import*

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

No other criteria are envisaged.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The exception is adequate and there are no plans to amend the legislation in force, owing to the fact that a balance is achieved between the public interest and the private interest, since the patent is not infringed as long as it is valid and, when launching the generic version, the interested party may carry out the necessary studies and tests to prepare the product that he will launch on the market until the validity of the patent ends for a reasonable period of time.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There is no problem since where the third party makes available to the public the product that is protected by a patent, the patent owner may immediately take the appropriate legal action and request, within the patent infringement proceedings, that the product be seized as a precautionary measure.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

International

If the exception is contained in statutory law, please provide the relevant provision(s):

“Article 22. The right conferred by a patent shall not produce any effect against:

...

II. any person who markets, acquires or uses the product patented or obtained by the patented process, immediately after said product has been lawfully marketed;

...”

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

The main aim of this exception is to guarantee the free circulation of goods that have been marketed lawfully, which will produce greater competition within the national market, and benefit consumers with lower prices, but above all clearly signal the prerogatives of the patent owner.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In January 2005, the Plenum of the Higher Chamber of the Federal Court of Fiscal and Administrative Justice issued the following opinion in relation to the exhaustion of the right conferred by a patent, which reaffirmed the application of Article 22(II) of the LPI:

Registration No.: 40,326

Closed

Period: Fifth

Authority: Plenum

Source: R.T.F.J.F.A. Fifth Period, Year V. No.58. October 2005.

Report: V-TASS-221

Page: 454

LAW ON INDUSTRIAL PROPERTY

PATENTS. CASE IN WHICH THE USER OF AN INVENTION DOES NOT INFRINGE THE INDUSTRIAL PROPERTY RIGHTS OF THE OWNER. *Where in the administrative dispute hearing, the aspect relating to the use of a patented article by a third party without the patent owner's consent is the subject of the dispute, it is essential to specify which acts are alleged to have infringed the industrial property rights, as well as the person or transaction to which they are attributed, and should the person concerned endeavor to introduce lawfully acts performed by a person other than that examined during the administrative proceedings in which the challenged decision is upheld, as might be the case with the business from which the third party user concerned acquires the protected property, the supposed infringement committed by that provider, this may in no way imply extensive liability on the part of the user, since there are no legal grounds to sanction the person acquiring the property, if he uses it once it has been lawfully marketed, exclusively for the conduct of activities specific to his field, without it being marketed. (2) Hearing No. 8622/02-17-01-7/399/03-PL-10-04. Settled by the Plenum of the Higher Chamber of the Federal Court of Fiscal and Administrative Justice, at the session of January 14, 2005, by a majority of four votes in favor and three votes against. Presiding Judge: Guillermo Domínguez Belloc. Secretary: Gabriela Badillo Barradas. (Ruling approved at the hearing of January 17, 2005).*

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Yes

Please explain your answer by citing legal provision(s) and/or decision(s):

Article 25(I) and (II) of the LPI states the following:

"Article 25. The exclusive right to work the patented invention shall confer on its owner the following prerogatives:

I. Where the subject matter of the patent is a product, the right to prevent other persons from manufacturing, using, selling, offering for sale or importing the patented product, without his consent, and

II. Where the subject matter of the patent is a process, the right to prevent other persons from using that process, and from using, selling, offering for sale or importing the product obtained directly from that process, without his consent..."

Notwithstanding the fact that mechanisms exist to support the patent rights owner in preventing the import of patented products or products obtained directly from a patented process, those products shall not invalidate the doctrine adopted by Mexico in relation to the exhaustion of patent rights, provided that the import into Mexico of products patented or obtained directly from a patented process does not constitute an infringement as per Article 213 of the LPI.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Yes, it is considered adequate, since the rights of the patent owner are observed and an excess situation avoided whereby any person who later uses the patented product or process has once again to pay for the corresponding royalties.

The exhaustion regime for patent rights in Mexico is adequate for achieving the aim of guaranteeing the free circulation of goods and generating greater competition within the domestic market, thereby placing that objective above the interests specific to the owners of patent rights and of the authorized distributors and/or licensees, with the main beneficiary being the Mexican consumer public which obtains genuine products.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

N/A

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

With respect to "Compulsory Licenses", Articles 70 and 77 of the LPI state the following:

Article 70. In relation to inventions, after three years beginning from the date of the patent grant, or four years from the application filing, whichever comes later, any person may request the Institute to grant a compulsory license for working the patent, where such working has not taken place, unless duly justified reasons exist therefor.

The grant of a compulsory license shall not be made, where the patent owner or any person who has a contractual license granted has been importing the product patented or obtained by the patented process.

Article 77. For reasons of national emergency or security and as long as such reasons exist, including serious diseases declared as a priority by the General Health Council, the Institute shall, by means of a declaration to be published in the Federation Official Gazette, decide

that certain patents are worked through the grant of public utility licenses, in the cases in which, where this is not done, the production, provision or distribution of basic essentials or medicines for the population is prevented, obstructed or made more expensive.

In cases of serious diseases which are the cause of an emergency or a threat to national security, the National Health Council shall declare such to be a priority, at its own initiative or at the written request of national institutions specializing in diseases, which are accredited by the Council, in which the need for priority attention is justified. Once the Council Declaration has been published in the Official Federation Gazette, pharmaceutical firms may request the grant of a public utility license from the Institute, which shall grant such a license, subject to a hearing with the parties, as soon as the case merits it, in accordance with the opinion of the General Health Council, within a maximum period of 90 days, beginning from the date of filing the application with the Institute.

The Health Secretariat shall fix the conditions for production and quality, duration and scope of the license in question, and also the characterization of the applicant's technical capacity. The Institute shall fix, by listening to both parties, a reasonable amount for the royalties payable to the patent owner.

The grant shall cover one or all of the prerogatives, to which Article 25(I) or (II) of this Law refer.

Apart from the grant of public utility licenses, to which the second and third paragraphs of this Article refer, for the grant of the other licenses the terms of the second paragraph of Article 72 shall be adopted. None of the licenses considered in this Article may be exclusive or transferable.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Public health
National security
National emergency and/or extreme urgency*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

An attempt is made to avoid misuse on behalf of patent owners, with respect to the exclusivity that patents give them; similarly, said exception contributes to the transfer and dissemination of technology, which basically serves the general interest and informs consumers of the advantage of having a patented product or process on the market within their reach, although it is not on behalf of the patent owner.

The use of the technology for the benefit of the economy and, on the other hand, the preservation of national health and security as the supreme interest above and beyond all the rights of the patent owner.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

There is no specific definition of the terms “non-working” or “insufficient working”, although the specific provisions state that working is to be understood not to have taken place, in the case of patents, after three years beginning from the date of grant of the patent and, in the case of applications, the period is four years beginning from the application filing.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

In actual fact, Article 70 of the LPI states that a compulsory license shall not be granted, where the patent owner or any person who has a contractual license granted, has been importing the product patented or obtained by the patented process.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

After three years beginning from the date of grant of the patent and, in the case of applications, the period is four years beginning from the application filing.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

Article 70 of the LPI states:

Article 70. In relation to inventions, after three years beginning from the date of the patent grant, or four years from the application filing, whichever comes later, any person may request the Institute to grant a compulsory license for working the patent, where such working has not taken place, unless duly justified reasons exist therefor.

A compulsory license shall not be granted, where the patent owner or any person who has a contractual license granted has been importing the product patented or obtained by the patented process.

As may be appreciated, Article 70 of the LPI uses the terms “duly justified reasons”, which leaves the owner with the possibility of demonstrating to the Mexican Institute of Industrial Property the reasons for non-working.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

No such definitions.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

No such practices.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

No such conditions.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Article 72. Before granting the first compulsory license, the Institute shall give the patent owner the opportunity, within a period of one year, beginning from the personal notification given to the owner, to undertake working of the patent.

Subject to a hearing with the parties, the Institute shall take a decision on the grant of the compulsory license and, where it decides to grant such a license, shall fix its duration, conditions, scope and amount of the royalties payable to the patent owner.

Where a compulsory license is requested and another such license exists, the person who has the previous license shall be notified and heard.

In accordance with the provisions of Article 72 of the LPI, the Mexican Institute of Industrial Property shall be responsible for deciding the amount of the royalties for the grant of a compulsory license, in accordance with the opinion of the licensor and licensee.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Article 77 of the LPI establishes the grant of public utility licenses for reasons of national emergency or security.

A case of national emergency or security shall exist where a serious disease is declared to be a priority by the General Health Council, in which case the Mexican Institute of Industrial Property shall decide that certain patents are worked through the grant of public utility licenses or, in the cases where this is not done, the production, provision or distribution of basic essentials or medicines for the population is prevented, obstructed or made more expensive.

One example of the application of the aforementioned Article 77 is that which originated with the A(H1N1) influenza epidemic in April 2009, a virus which spread in Mexico City and

surrounding areas, causing at least 20 deaths and as of Friday April 24 placing that area on alert; however, it was not necessary to take the step of granting public utility licenses provided that the pharmaceutical companies responsible for the production of the antivirals Tamiflu and Relenza, within the scope of the respective patents, guaranteed the supply of those medicines and, as a result, no actions made access thereto more expensive or obstructed such access.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

To date, no public utility license has been granted in Mexico within the scope of Article 77 of the LPI.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The exception is adequate and no amendments to the legislation in force are planned.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

None.

Government use

81.-88

[Note from the Secretariat: the applicable law of Mexico does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 22 of the LPI states the following:

V. A third party who, in the case of patents relating to live material, uses the patented product as an initial source of variation or propagation in order to obtain other products, apart from where said use is repeated,

VI. A third party who, in the case of patents relating to products consisting of live material, uses, places in circulation or markets the patented products for purposes that are not multiplication or propagation, after these have been lawfully marketed by the patent owner or the person who has a license granted.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

The conventional activity of farmers to use live material as a source of variation (to obtain new varieties) shall not be considered a sanction.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

No interpretations of this kind have been given.

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The exception is adequate and no amendments to the legislation in force are planned.

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

Particular cases have not occurred but there is great concern regarding the interpretation of the section of Article 22 which relates to the traditional practice of Mexican farmers, and above all as regards transgenic plants, and possible contamination by pollen of traditional crops. This is due to the imminent approval of commercial transgenic crops.

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

This is included in the above.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

With regard to Article 22(V) of the LPI, the aim is not to hamper technological development, allowing activities that promote and foster inventive industrially applicable activity, technical improvements and the dissemination of technological knowledge within the field of patents relating to live material.

With regard to Article 22(VI) of the LPI, this section envisages the exhaustion of patent rights relating to products consisting of live material, the main aim of which is to guarantee the free circulation of goods that have been lawfully marketed, which will produce better competition within the domestic market, and benefit consumers with lower prices.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

None

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

None

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The exception is adequate and no amendments to the legislation in force are planned.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

None

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Mexico does not provide other exceptions and limitations.]

Country: MONACO
Office: Intellectual Property Division

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Industrial character, industrial application and novelty (Articles 1 and 2 of Law No. 606 of June 20, 1955).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Excluded from patentability are (Articles 3 and 24 of Law No. 606 of June 20, 1955):

1. *a discovery or application which is not novel;*
2. *drugs;*
3. *loan and financing plans and combinations;*
4. *theoretical or purely scientific principles, methods, systems, discoveries and concepts, the industrial application of which has not been indicated;*
5. *a discovery or application contrary to ordre public, good morals and laws of the Principality;*
6. *projects, the title of which fraudulently indicates a subject other than the actual subject of the invention;*
7. *where the description of the invention is insufficient to allow the invention to be carried out.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The patent confers on the patentee the exclusive right to exploit the protected invention.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

[Note from the Secretariat: response was not provided.]

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4.-10.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to private and/or non-commercial use.]

Section III: Experimental use and/or scientific research

11.-22.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to experimental use and/or scientific research.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31.-41.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to prior use.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42.-50.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to the use of articles on foreign vessels, aircrafts and land vehicles.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60.-64.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to exhaustion of patent rights.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Articles 33 to 43 of Law No. 606 of June 20, 1955

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Anti-competitive practices and/or unfair competition*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The legislative text does not define these terms.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three years of non-working.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

The legislation does not make any specification in this regard and leaves any evaluation to the discretion of the judge.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

In order to assess the existence of an anti-competitive practice, Article 36 of Law No. 606 of June 20, 1955 state inter alia that the judge "shall take account of all the circumstances and, in particular, conditions and interest of possible exploitation of the patent".

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

[Note from the Secretariat: response was not provided.]

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

No, this question lies within the sovereign evaluation of judges as to the substance.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

This procedure has never been implemented to date.

79.-80.

N/A

Government use

81.-88.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Monaco does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Monaco does not provide other exceptions and limitations.]

Country: MOROCCO
Office: Moroccan Industrial and Commercial Property Office (OMPIC)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

An invention is patentable if it meets the criteria of novelty, inventive step and industrial applicability.

(Ref.: Article 22 of Law No. 17-97 on the Protection of Industrial Property)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The following are exclusions from patentability in accordance with Law No. 17-97 on the Protection of Industrial Property:

- (1) discoveries as well as scientific theories and mathematical methods;*
- (2) esthetic creations;*
- (3) schemes, rules and methods for performing intellectual activities, playing games or doing business, as well as computer programs; and*
- (4) presentations of information.*

(Ref.: Article 23 of Law No. 17-97 on the Protection of Industrial Property)

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

A patent grants its owner or its rights holders an exclusive right to use the invention.

(Ref.: Article 16 of Law No. 17-97 on the Protection of Industrial Property)

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights granted by a patent do not cover:

(a) *acts done privately and for non-commercial purposes;*

(Ref.: Article 55 of Law No. 17-97 on the Protection of Industrial Property)

5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights granted by a patent do not cover:

(b) *acts carried out for experimental purposes relating to the subject matter of the patented invention;*

(Ref.: Article 55 of Law No. 17-97 on the Protection of Industrial Property)

12.-13.

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No.

15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

No.

16.-20.

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is appropriate.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights granted by a patent do not cover:

(c) the extemporaneous preparation of medicine for individual cases in a pharmacy in accordance with a medical prescription, nor acts concerning the medicine so prepared;

(Ref.: Article 55 of Law No. 17-97 on the Protection of Industrial Property)

24.-25.

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Pharmacists.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is appropriate.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights granted by a patent do not cover:

(f) acts performed by any person who, in good faith, on the date of filing the application or, where priority is claimed, on the priority date of the application on the basis of which the patent is granted in the territory of Morocco, was using the invention or was making effective and serious preparations toward so using, provided that such acts do not differ, by their nature or purpose, from effective or expected prior use. The right of the prior user may only be transferred with the undertaking to which it belongs;

(Ref.: Article 55 of Law No. 17-97 on the Protection of Industrial Property)

32.-34.

[Note from the Secretariat: response was not provided.]

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

(Ref.: Article 55(f) of Law No. 17-97 on the Protection of Industrial Property)

38.-39.

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is appropriate.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

[Note from the Secretariat: response was not provided.]

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The rights granted by a patent do not cover:

(e) the use of patented objects on board aircraft, land vehicles or vessels of Member Countries of the International Union for the Protection of Industrial Property when these temporarily or accidentally enter the airspace, territory or territorial waters of Morocco;

(Ref.: Article 55 of Law No. 17-97 on the Protection of Industrial Property)

44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes. The terms "temporarily" and "accidentally" are employed.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is appropriate.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-57.

[Note from the Secretariat: response was not provided.]

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework will be amended shortly as follows:

“The rights granted by a patent do not cover:

(d) studies and trials required to obtain the authorization for placing a medicinal product on the market, as well as acts necessary to carry them out and to obtain authorization;”

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

(d) acts concerning the product covered by such patent, carried out in the territory of Morocco, after the product has been put on the market in Morocco by the patent owner or with his express consent;

(Ref.: Article 55 of Law No. 17-97 on the Protection of Industrial Property)

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

The exhaustion regime is appropriate.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Articles 60 to 66 of Law No. 17-97 on the Protection of Industrial Property.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

“non-working” or “insufficient working”: if at the time of the application, and in the absence of legitimate excuses, the owner of the patent or its rights holder: has not started to work or to make effective and serious preparations to work the invention to which the patent relates in the territory of the Kingdom of Morocco; has not marketed the product to which the patent relates in sufficient quantities to meet the needs of the Moroccan market; or where working or marketing of the patent in Morocco has been abandoned for more than three years.

(Ref.: Article 60 of Law No. 17-97 on the Protection of Industrial Property)

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

The importation of a patented product or of a product carried out by means of a patented process constitutes “working” of a patent.

(Ref.: Articles 53 and 60 of Law No. 17-97 on the Protection of Industrial Property)

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three years after the issuance of the patent or four years after the filing date of the patent application.

(Ref.: Article 60 of Law No. 17-97 on the Protection of Industrial Property)

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

[Note from the Secretariat: response was not provided.]

73.-74.

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Where a patent-protected invention cannot be worked without infringing the rights of a prior patent whose owner refuses to grant a license under reasonable commercial conditions and arrangements, the later patent owner may obtain a compulsory license from the courts, provided that:

- (a) the invention claimed in the later patent involves significant technical progress and is of considerable economic interest compared with the invention claimed in the prior patent;*
- (b) the owner of the prior patent is entitled to a cross-license agreement under reasonable conditions to utilize the invention claimed in the later patent; and*
- (c) the license relating to the prior patent is non-transferable except where the later patent is also transferred.*

(Ref.: Article 66 of Law No. 17-97 on the Protection of Industrial Property)

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

A compulsory license is granted under conditions set out by the courts, particularly as concerns the amount of royalties payable. Such royalties are established according to the case in question, taking into account the economic value of the license.

(Ref.: Article 62 of Law No. 17-97 on the Protection of Industrial Property)

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Never

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is appropriate.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Articles 67, 71 and 75 of Law No. 17-97 on the Protection of Industrial Property.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Public health

National security

Other, please specify: National economic needs

84.-85.

[Note from the Secretariat: response was not provided.]

86. Please indicate how many times and in which technological areas government use has been issued in your country:

Never.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework will be amended shortly as follows:

“Where public health so requires, patents issued for medicinal products, for processes for obtaining medicinal products, for products necessary to obtain such medicinal products or for processes for making such products, may, where such products are not available to the public in sufficient quantity or quality or at unusually high prices, automatically be worked.

Ex officio working is enacted by an administrative act on the request of the public health administration.

The above provisions also apply to medicinal products for exportation to a country which does not have any manufacturing capacity or with insufficient manufacturing capacity in accordance with relevant international agreements in force.”

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Morocco does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Morocco does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Morocco does not provide other exceptions and limitations.]

Country: NETHERLANDS (AND CURAÇAO AND ST. MAARTEN)
Office: Netherlands Patent Office (NL Octrooicentrum)

In the questionnaire references are made to the Netherlands patent act and the parliamentary papers. The official text of the Netherlands patent act and the parliamentary papers can be found on the website of the Netherlands Patent Office:

- Netherlands Patent Act 1995: www.agentschapnl.nl/onderwerp/wet-en-regelgeving-octrooien;
- Parliamentary papers: www.agentschapnl.nl/onderwerp/wetsgeschiedenis-octrooien.

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

According to art. 2(1) of the Netherlands Patent Act of 1995 (hereinafter referred to as: NPA 1995) inventions that are new, that involve an inventive step and that are susceptible of industrial application shall be patentable. In addition to art. 2(1) NPA 1995, art. 2a NPA 1995 contains a specific provision for inventions relating to biological material.

Novelty is defined in art. 4 NPA 1995, inventive step in art. 6 NPA 1995 and susceptibility of industrial application in art. 7 NPA 1995.

In principle, the above mentioned requirements are interpreted according to the guidelines and the case law of the European Patent Office under the provisions of the European Patent Convention. See for example a recent decision of the District Court The Hague (BIE 2011/5, Sandoz/Glaxo).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

According to art. 2(1) NPA 1995, the following subject matter or activities are excluded from patentability, because of not being regarded as inventions in the meaning of art. 2(1) NPA 1995:

- a. discoveries, as well as scientific theories and mathematical methods;*
 - b. aesthetic creations;*
 - c. schemes, rules and methods for performing mental acts, playing games or doing business, as well as computer programs; and*
 - d. presentations of information,*
- but only insofar as it concerns the subject matter or activities referred to as such.*

According to art. 3(1) NPA 1995, the following inventions are not patentable:

- a. inventions whose commercial exploitation would be contrary to the public order or public morality;*
- b. the human body in its various stages of its formation and its development, as well as the sole discovery of one of its parts, including a sequence or partial sequence of a gene;*

- c. *plant or animal varieties;*
- d. *essentially biological processes consisting entirely of natural phenomena such as hybridisations or selections in order to produce plants or animals and the products obtained thereby;*
- e. *inventions that lead to an infringement of Articles 3, 8(j), 15(5) and 16(5) of the Convention on Biological Diversity; or*
- f. *methods of treating the human or animal body by means of surgery or medical treatment and diagnostic methods that are applied to the human or animal body, with the exception of products, in particular substances or compositions, for the application of such methods.*

Art. 3(2) NPA 1995 specifies that inventions whose commercial exploitation would be contrary to the public order or public morality within the meaning of article 3(1)(a) in any event include:

- a. *methods to clone human beings;*
- b. *methods to change the germinal genetic identity of human beings;*
- c. *the use of human embryos;*
- d. *methods to change the genetic identity of animals that would lead to those animals suffering without that yielding considerable medical benefit for human beings or animals, as well as the products acquired thereby; and question exhaustively.*
- e. *methods that endanger the life or the health of human beings, animals or plants or that cause serious damage to the environment.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Rights according to a national patent application

According to art. 71(1) NPA 1995, the patent holder may, under certain conditions, demand reasonable compensation from any party who has performed acts as referred to in art. 53(1) NPA 1995 in the period between the registration (= publication) of the application that has led to the patent and the grant of the patent on that application or a divisional application, insofar as the patent holder has been granted exclusive rights in respect of such acts.

According to art. 71(2) NPA 1995, the patent holder may also demand reasonable compensation from any party who, after the grant of the patent as referred to in art. 71(1) NPA 1995, has performed the acts referred to in that provision with regard to products that were put on the market during the period stipulated in that paragraph. The patent holder may demand the same compensation from any party who, after the grant of the patent, has used for the purposes of his business products as specified in art. 53(1)(a) or (b) or art. 53a NPA 1995 that were manufactured in his business in the period referred to in art. 71(1) NPA 1995.

The compensation referred to in art. 71(1) and 71(2) shall be due only in respect of acts that are performed after the expiry of 30 days following the date on which the party concerned was notified, by means of a bailiff's writ indicating precisely which part of the patent application relates to such acts, of the rights that vest in the patent holder by virtue of art. 71 NPA 1995.

The right that vests in the patent holder by virtue of art. 71 NPA 1995 shall not extend to acts performed by a party who is entitled to perform such acts by virtue of art. 55 NPA 1995 (i.e. prior use) or by agreement, nor shall it extend to acts related to products that were put on the market either prior to the registration of the patent application in question or thereafter by the applicant or a person entitled to do so as specified above.

Rights according to a European patent application

According to art. 72 NPA 1995, similar rights apply for European patent applications. The time period of art. 71(1) NPA 1995 is replaced by the period between the publication pursuant to art. 93 of the European Patent Convention of the application that has resulted in the grant of the patent and the publication, referred to in art. 97(4) of that Convention, of the notification of the grant of the European patent in respect of that application or in respect of a divisional application related thereto by virtue of art. 76 of that Convention. Moreover, the bailiff's writ as referred to in art. 71(3) NPA 1995, shall be served together with a translation into Dutch of the claims as contained in the publication of the European patent application in accordance with art. 93 of the European Patent Convention.

Rights according to a granted (national or European) patent

The exclusive rights granted with a patent are listed in art. 53(1) NPA 1995:

1. Subject to the provisions contained in Articles 54 to 60, a patent shall confer on its owner the exclusive right:
 - a. to make, use, put on the market or resell, hire out or deliver the patented product, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes;
 - b. to use the patented process in or for his business or to use, put on the market, or resell, hire out or deliver the product obtained directly as a result of the use of the patented process, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes.

In addition to art. 53(1) NPA 1995, art. 53a NPA 1995 provides specific provisions for exclusive rights relating to biological material:

1. With respect to a patent for biological material that has acquired certain characteristics as a result of the invention, the exclusive right shall include any biological material that is produced from such material by means of propagation or multiplication in the same or in a differentiated form and that has the same characteristics.
2. With respect to a patent for a process intended to produce biological material that has acquired certain characteristics as a result of the invention, the exclusive right shall include biological material that has been produced directly by that process and any other biological material that is produced from such material by means of propagation or multiplication in the same or in a differentiated form and that has the same characteristics.
3. With respect to a patent for a product that consists of or that contains genetic information, the exclusive right shall include any material in which that product is incorporated and in which the genetic information is included and performs its function, without prejudice to the provisions contained in art. 3(1)(b) NPA 1995 (see question 1).

Patent holders may enforce their rights towards parties that infringe these rights directly (art. 70 NPA 1995) or indirectly (art. 73 NPA 1995).

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;

*Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Art. 53 NPA 1995. The exclusive rights listed in art. 53(1) NPA 1995 are limited to activities 'in or for his business'. This means that private and non-commercial use are not included in the exclusive rights.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not applicable.

6. (a) What are the public policy objectives for providing the exception?

The objective of the patent act is to acknowledge the right of the inventor and to provide him, as a reward for his contribution to the state of the art, with an exclusive right to exploit the invention. Extending the exclusive rights to private and non-commercial activities, would not concord with the above mentioned objective.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

According to the Parliamentary Papers 197, 1904-1905, no. 3

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

The term 'in or for his business' is interpreted broadly, to include all kinds of professional activities, including universities and governmental/administrative activities. For example: District Court Alkmaar, 2 December 1991, BIE 1992/12: activities disbanding a bankrupt company are included in the term 'in or for his business'.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

Not applicable.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

There are no amendments foreseen.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Not applicable.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

According to art. 53(3) NPA 1995 the exclusive right shall not extend to acts solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

From the case law it follows that the research exemption has to be interpreted restrictively. For example:

Supreme Court, 18 December 1992, BIE 1993/81 (ICI/Medicopharma): Infringing activities may only be carried out under art. 53(3) NPA 1995 if justified by the aim of the research. Aims qualifying as justification are genuine scientific research on the invention and aims that follow from the objectives of the NPA, such as investigating whether the invention can be put into practice or investigating whether the invention can be improved (realising technical progress).

Supreme Court, 23 June 1995, NJ 1996, 463 or BIE 1995/33 (ARS/Organon): The research exception of art. 53(3) NPA 1995 is not meant for research for commercial purposes such as clinical trials, but is allowable in a commercial company. See also section VII of this questionnaire.

13. (a) What are the public policy objectives for providing the exception?

One of the general objectives of the NPA is to stimulate technical progress. This objective cannot be met if, at least, genuine scientific research on the patented invention would infringe patent rights.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The general objectives of the NPA were already formulated in the Parliamentary Papers 197, 1904-1905, no. 3. Although at that time no research exemption was implemented in the NPA, this exception developed in case law. According to the Parliamentary Papers 13209, 1974-1975, no. 3, in which the explicit inclusion of the research exception in the NPA was discussed, the exception should also apply to research aiming to determine whether or not it is profitable to obtain a license from the patent holder. Such research benefits the patent holder.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

There is no distinction. Research 'in or for a business' is part of the exception. However, activities infringing a patent only fall under the exception if it can be proven that this research is indeed scientific or that this research parallels the objectives of the NPA.

15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

With the introduction of the NPA of 1910, the research exception was implicit in the term 'in or for his business'. Art. 30(3) NPA 1910, the predecessor of art. 53(3) NPA 1995 was introduced in 1977. In the accompanying parliamentary papers research was explained to include scientific research, also in or for a business. Furthermore, the research exception was to include research of patented inventions by professional parties aiming to decide whether or not to obtain a license from the patent holder.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention
invent around the patented invention
other, please specify: genuine scientific research*

Note: the above mentioned activities are only allowed as far as they serve the objectives of the NPA. The precise scope of the exception is unknown.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Please explain by citing legal provision(s) and/or decision(s):

Art. 53(3) NPA 1995 concerns "research on the patented subject matter".

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

*A non-commercial purpose
A commercial purpose*

With respect to commercial purpose: research on a patented invention for licensing purposes is allowed.

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

The NPA does not make a distinction. According to case law, research on a patented invention for licensing purposes is allowed. Furthermore, also commercial organizations may benefit from the research exception. See question 12.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments are foreseen.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

This exception is not contained in statutory law. However, the pharmacy exception was part of the proposed art. 53(3) NPA in 1995 (Parliamentary Papers 22604, 1991-1992). Inclusion of the pharmacy exception was originally proposed in order to harmonize the NPA 1910 with the European community patent agreement (Parliamentary Papers 19131, 1984-1985, no. 3). The pharmacy exception was meant for the preparation of pharmaceuticals, by pharmacists, for direct use, on prescription, in individual cases. The exception never came into force, as it was on hold for entry into force of the community patent agreement.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

There is one example of legal proceedings in which a party defended itself by citing the pharmacy exception, however the court did not consider the argument, as it ruled that the pharmacy had forfeit any possible rights to the exception by a contract (District Court The Hague, 22 March 2006, case no. 04-1670. Merck & Co / Steunpunt Apotheek magistrale bereidingen Mierlo Hout B.V.)

25. (a) What are the public policy objectives for providing the exception? Please explain:

The proposal aimed for harmonization of the NPA with the Community Patent Agreement.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Parliamentary Papers 19131, 1984-1985, no. 3).

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

The proposed exception was meant for pharmacists.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

Note: this concerns the proposal, see above.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

See question 23: the exception never came into force.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Not applicable.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

According to art. 55(1) NPA 1995, any party who, in The Netherlands or Curaçao or Sint Maarten, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business, the subject matter of a patent application filed by another party on the filing date thereof or, if the applicant has a right of priority under art. 9(1) NPA 1995 or art. 87 of the European Patent Convention, on the filing date of the priority application, shall, notwithstanding the patent, continue to have the right to perform the acts referred to in art. 53(1) NPA 1995, that right being based on prior use, unless his knowledge was obtained from matter already made or applied by the applicant or from the applicant's descriptions, drawings or models.

According to art. 55(3) NPA 1995, a party who, in good faith, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business, the subject matter in respect of which a European patent has been granted to another party before the date on which a notification of a corrected translation has been entered in the patent register shall, notwithstanding the patent, continue to have the right to perform the acts referred to in art. 53(1) NPA 1995 insofar as such acts do not infringe the patent holder's exclusive right, which right in this case will be determined by the content of the claims in the patent specification and the description and drawings intended for the interpretation thereof contained in the earlier, defective translation into Dutch.

According to art. 53(6) NPA 1995, a product within the meaning of art. 53(1)(a) or (b) NPA 1995 that was manufactured in a business prior to the grant of a patent or, if a European patent is concerned, prior to the date of publication of the notification that the European patent has been granted in accordance with art. 97(3) of the European Patent Convention, may continue to be used on behalf of that business notwithstanding the patent.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not applicable.

33. (a) What are the public policy objectives for providing the exception? Please explain:

55(1) NPA 1995: whatever the reasons were for the prior user (as defined in art. 55(1) NPA 1995) to keep the invention secret (e.g. no interest in a patent, business strategy, etc.), it is considered unfair if the patent holder could maintain his rights against the prior user. Without a "prior use" provision applying for a patent would be a necessity instead of a free choice.

Art. 55(3) NPA 1995: with this provision art. 70(4) of the European Patent Convention has been implemented in the NPA.

Art. 53(6): it is considered unfair if a patent holder could prevent products already manufactured in a business prior to the grant of his patent, but not put on the market prior to the grant of the patent, being used on behalf of that business after the grant of the patent.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception of art. 55(1) NPA 1995 was already introduced in the NPA in 1910 (Parliamentary Papers 197, 1904-1905, no. 3).

The exception of art. 55(3) NPA 1995 was introduced in the NPA in 2003 (Parliamentary Papers 27193, 1999-2000, no. 3).

The exception of art. 53(6) NPA 1995 was introduced in the NPA in 1977 (Parliamentary Papers 13209, 1975-1976, no. 8).

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Prior use, i.e., the use as meant in art. 55(1) NPA 1995, is defined as: 'Any party who, in The Netherlands, Curaçao or Sint Maarten, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business...'. The prior use of art. 55(1) NPA 1995 is territorially limited, i.e., only prior use in the Kingdom of The Netherlands is taken into account.

Use in the sense of art. 53(6) NPA 1995 is defined as "A product within the meaning of paragraph (1)(a) or (b) of art. 53 NPA 1995 that was manufactured in a business...'. Use after filing or priority date but before grant of the patent, is interpreted restrictively according to case law. For example, from Supreme Court, 23 juni 1995, NJ 1996, 463 (ARS/Organon) it can be concluded that use of medicines by the manufacturer in clinical trials in hospitals does not fall within the scope of art. 53(6) NPA 1995.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

Prior use of art. 55(1) or 55(3) NPA 1995: no remuneration.

Prior use of art. 53(6) NPA 1995: according to art. 71 and 72 NPA 1995, for use after the filing or priority date, but before grant of the patent, the patentee may demand a reasonable compensation (see also question 2).

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

No

According to art. 55(4) NPA 1995, the prior use right of art. 55 (1) and 55(3) NPA 1995 may only be transferred to third parties as part of a transfer of the business.

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Not applicable.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

According to art. 23(5) NPA 1995, a party will remain authorised, notwithstanding the patent, to continue performing the acts stipulated in art. 53(1) NPA 1995 if the party in question has commenced, in or for his business, manufacturing or using an item in respect of which a patent is in force as a result of the restoration or has commenced implementing his decision to do so within the Netherlands or Curaçao or Sint Maarten in the period between the loss of rights or means of redress and the restoration to the prior situation.

According to art. 112a(6) of the European Patent Convention, concerning a petition for review by the Enlarged Board of Appeal, any person who, in a designated Contracting State, has in good faith used or made effective and serious preparations for using an invention which is the subject of a published European patent application or a European patent in the period between the decision of the Board of Appeal and publication in the European Patent Bulletin of the mention of the decision of the Enlarged Board of Appeal on the petition, may without payment continue such use in the course of his business or for the needs thereof.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The prior user of art. 55(1) NPA 1995 should not have obtained his knowledge from matter already made or applied by the applicant or from the applicant's descriptions, drawings or models. The prior user of art. 55(3) NPA 1995 should act in good faith.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Art. 112a(6) of the European Patent Convention has not yet been implemented in the NPA 1995.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

See above.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

According to art. 54 NPA 1995 the exclusive right of the patent owner shall not include:

(a) the use on board vessels of other countries of the subject matter of the patent in the body of the vessel or in the machinery, rigging, tackle and other accessories thereof when such vessels are in the waters of the Netherlands or Curaçao or Sint Maarten temporarily or accidentally, provided that the use is for the actual needs of the vessel only;

(b) the use of the subject matter of the patent in the construction or operation of aircraft or land vehicles or of the accessories of such aircraft or land vehicles belonging to other countries, when such aircraft or land vehicles are in the Netherlands or Curaçao or Sint Maarten temporarily or accidentally; or

(c) the acts specified in Article 27 of the Chicago Convention on International Civil Aviation of 7 December 1944 (Dutch Bulletin of Acts and Decrees, 1947, H 165), provided that those acts relate to an aircraft of a State other than the Kingdom of The Netherlands as mentioned under (c) in that Article.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not applicable.

44. (a) What are the public policy objectives for providing the exception? Please explain:

Smooth running of international traffic.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Parliamentary Papers 197, 1904-1905, no. 3.

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes, the exception applies to vehicles “temporarily” or “accidentally” present. There is no definition available.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

With respect to (a): use is allowed for the actual needs of the vessel only.

With respect to (b): in the construction or operation of aircraft or land vehicles or of the accessories of such aircraft or land vehicles.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments foreseen.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Not applicable.

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

According to art. 53(4) NPA 1995, the performance of necessary studies, tests and experiments in connection with the application of Article 10(1) to (4) of Directive 2001/83/EC on the Community Code relating to medicinal products for human use (Official EC Journal L 311) or Article 13(1) to (5) of Directive 2001/82/EC on the Community Code relating to veterinary medicinal products (Official EC Journal L 311) and the ensuing practical requirements shall not be deemed to constitute an infringement of patents relating to medicinal products for human use or medicinal products for veterinary use, respectively.

This Bolar type exception is an implementation of art. 10(6) of the EU Directive 2004/27/EC and art. 13(6) of EU Directive 2004/28/EC.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Relevant case law regarding the Bolar type exception stems from before the date of implementation of art. 53(4) NPA 1995 in the NPA. In the Supreme Court case of 23 June 1995, BIE 1997/41, (ARS/Organon) it was decided that clinical trials do not fall under the scope of the research exception. With that decision the existing research exception was interpreted in a narrow way. See also the case law discussed under section III above regarding the research exception.

53. (a) What are the public policy objectives for providing the exception? Please explain:

The Directives referred to in art. 53(4) NPA 1995 require that applications for authorization to place a medicinal product on the market have to be accompanied by a dossier containing particulars and documents relating to the results of tests and clinical trials carried out on the product and thus proving its quality, safety and efficacy. Nevertheless, under certain conditions, it is sufficient if an applicant demonstrates that the medicinal product is a generic of a reference medicinal product which is or has been authorized. According to the Directives, conducting the necessary tests and trials for demonstrating the equivalence shall not be regarded as contrary to patent rights or to supplementary protection certificates (SPC) for medicinal products. Without this Bolar-provision, which is implemented in art. 53(4) NPA 1995, the necessary tests and trials for demonstrating the equivalence could only start after expiration of the patent right or SPC relating to the reference medicinal product. As such tests and trials can take several months, in practice the duration of the patent or SPC protection would effectively be extended, which is considered to be an unintentional effect of patent law in relation to the market entrance of generic medical products.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Parliamentary Papers 30663, 2005-2006, nr. 3.

54. Who is entitled to use the exception? Please explain:

The exception is meant for the manufacturers of generic medicinal products.

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: medicinal products for human use or medicinal products for veterinary use.

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: the performance of necessary studies, tests and experiments for demonstrating the equivalence between a generic and reference medical product, the reference medical product being protected by a patent right or SPC.

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments foreseen.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

The precise scope of the exception is yet unclear, as the European Court of Justice has not ruled on the Bolar exception yet.. Historically, the Dutch courts have interpreted the scope of the 'old' research exemption quite narrow, especially with regard to clinical trials. It will be interesting to see how the new provision of article 10(6) of Directive 2004/27/EC will be interpreted in the near future. For instance, it is unclear which "trials and studies" are exempted and which activities constitute "consequential practical requirements". Does this include for instance stock-piling or taking pre-orders?

The Court of Appeal The Hague (case 105.007.171/01, 2 November 2010,) ruled recently on the question whether publication of a generic medicine in the G standard constitutes an act of infringement. The G standard is a Dutch database for available medicines. Users of the database were informed by the generic manufacturer that the generic medicine in question would only be available after expiry of the patent covering the original medicine. The Dutch court nevertheless decided that publication in the G standard is not exempted and therefore infringes the patent. It appeared that the Dutch court did not take the provision of Directive 2004/27/EC into account, despite the fact that the provision was already implemented into national legislation.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

According to art. 53(5) NPA 1995, if a product as referred to in art. 53(1) NPA 1995 has been put on the market lawfully in the Netherlands or Curaçao or Sint Maarten or in one of the Member States of the European Union or in another State that is party to the Agreement concerning the European Economic Area by the patent holder or with his consent, the person who obtains or later holds the product shall not be deemed to have contravened the patent by using, selling, hiring out or delivering that product or by otherwise dealing in it in or for his business, or by offering, importing, or stocking the product for any of those purposes.

With respect to exclusive rights relating to biological material (provided for in art. 53a NPA 1995, see also question 2), art. 53b NPA 1995 states that the exclusive right shall not include biological material that is obtained by propagation or by multiplication of biological material that has been put on the market lawfully in the Netherlands or Curaçao or Sint Maarten or in one of the Member States of the European Union or in another State that is party to the Agreement concerning the European Economic Area by the patent holder or with his consent if the propagation or multiplication necessarily ensues from the use for which the biological material has been put on the market, provided that the derived material is not subsequently used for other propagations or multiplications.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

*From case law it has become clear that for the exhaustion it is decisive whether or not a product has been put on the market lawfully:
Supreme Court, 6 March 1936, NJ 1936, 588 and Supreme Court, 6 June 1941, NJ 1941, 812 : products put on the market under a compulsory license or prior use are deemed to be lawfully put on the market.*

ECJ, 9 July 1985, NJ 1985, 456; BIE 1986/49 (Pharmon/Hoechst): for the European Union, products put on the market in another country under a compulsory license are deemed not to be put lawfully on the market. Therefore these products may only be imported with the consent of the patentee.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

Exhaustion within the Netherlands: to limit the benefits of a patent to a single sale and prevent the patent holder of exercising complete control over the life span of a patented product.

Exhaustion within the European Economic Area: to allow for a free market across the European member states. This provision has developed in the case law of the European Court of Justice, e.g. ECJ, 31 October 1974, NJ 1975, 58; BIE 1975/1 (Centrafarm/Sterling Drug).

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Exhaustion within the Netherlands: Parliamentary Papers 197, 1904-1905, no. 3.

Exhaustion within the European Economic Area: Parliamentary Papers 22604, 1991-1992, no. 3.

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

As far as known, there is no relevant case law.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

There are no amendments to the NPA foreseen in this respect.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Subject to specific conditions, the following exceptions are contained in the NPA 1995:

Public interest

If the Minister of Economic affairs considers it in the public interest he may grant a licence under a patent to a party that he designates (see art. 57(1) NPA 1995).

Non-usus

If, after three years have elapsed since the grant of the patent, neither the patent holder nor any other party who has been granted a licence operates an industrial establishment in the Kingdom in which the product concerned is being made or where the process concerned is being applied in good faith and on a sufficient scale, the patent holder shall be obliged to grant the licence needed for operating such an establishment unless valid reasons are shown to exist for the absence of such an establishment (see art. 57(2) NPA 1995).

Dependent patent

The patent holder is obliged at all times to grant a licence required for the use of a patent granted in respect of an application that has the same or a later date of filing insofar as the patent for which the licence is requested represents a considerable technical advance involving a considerable economic value. The scope of such a licence shall not extend further than is necessary for the use of the licensee's patent. The latter will be obliged to grant a reciprocal licence under his patent to the holder of the other patent. (see art. 57(4) NPA 1995).

Plant breeders

The patent holder shall grant a plant breeder a licence in exchange for a reasonable fee if the plant breeder cannot obtain or exploit a plant breeder's right in respect of the plant variety without infringing the patent that was granted earlier and the licence is necessary for the exploitation of the plant variety to be protected, which represents a significant technical advance involving a considerable economic value in respect of the invention protected by the patent (see art. 57(5) NPA 1995).

If a patent holder is granted a licence on the ground of art. 42(2) of the Dutch Seeds and Planting Materials Act, the patent holder shall grant the holder of the plant breeder's right a reciprocal licence, at the latter's request, to use the protected invention subject to reasonable conditions (see art. 57(6) NPA 1995).

National security

In the interest of the defence of the Kingdom it may be provided by Royal Decree that the State shall be authorised to perform or cause others to perform acts, to be described precisely in that Decree, that the patent holder to be specified in that Decree has the exclusive right to perform pursuant to art. 53 and 53a NPA 1995 (see art. 59 NPA 1995).

Euratom treaty

A licence may be created by a decision of the Arbitration Tribunal referred to in art. 20 of the Treaty establishing the European Atomic Energy Community (EURATOM) (Treaty Bulletin 1957, 92) or a decision by the Minister of Economic Affairs pursuant to Article 21 of this treaty (see art. 60 NPA 1995).

Competitiveness

According to art. 31 TRIPs compulsory licenses could be used against anti-competitive practices.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Case law of the European Court of Justice regarding unfair competition: see ECJ, 16 December 1999, BIE 2001/72: the use of IP-rights can constitute unfair competition.

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention (see art 57(2) NPA 1995)

Anti-competitive practices and/or unfair competition (see art. 31 TRIPs, ECJ case law)

Public health (if public interest, see art. 57(1) NPA 1995)

National security (see art. 59 NPA 1995)

National emergency and/or extreme urgency (if public interest, see art. 57(1) NPA 1995)

Dependent patents (see art. 57(4) NPA 1995)

Other, please specify:

- compulsory license for plant breeder (art. 57(5) and 57(6) NPA 1995)

- compulsory license as a result of the Euratom Treaty (art. 60 NPA 1995)

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Exceptional circumstances and national security may put aside the rights of a patent holder. Furthermore, innovation would be hampered if a patent holder could prevent, by not providing licenses (for dependent patents), the use and further improvements on an invention. The provisions related to plant breeders are based on Directive 98/44/EG concerning the protection of biotechnological inventions.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Public interest, dependent patents: Parliamentary Papers 197, 1904-1905, no. 3.

National security: Parliamentary Papers 3451, 1953-1954, no. 3.

Non-usus, Euratom treaty: Parliamentary Papers 6429, 1960-1961, no. 3.

Plant Breeders: Parliamentary Papers 26568, 1998-1999, no. 3.

69. If the applicable law provides for the grant of compulsory licenses on the ground of "nonworking" or "insufficient working", please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Art. 57(2) NPA 1995: If, after three years have elapsed since the grant of the patent, neither the patent holder nor any other party who has been granted a licence operates an industrial establishment in the Kingdom or in another State to be designated by the Implementing Regulations in which the product concerned is being made or where the process concerned is being applied in good faith and on a sufficient scale, the patent holder shall be obliged to grant the licence needed for operating such an establishment unless valid reasons are shown to exist for the absence of such an establishment. This obligation shall apply in respect of the holder of a European patent if, after three years have elapsed since the date on which the notification of the grant of the European patent was published in accordance with art. 97(4) of the European Patent Convention, an industrial establishment as referred to above is not in operation in the Netherlands or in the Curaçao or Sint Maarten or in another State to be designated by the Implementing Regulations.

According to art. 28 of the Implementing Regulations of the NPA 1995, art. 57(2) NPA 1995 includes all member states of the European Union, all states of the European Economic Space and those member states of the WHO where an industrial establishment as meant in art. 57(2) NPA 1995 is operated such that in the Kingdom the patented product, or the product manufactured by the patented process, is available on a sufficient scale.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

According art. 57(2) NPA 1995 juncto art. 28 of the Implementing Regulations and the case law of the National Patent Office (Special Board, 5 September 1995, BIE 1996/43) importation constitutes working of the patent.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three years after the grant of the patent (see art. 57(2) NPA 1995).

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

As far as known, there is no relevant case law.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Not applicable.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anticompetitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

There are no legal provisions except for art. 31 TRIPs. As far as known, there is no case law related to patents.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Art. 57(4) NPA 1995: The patent holder is obliged at all times to grant a licence required for the use of a patent granted in respect of an application that has the same or a later date of filing or, if a right of priority exists in respect of the application, the same or later date of priority, insofar as the patent for which the licence is requested represents a considerable technical advance involving a considerable economic value; however the patent holder will be obliged to grant a licence required for the use of a European patent only after the term for filing an opposition to the European patent has expired or after opposition proceedings thus instituted have ended. The scope of such a licence shall not extend further than is necessary

for the use of the licensee's patent. The latter will be obliged to grant a reciprocal licence under his patent to the holder of the other patent.

A license should be required for use of the dependent patent; a license is required if without it exploitation of the patent would be technically and economically unfeasible, see case law of the National Patent Office (Board of Appeal, 23 February 1984, BIE 1986/53 and Board of Appeal, 8 September 1986, BIE 1986/87).

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

According to art. 57(4) NPA 1995 (dependent patent), the patentee obtains a crosslicense. According to art. 58(6) NPA 1995, on the ground of a claim brought by the initiating party, in the absence of agreement the court shall fix the fee that the licensee must pay to the patent holder.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

A compulsory license under art. 57(1) may be granted for reasons of public interest. According to the Decision of the Minister of Economic Affairs, BIE 1981, nr. 38, the objectives of the governmental policy belong to the public interest.

Until 2011 no licenses have been granted under this provision yet.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

There is no information available.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Art. 31 TRIPs has not yet been implemented in the NPA 1995. Compulsory licensing is rare, there are no further amendments foreseen.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

Not applicable.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Pre-grant

According to art. 44(1) NPA 1995, concerning confidential patent applications, in the event that the Minister of Defence is of the opinion that it is in the interest of the defence of the Kingdom, for the State to use, put into practice or cause to be used or to be put into practice the subject matter of a confidential patent application, he may take measures to that effect

after giving notice of the decision in question. That decision shall contain a precise description of the acts that the State must be able to perform or cause to be performed.

Post-grant

According to art. 59(1) NPA 1995, compulsory licenses for national security interests also cover a right for the government to use patented inventions.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not applicable.

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

National security

84. (a) What are the public policy objectives for providing government use in your country?

Providing the government a right to use the technology described in confidential patent applications or patented technology for national security objectives.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Art. 44(1) NPA 1995: Parliamentary Papers 7960, 1964-1965, no. 3.

Art. 59(1) NPA 1995: Parliamentary Papers 3451, 1953-1954, no. 3.

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Not applicable.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

This information is not available.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments foreseen.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

Not applicable.

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

According to art. 53c NPA 1995, the sale of vegetable propagation material or another form of putting vegetable propagation material on the market by the patent holder or with his consent to a farmer for the purposes of agricultural exploitation implies a right for the latter party to use the products of his harvest for further propagation or multiplication by himself in his own company, with due observance of art. 14 of Regulation (EC) no. 2100/94 of the Council of the European Union of 27 June 1994 on Community plant variety rights (Official EC Journal L 227).

Furthermore, the sale of breeding cattle or another form of putting breeding cattle on the market by the patent holder or with his consent to a farmer implies for the latter party the right to use the cattle that is protected by a patent for agricultural purposes. This use is in any event taken to include making the animal or animal propagation material available for use in a farmer's agricultural company, but not selling within the context of or with a view to commercial cattle breeding.

The farmer's privilege for plant material (art. 53c(1)) constitutes the implementation of Directive nr. 98/44/EG of 6 July 1998 concerning the protection of biotechnological inventions. At the same time a farmer's privilege for animal material was implemented.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

Not applicable.

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

A farmer may use the products of his harvest for further propagation or multiplication by himself in his own company.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Parliamentary Papers 26568, 1998-1999, 26568, nr. 3.

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The scope of the exception is defined in art. 14 of Regulation (EC) no. 2100/94 and the implementing regulation no. 874/2009. For example:

- the farmer's privilege only applies to specific agricultural plant species;*
- there shall be no quantitative restriction of the level of the farmer's holding to the extent necessary for the requirements of the holding;*
- the product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, without prejudice to certain restrictions which Member States may establish regarding the organization of the processing of the said product of the harvest, in particular in order to ensure identity of the product entered for processing with that resulting from processing;*

- *small farmers shall not be required to pay any remuneration to the holder;*
- *other farmers shall be required to pay an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area; the actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned;*
- *etc.*

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments foreseen.

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

Not applicable.

Breeders' use of patented inventions

95.-98.

Not applicable.

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Recently the Dutch Association of plant breeders has started a public debate on the desirability of the introduction of a breeders exemption. They have pointed out that the pool of plant varieties available for further breeding activities has declined rapidly over the last decade, due to increasing existing patent rights. In preparation is the introduction of a limited breeders exception in the NPA 1995, This limited breeders exception will apply to the use of patented biological material for breeding purposes, i.e. to discover and develop new plant varieties. The exception will not apply to the commercial exploitation of new plant varieties that are acquired using patented biological material, at least as long as the biological material of that new variety possesses the specific traits that were produced by the invention concerned.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

See question 99.

Section XI: Other Exceptions and Limitations

101.-103.

Not applicable.

Country: NEW ZEALAND
Office: Competition, Trade and Investment Branch, Ministry of Economic Development

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The relevant legislation is the Patents Act 1953. To be patentable, an invention must be a "manner of manufacture", and be "new". There is no examination for obviousness, or utility, although obviousness and lack of utility are grounds for third parties to oppose the grant of a patent, or to apply for the revocation of a granted patent. Text of the act can be found at: <http://www.legislation.govt.nz/act/public/1953/0064/latest/DLM280031.html>

The term "manner of manufacture" has been interpreted by the New Zealand Courts to exclude such things as "products of nature", mathematical operations, bare principals, mathematical algorithms, schemes or plans, and methods of medical treatment of humans.

An invention will be considered "new" if a description of the invention has not been published in New Zealand prior to the priority date of the relevant claims (a "local novelty" standard).

There is currently a Patents Bill before the New Zealand Parliament that will replace the Patents Act 1953. Under the provisions of this new Bill, to be patentable, an invention must be a "manner of manufacture", new, involve an inventive step, be useful, and not be excluded subject matter. All of these criteria must be satisfied before a patent can be granted. Novelty and inventive step will be determined on the basis of matter that has been made available to the public, whether by written or oral description, or by use or in any other way, anywhere in the world prior to the priority date of the relevant claims. The text of the Bill can be found at: <http://www.legislation.govt.nz/bill/government/2008/0235/latest/viewpdf.aspx>

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Under New Zealand's current legislation (the Patents Act 1953), there is only one statutory exclusion: grant of a patent may be refused if use of the invention would be contrary to morality. Very few patents have been refused under this provision, and there are no relevant judicial decisions.

The Patents Bill currently before Parliament includes explicit exclusions from patentability. These are:

- Inventions whose commercial exploitation would be contrary to public order or morality;*
- Human beings and biological processes for their generation;*
- Methods of treatment of human beings by surgery or therapy;*
- Methods of diagnosis practiced on human beings;*
- Computer programs;*

- *Plant varieties.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Under the Patents Act 1953, a patent owner has the exclusive right to “make, use, exercise and vend the invention during the term of the patent, subject to the provisions of any statute or regulation currently in force. (See Patents Form A, Third Schedule, Patents Act 1953).

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Experimental use and/or scientific research;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI “Other Exceptions”.

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

[Note from the Secretariat: the applicable law of New Zealand does not provide exceptions related to private and/or non-commercial use.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

New Zealand’s current patent legislation, the Patents Act 1953, does not contain a statutory experimental use exception. The new Patents Bill, currently before the New Zealand Parliament does contain an experimental use exception.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

Under the Patents Act 1953, questions of whether or not a particular use is experimental are determined through case law. The most relevant case-law would appear to be Smith Kline & French Laboratories Ltd vs Attorney General (1991) 4 TCLR 199. In this decision, the Judge stated:

“Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself, and does no more than further

his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance in the actual market place, then he infringes”.

It would appear from this decision that it is the ultimate objective of the research which determines whether or not the use of a patented invention for research or experimental purposes infringes a patent. “Non-commercial” research would not infringe, while “commercial” research would. It is not clear though, just where the boundary between “commercial” and “non-commercial” research lies.

13. (a) What are the public policy objectives for providing the exception?

Question not applicable as the experimental use exception is provided by caselaw.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not applicable (see answers to question 13(a)).

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The relevant case law suggests that the nature of the organization involved is not relevant to whether a use is “experimental”, rather, it is the nature of the use (whether “non-commercial” or “commercial”) that determines whether a particular use is experimental. “Commercial” use, will generally not be considered to be experimental use, but the boundary between “commercial” and “non-commercial” use is unclear.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The relevant caselaw does not define these concepts.

- 16.

[Note from the Secretariat: response was not provided.]

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

[Note from the Secretariat: response was not provided.]

Please explain by citing legal provision(s) and/or decision(s):

The relevant case law does not deal with these issues.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

While the relevant case law makes a distinction between a “commercial” purpose (which is not considered experimental use) and “non-commercial” (which may be considered as “experimental” use, there are no explicit definitions of these terms – the question of whether a particular use or purpose is “commercial” or “non-commercial” is likely to be considered on a case by case basis.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

No other criteria are currently applied.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The current legal framework relating to experimental use of patented inventions is not considered adequate as there is considerable uncertainty as to what does or does not constitute experimental use. The new Patents Bill that is currently before the New Zealand Parliament contains an explicit experimental use exception. The exception (clause 136 of the Bill) provides that it is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention. Clause 136 also contains a non-exhaustive list of acts which are considered to have an experimental purpose: determining how an invention works, determining the scope of an invention, determining the validity of the claims and seeking to make an improvement to the invention (for example determining new properties, or new uses of the invention).

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of New Zealand does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

There is no prior use exception in New Zealand’s patent legislation, however, secret use of an invention prior to the grant of a patent may be grounds for revocation of the patent. (s41(1)(l) of the Patents Act 1953. That is, while prior secret use is not a defence against infringement, the prior user can initiate proceedings to revoke the patent.

32.-37.

[Note from the Secretariat: response was not provided.]

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Where a lapsed patent has been restored, the restoration is subject to conditions protecting the interests of third parties who may have used or made preparations to use the the patented invention after the patent lapsed, but before restoration (s35(7) of the Patents Act 1953)

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The new Patents Bill, currently before Parliament will contain an explicit prior use provision (clause 138A of the Bill).

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The exception is provided in section 79 of the Patents Act 1953.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

The exception is provided for compliance with Article 5ter of the Paris Convention.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not applicable.

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law refers to accidental or temporary entry of the foreign transportation means into New Zealand. These terms are not defined in the legislation, and there is no applicable case law.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 79 of the Patents Act 1953 provides that the patented product must be used on board the transportation means and for its actual needs only.

48.-50.

Not applicable.

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

The exception is provided for in section 68B of the Patents Act 1953.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

Case law does not provide for this type of exception in New Zealand. The New Zealand courts have indicated that any such exception must be provided for through amendment to the legislation.

53. (a) What are the public policy objectives for providing the exception? Please explain:

The reason for providing the exception is to facilitate the entry of generic products onto the New Zealand market when a patent expires. It was also intended to ensure that New Zealand manufacturers of generic products could enter the export market promptly when the relevant New Zealand patent(s) expired.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The exception (known as the Regulatory Review Exception) was inserted into the Patents Act 1953 by the Patents Amendment Act 2002.

54. Who is entitled to use the exception? Please explain:

Any person may use the exception.

55. The exception covers the regulatory approval of:

any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Making
Using
Selling
Offering for sale
Import
Export*

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to the law are planned; the exception will be retained in the new Patents Bill.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Not applicable.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Uncertain, please explain:

The circumstances in which patent rights are exhausted will depend on the conditions under which the patent owner has decided to make the patented product available.

If the exception is contained in statutory law, please provide the relevant provision(s):

[Note from the Secretariat: response was not provided.]

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Exhaustion is determined by case law: Betts V Wilmott (1871) 6 Ch App 240. Whether the rights are exhausted or not is likely to depend on any conditions attached to the initial sale by the patentee.

61.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 46 of the Patents Act 1953 provides for compulsory licenses.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Refusal to grant licenses on reasonable terms

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

To ensure that New Zealand businesses and consumers have reasonable access to patented products at reasonable prices.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69.-70.

Not applicable.

71.-72.

[Note from the Secretariat: response was not provided.]

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

There is no definition of these terms in the legislation, and there appear to be no legal decisions by the New Zealand courts defining these terms (although it is likely that decisions

made under the UK Patents Act 1949 would be applied by the New Zealand courts if the need arose).

74.-75.

Not applicable

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Section 46(6) of the Patents Act 1953 requires that licensee must pay “such remuneration to the patentee as may be agreed” between the licensee and the patentee. If they cannot agree, the Court will determine the remuneration.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Not applicable

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Very few compulsory licenses have been granted in New Zealand, and those that have been issued have related to pharmaceuticals.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The only amendments contemplated are those necessary to allow New Zealand to become an exporting member under the Protocol to amend the TRIPS Agreement implementing the Doha Declaration on the TRIPS Agreement and public health (see clauses 165A – 165D of the new Patents Bill).

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 55 – 58C of the Patents Act 1953 provide for Crown use of patented inventions without the authority of the patentee.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

National security

National emergency and/or extreme urgency

Other, please specify: While the applicable law refers to matters of national security or national emergency, it does not specifically exclude the other grounds.

84. (a) What are the public policy objectives for providing government use in your country?

The prime public policy objectives relate to ensuring that the public has access to patented products, and it has not been possible to obtain the product from the patentee on reasonable terms and conditions.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The Patents Act 1953 defines national emergency by reference to the Civil Defence Emergency Management Act 2002 (see <http://www.legislation.govt.nz/act/public/2002/0033/latest/DLM149789.html>) .

86. Please indicate how many times and in which technological areas government use has been issued in your country:

There have been no instances of the Crown use provisions being invoked.

87.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of New Zealand does not provide exceptions related to farmers’ use of patented inventions.]

Breeders’ use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of New Zealand does not provide exceptions related to breeders’ use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of New Zealand does not provide other exceptions and limitations.]

Country: OMAN (SULTANATE OF)
Office: Intellectual Property Department

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard used is that the invention meets the three conditions for granting (Novelty, Inventive step and industrial applicability)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

(1) The following shall be excluded from patent protection:

- (a) Discoveries, scientific theories and mathematical methods;*
- (b) Schemes, rules or methods for doing business, performing purely mental acts or playing games;*
- (c) Natural substances; this provision shall not apply to the processes of isolating those natural substances from their original environment;*
- (d) Known substances for which a new use has been discovered; this provision shall not apply to the use itself, where it constitutes an invention under Section 1;*
- (e) Animals other than micro-organisms, and essentially biological processes for the production of animals and their parts, other than non-biological and microbiological processes;*
- (f) Inventions, the prevention within the territory of Oman of the commercial exploitation of which is necessary to protect ordure public and morality; such exclusion shall not be made merely because the exploitation of those inventions is prohibited by law.*

(2) The provisions of subsection (1) shall not apply to the following inventions:

- (a) Process inventions which, in whole or in part, consist of steps that are performed by a computer and are directed by a computer program; and*
- (b) Product inventions consisting of elements of a computer-implemented invention, including in particular:
 - (i) Machine-readable computer program code stored on a tangible medium such as a floppy disk, computer hard drive or computer memory; and*
 - (ii) a general purpose computer whose novelty over the prior art arises primarily due to its combination with a specific computer program.**

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Section 13

- (1) (a) *Where*
- (i) *the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or*
 - (ii) *a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or*
 - (iii) *the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or*
 - (iv) *the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation; or*
 - (v) *when a patent (the “second patent”) claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the “first patent”) without infringing which the second patent cannot be exploited.*
- (2) *A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(a)(iv), before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.*
- (3) *Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.*
- (4) (a) *Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.*
- (b) *Notwithstanding paragraph (a), the Minister shall not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(ii), if and when the conditions which led to such compulsory license are likely to recur.*
- (5) *The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.*
- (6) *The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:*
- (i) *the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and*

- (ii) *the conclusion of license contracts by the owner of the patent; and*
(ii) *the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).*
- (7) (a) *A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.*
- (b) *Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.*
- (8) *The exploitation of the invention by the Government agency or third person licensed by the Minister shall be predominantly for the supply of the market in Oman except when the compulsory license concerns a patent claiming a pharmaceutical product or a process of making a pharmaceutical product, and the purpose of the license is to export the patented products or the products manufactured by the patented process for a foreign territory or country with no or with insufficient manufacturing capacity, in accordance with the terms and conditions of the Decision of the General Council of the WTO of August 30, 2003.*
- (9) *Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.*
- (10) *Where a compulsory license is granted under subsection (1)(v),*
- (a) *the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and*
(b) *the license of the first patent shall be non-assignable except with the assignment of the second patent.*
- (11) *The provisions of this Section shall apply, where appropriate and mutatis mutandis, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.*
3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):
- Private and/or non-commercial use;*
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;

*Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (b) (i)

5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (a) (iii)

12.-15.

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

Invent around the patented invention

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Research and/or experimentation must be conducted with or using the patented invention ("research with")

Please explain by citing legal provision(s) and/or decision(s):

*The rights under the patent shall not extend: to acts done only for experimental purposes relating to a patented invention
Section 11*

(4) (a) *The rights under the patent shall not extend:*

- (i) *to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or*
- (ii) *to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or*
- (iii) *to acts done only for experimental purposes relating to a patented invention; or*
- (iv) *to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");*
- (v) *to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.*

18.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Oman does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (a) (iv)

32.-33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 11

(4) (a) *The rights under the patent shall not extend:*

- (i) *to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or*

- (ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or
- (iii) to acts done only for experimental purposes relating to a patented invention; or
- (iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");
- (v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

Section 13

(B) The Minister may - without the consent of the owner of the patent - to decide that any governmental entity or other person exploiting the invention, and this exploitation is limited to the purpose for which licenses it for, to pay adequate compensation to the owner of the patent depending on the circumstances of each case, taking into account the value Economic Minister's decision, and the provisions of the General Council Decision of the WTO that it was appropriate for the reward, which was decided at the grant of a patent for the invention of the mandatory drug product or an industrial process for the manufacture of this product.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

Section 11

(4) (a) The rights under the patent shall not extend:

- (i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or*
- (ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or*
- (iii) to acts done only for experimental purposes relating to a patented invention; or*
- (iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");*
- (v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required*

under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman

(6) *The right of the prior user referred to in subsection (4)(a)(iv) of this Section may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.*

38.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (b) (ii)

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law is silent on those issues

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

The applicable law is silent on those issues

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 13

52.-53.

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

(1) (a) *Where*

(i) *the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or*

(ii) *a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or*

(iii) *the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or*

(iv) *the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation; or*

(v) *when a patent (the "second patent") claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the "first patent") without infringing which the second patent cannot be exploited.*

(2) *A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(a)(iv), before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.*

(3) *Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.*

(4) (a) *Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.*

(b) *Notwithstanding paragraph (a), the Minister shall not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(ii), if and when the conditions which led to such compulsory license are likely to recur.*

- (5) *The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.*
- (6) *The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:*
- (i) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and*
 - (ii) the conclusion of license contracts by the owner of the patent; and*
 - (ii) the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).*
- (7) (a) *A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.*
- (b) Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.*
- (8) *The exploitation of the invention by the Government agency or third person licensed by the Minister shall be predominantly for the supply of the market in Oman except when the compulsory license concerns a patent claiming a pharmaceutical product or a process of making a pharmaceutical product, and the purpose of the license is to export the patented products or the products manufactured by the patented process for a foreign territory or country with no or with insufficient manufacturing capacity, in accordance with the terms and conditions of the Decision of the General Council of the WTO of August 30, 2003.*
- (9) *Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.*
- (10) *Where a compulsory license is granted under subsection (1)(v),*
- (a) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and*
 - (b) the license of the first patent shall be non-assignable except with the assignment of the second patent.*
- (11) *The provisions of this Section shall apply, where appropriate and mutatis mutandis, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.*

55. The exception covers the regulatory approval of:

any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Export

Other. Please specify: Exploitation

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

Regional

International

If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 13

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Yes

Please explain your answer by citing legal provision(s) and/or decision(s):

Section 13

(6) The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:

(i) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and

(ii) the conclusion of license contracts by the owner of the patent; and

(ii) the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 13

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Refusal to grant licenses on reasonable terms

Anti-competitive practices and/or unfair competition

Public health

National security

National emergency and/or extreme urgency

Dependent patents

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 11

(5) Without prejudice to the provisions of subsection 4(a) of this Section, the Minister shall have the authority, ex officio or at the request of any interested party, of declaring the patent rights exhausted, and thus of authorizing others to import the patented product or a product manufactured directly or indirectly by means of the patented invention (“the product”) from another territory when that product is not available in the territory of Oman or is available in the territory of Oman with unreasonably low quality standards or in a quantity that is not sufficient to meet the local demand or at prices that the Minister deems abusive or for any other reason of public interest, including anticompetitive practices, provided that:

- (i) *the product has been put in the channels of commerce in the territory from which it will be imported by the owner of the patent or with his consent; and*
- (ii) *a patent claiming the product or the process for its manufacture is in force in the territory from which the product will be imported and is owned by the same person who owns the patent in Oman or by a person under his control:*

- (a) *If the importer fails to fulfill the purpose that justified the Minister's decision to consider the patent rights exhausted, the Minister shall, ex officio, or at the request of the patent owner, cancel the authorization.*
- (b) *If the conditions that gave rise to the Minister's decision to consider the patent exhausted cease to exist, the Minister may, ex officio or at the request of the patent owner, cancel the authorization, provided that the legitimate interests of the importer are taken into account, including but not exclusively that the importer will retain the right to commercialize the products that remain on stock.*

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

TITLE III: PROTECTION AGAINST UNFAIR COMPETITION
Section 60

(1) *The provisions of this Title shall apply independently of, and in addition to, any legislative provisions protecting inventions, utility models, industrial designs, layout-designs, distinctive signs, literary and artistic works and other intellectual property subject matter.*

(2) (a) *In addition to the acts and practices referred to in Articles 61 to 65, any act or practice, in the course of industrial or commercial activities, that is contrary to honest practices shall constitute an act of unfair competition.*

(b) An act or practice that is contrary to honest practices, for the purposes of this Title, shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

An act or practice that is contrary to honest practices, for the purposes of this Title, shall also mean acts of breach of legal duties in general when their purpose or their consequence is to obtain illicit advantages over competitors, such as the breach of environmental or labor law.

(c) *Any natural person or legal entity damaged or likely to be damaged by an act of unfair competition shall be entitled to the remedies referred to in Title IV.*

SECTION 61

(1) *Any act or practice, in the course of industrial or commercial activities, that causes, or is likely to cause, confusion with respect to another's enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.*

(2) *Confusion may, in particular, be caused with respect to*

(i) a trademark, whether registered or not or a trade name.

(ii) any distinctive sign other than a trademark or a trade name

(iii) ; the appearance of a product or the presentation of products or services as well as of the place of business]

SECTION 62

(1) *Any act or practice, in the course of industrial or commercial activities, that damages, or is likely to damage, the goodwill or reputation of another's enterprise shall constitute an act of unfair competition, regardless of whether such act or practice causes confusion.*

(2) (a) *Damaging another's goodwill or reputation may, in particular, result from the dilution of the goodwill or reputation attached to*

(i) a trademark, whether registered or not;

(ii) a trade name;

(iii) any distinctive sign other than a trademark or a trade name;

(iv) the appearance of a product;

- (v) *the presentation of products or services as well as of the place of business;*
- (vi) *a celebrity or a well-known fictional character.*

(b) For the purposes of these provisions, “dilution of goodwill or reputation” means the lessening of the distinctive character or advertising value of a trademark, trade name or other business identifier, the appearance of a product or the presentation of products or services or of a celebrity or well-known fictional character.

SECTION 63

(1) Any act or practice, in the course of industrial or commercial activities, that misleads, or is likely to mislead, the public with respect to an enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Misleading may arise out of advertising or promotion and may, in particular, occur with respect to

- (i) the manufacturing process of a product;*
- (ii) the suitability of a product or service for a particular purpose;*
- (iii) the quality or quantity or other characteristics of products or services;*
- (iv) the geographical origin of products or services;*
- (v) the conditions on which products or services are offered or provided;*
- (vi) the price of products or services or the manner in which it is calculated.*

SECTION 64

(1) Any false or unjustifiable allegation, in the course of industrial or commercial activities, that discredits, or is likely to discredit, another’s enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Discrediting may arise out of advertising or promotion and may, in particular, occur with respect to

- (i) the manufacturing process of a product;*
- (ii) the suitability of a product or service for a particular purpose;*
- (iii) the quality or quantity or other characteristics of products or services;*
- (iv) the conditions on which products or services are offered or provided;*
- (v) the price of products or services or the manner in which it is calculated.*

SECTION 65

(1) Any act or practice, in the course of industrial or commercial activities, that results in the disclosure, acquisition or use by others of undisclosed information without the consent of the person lawfully in control of that information (hereinafter referred to as “the rightful holder”) and in a manner contrary to honest commercial practices shall constitute an act of unfair competition.

For the purposes of this Section, “a manner contrary to honest commercial practices” shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

(2) For the purposes of this Section, information shall be considered “undisclosed information” if it has secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question or it has

commercial value because it is secret and it has been subject to reasonable steps under the circumstances by the person lawfully in control of the information to keep it secret.

- (3) (a) *Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in*
- (i) *an unfair commercial use by a governmental authority of undisclosed test or other data concerning safety and efficacy of the product which have been submitted to that authority as a condition of obtaining approval of the marketing of new pharmaceutical or agricultural chemical products, or*
 - (ii) *the disclosure of such data, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*
- (b) *For the purposes of this Subsection, a pharmaceutical product shall be considered new if it contains a chemical entity that has not been previously approved in the territory of Oman for use in a pharmaceutical product; a new agricultural chemical shall be considered new if it contains a chemical entity that has not been previously approved in the territory of Oman for use in an agricultural chemical product.*
- (4) (a) *Subsection (4)(a)(i) shall be construed as precluding any governmental agency, without the consent of the person or entity who first obtained marketing approval of a pharmaceutical or agricultural chemical product in Oman (the originator) from relying on or referring to the undisclosed test data or other undisclosed data submitted by the originator, for the purposes of approving any other product, for at least five (5) years for pharmaceutical products, and ten (10) years for agricultural chemical products, from the date of marketing approval in Oman.*
- (b) *The provisions of paragraph (a) of this Subsection shall apply, mutatis mutandis, in the event Oman adopts the practice of granting marketing approval based on evidence of marketing approval granted in another territory.*
- (c) *Where the competent authority of Oman requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of a pharmaceutical product, other than information related to bioequivalency, that competent authority shall not, without the consent of the originator, authorize another to market a same or a similar product based on the new clinical information submitted in support of the marketing approval or evidence of the marketing approval based on the new clinical information, for at least three years from the date of marketing approval in Oman.*
- (d) *The provisions of paragraph (c) of this Subsection shall apply, mutatis mutandis, in the event Oman adopts the practice of granting marketing approval based on evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory.*
- (e) *Where the originator's product is covered by a patent in force in the territory of Oman, the competent authority, notwithstanding the provisions of this Subsection, but without prejudice to the provisions of paragraph (e), shall not approve another product without the prior consent of the patent owner. If a request of marketing approval that requires or implies reliance on the originator's undisclosed data is submitted by another person during the term of a patent, the competent authority shall inform the patent owner of such a request.*

Section 13

(7) (a) *A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.*

(b) Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

When a patent (the "second patent") claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the "first patent") without infringing which the second patent cannot be exploited

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Section 13

(B) The Minister may - without the consent of the owner of the patent - to decide that any governmental entity or other person exploiting the invention, and this exploitation is limited to the purpose for which licenses it for, to pay adequate compensation to the owner of the patent depending on the circumstances of each case, taking into account the value Economic Minister's decision, and the provisions of the General Council Decision of the WTO that it was appropriate for the reward, which was decided at the grant of a patent for the invention of the mandatory drug product or an industrial process for the manufacture of this product.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The applicable law is silent on those issues

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Neither a compulsory license nor a government use license has ever been issued in the Sultanate of Oman.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11-4e and Section 13.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

84.

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The applicable law is silent on those issues

86. Please indicate how many times and in which technological areas government use has been issued in your country:

Neither a compulsory license nor a government use license has ever been issued in the Sultanate of Oman.

87.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 – 4 to 6.

90.-91.

[Note from the Secretariat: response was not provided.]

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

Section 11

(4) (a) The rights under the patent shall not extend:

(i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or

(ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or

(iii) to acts done only for experimental purposes relating to a patented invention; or

(iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");

(v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.

(6) The right of the prior user referred to in subsection (4)(a)(iv) of this Section may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.

93.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of the Sultanate of Oman does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

*Industrial Property Law 67/2008 - Section 66
Infringement Proceedings*

- (6) (a) *With respect to a medical practitioner's performance of a medical activity that constitutes an infringement of a patent for a diagnostic, therapeutic and surgical methods for the treatment of humans or animals, the provisions of Title IV of this Act shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.*
- (b) *For the purposes of this Subsection:*
- (i) *the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent;*
- (ii) *the term "medical practitioner" means any natural person who is licensed by a State to provide the medical activity described in paragraph (b)(1) or who is acting under the direction of such person in the performance of the medical activity;*
- (iii) *the term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.*

102.-103.

[Note from the Secretariat: response was not provided.]

Country: PAKISTAN
Office: IPO-Pakistan, Cabinet Division, Govt. Of Pakistan

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Novelty, Inventive Step and Industrial Applicability, under Section 7 (1) of the Patents Ordinance, 2000 (as amended in 2002) is used to determine the patentability criteria of inventions.

Similar criteria/standard is used for all fields of inventions

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Sub-section (2) of Section 7 of the Patents Ordinance, 2000 (as amended in 2002), the following shall not be regarded as invention within the meaning of sub-section (1) of Section 7 of Patents Ordinance, 2000, namely:-

- (a) a discovery, scientific theory or mathematical method;*
- (b) a literary, dramatic, musical or artistic work or any other creation of purely aesthetic character whatsoever;*
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business;*
- (d) the presentation of information; and*
- (e) substances that exist in nature or if isolated therefrom*

Besides, the Section 7 Sub-section 4 of the Patents Ordinance, provides that a Patent shall not be granted:-

- (a) for invention the prevention of commercial exploitation of which would be necessary to protect the "ordre public" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by any law for the time being in force;*
- (b) for plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes;*
- (c) for diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
- (d) for a new or subsequent use of a known product or process; and*
- (e) for a mere change in physical appearance of a chemical product where the chemical formula or process of manufacture remains the same provided that this clause shall not apply to an invention fulfilling the criteria of patentability.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant

provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Section 30 sub-section 1 of the Patents Ordinance, 2000 (as amended in 2002), confer following rights on a holder of Patent:-

(a) Where the subject matter of Patent is a product, the holder of valid patent may prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product; and

(b) where the subject matter of a patent is a process, the holder of a valid patent may prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

Section 22 of the Patent Ordinance 2000 clarifies that On the acceptance of a complete specification the Controller of Patents shall publish it in the official Gazette and the applicant shall have the like privileges and rights as if the invention had been sealed on the date of the acceptance of the application.

Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Not available

5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 30(5)(c) and (f) of Patents Ordinance 2000 (as amended in 2002).

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

Promote creativity, encourage improvement & scientific development

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

In compliance of obligations as a member of WTO, Pakistan brought the IP Laws in consonance with the TRIPS and Patent & Designs Act, 1911 was substituted by Patents Ordinance, 2000.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

NO. As a matter of fact acts done for teaching purposes in educational or research institutions are allowed to conduct experimentation or research. Majority of these educational and research institutes are in public sector and a few statutory & non-statutory institutions/organization, which are not-for-profit entites.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

Not defined

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*seek an improvement to the patented invention
invent around the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

*Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
Research and/or experimentation must be conducted with or using the patented invention (“research with”)*

Please explain by citing legal provision(s) and/or decision(s):

No-precedent

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

Not defined

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not available

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

This exception has never been in issue as yet

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

This exception has never been in issue, as yet

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Pakistan does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 30(5)(d) of the Patents Ordinance, 2000 (as amended in 2002), per verbatim reproduced as under:-

“acts performed by any person who in good faith, before the filling or, where priority is claimed, the priority date of the application on which the patent is granted in Pakistan, was using the invention or was making effective and serious preparations for such use”

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not available

33. (a) What are the public policy objectives for providing the exception? Please explain:

To foster creativity, research & technological development

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not available

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Not defined

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

[Note from the Secretariat: response was not provided.]

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

If the Patent is ceased to have effect by reason of failure to pay any renewal fee before the expiration of that year and extended period of six months, an application for the restoration may be made to the Controller within eighteen months from the date on which the Patent ceased to have effect. The Controller shall by order restore the patent on payment of any unpaid renewal fee and additional fee. Section 45(5) of the Patents Ordinance, 2000 (as amended in 2002) describes that:

“Where an order is made under this section and, between the end of the period of six months beginning with the date when the patent concerned ceased to have effect and the date of the application under this section, any person has begun in good faith to use the patented invention or has made effective and serious preparations to make use of the invention, he shall, after the order comes into force, have the right to make use of the invention and the said use shall not amount to an infringement of the patent concerned.”

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Sec 45 (6) of the Patent Ordinance, 2000 amended in 2002 "Where a patented product is disposed of by any person to another in exercise of a right conferred by Sec 45 sub-section (5), that other and any other person claiming through him shall be entitled to deal with the product in the same way as if it had been disposed of by a sole registered proprietor.

According to the Rule 25 (9) of the Patent Rules, 2003 "In every order of the Controller restoring a patent the following provision shall be inserted for the protection of persons who have begun to avail themselves of the patented invention between the date when the patent ceased to have effect and the date of the application,-

No action or other proceeding shall be commenced or prosecuted nor any damage recovered in respect of any manufacture, use or sale of the patented product in the interim period as herein after defined by any person to have effect, the _____, who after such date and before the _____, the date of the application has made, used, exercised or sold the patented product or has manufactured or installed any plant, machinery or apparatus claimed in the specification of the patent or for carrying out a method or process so claimed."

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The Courts or the Administrative Authorities have not come across where the exception under reference has been invoked by any party, therefore, exception is presumed to be adequate however, amendments could be made in exigency.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No precedent

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 30 (5) (b) of the Patents Ordinance, 2000 (as amended in 2002)

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not available

44. (a) What are the public policy objectives for providing the exception? Please explain:

To foster creativity & research & more particularly to meet the obligations under the TRIPS

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The Patent & Designs Act, 1911 (repealed) was substituted by Patents Ordinance, 2000, containing exceptions qua non-commercial use through Presidential Ordinance i.e. [Ordinance No.LXI of 2000, promulgated under Article 89 of the Constitution of Islamic Republic of Pakistan, 1973].

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Section 30(5)(b) of Patents Ordinance, 2000 (as amended in 2002) contained specific term "temporarily" and/or "accidentally", however, these terms have not been defined in the applicable law.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Never invoked

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Presumed to be adequate

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Exception never invoked

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 30(5)(e) of the Patents Ordinance, 2000, added through Patents (Amendment) Ordinance, 2002 (Ordinance No.XCV of 2002), dated 26th October, 2002, published in the Gazette of Pakistan, Extra Ordinary, Part-I on Saturday, the 26th October, 2002 at Pages 1555-1564

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

Primary objective is to speed up the commercialization of a generic product after the expiry of Patent, foster creativity and to provide quality & less expensive products through the local manufacturing units, aiming at to help the masses in general & industrial development in particular.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not available

54. Who is entitled to use the exception? Please explain:

Any person

55. The exception covers the regulatory approval of:

any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Making
Using
Selling
Offering for sale
Import
Export*

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not provided

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Presumed to be adequate

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Exception never invoked

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

International

If the exception is contained in statutory law, please provide the relevant provision(s):

Section 30(5)(a) of Patents Ordinance, 2000 (as amended in 2002) states that "acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses".

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not available

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

WTO TRIPS compliance

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not available

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

No specific legal provisions are available in Patent Ordinance, 2000. The Patented products relating to medicine supplied to Government agencies have been allowed to contain express notice of restriction i.e. "Not for sale"

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Presumed to be adequate

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 58 & 59 of the Patents Ordinance, 2000 (as amended in 2002)

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Refusal to grant licenses on reasonable terms

Anti-competitive practices and/or unfair competition

Public health

National security

National emergency and/or extreme urgency

Dependent patents

Other, please specify: ...where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

To curb monopolization & cartelization and to safeguard the national interest

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not available

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Not defined

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Not defined in statute or by precedents

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

After expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

Section 59 (2) of the Patent Ordinance 2000 (amended in 2002) states that "A non-voluntary license shall not be issued if the owner of the patent satisfies the Controller that circumstances exist which justify the no exploitation or insufficient exploitation of the patented invention in Pakistan."

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

The determination of what constitutes "reasonable terms and conditions and reasonable period of time" is to be made by the Federal Govt of Pakistan.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

It is the prerogative of Federal Govt and Judicial body to determine what constitutes anti-competitive practices.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Section 59 (5) of the Patent Ordinance 2000 (amended in 2002), clearly stipulates that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Controller, upon the request of the owner of the later patent, may issue a non-voluntary license to the extent necessary to avoid infringement of the earlier patent.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Patents holder is entitled to adequate remuneration commensurating to inventions economic value, under Section 58(3)-of the Patents Ordinance, 2000 (as amended in 2002)

Rule 44(1) of Patent Rules, 2003 states that "For the purpose of this Ordinance the patentee shall be entitled to a payment up to three percent remuneration by the licensee, on the basis of total sales of that chemical product taking into consideration its trade price, under clause (iii) of sub-section (3) of section 59.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Federal Government is the authority to determine the grounds for national emergency or circumstances of extreme emergency.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Not a single time compulsory license has been issued in our country.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Presumed to be adequate

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

No precedent

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 58 & 59 of the Patents Ordinance, 2000 (as amended in 2002)

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

No case law as yet

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Refusal to grant licenses on reasonable terms

Anti-competitive practices and/or unfair competition

Public health

National security

National emergency and/or extreme urgency

Dependent patents

Other, please specify: ...where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology.

84. (a) What are the public policy objectives for providing government use in your country?

Inter alia, To protect the public interest in particular national security, nutrition, health or the development of other vital sectors of the national economy

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not available

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Not defined

86. Please indicate how many times and in which technological areas government use has been issued in your country:

Not a single example exist

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Presumed to be Adequate

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

No precedent

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Pakistan does not provide exceptions related to farmers’ use of patented inventions.]

Breeders’ use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Pakistan does not provide exceptions related to breeders’ use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Clause (iv) sub section (1) Section 58 of Patent Ordinance 2000 states where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology,

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

Not available

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not available

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

Not available

In addition, in relation to each exception and limitation, please explain:

(iii) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

Presumed to be adequate

(iv) if there have been any challenges encountered in the practical implementation of the exception in your country:

None

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

The Competition Commission of Pakistan has the responsibility to ensure free competition in all spheres of commercial and economic activity and endeavoring to prevent or eliminate anti competitive behavior in order to promote economic efficiency and to protect the rights of the general public.

As far as the anti competitive practices in patent is concern, if one undertaking execute any agreement/contract, License agreement for granting its patent rights to other undertaking and such agreement/contract/license agreement contains any anti-competitive clauses then they have to seek exemption from the Commission under Section 5 of the Competition Act, 2010 read with General Enforcement Regulations, 2007.

But in case if some one deceptively uses the patents of the other undertaking just for obtaining the good reputation of that company and shows that the products which he/she is going to sale is the product of that company, then the commission will take action against that company under section 10 of the Competition Act, 2010.

Country: PORTUGAL
Office: Instituto Nacional da Propriedade Industrial – INPI
(Portuguese Institute of Industrial Property)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The standard is set in the Código da Propriedade Industrial – CPI (Industrial Property Code), articles 52 to 54. The CPI is the Portuguese statutory law regarding industrial property. You can find an English version in our web page, namely in http://www.marcaspatentes.pt/files/collections/eng_US/1/Industrial%20Property%20Code%20%28Searchable%20PDF%29.pdf.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

“Article 52 – Limitations on object

1 – The following are exceptions to the previous article:

- a) Discoveries, scientific theories and mathematical methods;*
- b) Materials or substances already existing in nature and nuclear materials;*
- c) Aesthetic creations;*
- d) Schemes, rules or methods for intellectual acts, playing a game or doing business and computer programs, as such, with no contributions;*
- e) Presentations of information.*

2 – (Revoked.)

3 – Paragraph 1 only excludes patentability if the object for which a patent is requested is limited to the elements mentioned in it.

Article 53 – Limitations on patent

1 – Inventions whose commercial exploitation is against the law or contrary to public policy, public health or morality are not patentable and their exploitation may not be considered as such due to the simple fact that it is forbidden by law or regulations.

2 – Under the previous paragraph, the following are not patentable:

- a) Processes for cloning human beings;*

- b) Processes for modifying the germinal genetic identity of human beings;*
- c) The use of human embryos for industrial or commercial purposes;*
- d) Processes for modifying the genetic identity of animals which may cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.*

3 – The following are also not patentable:

- a) The human body, at the various stages of its formation and development and the simple decoding of one of its elements, including the discovery of a sequence or partial sequence of a gene, without prejudice to (1)(c) of the following article;*
- b) Plant and animal varieties and essentially biological processes for obtaining plants or animals;*
- c) Surgical or therapeutic methods for treating the human or animal body and diagnostic methods used on the human or animal body, though products, substances or compositions used in any of these methods may be patented.*

Article 54 – Special cases of patentability

1 – The following may be patented:

- a) A substance or composition included in the state of the art for use in a method referred to in paragraph (3)(c) of the previous article, on the condition that this use for any method mentioned therein is not included in the state of the art;*
- b) The substance or composition referred to in the previous paragraph for any other specific use in a method mentioned in paragraph (3)(c) of the previous article, provided that this use is not included in the state of the art;*
- c) A new invention that involves an inventive step and is susceptible of industrial application relating to any isolated element of the human body or produced in any other way by a technical process, including a sequence or partial sequence of a gene, even though the structure of this element is identical to that of a natural element, provided that the industrial application of a sequence or partial sequence of a gene is expressly observed and specifically described in the patent application;*
- d) An invention relating to plants or animals, if its technical feasibility is not confined to a particular plant variety or breed of animal;*
- e) A biological material isolated from its natural environment or produced on the basis of a technical process, even if it pre-exists in a natural state;*
- f) An invention relating to a microbiological process or other technical processes or products obtained by means of these processes.*

2 – An essentially biological process for obtaining plants or animals is any process that consists wholly of natural phenomena, such as crossing or selection.

3 – A microbiological process is any process involving or performed upon or resulting in microbiological material.

4 – Biological material is any material that contains genetic information and is capable of reproducing itself or being reproduced in a biological system.”

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The matter of exclusive rights granted with a patent is set forth in CPI, articles 101 to 104.

“Article 101 – Rights conferred by patent

1 – A patent confers the exclusive right to exploit the invention anywhere in Portuguese territory.

2 – A patent also confers upon its holder the right to prevent others from manufacturing, offering, storing, commercializing or using a patented product or importing or possessing it for any of the aforementioned purposes without his consent.

3 – A patentee may oppose all acts constituting a violation of his patent, even if they merge with another patent with a later priority date, with no need to impugn titles or request annulment of patents with which this right merges.

4 – The rights conferred by a patent shall not exceed the scope defined by the claims.

5 – A patentee may ask the National Industrial Property Institute, on payment of a fee, to limit the scope of protection of the invention by altering the claims.

6 – If the examination shows that the request for limitation can be granted, the National Industrial Property Institute shall promote the publication of a notice of the alteration of the claims, otherwise the request shall be denied and the decision communicated to the requester.”

Articles 102 to 104 CPI deal with limitation, exhaustion and non-opposability, respectively. For details, please see below the answers to other more specific questions.

We believe the extent of protection, as provided for by article 97 CPI, to be of relevance in this context.

“Article 97 – Extent of protection

1 – The extent of the protection conferred by a patent shall be determined by the content of the claims and the description and drawings shall serve to interpret them.

2 – If a patent concerns a process, the rights conferred by it shall cover the products obtained directly by the patented process.

3 – The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

4 – The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to

biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

5 – The protection conferred by a patent of a product that contains or consists of genetic information shall extend to any material in which the product is incorporated, contained and performs its function, save as provided for in Article 53(3)(a).

6 – By way of derogation of paragraphs 3 to 5 of this article:

a) The sale or other form of commercialization of plant propagating material to a farmer by the holder of the patent, or with his consent for agricultural use, implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm;

b) The sale or any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.”

Regarding publications, article 5 CPI, is the relevant provision.

“Article 5 – Provisional protection

1 – An application for a patent, utility model or registration provisionally grants the applicant the right, as of its publication in the Industrial Property Bulletin, to the same protection as that granted by the right, to be considered in the calculation of any compensation.

2 – The provisional protection referred to in the previous paragraph is opposable, even before publication, by anyone who has been notified of the submission of the application and received the details of the case.

3 – Verdicts in suits brought on the basis of provisional protection cannot be delivered before the final granting or refusal of a patent, utility model or registration and the case shall be suspended at the end of the arguments.”

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Experimental use and/or scientific research;

Preparation of medicines;

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

Acts for obtaining regulatory approval from authorities;

Exhaustion of patent rights;

Compulsory licensing and/or government use;

Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other

parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI “Other Exceptions”.

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision is article 102 CPI, subheading a).

“Article 102 – Limitation of rights conferred by a patent

The rights conferred by a patent do not extend to:

*a) Acts performed in private and not for commercial purposes;
(...)”*

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there is no relevant case law on this matter.

6. (a) What are the public policy objectives for providing the exception?

Not to restrain the individual non-commercial activity, since it does not harm the right owner.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

The CPI does not provide a definition for the concepts “non-commercial”, “commercial” and/or “private”, as well as it does not provide for a definition of invention nor for a definition of technical character an invention should have.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

To our knowledge, there is no relevant case law on this matter.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section III: Experimental use and/or scientific research⁵

11. If the exception is contained in statutory law, please provide the relevant provision(s):

“Article 102 – Limitation of rights conferred by a patent

The rights conferred by a patent do not extend to:

(...)

c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them;

(...)”

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there is no relevant case law on this matter.

13. (a) What are the public policy objectives for providing the exception?

To support R&D activities without IP restrictions, contributing this way to the innovation effort.

To ensure pharmaceutical companies wanting to produce a medicine which patent is about to expire the right to perform the required experiments before the patent's expiration date in order to get government permission to produce them, so saving time.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention. However it only referred to “Acts performed exclusively for trial or experimental purposes”, the remaining text was only added in 2003.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

Our national law does not make any distinction concerning the nature of the organization conducting the experimentation or research.

⁵ Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The applicable law does not provide any definition of the concepts “experimental use” and/or “scientific research”.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- seek an improvement to the patented invention
- invent around the patented invention
- other, please specify:

Neither of the criteria is relevant.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

- Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
- Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- Both of the above

Neither of the criteria is relevant.

Please explain by citing legal provision(s) and/or decision(s):

To our knowledge, there are no relevant legal provisions nor case law on this matter.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant.

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

The applicable law does not make a distinction between “commercial” and “noncommercial” purpose.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The applicable law does not provide any other criteria to be applied in determining the scope of the exception.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision is article 102 CPI, subheading b).

“Article 102 – Limitation of rights conferred by a patent

The rights conferred by a patent do not extend to:

(...)

*b) The preparation of medicinal products performed at the time and for individual cases on the basis of a doctor’s prescription at pharmaceutical laboratories or acts relating to the medicinal products prepared in this way;
(...)”*

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there are no relevant legal provisions or case law on this matter.

25. (a) What are the public policy objectives for providing the exception? Please explain:

Not to limit access to treatment and not to interfere with the relationship doctor/patient.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal’s accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Anyone entitled to prepare this kind of medicinal products.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The applicable law does not provide any other criteria to be applied in determining the scope of the exception.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Regarding prior use, the applicable provision is article 104 CPI. This article is directed at non-opposability.

“Article 104 – Non-opposability

1 – The rights conferred by a patent are not opposable in the Portuguese territory before the date of the application or of priority, if it is claimed against someone who, in good faith, has learned of the invention by his own means and used it or made effective, serious preparations to use it.

2 – The previous paragraph does not apply if the knowledge is the result of unlawful or immoral acts against the patentee.

3 – The burden of proof lies with the person invoking the situations set forth in paragraph 1.

4 – Prior use or preparations therefore based on the information referred to in Article 57(1)(a) does not prejudice good faith.

5 – In the cases set forth in paragraph 1, the beneficiary has the right to pursue or commence use of the invention, within the limits of his prior knowledge, for his own business purposes, but may only transfer it in conjunction with the business establishment in which use is made.”

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there is no relevant case law on this matter.

33. (a) What are the public policy objectives for providing the exception? Please explain:

Not to harm persons (inventors) who reached the same invention as described in the patent on their own at an earlier date.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The CPI does not provide for the scope of "use", as well as it does not define the concepts "non-commercial", "commercial" and/or "private", as well as it does not provide for a definition of invention nor for a definition of technical character an invention should have.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The CPI does not provide for any such remuneration.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The applicable provision is article 104 CPI, paragraph 5, as transcribed above in the context of the answer to question 31.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

The relevant provision is set in article 8 CPI, regarding re-establishment of rights, namely paragraphs 6 and 7.

"Article 8 – Re-establishment of rights"

(...)

6 – Applicants for or owners of rights that are re-established may not invoke them to a third party who, in good faith, in the period between the loss of the rights granted and the publication of the notice of re-establishment of the rights, has begun operation or sale of the object of the right or has made actual, serious preparations for its operation or sale.

7 – Third parties who may avail themselves of the provision in the previous paragraph may oppose the decision to re-establish rights of the applicant or owner within two months of the date of publication of the notice of re-establishment of the right.”

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The CPI does not provide for other criteria to be applied in determining the scope of the exception regarding prior use.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provisions are set forth in article 102 CPI, subheadings d) to f).

“Article 102 – Limitation of rights conferred by a patent

The rights conferred by a patent do not extend to:

(...)

d) Use on board ships from other countries belonging to the Union[] or WTO of a patented invention in the hull, machinery, rigging, gear or other accessories of the ship, if they temporarily or accidentally enter the waters of the country, provided that said invention is used exclusively to serve the ship’s needs;*

e) The use of a patented invention in the construction or operation of aircraft or land vehicles of other countries belonging to the Union[] or WTO or their accessories, if they temporarily or accidentally enter national territory;*

f) The acts set forth in Article 27 of the Convention of 7 December 1944 concerning international civil aviation if they have regard to aircraft from another state to which the provisions of said article apply.”

[*] “Union” stands for “Union for the Protection of Industrial Property”, established under the “Paris Convention of the Union for the Protection of Industrial Property” (Paris Convention of 20 March 1883 and its revisions).

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there is no relevant case law on this matter.

44. (a) What are the public policy objectives for providing the exception? Please explain:

The binding of the Portuguese state to international treaties such as the Convention on International Civil Aviation signed on December 7, 1944.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.

Harmonization with article 5ter of the Paris Convention was intended.

In subheadings d) and e) of article 102 CPI, the mention to WTO was introduced in 2003, the current, although amended, CPI version. The earlier (revoked) 1995 CPI did not mention WTO.

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as “temporarily” and/or “accidentally” or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes, it applies such terms. Article 102 CPI, subheadings d) and e) do so. Please, read the answer to question 42, where the corresponding transcription of the law was made. There are no definitions for those terms.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, it provides for such restrictions.

In what vessels are concerned, article 102 CPI, subheading d) restricts the exception, as it is “(...) provided that said invention is used exclusively to serve the ship's needs”, as already transcribed above in the context of the answer to question 42.

Regarding aircrafts and land vehicles, article 102 CPI, subheading e), states the exception to be restricted to "(...) the construction or operation (...)" of such aircrafts and land vehicles, as already transcribed above in the context of the answer to question 42.

The CPI does not provide corresponding provisions for spacecraft.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The CPI does not provide for other criteria to be applied in determining the scope of the exception regarding use of articles on foreign vessels, aircrafts and land vehicles.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section VII: Acts for obtaining regulatory approval from authorities

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision is Article 102 CPI, subheading c).

"Article 102 – Limitation of rights conferred by a patent

The rights conferred by a patent do not extend to:

(...)

c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them;

(...)"

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there are no relevant legal provisions nor case law on this matter.

53. (a) What are the public policy objectives for providing the exception? Please explain:

Not to extend the monopoly beyond its legal term. Please, read also the answer to question 13 (a).

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention. The part "(...) including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them" of Article 102 CPI, subheading c), mentioned in the answer to question 51, was introduced in 2003. Before that, in the 1995 CPI, only the initial part "Acts performed exclusively for trial or experimental purposes (...)" was present.

54. Who is entitled to use the exception? Please explain:

Any legal person that wishes to commercialize a patented product as soon as the respective patent expires.

55. The exception covers the regulatory approval of:

any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Making
Using*

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

The applicable law does not provide any other criteria to be applied in determining the scope of the exception.

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law on such matters.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

The patentees do not agree with this exception and, especially in the pharmaceutical area, they try to prevent the obtaining of regulatory approvals setting up interim relief in the appropriate court. Court decisions are not unanimous regarding this issue.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision is article 103 CPI. It applies to a patent valid in the Portuguese territory, be it a patent deriving from a Portuguese national application filing, a validated European patent or an international application filing.

“Article 103 – Exhaustion of rights

1 – The rights conferred by a patent do not allow its holder to forbid acts related to the products protected by it after its sale by the patentee or with his consent, in the European economic area.

2 – The protection referred to in Article 97(3) to 97(5) does not cover biological material obtained by propagation or multiplication of a biological material sold by the patentee or with his consent, in the European economic area, if the propagation or multiplication is the necessary result of the use for which the biological material was placed on the market, provided that the material obtained is not then used for further propagation or multiplication.”

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there is no relevant case law on this matter.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

This limitation assures free circulation of products within the European Economic Area (EEA).

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Paragraph 1 of article 103 CPI was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention. The legal provision set forth in paragraph 2 of article 103 CPI was introduced in 2003 as a result of the transposition of Directive 98/44/EC on the legal protection of biotechnological inventions. It was absent from the 1995 (revoked) CPI.

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

The CPI does not provide for such a provision.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

To our knowledge, the applicable regime is considered adequate.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant CPI provisions are set forth in articles 107 to 112. Please find corresponding transcriptions just below.

Article 107 – Compulsory licenses

1 – Compulsory licenses may be granted for a certain patent, in any of the following cases:

- a) Lack or insufficient exploitation of a patented invention;*
- b) Dependency between patents;*
- c) Reasons of public interest.*

2 – Compulsory licenses shall be non-exclusive and may only be transferred with the part of the company or establishment that exploits them.

3 – Compulsory licenses may only be granted if the potential licensee has made efforts to obtain a contractual license from the patentee on acceptable commercial conditions and said efforts have not been successful within a reasonable period of time.

4 – A compulsory license may be revoked without prejudice to the appropriate protection of the licensee's legitimate interests if and when the circumstances that gave rise to it cease to exist or are not likely to occur again. The competent authority may re-examine the continuation of said circumstances on duly justified request.

5 – If a patent concerns semiconductor technology, compulsory licenses may only be granted for a non-commercial, public purpose.

6 – The patentee shall receive appropriate payment in each concrete case on the basis of the economic value of the license.

7 – A decision granting or denying payment is subject to judicial or arbitral appeal under Articles 48 to 50.

Article 108 – License due to failure to exploit the invention

1 – After the time limits referred to in Article 106(2) have expired, a patentee who, without a good reason or legal basis, does not exploit an invention, directly or under license, or does

not do so in such a way as to meet national needs, may be obliged to grant a license for its exploitation.

2 – A patentee may also be obliged to grant an exploitation license for an invention if he ceases to exploit it for three consecutive years without a good reason or legal basis.

3 – Objective technical or legal reasons beyond the patentee's control and irrespective of his situation making the exploitation of the invention impossible or insufficient are considered good reason, but not economic or financial difficulties.

4 – For as long as a compulsory license remains in force, the patentee may not be obliged to grant another before the previous one is cancelled.

5 – A compulsory license may be cancelled if the licensee does not exploit the invention in such a way as to meet national needs.

Article 109 – Dependent licenses

1 – If it is not possible to exploit a patented invention, without prejudice to the rights conferred by a previous patent, and the two inventions are used for different industrial purposes, a license may only be granted if the first invention is essential to the exploitation of the second, and only in the part necessary for said exploitation, and the holder of the first patent is entitled to fair compensation.

2 – If inventions protected by dependent patents serve the same industrial purpose and a compulsory license is to be granted, the previous patentee may also demand a compulsory license for the previous patent.

3 – If an invention concerns a process for preparing a chemical, pharmaceutical or food product protected by a current patent, and whenever this process patent represents notable technical progress in relation to the previous patent, both the holder of the process patent and the holder of the product patent are entitled to demand a compulsory license for the other holder's patent.

4 – If the obtainer of a plant variety cannot obtain or exploit a plant securing right without infringing a prior patent, he may request a compulsory license for non-exclusive exploitation of the invention protected by the patent, provided that this license is necessary for the exploitation of the same plant variety, on payment of appropriate remuneration.

5 – Whenever a license of the type provided for in the previous paragraph is granted, the patentee is entitled to a reciprocal license on reasonable terms to use the protected variety.

6 – If the holder of a patent for a biotechnological invention is unable to exploit it without infringing a previous plant variety securing right, he may request a compulsory license for non-exclusive exploitation of the variety protected by the securing right on payment of an appropriate sum.

7 – Whenever a license of the type provided for in the previous paragraph is granted, the holder of the securing right is entitled to a reciprocal license on reasonable terms to use the protected invention.

8 – Applicants for the licenses referred to in paragraphs 4 and 6 must prove that:

a) *They approached the patentee or plant securing right holder in vain to obtain a contractual license;*

b) *The plant variety or invention represents important technical progress of considerable economic interest in relation to the invention claimed in the patent or to the plant variety being protected.*

9 – *This article also applies whenever one of the inventions is protected by a patent and the other by a utility model.*

Article 110 – Public interest

1 – *A patentee may, in the public interest, be obliged to grant a license for the exploitation of his invention.*

2 – *There are considered to be reasons of public interest if the start, increase or generalization of the exploitation of the invention, or an improvement in the conditions of its exploitation, is of vital importance to public health or national defense.*

3 – *There are also considered to be reasons of public interest if failure to exploit or insufficient quality or quantity of exploitation is highly detrimental to the country's economic or technological development.*

4 – *The government shall be responsible for granting a license in the public interest.*

Article 111 – Requests for compulsory licenses

1 – *Compulsory licenses shall be requested from the National Industrial Property Institute. Applicants shall submit proof to justify their request.*

2 – *Requests for compulsory licenses shall be examined in the order in which they are submitted to the National Industrial Property Institute.*

3 – *On receiving a request for a compulsory license, the National Industrial Property Institute shall give the patentee two months in which to say anything he sees fit and to submit proof.*

4 – *The National Industrial Property Institute shall consider the parties' arguments and the guarantees of exploitation of the invention offered by the applicant for the compulsory license and decide, within two months, whether or not it should be granted.*

5 – *If it decides in favor, it shall give both parties one month to appoint an expert who, together with the expert appointed by the National Industrial Property Institute, shall agree, within two months, on the conditions of the compulsory license and the compensation to be paid to the patentee.*

Article 112 – Notification of and appeal against grant or refusal of a license

1 – *The National Industrial Property Institute shall inform both parties of the grant or refusal of a license and its exploitation conditions.*

2 – *Appeals may be lodged against the decision of the National Industrial Property Institute to grant or refuse the license, or only the conditions in which it has been granted, to the competent court under the terms of articles 39 et seq., within three months of the date of the notification referred to in the previous paragraph.*

3 – A decision to grant shall only be effective after its confirmation and annotation at the National Industrial Property Institute, where the appropriate fees shall be paid as for an ordinary license.

4 – An extract of the registration referred to in the previous paragraph shall be published in the Industrial Property Bulletin.”

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there is no relevant case law on this matter.

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Refusal to grant licenses on reasonable terms

Public health

National security

Dependent patents

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

To avoid abuse of the monopoly that is granted with a patent.

To avoid obstacles to technological and economical development.

To promote public health.

To guarantee national security.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The provisions set forth in article 108 CPI, paragraphs 4 to 8, regarding plant varieties or biotechnological inventions, were introduced in 2003. The earlier (revoked) 1995 CPI did not provide for this.

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law is the one set forth in article 108 CPI. Please read its transcription, included in the answer to question 65. Also relevant in this context we believe to be the provisions of article 106 CPI.

“Article 106 – Obligation to exploit

1 – The patentee is obliged to exploit a patented invention directly or through a person authorized by him and to market the results obtained in order to fulfill the needs of the national market.

2 – Exploitation shall begin within four years of the date of the patent application or three years of the grant date, whichever is greater.

3 – It is possible to enjoy patent rights with no discrimination as to place of invention, the technological field or the fact that the products are imported from any country belonging to the European Union or WTO or produced locally.”

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, importation in that sense constitutes “working” of a patent. The relevant legal provision is established in article 106 CPI, paragraph 3, as transcribed above in the context of the answer to question 69.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

The CPI does not provide for a time period, as such, to be respected before a compulsory license can be requested. Please read the transcription of article 107 CPI, paragraph 3, made in the context of the answer to question 65. Note that said provision only mentions a “(...) reasonable period of time”. Nevertheless, article 106 CPI, paragraph 2, does provide for time periods for the patented invention to be “worked”. Please read the corresponding transcription made in the context of the answer to question 69.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

The applicable law is the one provided for by article 108 CPI, paragraph 3. Again, please read the transcription of said provision made in the context of the answer to question 65.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

The relevant provision is article 107 CPI, paragraph 3. Please read the corresponding transcription made in the context of the answer to question 65. The answer given to question 71 already addressed this matter. To our knowledge, there are no definitions in the relevant legal provisions nor in the case law.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The CPI does not provide for the grant of compulsory licenses on such grounds.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

The relevant provisions are set forth in article 109 CPI. Please read the corresponding transcription made in the context of the answer to question 65.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Yes, the law provides for a remuneration policy in such a context. The relevant provisions are the ones stated in article 107 CPI, paragraphs 6 and 7, article 109 CPI, paragraphs 1 and 4 to 7, and article 111 CPI, paragraph 5. Please read the corresponding transcriptions made in the context of the answer to question 65.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The CPI does not provide for the grant of compulsory licenses on such grounds.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

In our country one compulsory license was issued regarding plant protection products.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Government use of patent rights in pursuing public interest is not specifically provided for in the CPI. Only article 105 CPI, as transcribed below, addresses state ownership of patent rights.

Article 105 CPI provides for loss and expropriation of a patent.

“Article 105 – Loss and expropriation of a patent

1 – Anyone who is liable for obligations undertaken in relation to third parties or whose patent is expropriated in the public interest may be deprived of a patent under the law.

2 – Any patent may be expropriated in the public interest on payment of fair compensation, if the need for dissemination of the invention or use by public bodies so requires.

3 – The Expropriation Code is applicable, with the necessary adaptations.”

Regarding public interest, the already mentioned and transcribed above provisions stated in articles 107 to 112 CPI on compulsory licensing include the pursuing of several forms of public interest, but without demanding any kind of ownership of patent rights by the state.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

To our knowledge, there is no relevant case law on this matter.

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Other, please specify: Public interest, as stated above in the answer to question 81.

84. (a) What are the public policy objectives for providing government use in your country?

To pursue public interest.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Legal provisions for the pursuit of public interest through state ownership of patent rights have been essentially the same for decades.

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The CPI does not provide for the grant of government use on such grounds.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

To our knowledge, the government has never used this exception.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision is article 103 CPI, paragraph 2. It applies to a patent valid in the Portuguese territory, be it a patent deriving from a Portuguese national application filing, a validated European patent or an international application filing. Please read the transcription made in the context of the answer given to question 60.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

To our knowledge, there is no relevant case law on this matter.

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

To avoid abuse of the monopoly that is granted with a patent, and to protect the farmers' rights.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The legal provision set forth in paragraph 2 of article 103 CPI was introduced in 2003 as a result of the transposition of Directive 98/44/EC on the legal protection of biotechnological inventions. It was absent from the 1995 (revoked) CPI.

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

To our knowledge, there is no relevant case law on this matter.

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

The relevant provision is article 103 CPI, paragraph 2. It applies to a patent valid in the Portuguese territory, be it a patent deriving from a Portuguese national application filing, a validated European patent or an international application filing.

Please read the transcription made in the context of the answer given to question 60.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

To our knowledge, there is no relevant case law on this matter.

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

To avoid abuse of the monopoly that is granted with a patent, and to protect the breeders' rights.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The legal provision set forth in paragraph 2 of article 103 CPI was introduced in 2003 as a result of the transposition of Directive 98/44/EC on the legal protection of biotechnological inventions. It was absent from the 1995 (revoked) CPI.

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

To our knowledge, there is no relevant case law on this matter.

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

There have not been any challenges related to the practical implementation of this exception in our country.

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

To our knowledge, there is no other exceptions and limitations provided by our patent law.

102. In relation to each exception and limitation, please indicate:

- (i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

Not applicable.

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Not applicable.

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

Not applicable.

In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

Not applicable.

(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

Not applicable.

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

Referring to the answer given to question 81, specifically to the transcription of article 105 CPI included therein, namely to its paragraph 3, mention is made to the "Expropriation Code", which is the Portuguese law regarding expropriations.

Country: SULTANATE OF OMAN
Office: Intellectual Property Department

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard used is that the invention meets the three conditions for granting (Novelty, Inventive step and industrial applicability).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

(1) *The following shall be excluded from patent protection:*

(a) *Discoveries, scientific theories and mathematical methods;*

(b) *Schemes, rules or methods for doing business, performing purely mental acts or playing games;*

(c) *Natural substances; this provision shall not apply to the processes of isolating those natural substances from their original environment;*

(d) *Known substances for which a new use has been discovered; this provision shall not apply to the use itself, where it constitutes an invention under Section 1;*

(e) *Animals other than micro-organisms, and essentially biological processes for the production of animals and their parts, other than non-biological and microbiological processes;*

(f) *Inventions, the prevention within the territory of Oman of the commercial exploitation of which is necessary to protect ordure public and morality; such exclusion shall not be made merely because the exploitation of those inventions is prohibited by law.*

(2) *The provisions of subsection (1) shall not apply to the following inventions:*

(a) *Process inventions which, in whole or in part, consist of steps that are performed by a computer and are directed by a computer program; and*

(b) *Product inventions consisting of elements of a computer-implemented invention, including in particular:*

(i) *Machine-readable computer program code stored on a tangible medium such as a floppy disk, computer hard drive or computer memory; and*

(ii) a general purpose computer whose novelty over the prior art arises primarily due to its combination with a specific computer program.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Section 13

(1) (a) Where

(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or

(ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or

(iii) the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or

(iv) the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation; or

(v) when a patent (the "second patent") claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the "first patent") without infringing which the second patent cannot be exploited.

(2) A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(a)(iv), before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.

(3) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(4) (a) Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister shall not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance

of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(ii), if and when the conditions which led to such compulsory license are likely to recur.

- (5) *The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.*
- (6) *The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:*
- (i) *the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and*
 - (ii) *the conclusion of license contracts by the owner of the patent; and*
 - (ii) *the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).*
- (7) (a) *A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.*
- (b) *Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.*
- (8) *The exploitation of the invention by the Government agency or third person licensed by the Minister shall be predominantly for the supply of the market in Oman except when the compulsory license concerns a patent claiming a pharmaceutical product or a process of making a pharmaceutical product, and the purpose of the license is to export the patented products or the products manufactured by the patented process for a foreign territory or country with no or with insufficient manufacturing capacity, in accordance with the terms and conditions of the Decision of the General Council of the WTO of August 30, 2003.*
- (9) *Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.*
- (10) *Where a compulsory license is granted under subsection (1)(v),*
- (a) *the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and*

(b) *the license of the first patent shall be non-assignable except with the assignment of the second patent.*

(11) *The provisions of this Section shall apply, where appropriate and mutatis mutandis, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (b) (i)

5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (a) (iii)

12.-15.

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

invent around the patented invention

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

Research and/or experimentation must be conducted with or using the patented invention (“research with”)

Please explain by citing legal provision(s) and/or decision(s):

The rights under the patent shall not extend: to acts done only for experimental purposes relating to a patented invention

Section 11

(4) (a) The rights under the patent shall not extend:

(i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner’s rights; or

(ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or

(iii) to acts done only for experimental purposes relating to a patented invention; or

(iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the “prior user”);

(v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.

18.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of the Sultanate of Oman does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (a) (iv)

32.-33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 11

(4) (a) The rights under the patent shall not extend:

(i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner’s rights; or

(ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or

(iii) to acts done only for experimental purposes relating to a patented invention; or

(iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the “prior user”);

(v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

Section 13

(B) The Minister may - without the consent of the owner of the patent - to decide that any governmental entity or other person exploiting the invention, and this exploitation is limited to

the purpose for which licenses it for, to pay adequate compensation to the owner of the patent depending on the circumstances of each case, taking into account the value Economic Minister's decision, and the provisions of the General Council Decision of the WTO that it was appropriate for the reward, which was decided at the grant of a patent for the invention of the mandatory drug product or an industrial process for the manufacture of this product.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

Section 11

(4) (a) *The rights under the patent shall not extend:*

(i) *to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or*

(ii) *to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or*

(iii) *to acts done only for experimental purposes relating to a patented invention; or*

(iv) *to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");*

(v) *to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman*

(6) *The right of the prior user referred to in subsection (4)(a)(iv) of this Section may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.*

38.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 -(4) (b) (ii)

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law is silent on those issues.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

The applicable law is silent on those issues.

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 13

52.-53.

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

(1) (a) *Where*

(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or

(ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is

satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or

(iii) the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or

(iv) the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation; or

(v) when a patent (the "second patent") claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the "first patent") without infringing which the second patent cannot be exploited.

(2) A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(a)(iv), before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.

(3) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(4) (a) Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister shall not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(ii), if and when the conditions which led to such compulsory license are likely to recur.

(5) The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(6) The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:

(i) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and

(ii) the conclusion of license contracts by the owner of the patent; and

(ii) the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).

(7) (a) *A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.*

(b) *Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.*

(8) *The exploitation of the invention by the Government agency or third person licensed by the Minister shall be predominantly for the supply of the market in Oman except when the compulsory license concerns a patent claiming a pharmaceutical product or a process of making a pharmaceutical product, and the purpose of the license is to export the patented products or the products manufactured by the patented process for a foreign territory or country with no or with insufficient manufacturing capacity, in accordance with the terms and conditions of the Decision of the General Council of the WTO of August 30, 2003.*

(9) *Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.*

(10) *Where a compulsory license is granted under subsection (1)(v),*

(a) *the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and*

(b) *the license of the first patent shall be non-assignable except with the assignment of the second patent.*

(11) *The provisions of this Section shall apply, where appropriate and mutatis mutandis, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.*

55. The exception covers the regulatory approval of:

Any products

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

*Export
Exploitation*

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National
Regional
International

If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 13

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Yes

Please explain your answer by citing legal provision(s) and/or decision(s):

Section 13

(6) The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:

(i) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and

(ii) the conclusion of license contracts by the owner of the patent; and

(ii) the continued exercise, by the owner of the patent, of his rights under Section 11(1), (2) and (3).

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 13

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 11

(5) Without prejudice to the provisions of subsection 4(a) of this Section, the Minister shall have the authority, ex officio or at the request of any interested party, of declaring the patent rights exhausted, and thus of authorizing others to import the patented product or a product manufactured directly or indirectly by means of the patented invention (“the product”) from another territory when that product is not available in the territory of Oman or is available in the territory of Oman with unreasonably low quality standards or in a quantity that is not sufficient to meet the local demand or at prices that the Minister deems abusive or for any other reason of public interest, including anticompetitive practices, provided that:

(i) the product has been put in the channels of commerce in the territory from which it will be imported by the owner of the patent or with his consent; and

(ii) *a patent claiming the product or the process for its manufacture is in force in the territory from which the product will be imported and is owned by the same person who owns the patent in Oman or by a person under his control:*

(a) If the importer fails to fulfill the purpose that justified the Minister's decision to consider the patent rights exhausted, the Minister shall, ex officio, or at the request of the patent owner, cancel the authorization.

(b) If the conditions that gave rise to the Minister's decision to consider the patent exhausted cease to exist, the Minister may, ex officio or at the request of the patent owner, cancel the authorization, provided that the legitimate interests of the importer are taken into account, including but not exclusively that the importer will retain the right to commercialize the products that remain on stock.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

TITLE III: PROTECTION AGAINST UNFAIR COMPETITION

Section 60

(1) The provisions of this Title shall apply independently of, and in addition to, any legislative provisions protecting inventions, utility models, industrial designs, layout-designs, distinctive signs, literary and artistic works and other intellectual property subject matter.

(2) (a) In addition to the acts and practices referred to in Articles 61 to 65, any act or practice, in the course of industrial or commercial activities, that is contrary to honest practices shall constitute an act of unfair competition.

(b) An act or practice that is contrary to honest practices, for the purposes of this Title, shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

An act or practice that is contrary to honest practices, for the purposes of this Title, shall also mean acts of breach of legal duties in general when their purpose or their consequence is to obtain illicit advantages over competitors, such as the breach of environmental or labor law.

(c) Any natural person or legal entity damaged or likely to be damaged by an act of unfair competition shall be entitled to the remedies referred to in Title IV.

Section 61

(1) Any act or practice, in the course of industrial or commercial activities, that causes, or is likely to cause, confusion with respect to another's enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Confusion may, in particular, be caused with respect to

(i) a trademark, whether registered or not or a trade name.

(ii) any distinctive sign other than a trademark or a trade name

(iii) the appearance of a product or the presentation of products or services as well as of the place of business]

Section 62

(1) Any act or practice, in the course of industrial or commercial activities, that damages, or is likely to damage, the goodwill or reputation of another's enterprise shall constitute an act of unfair competition, regardless of whether such act or practice causes confusion.

(2) (a) Damaging another's goodwill or reputation may, in particular, result from the dilution of the goodwill or reputation attached to

- (i) a trademark, whether registered or not;
- (ii) a trade name;
- (iii) any distinctive sign other than a trademark or a trade name;
- (iv) the appearance of a product;
- (v) the presentation of products or services as well as of the place of business;
- (vi) a celebrity or a well-known fictional character.

(b) For the purposes of these provisions, “dilution of goodwill or reputation” means the lessening of the distinctive character or advertising value of a trademark, trade name or other business identifier, the appearance of a product or the presentation of products or services or of a celebrity or well-known fictional character.

Section 63

(1) Any act or practice, in the course of industrial or commercial activities, that misleads, or is likely to mislead, the public with respect to an enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Misleading may arise out of advertising or promotion and may, in particular, occur with respect to

- (i) the manufacturing process of a product;
- (ii) the suitability of a product or service for a particular purpose;
- (iii) the quality or quantity or other characteristics of products or services;
- (iv) the geographical origin of products or services;
- (v) the conditions on which products or services are offered or provided;
- (vi) the price of products or services or the manner in which it is calculated.

Section 64

(1) Any false or unjustifiable allegation, in the course of industrial or commercial activities, that discredits, or is likely to discredit, another’s enterprise or its activities, in particular, the products or services offered by such enterprise, shall constitute an act of unfair competition.

(2) Discrediting may arise out of advertising or promotion and may, in particular, occur with respect to

- (i) the manufacturing process of a product;
- (ii) the suitability of a product or service for a particular purpose;
- (iii) the quality or quantity or other characteristics of products or services;
- (iv) the conditions on which products or services are offered or provided;
- (v) the price of products or services or the manner in which it is calculated.

Section 65

(1) Any act or practice, in the course of industrial or commercial activities, that results in the disclosure, acquisition or use by others of undisclosed information without the consent of the person lawfully in control of that information (hereinafter referred to as “the rightful holder”) and in a manner contrary to honest commercial practices shall constitute an act of unfair competition.

For the purposes of this Section, “a manner contrary to honest commercial practices” shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

(2) *For the purposes of this Section, information shall be considered “undisclosed information” if it has secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question or it has commercial value because it is secret and it has been subject to reasonable steps under the circumstances by the person lawfully in control of the information to keep it secret.*

(3) (a) *Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in*

(i) *an unfair commercial use by a governmental authority of undisclosed test or other data concerning safety and efficacy of the product which have been submitted to that authority as a condition of obtaining approval of the marketing of new pharmaceutical or agricultural chemical products, or*

(ii) *the disclosure of such data, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

(b) *For the purposes of this Subsection, a pharmaceutical product shall be considered new if it contains a chemical entity that has not been previously approved in the territory of Oman for use in a pharmaceutical product; a new agricultural chemical shall be considered new if it contains a chemical entity that has not been previously approved in the territory of Oman for use in an agricultural chemical product.*

(4) (a) *Subsection (4)(a)(i) shall be construed as precluding any governmental agency, without the consent of the person or entity who first obtained marketing approval of a pharmaceutical or agricultural chemical product in Oman (the originator) from relying on or referring to the undisclosed test data or other undisclosed data submitted by the originator, for the purposes of approving any other product, for at least five (5) years for pharmaceutical products, and ten (10) years for agricultural chemical products, from the date of marketing approval in Oman.*

(b) *The provisions of paragraph (a) of this Subsection shall apply, mutatis mutandis, in the event Oman adopts the practice of granting marketing approval based on evidence of marketing approval granted in another territory.*

(c) *Where the competent authority of Oman requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of a pharmaceutical product, other than information related to bioequivalency, that competent authority shall not, without the consent of the originator, authorize another to market a same or a similar product based on the new clinical information submitted in support of the marketing approval or evidence of the marketing approval based on the new clinical information, for at least three years from the date of marketing approval in Oman.*

(d) *The provisions of paragraph (c) of this Subsection shall apply, mutatis mutandis, in the event Oman adopts the practice of granting marketing approval based on evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory.*

(e) *Where the originator’s product is covered by a patent in force in the territory of Oman, the competent authority, notwithstanding the provisions of this Subsection, but without*

prejudice to the provisions of paragraph (e), shall not approve another product without the prior consent of the patent owner. If a request of marketing approval that requires or implies reliance on the originator's undisclosed data is submitted by another person during the term of a patent, the competent authority shall inform the patent owner of such a request

Section 13

(7) (a) A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time.

(b) Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

When a patent (the "second patent") claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the "first patent") without infringing which the second patent cannot be exploited.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Section 13

(B) The Minister may - without the consent of the owner of the patent - to decide that any governmental entity or other person exploiting the invention, and this exploitation is limited to the purpose for which licenses it for, to pay adequate compensation to the owner of the patent depending on the circumstances of each case, taking into account the value Economic Minister's decision, and the provisions of the General Council Decision of the WTO that it was appropriate for the reward, which was decided at the grant of a patent for the invention of the mandatory drug product or an industrial process for the manufacture of this product.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The applicable law is silent on those issues

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Neither a compulsory license nor a government use license has ever been issued in the Sultanate of Oman.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11-4e and Section 13.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

84. (a) What are the public policy objectives for providing government use in your country?

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The applicable law is silent on those issues.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

Neither a compulsory license nor a government use license has ever been issued in the Sultanate of Oman.

87.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Industrial Property Law 67/2008 - Section 11 – 4 to 6.

90.-91.

[Note from the Secretariat: response was not provided.]

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

Section 11

(4) (a) The rights under the patent shall not extend:

(i) to acts in respect of articles which have been put on the market in Oman by the owner of the patent or with his consent, consequently exhausting the patent owner's rights; or

(ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Oman; or

(iii) to acts done only for experimental purposes relating to a patented invention; or

(iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Oman (the "prior user");

(v) to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for purposes related to generating such information, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman

(6) The right of the prior user referred to in subsection (4)(a)(iv) of this Section may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.

93.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of the Sultanate of Oman does not provide exceptions related to the breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

*Industrial Property Law 67/2008 - Section 66
Infringement Proceedings*

(6) (a) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement of a patent for a diagnostic, therapeutic and surgical methods for the treatment of humans or animals, the provisions of Title IV of this Act shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(b) For the purposes of this Subsection:

(i) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent;

(ii) the term "medical practitioner" means any natural person who is licensed by a State to provide the medical activity described in paragraph (b)(1) or who is acting under the direction of such person in the performance of the medical activity;

(iii) the term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic;

102.-103.

[Note from the Secretariat: response was not provided.]

Country: REPUBLIC OF KOREA
Office: Korean Intellectual Property Office

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard for patentability includes industrial applicability (Article 29(1) of the Korean Patent Act (hereinafter referred to as the Act), novelty (Article 29(1)) and inventive step (Article 29(2)). Such legal standards do not change according to technical fields.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Notwithstanding Article 29, any invention that is liable to injure public order, morality or public health shall not be patented (Article 32).

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

A patentee shall have an exclusive right to “work” a patented invention (Article 94), and exercise the right exclusively (Article 126). Pursuant to Article 2(3) of the Act, “working” of an invention means the following acts:

- (a) acts of manufacturing, using, assigning, leasing, importing or offering for assignment or lease (including displaying for assignment or lease) an invented product;*
- (b) acts of using an invented process; and*
- (c) acts of using, assigning, leasing, importing or offering for assignment or lease a product manufactured by an invented process for manufacturing a product, in addition to the acts mentioned in subparagraph (b).*

Rights accorded to the patent applicant after publication of the patent application:

An applicant may demand a person who has commercially or industrially worked the filed invention after the laying-open of the invention to pay compensation after the registration of the patent right (Article 65(2)).

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;*

*Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 94: A patentee has an exclusive right to work a patented invention commercially and industrially.

Article 65(2): An applicant may demand a person who has commercially or industrially worked the filed invention after being warned as provided for in paragraph (1) or knowing that an application for the invention has been laid open, to pay compensation in an amount equivalent to what he/she would have normally received for the working of the invention from the date of the warning or the time when he/she knew that the patent application of the invention had been laid open to the time of the registration of the patent right.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

Considering the purpose of the Patent Act, which is to develop industries, to provide the exception of private or theoretical working of a patented invention is legitimate.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 7.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 96(1): The effect of a patent right does not extend to any of the following subparagraphs:

(i) working a patented invention for research or experimental purposes (including approval and registration of drugs under the Korean Pharmaceutical Affairs Act and research or experiments for registration of agrochemicals under the Korean Agrochemicals Control Act)

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

To better understand the contents and effects of a patented invention, a third party shall be allowed to work the invention. Also, there are possibilities of developing an advanced invention based on the working of the patented invention. The working of a patented invention contributes greatly to the advancement of technologies and as long as a product developed based on the results of the working of the invention is not put on the market, the patentee does not suffer a direct loss.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- 14.-15.

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention
invent around the patented invention*

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

*Research and/or experimentation must be conducted on or relating to the patented invention ("research on")
Research and/or experimentation must be conducted with or using the patented invention ("research with")*

Please explain by citing legal provision(s) and/or decision(s):

Article 96(1): The effect of a patent right does not extend to any of the following subparagraphs:

(i) working a patented invention for research or experimental purposes (including approval and registration of drugs under the Korean Pharmaceutical Affairs Act and research or experiments for registration of agrochemicals under the Korean Agrochemicals Control Act).

18.-20.

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To better understand the contents and effects of a patented invention, a third party shall be allowed to work the invention. Also, there are possibilities of coming up with an advanced invention based on the working of the patented invention. The working of a patented invention contributes greatly to the advancement of technologies and as long as a product developed based on the results of the working of the invention is not put on the market, the patentee does not suffer a direct loss.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 96(2): The effects of a patent right for the invention of products used for diagnosis, therapy, alleviation, medical treatment or prevention of human disease (referred to as "medicines") that are manufactured by mixing two or more medicines, or for the invention of processes for manufacturing medicines by mixing two or more medicines, do not extend to acts of dispensing medicines under the Pharmaceutical Affairs Act or to medicines manufactured by such acts.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

Taking into account an act of preparing medicine by a doctor has a social mission with a particular purpose of helping citizens, when becoming patients, recover their health, it is considered inappropriate for the effect of a patent right to extend to an act of preparing medicine. Yet, it is interpreted that medicine itself is generally deemed to be prepared by a medicine manufacturer with a patent license granted, and legally sold by a doctor.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

A doctor

27.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 103: When filing a patent application, a person who has made an invention without prior knowledge of the contents of an invention described in an existing patent application, or who has learned how to make the invention from such a person and has been working the invention commercially or industrially in the Republic of Korea in good faith or has been making preparations to work the invention is entitled to have a nonexclusive license on the patent right for the invention under the patent application.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

Under the first-to-file system, if a holder of a patented invention in good faith is not allowed to work the invention, it could do an unexpected damage to the holder. Therefore, a non-exclusive license based on prior use is included in the first-to-file system to address any deficiencies in formalities. The non-exclusive license based on prior use is recognized to realized the fairness between a patent right holder and a prior user. Also, it would be a disadvantage to a national economy if the business facilities of a prior user are not allowed.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 103: “a person who has made an invention without prior knowledge of the contents of an invention described in an existing patent application, or who has learned how to make the invention from such a person and has been working the invention commercially or industrially in the Republic of Korea in good faith or has been making preparations to work the invention is”

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

Remuneration is not paid to the patentee considering the nature of free non-exclusive license.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes.

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes.

If yes, please explain what those conditions are:

Article 102(5): A nonexclusive license other than those described in paragraphs (3) and (4) may not be transferred without the consent of the patentee, unless the transfer is made with the underlying business or through inheritance or other general succession.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes.

If yes, please explain the conditions under which such use can continue to apply:

[Note from the Secretariat: response was not provided.]

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Article 104(1): Where a person has been commercially or industrially working an invention in the Republic of Korea, or has been making preparations to work the invention, before the registration of a request for an invalidation trial of the concerned patent or utility model, without knowing that the patented invention is subject to invalidation, the person is entitled, under any of the following circumstances, to have a nonexclusive license on that patent right or a nonexclusive license on the exclusive license to the patent right existing when the patent or utility model registration was invalidated; however, the nonexclusive license must be limited to the invention or device being worked or for which preparations for working are being made, and to the purpose of such working or preparations:

- 1. the original patentee, where one of two or more patents granted for the same invention has been invalidated;*
- 2. the original owner of a utility model right, where a patented invention and a device registered as a utility model are the same and the utility model registration has been invalidated;*
- 3. the original patentee, where the patent has been invalidated and a patent for the same invention has been granted to an entitled person;*
- 4. the original owner of a utility model right, where the utility model registration has been invalidated and a patent for the same invention as the device has been granted to an entitled person; or*
- 5. in the cases referred to in subparagraphs (i) to (iv), a person who, at the time of registering a request for an invalidation trial of an invalidated patent right or utility model right, has been granted an exclusive license, a nonexclusive license or a nonexclusive license on*

the exclusive license and the license has been registered; however, a person falling under Article 118(2) is not required to register the license.

40.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 96(1): The effect of a patent right does not extend to any of the following subparagraphs:

2. vessels, aircraft or vehicles merely passing through the Republic of Korea, or machinery, instruments, equipment or other accessories used on the vessels, aircraft or vehicles

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

Even though the working of transportation methods infringes the rights of a patentee, damage which vessels, aircraft or vehicles merely passing through the Republic of Korea would do to a patentee is, if any, little since such transportation methods just pass through the country in a short time. If such transportation methods are banned from passing through Korea, it would raise a critical problem in the international transportation system. It is based on Article 5(3) of the Paris Convention for the Protection of Industrial Property.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 96(1)(2): "merely passing through the Republic of Korea,"

47.-48.

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Even though the working of transportation methods infringes the rights of a patentee, damage which vessels, aircraft or vehicles merely passing through the Republic of Korea would do to a patentee is, if any, little since such transportation methods just pass through the country in a short time. If such transportation methods are banned from passing through Korea, it would raise a critical problem in the international transportation system.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 96(1): The effect of a patent right does not extend to any of the following subparagraphs:

(i) working a patented invention for research or experimental purposes(including approval and registration of drugs under the Korean Pharmaceutical Affairs Act and research or experiments for registration of agrochemicals under the Korean Agrochemicals Control Act)

52.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60.-64.

[Note from the Secretariat: the applicable law of the Republic of Korea does not provide exceptions related to exhaustion of patent rights.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 107

(1) Where a patented invention falls under any of the following subparagraphs, a person who intends to work the patented invention may request the Commissioner of the Korean Intellectual Property Office to make an adjudication (referred to as "an adjudication") for the establishment of a nonexclusive license, provided no agreement is reached despite having a consultation (referred to as "a consultation" in this Article) under reasonable conditions with the patentee or exclusive licensee on the grant of a nonexclusive license for the patented invention or a consultation is impossible to arrange; however, the person may request an

adjudication even in the absence of a consultation if the patented invention is to be worked non-commercially for the public interest or in any case that falls under subparagraph 4:

- 1. where the patented invention has not been worked for more than three consecutive years in the Republic of Korea, except for natural disasters, unavoidable circumstances or other justifiable reasons prescribed by Presidential Decree;*
- 2. where the patented invention has not continuously been worked commercially or industrially in the Republic of Korea on a substantial scale during a period of three years or more without justification, or where the domestic demand for the patented invention has not been satisfied to an appropriate extent and under reasonable conditions;*
- 3. where working the patented invention non-commercially is necessary for the interests of the public; or*
- 4. where working the patented invention is necessary to remedy a practice determined to be unfair after the judicial or administrative process;*
- 5. where working the patented invention is necessary for the export of medicine to a country (referred to as "an importing country") that intends to import the medicine (including effective ingredients that are necessary for the production of the medicine and diagnostic kits necessary for the use of the medicine) in order to treat diseases that threaten the health of the majority of its citizens.*

(2) Paragraph (1) 1 and 2 of this Article does not apply unless a period of four years has elapsed after the filing date of the application for the patented invention.

(3) In adjudicating the authorization of a nonexclusive license, the Commissioner of the Korean Intellectual Property Office shall consider the necessity of each request.

(4) When the Commissioner of the Korean Intellectual Property Office makes an adjudication under subparagraphs 1 to 3 or 5 of paragraph (1), the following conditions apply to the person for whom the adjudication was made:

- 1. where the adjudication is made under subparagraphs 1 to 3 of paragraph (1), the nonexclusive license must be implemented for the primary purpose of meeting domestic demand; and*
- 2. where the adjudication is made under subparagraph 5 of paragraph (1), all the medicine produced under the terms of the adjudication must be exported to importing countries.*

(5) The Commissioner of the Korean Intellectual Property Office shall ensure that reasonable consideration is given to every adjudication. When making an adjudication under subparagraph 4 or 5 of paragraph (1), the Commissioner of the Korean Intellectual Property Office may consider the factors in each of the following subparagraphs:

- 1. where an adjudication is made under subparagraph 4 of paragraph (1), the need to rectify unfair transactions; and*
- 2. where an adjudication is made under subparagraph 5 of paragraph (1), the economic value generated in importing countries by the working of the patented invention.*

(6) For semiconductor technology, a request for adjudication may be made only in the cases set forth in subparagraph (1) 3 (where the noncommercial working of the patented invention is permitted in a limited way for the interests of the public) and (1) 4.

(7) An importing country is limited to a country which is either a World Trade Organization (WTO) member country that has notified the WTO of the following particulars or a non-WTO

member country listed in a Presidential decree, and which has notified the Republic of Korea of the following particulars:

1. the name of the medicine and the quantity required by an importing country;
2. where the importing country is not one of the least developed countries listed in a resolution of the General Assembly of the United Nations, confirmation by the importing country that it has insufficient or no manufacturing capability to produce the medicine concerned; and
3. where the medicine concerned is patented in the importing country, confirmation by the importing country that it has granted or intends to grant a compulsory license.

(8) The term medicine in paragraph (1) 5 of this Article refers to any of the definitions in the following subparagraphs:

1. patented medicine;
2. medicine manufactured by means of a patented process;
3. patented effective ingredients necessary for the production of the medicine; or
4. patented diagnostic kits necessary for the production of the medicine.

(9) The documents for submission and other necessary matters concerning a request for adjudication are prescribed by Presidential Decree.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Anti-competitive practices and/or unfair competition
Public health*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Where a patentee abuses a patent right such as intentionally not working a patented invention or being reluctant to cooperate for the working of the invention by another person other than the patentee, a third party shall be allowed to work the patented invention to contribute to industrial development, which serves the purpose of the Patent Act.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 107(1) 2 : where the patented invention has not continuously been worked commercially or industrially in the Republic of Korea on a substantial scale during a period of three years or more without justification, or where the domestic demand for the patented invention has not been satisfied to an appropriate extent and under reasonable conditions

70. Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Article 2: The definitions of terms used in this Act are as follows:

3. "working" means any of the following acts:

(a) acts of manufacturing, using, assigning, leasing, importing or offering for assignment or lease (including displaying for assignment or lease) an invented product;

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

[Note from the Secretariat: response was not provided.]

If yes, what is the time period?

Article 107(2): Paragraph (1) 1 and 2 of this Article do not apply unless a period of four years has elapsed after the filing date of the application for a patented invention.

72.-75.

[Note from the Secretariat: response was not provided.]

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Article 106(2) 3: When the Government or any person, other than the Government, works a patented invention pursuant to paragraph (1), he/she or it shall promptly notify the patentee, exclusive licensee or non-exclusive licensee of the pact of working under paragraph (1).

Article 110(2): The remuneration for the license and the method and time of payment must be specified in an adjudication.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Article 106(2)(i): "in time of war, uprising, or other similar emergency"

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

In December 1980, the patent on the method of manufacturing Bis-thio benzene (owned by Nippon Soda Co. of Japan) was granted the non-exclusive license since it had not been commercially worked for the previous three years without justifiable grounds.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Issuing compulsory licenses is considered adequate since the Commissioner of KIPO grants a non-exclusive license by the request made by a person who intends to work a patented invention after undertaking certain procedures, in order to serve the purpose of the Patent Act.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 106 bis (1) Where the non-commercial working of a patented invention is necessary for national defense in time of war, uprising, or other similar emergency or for the public interest, the government may expropriate the patent right (in the case of subparagraph 1 only), work the patented invention or require a person other than the government to work the patented invention.

(2) Where a patent right is expropriated, the rights to the invention other than the patent right are extinguished.

(3) If the Government expropriates a patent right, or the Government or a person other than the Government works the patented invention under paragraph (1), the Government or that person shall pay reasonable remuneration to the patentee, exclusive licensee or nonexclusive licensee.

(4) Matters necessary for expropriating and working a patent right as well as remuneration for these acts are prescribed by Presidential Decree.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*National security
National emergency and/or extreme urgency*

84. (a) What are the public policy objectives for providing government use in your country?

To prepare for expected concerns that if inventions crucial for national security are monopolized by a certain person, it could adversely affect national security.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Article 106 bis (1): Where the non-commercial working of a patented invention is necessary for national defense in time of war, uprising, or other similar emergency or for the public interest.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

[Note from the Secretariat: response was not provided.]

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Article 73 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (Security Exceptions: the government's position on restriction of an individual's property right is minimized) is reflected in the legal framework to limit the issuance of government use only in time of war, uprising, or other similar emergencies.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 57(1) of the Seed Industry Act: A variety protection right-holder shall have an exclusive right to license the protected variety for business purposes.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

Where a variety protection right-holder abuses a protected variety, such as intentionally not working the protected variety or being reluctant to cooperate for the working of the variety by another person other than the variety protection right-holder, a third party shall be allowed to work the protected variety to contribute to industrial development, which serves the purpose of the Seed Industry Act.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

Article 68 of the Seed Industry Act (Rulings on Establishment of Non-Exclusive Licenses):

(1) Where a protected variety falls under any of the following subparagraphs, a person who intends to license the protected variety may apply for a ruling on the establishment of a non-exclusive license (hereinafter referred to as "ruling") to the Minister for Food, Agriculture, Forestry and Fisheries: Provided, That an application for a ruling pursuant to subparagraph 1 or 2 may be made only where he/she is unable to consult on the grant of a non-exclusive license with a variety protection right-holder or an exclusive licensee of the protected variety, or fails to reach an agreement after consultation:

- 1. Where a protected variety has not been licensed for three or more consecutive years in the Republic of Korea without a natural disaster other force majeure or other justifiable grounds prescribed by Presidential Decree;*
- 2. Where a protected variety has not been licensed for three or more consecutive years in the Republic of Korea, without justifiable grounds, on a reasonable business scale or has failed to satisfy the domestic demand in due degree and on reasonable conditions;*
- 3. Where a protected variety is required to be licensed non-commercially because an urgent adjustment of supply and demand or dissemination is required due to a war, a natural disaster or a calamity;*
- 4. Where a protected variety is required to be licensed in order to correct matters recognized as unfair trading practices in accordance with judicial or administrative procedures.*

(2) Paragraph (1) shall not apply to a protected variety where three years have not passed from the date of registration for the establishment of a variety protection right.

(3) Where the Minister for Food, Agriculture, Forestry and Fisheries makes a ruling, he/she shall review the necessity for the establishment of a nonexclusive license for each application.

(4) Where the Minister for Food, Agriculture, Forestry and Fisheries makes a ruling, he/she shall set conditions that a non-exclusive license shall be mainly used for the purpose of supply for the domestic demand: Provided, That this shall not apply where he/she makes a ruling on the application pursuant to paragraph (1) 4.

(5) Where the Minister for Food, Agriculture, Forestry and Fisheries makes a ruling pursuant to paragraph (1) 4, he/she may take the purport that the ruling is to correct unfair trading practices, into consideration in the decision of such royalties.

(6) Where the Minister for Food, Agriculture, Forestry and Fisheries makes a ruling, he/she shall undergo deliberation by the Seed Council pursuant to Article 158.

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Where a variety protection right-holder abuses a protected variety, such as intentionally not working the protected variety or being reluctant to cooperate for the working of the variety by another person other than the variety protection right-holder, a third party shall be allowed to work the protected variety to contribute to industrial development, which serves the purpose of the Seed Industry Act.

94.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Republic of Korea does not provide other exceptions and limitations.]

Country: REPUBLIC OF MOLDOVA
Office: The State Agency on Intellectual Property

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Law on the protection of inventions No. 50/2008 of the Republic of Moldova can be found at: http://www.agepi.md/pdf/lege/lege-prot-inv_en.pdf

According to the Art.6 of the national Law 50/2008 on the protection of inventions:

(1) A patent shall be granted for any invention having as subject a product or a process, in all fields of technology, provided that such invention is new, involves an inventive step and is susceptible of industrial application.

(4) Inventions in the field of biotechnology shall be deemed patentable if they concern:

a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

c) a microbiological process or other technical process, or a product obtained by means of such a process other than a plant or animal variety;

d) an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

According to the Art.6 of the national Law 50/2008 on the protection of inventions:

(2) The following shall not be regarded as inventions within the meaning of paragraph (1):

a) discoveries, scientific theories and mathematical methods;

b) aesthetic creations;

c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

d) presentations of information.

(3) The provisions of paragraph (2) shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a patent application or patent relates to such subject-matter or activities as such.

According to the Art.7 (1) of the national Law 50/2008 on the protection of inventions patents shall not be granted in respect of:

a) inventions the publication or exploitation of which would be contrary to “ordre public” or morality, including those harmful for human, animal or plant life or health, and which are likely to cause serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by a clause;

b) plant or animal varieties;

c) essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

d) inventions concerning the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;

(2) Patents shall not be granted within the meaning of paragraph 1(a) in respect of biotechnological inventions which, in particular, concern the following:

a) processes for cloning human beings;

b) processes for modifying the germ line genetic identity of human beings;

c) uses of human embryos for industrial or commercial purposes;

d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Article 12. Subject-Matter Protected by a Short-Term Patent for Invention

(1) A short-term patent for invention shall be granted for any invention which is new, involves an inventive step and is susceptible of industrial application.

(2) An invention shall be considered as involving an inventive step within the meaning of paragraph (1) if it gives a technical or practical advantage.

(3) Additionally to Article 7, short-term patents for invention shall not be granted in respect of inventions concerning:

a) biological material;

b) chemical or pharmaceutical substances and/or processes.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

According to the Art.20 of the Law 50/2008 on the protection of inventions

(1) A patent shall confer on its owner an exclusive right to exploit the invention for the entire term thereof.

(2) The patent shall confer on its owner, in accordance with paragraph (1), the right to prevent third parties from performing, without his authorization, on the territory of the Republic of Moldova, the following acts:

a) manufacture, offering for sale, selling, use, importing or stocking for these purposes of the protected product;

b) the using of a process which is the subject-matter of the patent or, where the third party knows, or it is obvious in the circumstances, that the process cannot be used without the consent of the patent owner, offering of the process for use;

c) offering for sale, selling, use, importing or stocking for such purposes of the product obtained directly by a process which is the subject-matter of the patent.

According to the Article 21 "Prohibition of Indirect Exploitation of an Invention" of the Law 50/2008 on the protection of inventions

(1) A patent shall confer on its owner, in addition to the right conferred in accordance with Article 20, the right to prevent third parties not having his consent from supplying or offering to supply, on the territory of the Republic of Moldova, a person, other than a party entitled to exploit the patented invention, with means relating to an essential element of that invention, for carrying out the invention, when the third party knows, or it is obvious in the circumstances, that those means are suitable and intended for carrying out that invention.

(2) The provisions of paragraph (1) above shall not apply when the supplied or offered means are staple commercial products, except when the supplier or offerer deliberately incites his client to commit the acts prohibited by Article 20 paragraph (2).

(3) Persons performing acts referred to in Article 22 paragraph (1) letter a) and b) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph (1) above.

According to the Art.19 of the Law 50/2008 on the protection of inventions

(1) A patent application shall, from the date of its publication and up to grant of the patent, provisionally confer upon the applicant the protection provided for by Article 20 paragraph (2).

(2) Any natural or legal person who exploits the invention during the period referred to in paragraph (1) above shall be required, after grant of a patent, to pay a reasonable monetary compensation to the owner. The amount of such compensation shall be determined by agreement between the parties, taking account of the good faith of the person who exploited the invention, or by the court, where it cannot be determined by amicable arrangement.

(3) The effects of the patent application referred to in paragraph (1) shall be considered to be null and void when the patent application has been withdrawn by the applicant and when it has been withdrawn or refused in accordance with the provisions of this Law.

(4) The above provisions shall not apply to short-term patents.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art. 22 of the Law 50/2008 on the protection of inventions

(1) The rights conferred by a patent shall not extend to:

a) acts done privately and on a non-commercial scale;

(2) The use referred to in paragraph (1) above shall be allowed, provided that it does not unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In the contrary case, the patent owner is entitled to an adequate compensation for the injury suffered because of the unauthorized exploitation of the invention.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

Do not restrict the private and non-commercial use of inventions in order to contribute to the dissemination of the patent information

The public policy objectives for providing the exception is to:

- 1. Promote research;*
- 2. Avoid abuse of rights in cases of non-commercial (private) use;*
- 3. Contribute to the dissemination of the patent information;*

4. *Provide a mechanism to use a patented invention in case that it is not utilized by the owner and the late refuses to grant a license;*
5. *Provide a mechanism to use a patented invention in force majeure situation which endanger public security and/or health.*

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

No applicable law defines the concepts “non-commercial”, “commercial” and/or “private” and there are no court decisions regarding this issue. However, in the case that national legislation does not contain certain provisions, general principles contained in international treaties will be applied. In that way, in ruling such a case a court would conduct itself by provisions of the TRIPS Agreement and Paris Convention for industrial property protection.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

No other criteria are provided in the applicable law. In the absence of such provisions, court will take into consideration any other acceptable legal sources in order to decide on a case regarding exceptions and limitations

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments are foreseen.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges have been encountered as far as we know

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art. 22 of the Law 50/2008 on the protection of inventions

(1) The rights conferred by a patent shall not extend to:

b) acts done for experimental purposes relating to the subject-matter of the patented invention;

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

Do not restrict scientists and researchers in using inventions in order to conduct researches and contribute to the dissemination of the patent information

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The applicable law does not make a distinction between persons conducting experimentation or research

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

No applicable law defines the concepts “experimental use” and/or “scientific research” and there are no court decisions regarding this issue. However, in the case that national legislation does not contain certain provisions, general principles contained in international treaties will be applied. In that way, in ruling such a case a court would conduct itself by provisions of the TRIPS Agreement and Paris Convention for industrial property protection

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

Other, please specify: any actions which can be viewed as experimentation or research

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

*Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
Research and/or experimentation must be conducted with or relating to the patented invention (“research with”)*

Please explain by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

Applicable law does not contain definitions of those terms, as it is considered unnecessary in the case of commonly accepted meaning of a term.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments of the law are foreseen.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art. 22 of the Law 50/2008 on the protection of inventions:

(1) The rights conferred by a patent shall not extend to:

c) extemporaneous preparation once-only, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

Do not restrict the use of medicine in individual cases in order to improve access to medicines.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

The pharmacists are entitled to use the exception.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

It must be an extemporaneous once-only preparation, in a pharmacy.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

At the moment the applicable legal framework of the exception is considered adequate. No amendments to the law are foreseen.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges or court cases were registered in relation to the practical use of this exception.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Art. 25 of the Law 50/2008 on the protection of inventions:

(1) Any person who in good faith, before the filing date, or, where priority is claimed, the priority date of the application on which the patent is granted and within the territory of the Republic of Moldova was using the invention or was making effective and serious preparations for such use, shall be personally entitled, for the purposes of his enterprise or business, to continue such use or to use the invention within the limits and/or extent envisaged in such preparations, without having to pay a royalty and on condition that he does not extend the volume of production existent or planned at the day of filing or of the priority.

(2) The right of prior user referred to in paragraph (1) may only be transferred during the user's lifetime or by hereditary or testamentary succession together with his enterprise or business, or with that part of his enterprise or business in which the use or preparations for use have been made.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

The public policy objectives for providing the exception is to permit another person who independently developed the same invention as the invention protected by patent and started its use prior to filling date of the patented invention to continue its use in the same amount without paying royalty.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The applicable law defines the scope of “use” for it’s own enterprise/business. Also, the applicable law limits the use of the invention to the existing amount of production before the filling date or priority date or to the amount planned for which serious and real preparations were made.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No, it doesn’t.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

According to the Art. 25(2) of the Law 50/2008 on the protection of inventions the right of prior user may only be transferred during the user’s lifetime or by hereditary or testamentary succession together with his enterprise or business, or with that part of his enterprise or business in which the use or preparations for use have been made.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

According to the Art. 92(5) of the Law 50/2008 on the protection of inventions any person who has in good faith used or made effective and serious preparations for using an invention which is the subject of a published patent application or a patent in the period between the loss of any patent rights and publication of the mention of re-establishment of those rights, may without payment of any compensation and within the limits of the existing volumes continue such use in the course of his business or for the needs thereof.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

At the moment the applicable legal framework of the exception is considered adequate. No amendments to the law are foreseen.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art. 22 (1) d) e) of the Law 50/2008 on the protection of inventions:

(1) The rights conferred by a patent shall not extend to:

d) use of the subject-matter of a patented invention on board of any foreign vessel of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party which temporarily or accidentally enters the waters of the Republic of Moldova, provided that the invention is used exclusively for the needs of the vessel;

e) use of the subject-matter of the patented invention in the construction or operation of foreign aircraft or land vehicle or other means of transport of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party, or in the manufacture of spare parts for such vehicles when such means of transport temporarily or accidentally enter the territory of the Republic of Moldova.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

The public policy objective for providing the exception was to exclude patent infringement cases when means of transport temporarily or accidentally enter the territory of the Republic of Moldova. Another public policy objective was to harmonize national legislation with international treaties in the field of intellectual property.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Applicable law does not contain definitions of those terms, as it is considered unnecessary in the case of commonly accepted meaning of a term.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

According to the Art. 22 (1) d) e) of the Law 50/2008 on the protection of inventions the invention shall be used exclusively for the needs of the vessel;

According to the Art. 22 (2) of the Law 50/2008 on the protection of inventions the use shall be allowed, provided that it does not unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In the contrary case, the patent owner is entitled to an adequate compensation for the injury suffered because of the unauthorized exploitation of the invention.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

At the moment the applicable legal framework of the exception is considered adequate. No amendments to the law are foreseen.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of the Republic of Moldova does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

Article 23. Exhaustion of Rights

(1) The rights conferred by a patent shall not extend to acts concerning the patented product insofar as such acts are performed on the territory of the Republic of Moldova, after that product has been so put on the market in the Republic of Moldova by the patent owner or with his express consent.

(2) The protection referred to in Article 24 paragraphs (5) - (7) shall not extend to biological material obtained by propagation or multiplication of a biological material put on the market or offered for sale on the territory of the Republic of Moldova by the patent owner or with his consent, when the multiplication or propagation necessarily results from the use for which the biological material has been so put on the market, provided that the material obtained is not subsequently used for other propagation or multiplication.

(3) By way of derogation from Article 24 paragraphs (5) – (7), the sale or other form of commercialization of the plant propagating material to a farmer by the owner of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.

(4) By way of derogation from Article 24 paragraphs (5) – (7), the sale or other form of commercialization of breeding stock or other animal reproductive material to a farmer by the owner of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose, with the exception of breeding holdings; this includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

Do not restrict the use of inventions that are on the market in order to contribute to the dissemination of the information about patented product.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 28. Compulsory License

(1) If after the expiration of a period of 4 years from the day of filing of the patent application or 3 years from the grant of the patent, whichever is later, the patent owner has not exploited the patent in the territory of the Republic of Moldova or if he has not undertaken serious and effective preparations for such purpose, the courts may grant a compulsory license, on request, to any interested person. No distinction shall be made between the domestic products or imported products for the purposes of establishing the fact of the lack of exploitation or insufficient exploitation of the patent.

(2) A compulsory license shall be granted solely where the proposed user has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived in the cases referred to in paragraph (3) below. In such cases, the patent owner shall be notified as soon as reasonable practicable.

(3) A compulsory license may be granted in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

(4) In the case of semiconductor technology, a compulsory license may only be granted for public non-commercial use or to remedy a practice, determined after judicial or administrative process to be anti-competitive.

(5) A compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

(6) The respective methods and procedures for the implementation of principles contained in this article are laid down in the Regulations.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

1. Unblock the use of an invention in case that there's real and reasonable interest from third parties to use the invention, and the patent holder groundlessly refuses to grant a license and doesn't use the invention himself.

2. Public interest in case of national emergency or other circumstances of extreme urgency, especially cases concerning public health.

3. Cross license in cases of dependent patents directly linked to obtain a better technical result

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69.-70.

[Note from the Secretariat: response was not provided.]

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

After the expiration of a period of 4 years from the day of filing of the patent application or 3 years from the grant of the patent, whichever is later.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

No

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

According to the Art. 28(4) of the Law 50/2008 on the protection of inventions, in the case of semiconductor technology, a compulsory license may only be granted for public non-commercial use or to remedy a practice, determined after judicial or administrative process to be anti-competitive.

According to the Art. 29(1) of the Law 50/2008 on the protection of inventions, at the time of grant of a compulsory license to exploit the patent under Article 28 above, the court shall specify the types of use covered by such license and the terms and conditions to be observed. The following conditions shall apply:

d) any such use shall be authorized predominantly for the supply of the domestic market, except where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive;

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

According to the Art. 28 of the Law 50/2008 on the protection of inventions a compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

According to the Art. 29 of the Law 50/2008 on the protection of inventions the license holder shall pay the patent owner an adequate remuneration, taking into account the economic value of the authorization and, eventually, the need to remedy an anti-competitive practice.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

According to the Art.1(2) of the Law 93/2007 on Civil Protection Service and Extreme Situations, extreme situation is defined as interruption of normal life and activity of the population at an objective or in a region as a result of accidents, disasters, natural or socio-biological calamities which resulted or could result with human and economic losses.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Compulsory licenses have never been issued in our country.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

At the moment legal framework for the issuance of compulsory licenses is considered adequate to meet the objectives sought. However, in the light of the new TRIPS provisions (art.31bis) will be necessary to amend national legislation in order to meet new TRIPS standards laid down in art.31bis

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

There aren't separate provisions on Government use. However, compulsory license can be issued including to the government.

82.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art. 23(3) of the Law 50/2008 on the protection of inventions, the sale or other form of commercialization of the plant propagating material to a farmer by the owner of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

Do not restrict the use of inventions by farmers

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

92.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

According to the Art. 23(2) of the Law 50/2008 on the protection of inventions, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material obtained by propagation or multiplication of a biological material put on the market or offered for sale on the territory of the Republic of Moldova by the patent owner or with his consent, when the multiplication or propagation necessarily results from the use for which the biological material has been so put on the market, provided that the material obtained is not subsequently used for other propagation or multiplication.

According to the Art. 28(5) of the Law 50/2008 on the protection of inventions, a compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

Do not restrict the use of inventions for breeding purposes.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

98.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Republic of Moldova does not provide other exceptions and limitations.]

Country: RUSSIAN FEDERATION
Office: Federal Service for Intellectual Property, Patents and Trademarks (ROSPATENT)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Specialist assessment methods are used to assess inventive solutions according to the following criteria: novelty (worldwide novelty of technical solution), inventive step, and industrial applicability. These requirements are enshrined in the Civil Code of the Russian Federation (hereinafter, 'the Code'). Irrespective of the legislative definition of the conditions of technical solutions' patentability, it must be noted that the starting point in identifying an inventive solution's patentability is its ability to be assigned to an actual technical solution.*

Article 1349(1) of the Code states that "subjects of patent rights are the results of intellectual activity in a scientific and technical area, which satisfy the requirements established by this Code for inventions and utility models".

Russian legislation provides for exceptions to patent rights. Thus, under Article 1349(4) of the Code, the following "may not be subjects of patent rights:

- (1) methods of human cloning;*
- (2) methods of modifying the genetic integrity of cells of a human being's embryonic line;*
- (3) using human embryos for industrial and commercial purposes;*
- (4) other solutions that are contrary to the public interest, principles of humanity and morality".*

Article 1350 of the Code contains the following wording:

"A technical solution shall be protected as an invention in any field relating to a product... or process... Legal protection shall be granted where it is new, involves an inventive step, and is industrially applicable".

As a result, any result of human intellectual activity to which a form of patent protection may be applied is defined as a "product or process".

Attention is drawn to the technical nature of the solutions which relate to inventions. The term "technical solution" is considered by specialists as a practical means of meeting specific human needs.

However, the legislator does not define "technical solution", and accordingly, no model "selection" of technical solutions is laid down from among a number of possibilities. The issue of assigning a claimed solution to a technical solution is resolved by identifying the problem and the technical result of the claimed invention.

Article 1350(5) of the Code contains a list of exceptions to patentable technical solutions, namely:

- “5. The following shall not be deemed inventions:*
- (1) discoveries;*
 - (2) scientific theories and mathematical methods;*
 - (3) solutions only involving the external appearance of manufactured articles and intended to satisfy aesthetic requirements;*
 - (4) rules and methods of games, and intellectual or business activity;*
 - (5) computer software;*
 - (6) solutions consisting solely of the presentation of information.*

In accordance with this Paragraph, these subjects shall not be deemed inventions only where the patent application for the invention concerns said subject matter per se.

- 6. Legal protection as an invention shall not be granted to:*
- (1) plant varieties, animal breeds and biological methods for the obtaining thereof, with the exception of microbiological methods and products obtained by means of such methods;*
 - (2) topographies of integrated circuits.”*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

In accordance with the provisions of Article 1358 of the Code:

“1. The exclusive right to use an invention... under Article 1229 of this Code by any legal means (exclusive right in an invention), including by the means provided for in Paragraphs 2 and 3 of this Article, shall belong to the patent holder. The patent holder may dispose of the exclusive right in an invention.

- 2. Use of the invention shall be specifically deemed to be:*
- (1) importing on to the territory of the Russian Federation, manufacture, use, offer for sale, sale, other form of introduction into civil circulation, or storage for such purposes of a product that incorporates the invention...;*
 - (2) performance of acts provided for by subparagraph 1 of this Paragraph in relation to a product obtained directly by a patented process. Where a product obtained by a patented process is new, an identical product shall be deemed to be derived using the patented process, unless proven otherwise;*
 - (3) performance of acts provided for by subparagraph 2 of this Paragraph in relation to a device, the functioning (use) of which, in accordance with its purpose, automatically involves a patented process;*
 - (4) implementing a process in which the invention is used, specifically by applying said process.*

3. An invention shall be deemed to be used in a product or process where the product contains, and the process involves, every feature of the invention stated in an independent claim of the claims for the invention contained in the patent, or a feature equivalent thereto that has become known as such in this art prior to performing the actions in respect of the relevant product or process specified under Paragraph 2 of this Article. Where the use of an invention likewise involves all the features stated in an independent claim of the claims contained in the patent of another invention, the other invention shall also be deemed used.

Article 1392 of the Code provides for provisional legal protection of an invention, namely:

“1. An invention for which an application has been filed with the federal executive authority for intellectual property (Rospatent) shall enjoy provisional legal protection within the scope of the published claims of the invention, but not more than within the scope determined by the claims contained in the decision of said federal authority on the grant of a patent for the invention, from the date of publication of information on the application, until the date of publication of information on the grant of the patent (Article 1394).

2. Provisional legal protection shall be deemed not to have occurred where the invention application was withdrawn or recognized as withdrawn, or, with respect to the invention application, a decision on refusal to grant a patent has been taken, and the opportunity to file an appeal against this decision, as provided for by the Code, has been exhausted.

3. Any person using the claimed invention during the period specified in Paragraph 1 of this Article shall pay remuneration to the patent holder, after the grant of a patent thereto. The amount of remuneration shall be determined by agreement between the parties, or, in the event of a dispute, by a court.”

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI “Other Exceptions”.

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

*In general, the overall premise of introducing limitations of an exclusive right is “to ensure a balance between the patent holder’s monopoly rights and the legal interests of others.”
This concerns so-called cases of free use of a patented solution, which means non-contractual use, i.e. the patent holder’s consent is not required.*

It should be noted that no cases of non-contractual use shall apply to counterfeit goods, since such actions always constitute an infringement of the patent holder’s exclusive right.

The exceptions listed significantly limit the scope of the patent holder’s exclusive right. This is done primarily to facilitate the country’s scientific and technical progress, to address a range of social issues, and to fulfill the State’s international legal obligations.

Furthermore, it should be clarified that Article 10 of the Code, which defines the limits of civil rights, establishes the provisions underlying the exceptions and restrictions that limit a patent

monopoly. In accordance with that Article, in exercising civil rights the following are prohibited:

- actions undertaken with the sole purpose of causing harm to another person, as well as misuse of rights in other forms;
- exercising civil rights for the purpose of restricting competition, as well as abuse of a dominant market position.

In general, the limits of exercising civil rights are associated with reasonable actions performed in good faith by citizens and legal entities which are presumed by law.

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

According to Article 1359(4) of the Code, "use of the invention for personal, family, domestic or other non-business needs shall not infringe the exclusive right in an invention where the purpose of such use is not to generate profit or income."

In this case, use is meant in a broad sense, but not, however, for the purpose of generating profit or income. Using the subject matter of others' patent rights is possible, mainly where a person directly manufactures a product containing the patented solution (with his own hands, or to order).

In addition, it is irrelevant as to whether the product is manufactured as a result of parallel, independent creative work, or using other people's ideas (including directly using patent application materials). It should be recognized that "importation into the territory of the Russian Federation" is also subject to the product's free use by a person intending to use the product for private purposes. It seems, moreover, that personal use must be presumed. The use of a patented process as a "process for implementing actions" is permitted in all cases.

The case under consideration relates to citizens, but is perhaps also applicable to legal entities. Moreover, by analogy with Paragraph 5 of the Resolution of the Plenum of the Supreme Arbitration Court of the Russian Federation of October 22, 1997, No. 18, "On Certain Issues Related to the Application of the Provisions of the Civil Code of the Russian Federation on the Supply Contract", it should be recognized that "under purposes unrelated to personal use, the intended use of the product or process must be understood in order to safeguard the organization or citizen-entrepreneur's business (office equipment, office furniture, vehicles, etc.). Accordingly, for a legal entity, applying a patented solution to the clearing of snow inside a plant for the passage of employees could, in particular, be considered personal use. But damp cleaning of floors in a shopping center, for instance, should be deemed as safeguarding business activity.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The Russian Federation uses a statute-based system of civil law (Continental or Romano-Germanic), and in this regard Russia has no case law.

6. (a) What are the public policy objectives for providing the exception?
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

*The need to establish limitations on the patent monopoly, otherwise known as **cases of free use** of patented subject matter, has principally been dictated by the needs of society which,*

under certain circumstances, has an interest in the unfettered access of their members and business associations to the protected results of creative activity.

*The fundamental principles underlying the limitations are the **principle of unimpaired moral rights** of authors of technical and design innovations, and the **principle of the non-exclusive nature of free use**.*

Exceptions to the patent monopoly prescribed by the legislator are defined exhaustively.

Where the purpose of using the invention is not to generate income, and such use does not involve business activity, members of the public have an interest in unfettered access to the protected results of intellectual activity.

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

Civil legislation of the Russian Federation defines the concept of “business activity”, which is comparable to the concept of “commercial activity”.

Thus, Article 2(1) of the Code provides that “business activity shall be an independent activity conducted at one’s own risk, aimed at systematically deriving profit from the use of property, sale of goods, performance of work or rendering of services by persons registered in this capacity in the prescribed legal process”.

Based on the definition of “commercial use”, “commercial purposes” means use of a technical solution for deriving profit, while “non-commercial” means using the invention for other purposes (personal, socially beneficial, including in emergencies). For instance, “use of an invention in an emergency (natural disasters, calamities, accidents), provided that the patent holder is notified of such use as soon as possible, and is subsequently compensated reasonably” (Article 1359(3) of the Code).

Cases of “private” use are stated in Article 1359(4) of the Code, namely “use of an invention for private, family, domestic, or other needs unrelated to business activity, where the purpose of such use is not to derive profit or revenue.”

The term “private use” has not been enshrined in legislation, although it means an individual citizen’s personal use.

Thus, current Russian legislation does not treat use for needs unrelated to business activity and the generation of profit or revenue as an infringement of exclusive rights in an invention.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

Not applicable.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. The legal framework is considered adequate to meet the objectives sought.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Under Article 1359(2) of the Code, “conducting scientific research on a product or process incorporating an invention, or the conduct of an experiment on such a product or process, shall not constitute an infringement of the exclusive right in an invention.”

*Thus, in the Russian Federation, the application of this exception to the patent monopoly is limited only by **conducting** scientific research or experiments on the patented tool (in order to test it, and assess its effectiveness for scientific purposes, etc.) Development in this area should be the subject of research, and not a means thereof.*

The Russian legislator does not treat scientific research on a product or process in which patented inventions are involved as an infringement of the patent holder’s exclusive right. The presence in the Code of such laws appears totally reasonable, in particular taking into account that any person, prior to taking a decision on the expediency of requesting the patent holder to alienate a patent, or to conclude a license agreement, should have the opportunity to satisfy himself that the relevant subject matter possesses the characteristics in which he is interested.

*However, attention must be drawn to the fact that this only refers to an experiment or scientific research conducted in relation to the patented product or process **itself**, and not to an experiment or scientific research conducted with their application, for instance in measuring instruments or in other equipment facilitating the performance of an experiment or scientific research.*

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The Russian Federation uses a statute-based system of civil law (Continental or Romano-Germanic), and in this regard Russia has no case law.

13. (a) What are the public policy objectives for providing the exception?
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

The provision of this exception is founded on the need to provide a person potentially wishing to acquire rights in an invention with an opportunity to assure himself that the relevant subject matter possesses the characteristics in which he is interested.

Attention should be drawn to the Opinion of the Constitutional Court of the Russian Federation, which is directly related to issue examined above.*

*The complaint disputed the constitutionality of Article 11(3) of the Patent Law of the Russian Federation of September 23, 1992, No. 3517-1**, whereby performing scientific research or experiments on a tool containing a patent-protected invention is not recognized as an infringement of the patent holder’s exclusive right. In the applicant’s opinion, the practice of courts of general jurisdiction- to the extent that persons conducting scientific experiments or research on a product containing an invention, are permitted to derive profit (revenue)- contravenes Article 44 (Part 1) of the Constitution of the Russian Federation on the protection of intellectual property by law. The Constitutional Court of the Russian Federation failed to find grounds for accepting the complaint, and stated that the provision of Article 11(3), in conjunction with Article 10 of the Patent Law of the Russian Federation (as amended in 1992), could not be considered to infringe the applicant’s constitutional right to protection of his intellectual property by law, since **“it (the limitation) has been established***

in order to safeguard the balance of interests of all persons for whom freedom of scientific and technical creativity has been guaranteed, and does not presuppose the introduction of the patented solution”.

In other words, the disputed provision does not assume that the patent-protected invention will be marketed while a scientific experiment is carried out by third parties on a product incorporating the invention.

Opinion of the Constitutional Court of the Russian Federation of October 16, 2003, No. 389-O, “On refusal to accept a complaint by Vladimir Filippovich Starokozhev regarding infringement of his constitutional rights by Article 11(3) of the Patent Law of the Russian Federation”.

*** Repealed, due to the enactment of Part IV of the Civil Code of the Russian Federation on January 1, 2008.*

Taking into account the similarity of the contents of Article 11 of the Patent Law of the Russian Federation, as examined, with the contents of the current provision under Article 1359(2) of the Code, there can be no real doubt as to the Constitutional Court’s motivation at present.

The experimenter or researcher is not permitted to apply the patented product or process.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No requirements regarding the status of the person conducting the experimentation or research are laid down in Russian legislation.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

Under Russian legislation, third parties may only study the patented subject matter, and not use it as a means of conducting research, without infringing the exclusive right of the patent holder.

With regard to such concepts as “scientific research”, “scientific experiment”, etc., these are important for defining the boundaries of a specific exception’s effect beyond the scope of the patent right.

Thus, Article 2 of Federal Law No. 127-FZ of August 23, 1996, “On Science and State Science and Technology Policy”, defines the following:

*- **scientific (research) activity**- activity aimed at obtaining and applying new knowledge, including:*

****fundamental scientific research**- experimental or theoretical activity, aimed at obtaining new knowledge on fundamental laws governing the structure, functioning, and development of man, society, and the environment;*

****applied scientific research**- research aimed primarily at the application of new knowledge to achieve practical goals and to resolve specific issues.*

*- **scientific and technical activity**- activity aimed at obtaining and applying new knowledge in order to resolve technological, engineering, economic, social, humanitarian, and other issues, and to ensure the functioning of science, technology, and production as a single system.*

*- **experimental design**- activity based on knowledge acquired as a result of conducting scientific research or derived from practical experience, and aimed at preserving life and human health, creating new materials, products, processes, devices, services, systems or methods, and developing them further.*

The Federal Law mentioned above does not give a legal definition of the concept “scientific experiment”. At the same time, a scientific experiment is taken to mean a method of learning which can help in investigating real phenomena under controlled and managed conditions.

Limiting the patent holder’s exclusive rights when conducting scientific research is therefore governed by prioritizing public above personal interests. The distinction between scientific research and experimentation is that with research, study is undertaken of the subject matter in its pure form (without any additional influence thereon), whereas with experimentation, the subject being studied is placed under certain conditions, i.e. subjected to a certain influence from external forces.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Article 1359 of the Code does not indicate the purpose of the experimentation and/ or research.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

- Please explain by citing legal provision(s) and/or decision(s):

Under Article 1359 of the Code, conducting scientific research on a product or process which incorporates the invention, or conducting experimentation on said product or process, does not constitute an infringement of the exclusive right in an invention.

Conducting experimentation on a product in which an invention is incorporated (similar to conducting scientific research on a product in which a patented invention is incorporated) involves two situations.

Situation No. 1- where experimentation is conducted on such a product in which an invention is incorporated (for instance, a fuselage has been patented, but experimentation is conducted on the aeroplane in which the fuselage is incorporated; or a chemical compound has been patented, but experimentation is carried out on the foodstuff or medicine containing said compound).

Situation No. 2- where experimentation is conducted directly on the invention itself, since it also falls under the definition of a product in which every feature of the patented invention is incorporated (in the example above, in this situation the experimentation would be conducted directly on the chemical compound itself).

Accordingly, the first criterion, “Research and/or experimentation must be conducted on the patented invention”, is relevant to the determination of the scope of the exception.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

Russian legislation contains no special provisions relating to the intention of the experimentation and research.

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

Russian legislation contains no special provisions relating to the purpose of the experimentation and research.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. The legal framework is considered adequate to meet the objectives sought.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Not applicable.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

According to Article 1359(5) of the Code, “one-off preparation in pharmacies based on physicians’ prescriptions of medicines using the invention... shall not constitute an infringement of the exclusive right in an invention.”

It is assumed that preparation of medicine for subsequent storage and sale may not be considered a single use; therefore, preparation of a similar medicine for future use may be regarded as an infringement of the patent holder’s exclusive rights.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The Russian Federation uses a statute-based system of civil law (Continental or Romano-Germanic), and in this regard Russia has no case law.

25. (a) What are the public policy objectives for providing the exception? Please explain:
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

This rule concerns cases of use of inventions in the interests of the health of people and animals. These cases can take place in extreme situations when it is necessary to administer urgent medical help.

It should be noted that one-off preparation of medicine may be considered only in the amount specified in the prescription. Current regulation in Russian legislation of cases of free use of a patented drug or preparation process is excessively detailed: on the one hand, the essential features of preparation of a medicine according to a prescription assumes one-off

preparation, while on the other hand, the number of preparations of new doses of medicine for one prescription may be very high.

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Medicines are always prepared either from a specific substance, or by a specific process, owing to which such technical solutions may only be inventions (see Part 1 of Article 1350(1) of the Code). In other words, medicines are patented under Russian legislation, but benefits are granted to the patent holder for extending the exclusive right's term of validity (see Article 1363(2) of the Code).

The large number of persons involved in this case warrants attention: for instance, the physician who writes the prescription, the dispensing chemist who prepares the medicine at the pharmacy, and the person for whom the medicine is prepared. In this case, there is no need to highlight the fact that for free use of the medicine, little is prepared, and it is still necessary to sell it, i.e. market it. However, there is no commercial transaction in this case: the medicine is prepared for a fee, but at the behest of the person presenting the prescription, i.e. there is a supply contract. Accordingly, this process does not pre-suppose marketing of the prepared medicine (sale by the customer of the prepared medicine would constitute an infringement of the exclusive right). It should be noted that the physician is not restricted by the number of prescriptions that he may write for the same medicine to many patients.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

This case refers to "one-off preparation in pharmacies based on physicians' prescriptions of medicines incorporating the invention" (Article 1359(5) of the Code).

However, one-off preparation in pharmacies based on physicians' prescriptions of medicines is pointless if it is not accompanied by permission to sell them to patients. At the same time, such preparation of medicines should be genuinely one-off and not develop into preparation of inventories of said medicines for future sale, which in the context of large cities, could harm the patent holder's economic interests appreciably.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. The legal framework is considered adequate to meet the objectives sought.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Not applicable.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 1361 of the Code provides that:

“Any person who, before the priority date of an invention, was using in good faith within the territory of the Russian Federation an identical solution created independently from the author, or made the necessary preparations for such use shall have the right to proceed with that use free of charge provided that the scope thereof is not extended (the right of prior use).”

*In this case, the prior user’s actions shall not constitute an infringement of the patent holder’s rights, since “the right of prior use relates to conditions excluding responsibility for use of patented subject matter.”**

Prior use is qualified as a case of free (i.e. free of charge) use of a simultaneously created (i.e. his own, not that of others) invention. Therefore, the right of prior use is a subjective civil right with unique characteristics within the territory of Russia.

Independence is demonstrated through the independent nature of the prior user’s creativity: meaning that the solution had not been developed on the basis of descriptions and drawings of the person who obtained the patent.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The Russian Federation uses a statute-based system of civil law (Continental or Romano-Germanic), and in this regard Russia has no case law.

33. (a) What are the public policy objectives for providing the exception? Please explain:
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

Article 4 of the Paris Convention for the Protection of Industrial Property implies that when a convention application is filed, the right of prior use arises where a third party had started using the invention prior to the filing of the initial application. In addition, use of the invention, which took place between the filing of the initial application and the filing of the convention application, does not constitute a reason for the right of prior use to commence. Under said Article, rights acquired by third parties before the filing date of the first application that serves as the basis for the right of priority are reserved in accordance with the domestic legislation of each State party to the Convention.

** Paragraph 11 of the Resolution of the Plenum of the Supreme Court of the Russian Federation of April 26, 2007, No. 14, “On the practice for the examination by courts of criminal cases relating to the infringement of copyright and related rights, an inventor’s and patent rights, and also on the unlawful use of a trademark”.*

The classical meaning of prior use is to incentivize parallel creativity of persons who, for one reason or another, were unable to patent the results of their technical work at the appropriate time. Thus, a person possessing the right of prior use is the first inventor who for some reason was unable, or did not wish, to patent the invention. The right of prior use is intended to protect the interests of third parties that have already invested capital in production.

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The legislation of the Russian Federation does not contain any conditions pertaining to the scope of “use” of an invention within the framework of the right of prior use. The general concept of “use” of an invention is defined in Article 1358(2) of the Code, and more precisely, specific ways of using patented subject matter are listed therein. Thus, “use” of an invention is considered specifically to be:

- “(1) importing on to the territory of the Russian Federation, manufacture, use, offer for sale, sale, other form of introduction into civil circulation, or storage for such purposes, of a product that incorporates the invention;*
- (2) performance of acts provided for by subparagraph 1 of this Paragraph in relation to a product obtained directly by a patented process. Where a product obtained by a patented process is new, an identical product shall be deemed to be derived using the patented process, unless proven otherwise;*
- (3) performance of acts provided for by subparagraph 2 of this Paragraph in relation to a device, the functioning (use) of which in accordance with its purpose automatically involves a patented process;*
- (4) implementing a process in which the invention is used, in particular by applying said process.*

An invention shall be deemed to be used in a product or process where the product contains, and the process involves every feature of the invention stated in an independent claim of the claims for the invention contained in the patent, or a feature equivalent thereto that has become known as such in this art prior to performance in respect of the relevant product or process of the actions specified above.

Where the use of an invention likewise involves all the features stated in an independent claim of the claims contained in the patent of another invention, the other invention shall also be deemed used.

Use of an invention is permitted during the term of patent validity only if the scope does not exceed that achieved before the priority date, or, where use had not commenced before that date, if the scope does not exceed the level corresponding to applicable preparations. Therefore, if the prior user broadened the scope of use after the priority date, the patent holder is entitled to prohibit him from doing so, and the prior user may reserve such scope or broaden it further only with the patent holder’s permission, specifically by means of a license agreement.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No, free-of-charge use of an identical technical solution is provided for under the conditions stated in Article 1361 of the Code.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

The holder of the right of prior use is not entitled to obtain a license to use the invention, as the right of prior use occurs under conditions specified in Article 1361 of the Code.

A similar decision is also contained in a court decision, namely, "The right of prior use arises not as a result of a court decision, but under the conditions specified in Article 12 of the Patent Law of the Russian Federation". (These are currently the provisions of Article 1361 of the Code).*

At the same time, Russian legislation makes it possible to transfer the right of prior use to a third party. Thus, Article 1361(2) of the Code prescribes a method for transferring the right of prior use to another person:

"The right of prior use may only be transferred to another person together with the enterprise at which use of the identical solution took place, or the necessary preparations for such use had been made."

The above means that the right of prior use comprising part of the enterprise is not permitted; a transaction is necessary in respect of the enterprise as a whole, and equally, neither is a transfer of said right permitted which is independent and distinct from this enterprise. In addition, it is possible the term "transferred" in the wording of the provision that "the right of prior use may be transferred to another person", has a narrow interpretation; for instance, on transferring the right of prior use within the framework of a sale contract for the enterprise (Article 559 of the Code), i.e. surrender of the right of prior use is only permitted together with the enterprise as a whole. However, the legislator apparently had a broad interpretation of this term in mind, including transfer of the right of prior use, and under an enterprise lease contract (Article 656 of the Code), and also cases of the right of prior use passing to others without a contract (inheritance, reorganization of legal entity, and foreclosure of the patent holder's property).

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The provisions of Article 1361 of the Code establish said conditions.

In addition, the following circumstances constitute the pre-conditions of the right of prior use:

- firstly, evidence of use of, or preparations to use, a technical solution;*
- secondly, use must take place within the territory of the Russian Federation, and preparations to use within the territory of the Russian Federation, or outside its territorial borders;*
- thirdly, the technical solution being used, or for which preparations are being made to use, must have been created independently of the author of the protected solution;*
- fourthly, the technical solution being used, or for which preparations are being made to use, must be identical to the protected solution;*
- fifthly, evidence of use or preparations to use must take place before the priority date of the claimed protected solution;*

** Paragraph 8 of the Review of the Practice of Examination by Courts of Arbitration of Cases Involving the Use of Intellectual Property Law, as ratified by the Information Letter of the Presidium of the Supreme Court of Arbitration of the Russian Federation of December 13, 2007, No. 122.*

- sixthly, any use must be bona fide, i.e. the person who used the technical solution neither knew, nor should have known, about the essential features of the claimed protected solution. These circumstances can arise and develop, as a rule, with the parallel development of the same scientific or technical problems by different organizations or inventors. In addition, according to the meaning of Article 1361(1) of the Code, a person*

vested by Law with the right of prior use, and the author of the technical solution being used, may be different persons.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Under Article 1400 of the Code, any person who, during the period between the expiry of the patent for the invention, utility model, or industrial design, and the date of publication in the Official Gazette of the federal executive authority for intellectual property of information on the restoration of the patent, began using the invention, or made preparations necessary for this within the specified time limit, shall retain the right to its future use free of charge provided that the scope of such use is not expanded (right of subsequent use).

The right of subsequent use involves free (i.e. without a license) use of the invention by the subsequent user after the restoration of the patent monopoly without the threat of accountability for infringement of another person's patent.

Subsequent use is essentially one of the types of limitation of the patent monopoly, along with the right of prior use, for example. However, it is the legislator's intention that the right of subsequent use should differ from the right of prior use in terms of scope, since, unlike the right of prior use, it may not be transferred to another person together with an enterprise.

The right of subsequent use is granted with a number of conditions:

- *use of the inventions began when preparations to that end had been undertaken during the period when the relevant subject matter was in the public domain (between the patent expiry date and its restoration);*
- *the scope of use of the invention for which patent protection has been reinstated must not be extended by the subsequent user.*

The provision on the right of subsequent use has been introduced in order to preserve the balance of interests of patent holders and third parties. The three-year period prescribed for the restoration of the patent is sufficient so that in some cases the third party can begin using the patented invention or do everything necessary to that end after the patent expiry date (i.e. on a legal basis). Obviously, in the case of restoration of the patent, said party must not have infringed it. The right of subsequent use is also intended to protect the interests of third parties.

The essential features of the right of subsequent use consists of the fact that a person who has used, or who has made necessary preparations to use, a protected technical solution after a temporary and premature annulment of the patent monopoly, retains the right of future use of said solution and after restoration of the monopoly.

The right of subsequent use was introduced into Russian patent legislation relatively recently. Said right came into legal existence in the amended Patent Law of the Russian Federation of February 7, 2003 (repealed). The regulation on the right of subsequent use has been enshrined, virtually unchanged, in Article 1400 of the Code.

The assumptions underpinning the right of subsequent use are as follows:

- *use of an invention, the validity of the patent for which was prematurely terminated because of non-payment of the maintenance fee for the document providing protection in due time may be reinstated, or necessary preparations to that end;*

- *use or preparations to that end took place between the date of premature termination of the patent because of non-payment of the fee (from the date of expiry of the prescribed time limit for payment of the patent maintenance fee) and the date of publication of information regarding the patent's restoration;*
- *termination of the patent was premature and was caused by non-payment of the maintenance fee of the patent for the invention within the prescribed time limit.*

The substance of the right of subsequent use is the legally guaranteed ability of any person to use a technical solution unlicensed and free of charge from the moment of premature termination of the patent. A condition of implementing the right of subsequent use is the requirement not to extend the scope of use compared with that in the period between the expiry of the patent and the date of publication regarding the patent's restoration.

In contrast with the right of prior use, the transfer of which is possible under certain conditions (see Article 1361 of the Code), the right of subsequent use has been excluded from civil circulation, at least in relation to its alienation, combined with production. It is assumed, however, that the right of subsequent use may pass in the order of succession, for instance, in the case of reorganization of a subsequent user-organization.

Another difference in the right of subsequent use from the right of prior use is the situation where the prior user works "his own" technical solution, created independently from the patent holder, at the same time as the subsequent user works "someone else's" innovation, i.e. not created by him.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Not applicable.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. The legal framework is considered adequate to meet the objectives sought.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

In considering the expediency of challenging the right of prior use in court, the right holder should bear in mind that if use preceding the priority date by its nature was such that it could lead to information on the patented solution being made public, then that may constitute a reason for recognizing the patent as invalid on the grounds of the solution's non-compliance with the condition of novelty.

Any applicant filing an application after public disclosure of information on an invention, and focusing on the benefit granted to him under the provisions regarding the grace period (Article 1350(3) of the Code - lasting six months from the date of disclosure of the essential features of the invention by the author), must bear in mind the possibility of other persons implementing the invention on the basis of that information, and the practical difficulties involved with proving that said persons could not have been related to the prior user.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Under Article 1359 of the Code, "Use of a product incorporating the invention in the structure, in auxiliary equipment, or in operating vehicles (river and marine, air, automobile, and railway transport) or spacecraft of foreign States provided that such vehicles or spacecraft are located within the territory of the Russian Federation, temporarily or accidentally, and that the aforesaid product or device is used solely for the needs of vehicles or spacecraft... shall not constitute an infringement of the exclusive right in an invention. Such an act shall not be recognized as an act of infringement of the exclusive right with respect to vehicles or spacecraft of those foreign States that grant similar rights with respect to vehicles and spacecraft registered in the Russian Federation."

Auxiliary equipment means equipment which facilitates the operation of the vehicle or spacecraft, but is not a constituent part thereof. For instance, for a car, a pump serves as such equipment.

The provisions of Article 1359 of the Code amend the territorial principle of the exclusive right's validity: if a solution used in a vehicle has only been patented in Russia, then foreign countries are not bound by said patent- in such countries, use of the solution is free. Accordingly, then, "importation" of these vehicles into Russia is classified as an infringement of the Russian patent holder's exclusive right (see Article 1358(2)(1) of the Code). Thus, the following limitations typify contemporary regulation. Firstly, patented subject matter is required to be used exclusively for the vehicle's or spacecraft's needs. Secondly, the case examined of free use is to be applied reciprocally between States. So, for instance, under Articles 15 and 16 of the Federal Law of August 20, 1993, No. 5663-1, "On Space Activity" (Amended and Updated), spacecraft (on condition of State registration of rights therein) may be used by the owner thereof, or by a person to whom rights to use (work) the spacecraft have been granted by the owner, or a person authorized by the owner, under due legal process, and the results of intellectual activity obtained in developing the spacecraft and space technologies are legally protected, and also exclusive rights in the intellectual property subject matter are likewise enjoyed, under the process stipulated by the Civil Code of the Russian Federation, and by other intellectual property laws of the Russian Federation.

In sum, the general principles in applying the limitation of patent rights considered have been set out in Article 5-ter of the Paris Convention for the Protection of Industrial Property (the Convention), which prescribes certain limitations of patent rights in the interests of freedom of transport. In international practice, these rules are applied in relation to other States' vessels, sailing under the flag of those States, and also air and land vehicles registered in other State parties to the Convention. Equally, the regulations concerning aircraft are subject to the provisions of the Convention on International Civil Aviation of 1944, which, in Article 17, provides that "aircraft have the nationality of the State in which they are registered."

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

The Russian Federation uses a statute-based system of civil law (Continental or Romano-Germanic), and in this regard Russia has no case law.

44. (a) What are the public policy objectives for providing the exception? Please explain:
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

As previously noted, the provisions contained in Article 1359(1) of the Code correspond to the contents of Article 5-ter of the Paris Convention on the Protection of Industrial Property.

An important condition is the exclusive use of a product or device which has been patented in the Russian Federation for the needs of vehicles or spacecraft. This exception is limited by the condition of reciprocity, i.e. by cases where similar rights are granted by the relevant foreign State in relation to vehicles or spacecraft registered in the Russian Federation.

Furthermore, it should be noted that the legislator's instructions on the exclusive use of the product or device for transportation requirements removes other cases of use of patented subject matter from the scope of this regulation, e.g. manufacture, sale, and storage thereof for the purposes of introduction into civil circulation.

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

The exception applies in relation to all listed subject matter.

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

*The specified terms are used in Article 1359 of the Code.
Thus, free use of patented subject matter in relation to foreign transportation means and spacecraft on the territory of the Russian Federation may be "temporary", i.e. in transit, or when transporting internationally, in tourism, etc. In other words, these are recurring visits. An accidental visit means a temporary situation caused by losing one's way or a natural disaster, which frequently results in an emergency landing of an aircraft, for instance.*

*Permission to cross the State border for Russian aircraft undertaking special international flights from airports or aerodromes closed to international flights, as well as foreign and Russian aircraft performing **emergency landings** in unspecified locations, is granted jointly by federal security service authorities of the Russian Federation and the administration of airports and aerodromes, or on the command of aviation units of the Armed Forces of the Russian Federation, with subsequent notification of the authorities of the Russian Federation concerned (Law of the Russian Federation "On the State Border of the Russian Federation", as amended, of February 7, 2011).*

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

*First of all, the product in which the invention is incorporated may be used **exclusively for the needs** of the vehicle or spacecraft.*

Actions such as production on board a vessel of any products or devices covered by the patent, for example, where such products and devices are not used for the needs of the vessel, and the production process itself may also be covered by the patent for the process, will be considered an infringement of exclusive rights. Similarly, free sale on board a vessel of products covered by the patent will be deemed an infringement, or use of the vessel as a floating hospital while temporarily moored in a port, on board which surgical operations are to be performed using surgical instruments for which patents are valid on the territory of said State.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Under Russian legislation, the use of a product which incorporates an invention shall not be considered an infringement of the exclusive right in relation to vehicles or spacecraft of those foreign States which grant the same rights in respect of vehicles or spacecraft registered in the Russian Federation.

In other words, these rules shall only be applied on a reciprocal basis, i.e. where similar rights are granted by the relevant foreign State in relation to vehicles registered in the Russian Federation.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. The legal framework is considered adequate to meet the objectives sought.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Owing to the fact that Russian airlines often lease aircraft belonging to companies from other States for freight and passenger transportation, a legal issue has arisen: do the regulations on temporary stationing of vehicles extend to leased aircraft, i.e. could the holder of a Russian patent sue for infringement of patent rights if, for example, the patented invention has been used in the engine of said foreign aircraft or any other part of its design?

Obviously, the decisive factor in this case is the aircraft's country of registration, and not the nationality of its owner. Where the leased aircraft has been registered in Russia, then clearly it could not be considered "foreign" within Russian territory. And in this case, general rules on prohibiting the use in civil circulation of articles which incorporate inventions patented in Russia without the permission of the patent holder, should apply. Where said prohibition is infringed, the aircraft lessor shall be subject to the provisions on liability for patent infringement.

An aircraft leased for passenger transportation in this case is clearly not accidentally in Russia, and the lease term is not evidence that it is on Russian territory "temporarily" in the sense defined by the Paris Convention.

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of the Russian Federation does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):
If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

*The Russian Federation operates the **national principle** of exhaustion of patent rights. Any product which incorporates a technical solution patented in Russia may be imported into Russia provided that said product had previously been introduced into civil circulation within the territory of the Russian Federation by the patent holder directly, or by another person authorized by the patent holder.*

Thus, for instance, Article 1359 of the Code directly specifies that “import into the territory of the Russian Federation, use, offer for sale, selling, other form of introduction into civil circulation or storage for these purposes of a product incorporating the invention, or utility model, or device, incorporating the industrial design, where such product or device had previously been introduced into civil circulation within the territory of the Russian Federation by the patent holder or by another person with the consent of the patent holder.”

Thus, the essence of the principle of exhaustion of rights is to limit the rights of the patent holder after manufacture of the patented product and its initial introduction into civil circulation by the patent holder himself or with his consent (by an authorized person who may be the licensee, for example) in relation to actions in furthering the commercial sale or use of said product (re-sale, lease, etc.). The patent holder’s control over such actions may be carried out on contractual terms, where this does not infringe anti-trust legislation, and, of course, where a counterparty infringes such terms, that party will not have tortious, but contractual, liability, i.e. he will not be deemed to have infringed the patent. It is assumed that, as a result of the patented subject matter’s introduction into civil circulation by himself or through an authorized person, the patent holder automatically exhausts his exclusive right, as he has already enjoyed the benefit of his monopoly.

Following the introduction of the product or device into civil circulation within the territory of the Russian Federation by the patent holder or any other authorized person, including a licensee, the principle of exhaustion of rights confers on said good (product) a property similar to that which is referred to as patent purity. It should be borne in mind that the principle of exhaustion of rights under the Code is territorial in nature, within the Russian Federation only, and re-sale of such products to other countries should take account of national patents and national legislation in relation to the interpretation of the principle of exhaustion of rights.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

The basis of the provision on exhaustion of patent rights, as stated in Article 1359 of the Code, is the idea of by-passing artificial barriers to free trade which may be erected by the

owners of exclusive rights. The essence of the rule on exhaustion of patent rights is that a patent holder, or other person acting with the permission of the patent holder, foregoes the legal monopoly on the use of the protected subject matter in an economic sense following its initial legitimate introduction into civil circulation. Subsequent movement of material bearers incorporating the technical solutions will be beyond the scope of the patent monopoly.

Opinion of the Constitutional Court of the Russian Federation of October 16, 2001, No. 211-O noted that the limitation specified in the provision on exhaustion of rights extends only to patented industrial property which has a material form, and does not encompass patent holders' exclusive rights in relation to processes patented as inventions. Nevertheless, there are certain conditions under which the patented process, when used in conjunction with a device, is also exhausted, but only when performing the process with said device, the rights in relation to which have already been exhausted.*

In the absence of provisions on the exhaustion of the patent holder's rights, the effect of the patent holder's exclusive right in relation to products and articles which he has already introduced into civil circulation would hinder the freedom of movement of goods on the market, thereby contravening the fundamental principle of freedom of trade.

Thus, for example, a patented car headlight manufactured at an optical-equipment factory under a license agreement with the patent holder who owns the patent for said headlight, would be subject to that same patent:

- *where the headlight is sold in a retail store as a spare part for a car;*
- *where the car is sold by the car factory at which the headlights bought from the optical-equipment factory were fitted;*
- *where the patented headlights or cars equipped with said headlights are stored by re-sellers;*
- *where the car is subsequently sold by said re-seller;*
- *where the car or separate headlights are sold via a network of chain stores or trading firms involved in selling wrecked cars, and previously used, but intact spare parts, etc.*

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

* *Opinion of the Constitutional Court of the Russian Federation of October 16, 2001, No. 211-O, "On Refusal to Accept a Complaint by Munir Munibaevich Bikchantaev Regarding Infringement of his Constitutional Rights by Article 11(7) of the Patent Law of the Russian Federation". The text of the Opinion was not officially published.*

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

At present, amendments to Article 1359 of the Code are being envisaged, in accordance with which importing on to the territory of the Russian Federation, use, offer for sale, sale, other form of introduction into civil circulation, or storage for such purposes of a product that incorporates the invention, not only where said product had previously been introduced into civil circulation within the territory of the Russian Federation by the patent holder, or by another person authorized by the patent holder, but also where the specified acts are performed without the patent holder's approval, but provided that said introduction into civil

circulation was performed lawfully in the cases prescribed by the Code, shall not constitute an infringement of the exclusive right in an invention.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

Not applicable.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 1362 of the Code stipulates that:

“1. If an invention fails to be used or is insufficiently used by the patent holder during the four years from the date of grant of the patent, which leads to insufficient offer of the relevant goods, works or services on the market, any person willing and ready to use such an invention, given the refusal of the patent holder to conclude with such a person a license agreement on terms corresponding to common practice, shall be entitled to initiate a legal action against the patent holder for the granting of a compulsory simple (non-exclusive) license for use of the invention within the territory of the Russian Federation. In the claim, said person should indicate the proposed terms of the granting to him of such a license, including the scope of use of the invention, and the amount, procedure, and terms of payments. If the patent holder is unable to prove that non-use or insufficient use by him of the invention was for valid reasons, the court shall rule on the granting of the license indicated in the first sub-paragraph of this Paragraph, and the terms of its granting. The total amount of payments for such a license should be prescribed in a court decision at a level not lower than the cost of a license determined under similar circumstances.

A compulsory simple (non-exclusive) license may be terminated by judicial procedure under a suit initiated by the patent holder if the circumstances that resulted in the granting of such a license cease to exist and their recurrence is unlikely. In that case, the court shall prescribe the time and procedure for termination of the compulsory simple (non-exclusive) license, and of the rights that arose under this license.

Granting in accordance with the rules of this Paragraph of a compulsory simple (non-exclusive) license for the use of an invention related to semiconductor technology shall be allowed exclusively for non-commercial use in State, social or other public interests, or in order to change the position which, in the due process, is deemed to be infringing the requirements of the anti-trust legislation of the Russian Federation.

2. If the patent holder cannot use the invention to which he has the exclusive right, without infringing thereby the rights of the holder of another patent (the first patent) for an invention, who has refused to conclude a license agreement on terms corresponding to common practice, the patent holder (of the second patent) shall be entitled to initiate court action against the holder of the first patent for the granting of a compulsory simple (non-exclusive) license for use of the invention of the holder of the first patent within the territory of the Russian Federation.

The terms of granting such a license proposed by the holder of the second patent, including the scope of use of the invention, and the amount, procedure, and schedule of payments should be indicated in the lawsuit. If this patent holder, enjoying the exclusive right in such a

dependent invention, proves that it is an important technical achievement and has significant economic advantages over the invention of the holder of the first patent, the court shall rule on the granting of a compulsory simple (non-exclusive) license to him. A right obtained under this license to use the invention protected by the first patent may not be transferred to other persons except in case of alienation of the second patent.

The total amount of payments for said compulsory simple (non-exclusive) license should be determined in a court decision at a level not lower than the cost of a license determined in comparable cases.

In the case of the grant of a compulsory simple (non-exclusive) license in accordance with this Paragraph, the holder of the patent for the invention, the right to the use of which is granted on the basis of said license, shall also be entitled to obtain a simple (non-exclusive) license for use of the dependent invention, in relation to which a compulsory simple (non-exclusive) license had been granted on terms corresponding to common practice.

3. *On the basis of the court ruling provided for by Paragraphs 1 and 2 of this Article, the federal executive authority for intellectual property shall effect State registration of the compulsory simple (non-exclusive) license.”*

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The Russian Federation uses a statute-based system of civil law (Continental or Romano-Germanic), and in this regard Russia has no case law.

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Dependent patents
Other, please specify:*

Among other conditions for the grant of compulsory licenses, Russian legislation provides for:

- *insufficient supply of appropriate goods, works or services on the market as a result of the specified non-use (insufficient use);*
- *the willingness of any person to use the patented subject matter specified.*

*It should be noted that under Article 1362 of the Code, the grant of a compulsory simple (non-exclusive) license for use of relevant patented subject matter within the territory of the Russian Federation is effected by bringing a court action against the patent holder while satisfying all the conditions listed (except dependent patents) **simultaneously**.*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

In patent law, compulsory licenses are due to the public interest, the interest of society in using the latest technology, the need for the development of science and technology in the interests of the whole of society, and the need to balance the interests of the patent holder and society.

In the Russian Federation, compulsory licensing is regarded as a limitation of the exclusive right in terms of freedom of disposal of that right. This is based on the provisions of Article 5 of the Paris Convention for the Protection of Industrial Property, in which the compulsory license is treated as a measure “to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent”.

The compulsory license has a distinct penal character, which inter alia, its name implies. A court decision therefore serves as the basis of this enforced contractual obligation.

The compulsory license defined in Article 1362 of the Code is directed against misuse of the exclusive right in an invention, and is granted in the public interest in favor of private individuals.

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The concepts of “insufficient working” and “established practice” are subjective, and where disputed, are subject in every specific case to proof in court by a person ready and willing to use the relevant technical solution.

Assessment of the degree of “non-working” or “insufficient working” is carried out by confirming that the patent holder has the necessary financial wherewithal, production facilities, raw materials, skilled workers, production and sales capacity, etc., to launch production.

Article 1362 of the Code also contains a number of terms which are subjective concepts and, in the event of a dispute, are subject to proof in court by persons requiring a compulsory license to be granted or terminated. Such terms include the following:

- *“readiness to use” patented subject matter;*
- *“insufficient supply” of relevant goods (works, services) on the market;*
- *“legitimate reasons” for non-working or insufficient working of patented subject matter;*
- *“license cost determined under comparable circumstances”;*
- *“circumstances justifying the grant of such a license shall cease to exist, and their recurrence is unlikely”.*

Thus, the readiness of a person requesting a compulsory license should be understood as having sufficient funds to carry out non-working (insufficient working) of subject matter (financial resources, availability of material resources, raw materials, skilled workforce, components, production facilities, etc.). Valid reasons for non-working (insufficient working) of patented subject matter might simply be arguments of a lawful nature (including legal, technical and economic), confirmed by competent authorities.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, it does constitute “working of the patent”.

Under Article 1358 of the Code, the importation of a product obtained directly by a patented process, constitutes use of an invention.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Article 1362 of the Code prescribes that this period is four years for an invention.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are "legitimate reasons"?

The issue of classifying the reasons for non-working or insufficient working as legitimate is assessed by a court according to the circumstances of the case. The patent holder must prove the legitimacy of the reasons which resulted in the non-working of the patented solution. Acceptance of this proof by the court involves rejecting the claim.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

*It follows from the contents of Article 1362 of the Code that where the invention or industrial design is not in use or is being insufficiently used by the patent holder within four years from the patent grant date, which results in insufficient supply of relevant goods, works or services on the market, any person ready and willing to use said invention upon the patent holder's refusal to conclude with said person a license agreement **on terms consistent with established practice**, shall be entitled to initiate a legal action against the patent holder for the granting of a compulsory simple (non-exclusive) license for use of the invention within the territory of the Russian Federation. In the claim, said person should indicate the proposed terms of the grant of such a license, including the scope of use of the invention, and the amount, procedure, and terms of payments.*

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The applicable law does not provide for this. Federal Law No. 135-FZ "On Protection of Competition" (as amended on November 29, 2010) is in force in the Russian Federation. In accordance with the provisions of Article 10(1), actions (lack of action) of an economic entity occupying a dominant position, which result or can result in prevention, restriction or elimination of competition, and (or) infringement of the interests of other persons are prohibited. Such actions include (subject to other conditions) withdrawal of goods from circulation, imposing contractual terms upon a counterparty which are unprofitable for that party, or unconnected with the subject of the contract, as well as consent to conclude a contract provided it includes provisions concerning goods in which the counterparty has no interest, and other requirements, and economically or technologically unjustified reduction or termination of the production of goods.

*In principle, these actions might lead to inadequate supply of goods on the market, which is one of the conditions for the grant of a compulsory license. However, in accordance with Article 10(4), these requirements **do not apply** to actions for implementing exclusive rights in relation to the results of intellectual activity, i.e. the above provisions of the Federal Law "On Protection of Competition" **do not apply to patented inventions**.*

In relation to the provision of Article 1362(1) of the Code, in accordance with which the grant of a compulsory simple (non-exclusive) license for the use of an invention related to semiconductor technology shall be allowed including in order to change the position which in the due process is deemed to be infringing the requirements of the anti-trust legislation of the Russian Federation, it should be noted that this infringement, taken separately, does not constitute grounds for granting a compulsory license. The other grounds listed in Article 1362(1) of the Code must also be present for a compulsory license to be granted.

As is well known, the patent form of protecting technical solutions is based on the social contract expressed in the Law. The inventor discloses the essential features of his technical solution, and in return society is obliged to refrain from using it for a certain period, during which the inventor can profit from the monopoly granted to him. In this case, the monopoly on using the technical solution restricts competition. Thus, the very essence of the patent form of protecting technical solutions presupposes restricting competition.

Russian legislation does not link the grant of compulsory licenses with the patent holder's actions which constitute unfair competition.

Russia's anti-trust authorities are not empowered to take decisions on the grant of compulsory licenses based on the results of reviewing cases on the infringement of legislation on the protection of competition. Compulsory licensing is not a way to counteract unfair competition in accordance with civil legislation and legislation on protection of competition.

In sum, the compulsory license is designed to prevent possible misuse of the exclusive right in order to maintain the balance of interests of the patent holder and society, and the grant of a compulsory license may not be the result of the patent holder performing actions that constitute unfair competition in the sense meant by the legislation on protection of competition.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

The grant of a compulsory license in the case of the so-called dependent invention, where the patent holder may not use his patented invention without infringing in so doing the rights of the holder of another (preceding) patent for the invention or utility model, is traditionally included among the exceptions to the patent monopoly. The rules governing this case of compulsory licensing are provided for in Article 1362(2) of the Code, which coincide with the provisions of Article 31 of the TRIPS Agreement.

A compulsory simple (non-exclusive) license valid within the territory of Russia in the case of a dependent invention is granted by the holder of a patent for a dependent invention bringing a court action against the holder of the first (independent) invention, with the simultaneous presence of the following conditions:

- *inability of the holder of the second patent to use his invention (dependent invention) without infringing the rights of the holder of the first patent for the invention or utility model;*
- *refusal of the holder of the first patent to conclude a license agreement with the holder of the second patent on terms consistent with common practice;*

- *proof in court by the holder of the second patent that his dependent invention constitutes an important technical achievement and enjoys significant economic advantages over the preceding patented invention or utility model.*

Compulsory licensing in the case of a dependent invention differs significantly from compulsory licensing in the case of non-working or insufficient working of patented subject matter. These two cases of compulsory licensing are united by the fact that underlying both is the patent holder's misuse of his exclusive right (patent monopoly). In the case of the dependent invention, misuse of the patent monopoly takes the form of the refusal of the patent holder, whose patent impedes the use of an important technical achievement for society, to conclude a license agreement with the patent holder for the dependent invention, which constitutes, in principle, a brake on the development of scientific and technical progress in the country.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

In accordance with Article 1362(2) of the Code, the total payment for a compulsory simple (non-exclusive) license should be prescribed in a court decision at a level no lower than the cost of a license determined under comparable circumstances.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Russian legislation does not provide for the grant of compulsory licenses for the use of inventions in national emergencies. Legislation does not treat the use of an invention in such situations as an infringement of patent rights if the patent holder is notified of such use as soon as practicable, and is consequently paid commensurate compensation.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

There is no jurisprudence relating to the review of specific cases on the grant of compulsory licenses in Russia at present.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. The provisions regulating the procedure for the grant of compulsory licenses currently appear to be sufficiently enshrined in legislation.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

Not applicable.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 1360 of the Code provides the Government of the Russian Federation with the right to allow use of an invention without the consent of the patent holder in the interests of defense and security, whilst notifying him of such use in the shortest possible time, and compensating him commensurately.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

The Russian Federation uses a statute-based system of law (Continental or Romano-Germanic), and in this regard Russia has no case law.

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

National security

*Other, please specify: From the list, restrictions on civil rights in the Russian Federation are due to **national security** and **defense interests**.*

Under Federal Law No. 390-FZ of December 28, 2010 "On Security", security means the state of protection of the vital interests of the individual, society and State from internal and external threats. It is achieved by pursuing a single State policy, a system of economic, political, organizational and other measures adequate in the face of threats to the vital interests of the individual, society and the State.

Using patented subject matter in the interests of national security is not in the public interest (in the broadest sense), but in the interests of the State, which are only indirectly linked to the public interest.

Using subject matter in the interests of national security means a permanent limitation of exclusive rights. In essence, this is reminiscent of compulsory licensing; even specialists have been of the opinion that taking a decision on using subject matter in the interests of national security should precede the patent holder's refusal to conclude a license agreement in the overall process.

Patented subject matter is used in the interests of national security on a non-contractual basis: the patent holder does not give permission to use the subject matter (and the court does not compel the patent holder to give his consent), but the State. Moreover, permission to use the patented subject matter in the interests of national security without the patent holder's agreement- the latter only being notified of the granting of permission in the shortest possible time.

In general, the provisions on exceptions in the interests of national security are aimed solely at the granting of permission to use, but not at exercising compulsory alienation of patent rights.

In accordance with Federal Law No. 61-FZ of May 31, 1996 "On Defense", defense means a system of political, economic, military, social, legal and other measures to prepare for armed defense, and armed defense of the Russian Federation, and the integrity and inviolability of its territory.

The legislator has not prescribed any real-life situations relating to exceptions in the interests of the defense of the country. Likewise, the legislator has not prescribed any particular way of notifying the patent holder that permission to use the relevant patented subject matter has been granted, as well as the amount of compensation and payment procedure.

The Russian model of using the patent-protected results of intellectual activity in the interests of defense and security is based on a simple, official license.

84. (a) What are the public policy objectives for providing government use in your country?
(b) Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

[Note from the Secretariat: response was not provided.]

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The exception relating to use of the invention in emergencies is stipulated in Article 1359 of the Code, but does not limit the number of persons entitled to said exception.

In accordance with Article 1 of Federal Law No. 68-FZ of December 21, 1994 “On Protecting Populations and Territories from Natural and Man-Made Disasters”:

****emergency**- this is a situation in a particular territory that has arisen as a result of an accident, natural hazard, disaster, natural or other disaster that might cause or has caused human casualties, damage to public health or the environment, significant financial losses, and disruption to everyday human life.*

86. Please indicate how many times and in which technological areas government use has been issued in your country:

There have been no cases of such use.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. The legal framework is considered adequate to meet the objectives sought.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

Not applicable.

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

- 89.-94.

[Note from the Secretariat: the applicable law of the Russian Federation does not provide exceptions related to farmers’ use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of the Russian Federation does not provide exceptions related to farmers' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Civil legislation of the Russian Federation provides for limitations of exclusive rights while performing duties and contracted work. Exceptions are set out below:

- where an employee (author) obtains a patent for a service invention as a result of his employer transferring patent rights to him, the employer shall be entitled to use said invention in his own business under a simple (non-exclusive) license (Article 1370(4) of the Code);*
- where an employee (author) has obtained a patent for an invention created by the employee using financial, technical, or other tangible assets of the employer, but not in the course of his employment duties or of a specific task set by the employer, the employer shall be entitled to demand the grant of a free-of-charge, simple (non-exclusive) license to use the invention for his own needs (Article 1370(5) of the Code);*
- where a patent for an invention created in performing a contract or in undertaking scientific research and development or technological work, which did not specifically envisage its creation, is obtained by the contractor (the performer), the customer shall be entitled to use said invention for the purposes for which the relevant contract was concluded under a simple (non-exclusive) license without payment of supplementary remuneration, unless the contract provides otherwise (Article 1371(1) of the Code);*
- where a patent for an invention created in performing a subcontract or in undertaking scientific research and development or technological work, belongs to the customer or third party designated by him, the contractor (performer) shall be entitled to use the invention created for his own needs under a free-of-charge, simple (non-exclusive) license (Article 1371(2) of the Code);*
- where an invention is created while performing work under a State or municipal contract, a free-of-charge, simple (non-exclusive) license for performing work or supplying products for State or municipal needs, may be granted by the State or municipal customer, or at their demand, to a designated third party (Article 1373(4) and (5) of the Code);*
- where an invention is used in emergencies (natural disasters, calamities, accidents), provided that the patent holder is notified as soon as possible of such use and he is remunerated commensurately (Article 1359(3)).*

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

A. *According to Article 1370(4) and (5) of the Code (Service Invention):*

"4. In the absence in the contract between the employer and employee of the provisions to the contrary (Paragraph 3 of this Article), the employee should notify the employer in writing of the creation while performing his employment obligations, or a specific task set by the employer, of any results which are patentable.

Where, within four months from the date of notification by the employee, the employer fails to file an application for the grant of a patent for the relevant service invention with the federal executive authority for intellectual property (Rospatent), fails to transfer the right to obtain a patent for a service invention to another person, and fails to inform the employee about keeping information on the relevant result of intellectual activity secret, the right to obtain a patent for said invention shall belong to the employee. In this case, the employer shall be entitled to use the service invention in his own business during the patent's term of validity under a simple (non-exclusive) license, and pay remuneration to the patent holder, the amount, terms, and payment method of which shall be determined by a contract between the employee and the employer, and where disputed, settled by a court.

If the employer obtains a patent for a service invention, or takes a decision to keep information on said invention confidential, and informs the employee of this, or transfers the right to obtain a patent to another person, or fails to obtain a patent on the basis of the application filed by him due to reasons for which he is responsible, the employee shall be entitled to remuneration. The amount of remuneration, the terms, and the procedure for payment by the employer shall be determined by a contract between him and the employee, and, in case of dispute, settled by a court.

The Government of the Russian Federation shall have the right to establish minimum rates of remuneration for service inventions.

5. An invention created by an employee using the employer's financial, technical, or other tangible assets, but not in the course of his employment duties or a specific task set by the employer, shall not be deemed a service invention. The right to obtain a patent and the exclusive right in such an invention shall belong to the employee. In this case, the employer shall be entitled of his own choosing to demand the grant of a free-of-charge, simple (non-exclusive) license for using the result of intellectual activity created for his own needs during the exclusive right's whole period of validity, or to reimbursement of the costs incurred by him in connection with the creation of such an invention."

B. *Under Article 1371 of the Code (Invention Created in Performance of Work under a Contract):*

"1. Where an invention is created in performing a subcontract or a contract for undertaking scientific research and development or technological work, which did not specifically envisage its creation, the right to obtain a patent and the exclusive right in said invention shall belong to the contractor (the performer), unless the contract between him and the customer provides otherwise.

In this case, the customer shall be entitled, unless otherwise provided by the contract, to use the invention created in such a manner for the purposes for which the relevant contract was concluded, under a simple (non-exclusive) license for the whole patent validity term without payment of supplementary remuneration for said use. In case of transfer by the contractor (performer) of the right to obtain a patent, or alienation of the patent as such to another person, the customer shall retain the right to use the invention on the aforesaid terms.

2. Where, under a contract between a contractor (performer) and a customer, the right to obtain a patent or an exclusive right in an invention has been transferred to the customer or to a third party designated by him, the contractor (performer) shall be entitled to use the created invention for his own needs under a free-of-charge, simple (non-exclusive) license for the whole patent validity term, unless provided otherwise by the contract."

C. *Under the provisions of Article 1373 of the Code (Invention Created in Performance of Work under a State or Municipal Contract):*

“4. Where a patent for an invention created in performing work under a State or municipal contract for State or municipal needs, does not belong under Paragraph 1 of this Article to the Russian Federation, a subject of the Russian Federation, or a municipality, the patent holder, at the behest of the State or municipal customer, shall be obliged to grant to the person designated by it a free-of-charge, simple (non-exclusive) license to use the invention for State or municipal needs.

5. Where a patent for an invention created in performing work under a State or municipal contract for State or municipal needs is obtained jointly in the name of the performer and the Russian Federation, or of the performer and a subject of the Russian Federation, or of the performer and a municipality, the State or municipal customer shall be entitled to grant a free-of-charge, simple (non-exclusive) license to use such an invention in order to perform work or supply products for State or municipal needs, after notifying the performer to this effect.

D. *Under Article 1359(3) of the Code (Acts which do not Infringe the Exclusive Right in an Invention):*

“using an invention, utility model, or industrial design in emergencies shall not constitute an infringement of the exclusive right in an invention, (natural disasters, calamities, accidents), provided that the patent holder is notified of such use as soon as possible, and is subsequently paid commensurate compensation.”

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and court decisions:

A. *Article 1370 of the Code specifies the legal regime of the service invention, created during the performance of employment obligations, or a specific task set by the employer (within the framework of official duties), during the period of employment. In this Article, the enshrinement of the employer’s exclusive rights in the service invention is presumed. Similarly, the right to obtain a patent belongs to the employer. Unless the author’s rights in the service product are specified in the employment contract, then he has agreed to cede these rights to the employer.*

One of the conceptual provisions of the Code is the enshrinement of the initial exclusive right in the result of intellectual activity created by creative work for its author (Article 1228(3) of the Code). This is particularly important for relations associated with a service product, the exclusive rights to which are transferred to the employer under an employment contract.

The contents of the Article imply that unless the administration, upon notice from the author, perform the appropriate acts demonstrating its commitment to securing the rights in the innovation created by the employee, the author’s initial right in the unclaimed service product or invention shall be reinstated, and he may file a claim himself and obtain a patent on his own behalf, or assign the right therein to another person. In this case, the employer obtains the right to use the patented solution in his own business only under a simple license (i.e. without the right of disposal), upon payment of monetary compensation to the patent holder (the author or his successor).

Rights to obtain a patent are not transferred automatically to the employer (by virtue of the employment contract), but only when he precisely expresses his will to use the protected solution or to keep it secret.

B. *Rights to so-called custom development, during the course of which new patentable solutions might be obtained, are discussed in Article 1371 of the Code. At present, the volume of the latest scientific and technical developments performed under civil contracts is increasing in the Russian Federation, without raising funds from the federal or municipal budget, so therefore the enshrinement of these legal relations in legislation is important.*

Provisions contained in the Code on governing the conditions for securing exclusive rights in the protected results of contractual work and research and development are optional in nature. The parties themselves must agree in the contract the essential issues for these relations, including deciding who will own the right to obtain a patent and the exclusive right in patentable results, the extent to which each party may use the results obtained and dispose of rights obtained, etc. Unless the parties include appropriate conditions in the contract, the relationship of the parties will be governed by the Code, whose purpose is to fill the gap resulting from the usual terms of disposal of exclusive rights to new developments prevailing in civil circulation. Securing the right to obtain the patent, and the exclusive right for the performer of works, is presumed. However, in this case, the customer is guaranteed the right to use patented contractual results for those purposes for which the contract had been concluded, under a “free-of-charge, simple license (i.e. without any additional payment, and without the right of disposal).”

Where the exclusive right has been secured for the customer, then the performer retains the right to use patented results for his own needs, likewise under a free-of-charge, simple license.

C. *Article 1373 of the Code concerns State and municipal contracts. It is established that unless a State customer, on concluding a contract, secures the right to obtain a patent and the exclusive right in an invention, which may have been created while performing contractual work, for the Russian Federation, subject of the Russian Federation, or municipality, then said rights are assigned to the performer of the work.*

D. *Use of patented subject matter, e.g. an invention, in emergencies, has its own peculiarities:*

**firstly, it is applied spontaneously (natural disasters, calamities, and accidents cannot be predicted);*

**secondly, by any entity which remediates the impact of emergencies;*

**thirdly, is short-term in nature (until remediation of an emergency’s impact).*

This exception to the patent holder’s exclusive right can be explained by the importance of using the invention urgently in the public interest in emergencies, where it is essential to prevent or remediate the impact of a natural or other disaster. This exception to the exclusive right therefore only concerns emergencies, and does not extend to any other disasters or accidents. The public shall be informed of the emergency, for whatever reason, either by the specific country’s State authorities, or by the international organizations providing assistance in such situations.

(iii) The entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

It would seem that the answer to this question follows on from the answers provided in relation to situations (i) and (ii) in question 102.

In addition, in relation to each exception and limitation, please explain:

- (i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

At present, it appears that the existing legal framework is adequate to govern legal relations in the area of creating inventions in the performance of duty, and in the performance of work under contract.

- (ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

Not applicable.

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

Not applicable.

Country: SLOVAK REPUBLIC
Office: Industrial Property Office of the Slovak Republic

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

According to article 5(1) of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (hereinafter referred to as "The Patent Act"; see http://www.upv.sk/swift_data/source/pdf/legislation/pravo_01435.pdf) patents are granted for inventions from all fields of technology, which are new, involve an inventive activity and are industrially applicable.

According to article 5(2) of The Patent Act patents are also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilized, including cases when invention relates to

- a) biological material which is isolated from its natural environment or is produced by means of a technical process, already occurred in a nature,*
- b) a plant or an animal, if a technical feasibility of an invention is not limited to a particular plant or animal variety,*
- c) a microbiological or other technical process or to a product obtained by such process,*
- d) an element isolated from a human body or produced by other means of a technical process, including a sequence or partial sequence of a gene also in the case when the structure of such element is identical with a structure of a naturally existing element.*

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Patents are not granted for

- a) discoveries, scientific theories and mathematical methods,*
- b) aesthetic creations,*
- c) schemes, rules and methods for performing intellectual acts, games or business,*
- d) programs for computers and*
- e) presentations of information,*

as these subject-matters or activities are not regarded as inventions (see Article 5(3) of The Patent Act). However, above listed subject-matters and activities are excluded from patentability only to the extent to which a patent application relates to such subject-matter or activity as such (see Article 5(4) of The Patent Act).

According to article 6(1) of The Patent Act patents are not granted either in respect of

- a) plant and animal varieties,*
- b) essentially biological processes for creation plants or animals,*
- c) methods of surgical or therapeutic treatment of human or animal body and diagnostic methods and methods of illness prevention practiced on human or animal body; this is not apply to products, in particular substances or compositions usable in any of above-mentioned methods of treatment, diagnostics or illness prevention,*

- d) inventions relating to human body in different stages of its formation or development or relating only to discovery of some elements of human body, including sequences or partial sequence of a gene,
- e) inventions commercial exploitation of which would be in contradiction with public order or good manners; the sole prohibition of exploitation of an invention by law shall not be considered to be in contradiction with public order or good manners. Article 6(2) of The Patent Act specifies that pursuant to article 6(1) patents are not granted in particular for
 - a) processes of cloning human beings,
 - b) processes of modifying germ line genetic identity of human beings,
 - c) utilization of human embryos for industrial or commercial purposes,
 - d) processes of modifying genetic identity of animals which are likely to cause suffering to animals without having substantial medical benefit for people or animals, neither on animals which are results of such processes.

Above listed inventions are excluded from patentability.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

According to article 14(1) of The Patent Act an owner of a patent shall have exclusive right to exploit an invention, to grant consent for exploitation of an invention, to assign a patent to another person or to establish right of lien to a patent.

According to article 15(1) of The Patent Act without consent of a patent owner following shall be prohibited

- a) *producing, exploitation, offering or placing on the market, or for this purpose storing or importing a product which is a subject-matter of a patent,*
- b) *exploitation of a production process which is a subject-matter of a patent (hereinafter referred to as "protected process") or offering such protected process for exploitation to another person,*
- c) *producing, exploitation, offering or placing on the market, or for this purpose storing or importing a product directly obtained by a protected process,*
- d) *supplying or offering for delivery to a person not entitled to exploit an invention any means enabling him to carry out an invention, if a person infringing right has been informed or with regard to circumstances he should have been informed that these means are intended or suitable to carry out an invention; this shall not apply if these means are currently available on the market and a supplier did not instigate the person not entitled to perform acts in contradiction with points (a) to (c).*

According to article 15(2) of The Patent Act exclusive rights pursuant to article 15(1) shall also belong to an applicant, starting from the day of publication of an application in the Official Journal of the Industrial Property Office of the Slovak Republic, provided that a patent has been granted for an invention, which is a subject-matter of an application. However, claiming of these rights vis-à-vis third parties shall be possible only as from the day on which effects of a patent begin.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 18(1)(e) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in activity conducted privately and for non-commercial purposes.

5.-6.

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

According to article 3(h) of The Patent Act "commercial exploitation" of a patent or an invention shall mean any activity related to a patent as a subject-matter of right or in relation to an invention as a subject-matter of a patent, performed by an owner or any other authorized person with a purpose of making profit.

The applicable law does not define the term "non-commercial" either the term "private".

8.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 18(1)(e) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in activity conducted for experimental purposes which shall also be studies and tests necessary for registration proceedings pursuant to a special regulation (Act No 140/1998 Coll. on Medicines and Medical Devices).

- 12.-13.

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The applicable law does not make any distinction concerning the nature of the organization conducting the experimentation or research.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The applicable law does not define the term “experimental use” either the term “scientific research”.

- 16.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 18(1)(e) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in individual preparation of a medicine in a pharmacy according to a medical prescription or in activity related to a medicine prepared in this way.

- 24.-25.

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

The applicable law does not specify who is entitled to use the exception.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 17(1) of The Patent Act right of a patent owner shall not be exercised vis-à-vis a person who before priority right has exploited an invention in a good faith or has made appropriate arrangements directly aiming at exploitation of an invention independently from an inventor or a patent owner (hereinafter referred to as "prior user") within the territory of the Slovak Republic. In case of doubts action of a prior user shall be considered acting in a good faith unless proved otherwise.

32.-33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The applicable law does not define the scope of "use" either provides for any quantitative or qualitative limitations on the application of the "use" by prior user.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The applicable law does not provide for a remuneration to be paid to the patentee for the exercise of the exception.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

According to article 17(2) of The Patent Act assignment or transfer of right of a prior user for exploitation of an invention is possible exclusively as a part of assignment or transfer of ownership of a company or its part, within which an invention is being utilized.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

According to article 52(1) of The Patent Act if a party to proceedings before the Office that, in spite of all due care required by the circumstances having been taken, was unable to observe a time limit for performing an act where the direct consequence of non-observance of this time limit is the termination of the procedure or the loss of any other right, it is entitled to request the Office for re-establishment of rights. If the Office grants the request, the legal effects of the decision issued as a consequence of non-observance of the time limit shall lapse or shall not arise (see article 52(7) of The Patent Act).

However, third party that has exploited an invention, which was a subject-matter of an application or a patent, or has made provable preparations directly aiming at utilization of such invention within the territory of the Slovak Republic in a good faith from validity of a decision issued as a consequence of non-observance of the time limit until the lapse of legal effects of this decision, shall be entitled to exploit an invention within his business activity without an obligation for remuneration for exploitation of an invention (see article 52(8) of The Patent Act). Assignment or transfer of right of an entitled user shall be possible exclusively as a part of assignment or transfer of a company or its part, within which an invention is being used (see article 52(9) of The Patent Act).

39.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 18(1)(a) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited on boards of vessels of other states which are contracting parties to Paris Convention on Protection of Industrial Property or parties to the World Trade Organization (hereinafter referred to as "Union countries") to which the Slovak Republic is a contracting party, in a body of a vessel, machinery, tackle, gear and other accessories, if these vessels temporarily or accidentally enter the territory of the Slovak Republic provided an invention is used exclusively for needs of a vessel.

According to article 18(1)(b) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in construction or operation of aircrafts or land vehicles of the Union countries, or in their components or other accessories when they temporarily or accidentally enter the territory of the Slovak Republic.

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

Vessels
Aircrafts
Land Vehicles

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law applies term "temporarily" as well as term "accidentally" but does not define them.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

According to article 18(1)(a) of The Patent Act the patented product must be used exclusively for needs of a vessel.

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 18(1)(f) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in activity conducted for experimental purposes which shall also be studies and tests necessary for registration proceedings pursuant to a special regulation (Act No 140/1998 Coll. on Medicines and Medical Devices)

52.-53.

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

The applicable law does not specify who is entitled to use the exception.

55. The exception covers the regulatory approval of:

Certain medicinal products.

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Conduct studies and tests necessary for registration of a medicine prescribed by Act No 140/1998 Coll. on Medicines and Medical Devices

57.-59.

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 16 of The Patent Act a patent owner shall not be entitled to prohibit third parties to dispose of a product which is a subject-matter of a patent after this product has been placed on the market in the member state of the European Union or in the state which is a contracting party to the Agreement on the European Economic Area by a patent owner or with his explicit consent. This shall not apply if there are reasons for extension of rights to a patent for such treatment.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 27(1) of The Patent Act on request the court shall be entitled to grant a compulsory license to any person who can prove the capability to exploit an invention, which

is a subject-matter of a granted patent, within the territory of the Slovak Republic, provided that

- a) 4 years have expired since filing of an application or 3 years have expired from granting a patent, where the time limit, which expires later, shall apply,*
- b) person requesting granting of a compulsory license has offered before filing a request to a patent owner a proper conclusion of a license agreement, whilst this offer was not accepted by a patent owner within three months from its filing, and*
- c) invention has not been exploited within the territory of the Slovak Republic without an appropriate reason by a patent owner, or it has been exploited insufficiently, while a subject-matter of a patented invention as a product has not been supplied to the market of the Slovak Republic in a sufficient quantity. Non-existence of an appropriate reason shall be presupposed, unless proved otherwise.*

According to article 27(2) of The Patent Act compulsory license may be granted only as a non-exclusive license, whilst its duration and scope shall be limited to purpose for which it has been granted provided that domestic market needs shall be satisfied preferentially.

According to article 27(3) of The Patent Act if a subject-matter of a patent is a technology of semiconductor products, compulsory license may be granted only for public non-commercial exploitation or in order to prevent a patent owner from further action, which pursuant to a decision of a competent body can be considered as an action abusing or restricting economic competition or in case of serious public interest menace.

According to article 27(4) of The Patent Act notwithstanding article 27(1)(a) and article 27(1)(b) compulsory license may be granted in case of serious public interest menace.

According to article 27(5) of The Patent Act notwithstanding presuppositions pursuant to article 27(1) and conditions pursuant to article 27(2), a court shall be entitled to grant a compulsory non-exclusive license for utilization of a biotechnological invention on request, if a cultivator shall not be able to exploit or acquire right to a plant variety without infringing earlier right to a patent, if the plaintiff proves that

- a) before filing a request he has offered to a patent owner a proper conclusion of a license agreement, whilst this offer was not been accepted by a patent owner within three months from its filing, and*
- b) plant variety represents an important technical progress of a considerable economic importance comparable with an invention which is a subject-matter of a request for granting a compulsory license.*

According to article 27(6) of The Patent Act in case of granting a compulsory license pursuant to article 27(5), a patent owner shall have right for granting a cross compulsory license for utilization of a plant variety pursuant to a special regulation (Act No 132/1989 Coll. on Protection of Rights to New Plant and Animal Variety as amended).

According to article 27(7) of The Patent Act if a patent owner has been granted a compulsory license for utilization of a plant variety pursuant to a special regulation (article 10 of the Act No 132/1989 Coll. on Protection of Rights to New Plant and Animal Variety as amended), an owner of a cultivator certificate shall have right for granting a cross compulsory license for utilization of a biotechnological invention.

According to article 27(8) of The Patent Act assignment or transfer of right of a compulsory license holder shall be possible exclusively as a part of an assignment or transfer of a company or of its part, within which an invention is being used on a basis of a compulsory license.

According to article 28(2) of The Patent Act in case of substantial change of circumstances, which led to granting a compulsory license, the court shall be entitled on a request of one of parties to license relation to cancel a decision on granting a compulsory license, provided that re-occurrence of reasons for granting a compulsory license is improbable or compulsory license rights have not been used during one year.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Serious public interest menace*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The applicable law does not define the term “non-working” either the term “insufficient working”.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

The applicable law does not specify whether the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four years have expired since filing of an application or three years have expired from granting a patent, where the time limit, which expires later, shall apply (see article 27(1)(a) of The Patent Act).

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

No

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

The applicable law does not define the term “reasonable terms and conditions”. The term “reasonable period of time” means three months from the request for the license (see article 27(1)(b) of The Patent Act).

74.-75.

[Note from the Secretariat: response was not provided.]

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

According to article 28(1) of The Patent Act right of a patent owner to adequate compensation shall remain unaffected by granting a compulsory license; article 26(3) of The Patent Act shall apply mutatis mutandis to purposes of determining compensation for exploitation of an invention, which is a subject-matter of a compulsory license.

According to article 26(3) of The Patent Act if no agreement on compensation for granted license has been concluded among parties to license agreement, notwithstanding negotiations relating thereto, amount of an adequate compensation as well as terms of payment shall be determined by a court on proposal of one of parties to license agreement taking into consideration importance of an invention and usual license prices in particular field. In case of a substantial change of circumstances decisive for determining an adequate compensation, the court shall be entitled on proposal of one of parties to license agreement to change amount of a compensation or terms of payment originally negotiated or settled by a court, if no agreement has been concluded among parties, notwithstanding negotiations relating thereto.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

[Note from the Secretariat: response was not provided.]

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Data relating to the number of compulsory licenses issued in the Slovak Republic is not available.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81.-88.

[Note from the Secretariat: the applicable law of the Slovak Republic does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 16(3) of The Patent Act acquisition of protected plant reproduction material by a farmer within the scope of a commercial relation with a patent owner or with his consent implies right of a farmer to utilize a product of his work for reproduction of this product in his farm. Provisions of a special regulation (Article 14 of the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights) shall apply mutatis mutandis for determination of a scope of right of a farmer and condition of claiming such right.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

92.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

According to article 16(4) of The Patent Act acquisition of protected animal reproduction material by a breeder within the scope of a commercial relation with a patent owner or with his consent implies for right of a breeder to use a protected livestock for agricultural purposes including using of an animal reproductive material for his agricultural activity with exception of sale of animal reproduction material form performing agricultural activities of a breeder with exception of a sale of an animal reproduction material in relation with business or for the purpose of business in the form of a subsequent reproduction activity.

96.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the Slovak Republic does not provide other exceptions and limitations.]

Country: SPAIN
Office: Spanish Patent and Trademark Office

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The legal standard used is Law No. 11/1986 of March 20, 1986, on Patents (hereinafter, Law on Patents), in Title II (Articles 4 to 9).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Pursuant to the Law on Patents (Articles 4 and 5), the exclusions from patentability are:

Article 4.

4. In accordance with the above paragraphs, the following are not considered inventions, in particular:

- (a) discoveries, scientific theories and mathematical methods;*
- (b) literary or artistic works or any other esthetic creation, as well as scientific works;*
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and computer programs; and*
- (d) presentations of information.*

Methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are industrially applicable.

Article 5. The following may not be the subject matter of a patent:

1. Inventions whose commercial exploitation would be contrary to public order or morality, without considering such working an invention solely because it is prohibited by a law or regulation. In particular, the following shall not be considered patentable under the provisions of the preceding paragraph:

- (a) procedures for cloning human beings;*
- (b) procedures for modifying the germ line genetic identity of human beings;*
- (c) uses of human embryos for industrial or commercial purposes; and*
- (d) procedures for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical or veterinary benefit to human beings or animals, and animals resulting from such procedures.*

2. Plant varieties and animal breeds. However, inventions that have plant or animal subject matter shall be patentable provided that the technical viability of the invention is not limited to a specific plant variety or animal breed.

3. *Essentially biological procedures for the production of plants or animals. For this purpose, essentially biological procedures shall mean those consisting entirely of natural phenomena such as crossing or selection. The provision of the preceding paragraph shall not affect the patentability of inventions whose subject matter is a microbiological process or any other technical process or a product obtained from such processes.*

4. *The human body, in the various stages of its formation or development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene. However, an isolated element of the human body or obtained by other means through a technical process, including the total or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a total or partial sequence of a gene must be disclosed in the patent application.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

The exclusive rights granted by a patent are indicated in Articles 50 and 51 of the Law on Patents and are the following:

Article 50.

1. *A patent shall give its owner the right to prevent any third party from undertaking the following acts without his consent:*

- (a) manufacturing, offering for sale, putting on the market or using the product that is the subject matter of the patent or importing or possessing the product for one of the above-mentioned purposes;*
- (b) making use of a process that is the subject matter of a patent or offering such use when the third party is aware, or the circumstances make it obvious, that use of the process without the consent of the patent owner is prohibited; and*
- (c) offering for sale, putting on the market or using the product directly obtained by the process that is the subject matter or importing or possessing the said product for any of the above-mentioned purposes.*

2. *Where the subject matter of a patent is a biological material that, as a result of the invention, has specific properties, the rights conferred by the patent shall extend to any biological material derived from the patented biological material by propagation or multiplication, in an identical or divergent form and possessing those same characteristics.*

3. *Where the subject matter of a patent is a process for the production of a biological material that, as a result of the invention, has specific characteristics, the rights conferred by the patent shall extend to biological material directly obtained through that patented process and to any other biological material obtained through propagation or multiplication, in an identical or divergent form and possessing those same characteristics.*

4. *Where the subject matter of a patent is a product containing or consisting of genetic information, the rights conferred by the patent shall extend, without prejudice to the provisions of Article 4.5, to all material in which the product is incorporated and in which the genetic information is contained and performs its functions.*

Article 51.

1. A patent shall also entitle its owner to prevent a third party from handing over or offering to hand over to unauthorized persons without his consent elements related to an essential part of the invention to be used for putting into effect, when the third party knows, or the circumstances make it obvious, that such elements are capable of putting the invention into effect and are to be used for that purpose.

2. The provisions set out in the preceding paragraph shall not apply when the elements referred to are products commonly found on the market, unless the third party incites the person handing over to commit acts prohibited in the preceding article.

The rights conferred by the publication of a patent are defined in Article 59:

1. A patent application shall, from the date of its publication, confer on its owner provisional protection consisting of the right to require reasonable remuneration appropriate to the circumstances from any third party who, between the date of that publication and that of the announcement that the patent has been granted, has made use of the invention in a manner that would have been prohibited had the patent already been granted.

2. That provisional protection shall also apply before the application's publication to any person informed of the filing of the application and its contents.

3. Where the subject matter of the patent application consists of a process concerning a microorganism, provisional protection shall only commence when the microorganism has been made available to the public.

4. Patent applications shall have none of the effects provided for in the preceding paragraphs when they have been or are considered to have been withdrawn or when they have been rejected as a result of a final decision.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Experimental use and/or scientific research;

Preparation of medicines;

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

Acts for obtaining regulatory approval from authorities;

Exhaustion of patent rights;

Compulsory licensing and/or government use;

Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 52 of the Law on Patents

The rights conferred by a patent shall not extend to:

1. (a) *acts carried out in private and not for any commercial purpose;*

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Not applicable.

6. (a) What are the public policy objectives for providing the exception?

These are not considered as acts of exploitation of the patent and, therefore, do not affect the content of the right of the patent. One of the objectives is teaching and in that field, patents may be used without fear of infringing them.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

Such concepts are not defined in the law.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

No other provisions exist.

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework is considered adequate since no amendments to the law are foreseen

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No problems have been encountered in relation to its implementation.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 52 of the Law on Patents

1. *The rights conferred by a patent shall not extend to:*

(b) acts carried out for experimental purposes related to the subject matter of the patented invention, in particular studies and trials for obtaining generic medicine authorization, in Spain or elsewhere, and the resulting practical requirements, including preparing, obtaining and using the active substance for such purposes.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

This limitation is expected to contribute to the ultimate goal of technological innovation, thereby guaranteeing that patent rights do not stifle research, by expressly authorizing that the subject matter of the patented invention may be used during its period of validity, as a starting point for scientific research and development, all for the benefit of society and technological progress.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

This Article of the Law on Patents was amended by Law No. 29/2006, of July 26, 2006, on the Guarantees and Rational Use of Medicines and Healthcare Products. This Law, in turn, incorporates Directive No. 2004/27/CE, of March 21, 2004. This amendment introduced into Spanish law the so-called "Bolar clause or provision", according to which, no infringement of patent rights shall be sought for working the patent for experimental purposes for studies and trials required for authorizing generic medicines.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No distinction is made in this regard.

15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

Such concepts are not defined in the law. However, following the above-mentioned amendment, for the purpose of clarification, this is exemplified by "the studies and the tests carried out to obtain authorization for generic medicines, either in Spain or abroad, and the subsequent practical requirements, including preparation, obtaining and use of the active element for such purposes".

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

*seek an improvement to the patented invention
invent around the patented invention*

17.

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19.-20.

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework is considered adequate. No amendment is foreseen.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Prior to the amendment of 2006, doubts had been expressed concerning the limitation of the patent right in the prior precept of the Law on Patents (which referred only to acts carried out for experimental purposes related to the subject matter of the patented invention) including studies and trials designed for the authorization of generic medicines. To clarify this scope and to transpose the above-mentioned European Directive No. 2004/27/CE, Article 52.1(b) has been amended and includes the following sentence "in particular the studies and the tests carried out to obtain authorization for generic medicines, either in Spain or abroad, and the subsequent practical requirements, including preparation, obtaining and use of the active element for such purposes".

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Art. 52.1(c) of the Law on Patents:

The rights conferred by the patent shall not extend to the extemporaneous preparation of medicines in pharmacies carried out individually in making up a prescription and acts related to the medicines thus prepared;

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

The objective is to provide patients with access to medicines prescribed by medical professionals and capable of being prepared in a pharmacy. That is, on the one hand, healthcare reasons are protected and on the other, such acts are considered as not impairing the usual working of the patent subject matter.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Article 52.1(c) of the Law on Patents refers to medicines prepared in pharmacies. Therefore, it may be understood that pharmacists are entitled to use the exception on the pharmacy premises.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

Pursuant to Article 52.1(c) of the Law on Patents, the exception is limited to one medicine and based on its preparation being done according to a medical prescription.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework is considered adequate since no amendment is expected.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No challenges have been encountered in relation to its implementation.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

This limitation is provided for under Article 54 of the Law on Patents, according to which:

1. the owner of a patent shall not have the right to prevent persons who, in good faith, prior to the date of priority of the patent, had worked the patented invention in Spain or had made serious and concrete preparations to work said invention, from continuing or commencing its working or from preparations in the same manner as before in such a way as to meet the reasonable needs of their enterprises. This right to work the invention shall only be transferable with the enterprise.

2. the rights conferred by the patent shall not extend to acts related to a product protected by it after the product has been put on the market by the person who enjoys the right to work the invention mentioned in the preceding paragraph.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

The aim is to reconcile the interests of the patent owner with those of a prior user acting in good faith. In this manner, the prior user is allowed to continue using or working the invention, albeit under more restrictive conditions than if he were the owner of a patent.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The scope of “use” is defined by its working in the form in which it has been carried out until then or for which serious and concrete preparations have been undertaken. Therefore, the prior user shall be permitted to continue to work the invention in the same manner or according to the preparations which had been undertaken until then or for the form in which preparations had been carried out. However, in both cases, this is restricted to such working having been carried out sufficiently to meet the reasonable needs of the enterprise.

Good faith is required of the prior user: the beneficiary of the right of prior use must be a third party who carried out the same invention as the patent owner prior to the patent owner, with no links or contact with the patent owner and having kept the invention secret. There shall be no good faith where the invention had been misappropriated or knowledge of the results obtained by the inventor had been acquired unfairly.

The working of or preparations to work the invention must have been carried out prior to the priority date of the application.

The invention should not have been disclosed prior to the priority date as a result of working the invention or of preparations to work it.

There must be an identity, at least as regards the relevant elements of the invention and technical development stage of the invention must have been similar.

The preparations or working must have been carried out in the territory of Spain.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The right may only be transferred with the enterprise to which it belongs.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Where a patent which has been restored following notice of its forfeiture, restoration shall be granted without prejudice to the rights conferred by forfeiture (Article 117 of the Law on Patents).

Where a time limit is not observed before the Spanish Patent and Trademark Office, resulting in the loss of the right (for instance, the resulting of a refusal to grant a patent), the patent may be reinstated. However, the patent owner may not enforce his patent before good faith third parties who have begun working with the subject matter of the invention in the period between the loss of rights and the notice of restoration (Article 25 of Law No. 17/2001, of December 7, 2001, on Trademarks, applicable to patents under the Seventh Additional Provision).

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to the law are expected in this regard.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 52.1 The rights conferred by the patent shall not extend to:

(d) use of the subject matter of a patented invention on board vessels of countries of the Paris Union for the Protection of Industrial Property, in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally

enter Spanish waters, provided that the subject matter of the invention is used exclusively for the needs of the vessel;

(e) use of the subject matter of the patented invention in the construction or operation of aircraft or land vehicles of countries that are members of the Paris Union for the Protection of Industrial Property, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter Spanish waters; and

(f) acts provided for in Article 27 of the Convention of December 7, 1944, on International Civil Aviation, when such acts relate to aircraft of a State to which the provisions of the said Article apply, which establishes that:

(a) while engaged in international air navigation, any authorized entry of aircraft of a contracting State into the territory of another contracting State or authorized transit across the territory of such State with or without landings shall not entail any seizure or detention of the aircraft or any claim against the owner or operator thereof or any other interference therewith by or on behalf of such State or any person therein, on the grounds that the construction, mechanism, parts, accessories or operation of the aircraft is an infringement of any patent, design, or model duly granted or registered in the State whose territory is entered by the aircraft, it being agreed that no deposit of security in connection with the foregoing exemption from seizure or detention of the aircraft shall in any case be required in the State entered by such aircraft;

(b) the provisions of paragraph (a) of this Article shall also be applicable to the storage of spare parts and spare equipment for the aircraft and the right to use and install the same in the repair of an aircraft of a contracting State in the territory of any other contracting State, provided that any patented part or equipment so stored shall not be sold or distributed internally in or exported commercially from the contracting State entered by the aircraft;

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

The objective of these exceptions is to facilitate the free transit of international means of transportation, without being constrained by the existence of patent rights in force.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The direct predecessor of this law is Article 5ter of the Paris Convention.

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

The law applies the terms “temporarily” or “accidentally” but does not define them.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

As regards vessels, these are indicated as places where the subject matter of the patent is employed: On the body of the vessel, on the machinery, tackle, gear and additional accessories.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

As regards vessels, it is stipulated that patent rights remain exempted exclusively for the needs of the vessel. Also, as regards other aircraft or land vehicles, these are exempt when they temporarily or accidentally enter the territory of Spain. Aircraft may only transit the territory of Spain when authorized.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes, since no amendments to the law are expected.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 52.1(b) of the Law on Patents:

The rights conferred by a patent shall not extend to acts carried out for experimental purposes which refer to the subject matter of the patented invention, in particular studies and trials carried out to obtain authorization for generic medicines, either in Spain or abroad, and the subsequent practical requirements, including preparation, obtaining and use of the active element for such purposes.

This paragraph was added to Article 52.1(b), which initially only stated: the rights conferred by the patent shall not extend to acts carried out for experimental purposes related to the subject matter of the patented invention; however, Law No. 29/2006, of July 26, 2006, on Guarantees and Rational Use of Medicines and Healthcare Products, under the Second Additional Provision, added the mention of studies and trials carried out to obtain authorization for generic medicines.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

Promoting the marketing of generic medicines once the patent has lapsed, since if manufacturers of generic medicines were prevented from starting to prepare and obtain approval for a generic medicine, it would delay putting generic medicines on the market, which in effect would amount to prolonging the term of protection once the patent expired.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

As already indicated under question 13(b), this Article of the Law on Patents was amended by Law No. 29/2006, of July, 26, 2006, on Guarantees and Rational Use of Medicines and Healthcare Products. In turn, this law incorporates Directive No. 2004/27/CE, of March 21, 2004. This amendment included in our legislation the so-called "Bolar clause or provision", according to which, no infringement of patent rights shall be sought for working the patent for experimental purposes for studies and trials required for authorizing generic medicines.

54. Who is entitled to use the exception? Please explain:

This is not specified; it means any natural or legal person seeking the authorization of generic medicines.

55. The exception covers the regulatory approval of:

certain products. Please describe which products: Generic medicines.

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Using

Other. Please specify: The law refers to studies and trials and the resulting practical requirements (to obtain authorization of generic medicines), including those providing for use, preparation and obtaining.

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. No amendments to the law are expected.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

There has been some debate on whether the amendment to Article 52.1(b) of the Law on Patents No. 11/1986 of March 20, 1986, on the Guarantees and Rational Use of Medicines and Healthcare Products, implementing Directive 2004/27/CE of the European Parliament and the Council of March 31, 2004, amending Directive 2001/83/CE of the European Parliament and the Council of November 6, 1983, has retroactive effect or not. The Explanatory Memorandum of Law No. 29/2006 states that the only effects of this introduction are for clarification purposes and that this is covered by the previous text of Article 52.1(b),

which establishes that patent rights shall not extend to acts carried out for experimental purposes. However, Ruling No. 424/2010 of the Supreme Court, a chamber of the Civil Courts, of June 30, 2010, states that prior to the entry into force of Law No. 29/2006, the provision of samples to public health authorities was not covered by the "experimental use exemption".

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National
Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

Articles 52(2) and (3) of the Law on Patents:

(2) The rights conferred by the patent shall not extend to acts relating to a product protected thereby once that product has been put on the market in the territory of a Member State of the European Community by the patent owner or with his consent.

(3) The rights conferred by the patent shall not extend to acts relating to biological material derived from the protected biological material, which is the subject of the patent, by propagation or multiplication, once this has been put on the market on the territory of a Member State of the European Union by the patent owner or with his consent, when the propagation or multiplication is the necessary result of the use for which the biological material was marketed, provided that the material obtained is not subsequently used for new propagation or multiplication.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

The aim of this exemption is that once the product has been legally marketed, its buyer may use or return it for free sale without his acts entailing an infringement of patent rights. The aim thus is to prevent the owner of a patent invoking his right to limiting later marketing of the protected products to observance of an imposed price or other clauses which restrict free competition.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The inclusion of this exemption in the Law on Patents stems from European Community case law, initiated by the rulings of the European Court of Justice of October 31, 1974 (C-15/74, Sterling Drug), July 14, 1981 (C-178/80, Merck) and July 9, 1985 (C-19/84, Pharmon).

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Yes.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Compulsory licenses are governed by Chapter II of Title IX of the Law on Patents.

Specifically, Article 86 establishes:

Where a particular patent is not the subject of the offer of ex-officio licenses and where one of the following situations exists, a compulsory license may be granted:

- (a) failure or insufficiency of working of the patented invention;*
- (b) export necessities;*
- (c) dependency of patents; or between patents and plant variety rights;*
- (d) existence of reasons of public interest for the grant.*

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Public health

National security

Dependent patents

Other, please specify: For reasons of public interest.

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Public interest is put before the exclusive rights of private scope which are granted by the patent.

(b) here possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

“Sufficient working” is considered to be that which is able to satisfy the demand of the national market.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes. Importation from one of the Member Countries of the World Trade Organization (WTO) is considered to be “working”.

Article 83 of the Law on Patents states that:

The owner of a patent shall be obliged to work the patented invention either himself or through a person authorized by him, by implementing it in Spain or on the territory of a Member of the World Trade Organization in such a manner that the working is sufficient to satisfy the demand of the national market.

This Article was amended by Law No. 66/1997, of December 30, 1997, on Fiscal, Administrative and Social Measures, to comply with the provisions of the TRIPS Agreement.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four years from the filing of a patent application or three years from publication in the Official Industrial Property Gazette, whichever expires later.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

Article 87(2) of the Law on Patents considers that legitimate reasons are deemed to be “objective difficulties of a legal and technical nature, independent of the will and circumstances of the owner of the patent, which make working of the invention impossible or prevent its working from being more extensive than it is”.

73.-74.

[Note from the Secretariat: response was not provided.]

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Article 89 of the Law on Patents stipulates that:

(1) Where it is not possible to work the invention protected by a patent without harming the rights conferred by an earlier patent or plant variety right, the owner of the subsequent patent may at any time require the granting of a non-exclusive compulsory license for the earlier patent subject matter or variety subject to the plant variety right in return for payment of an appropriate fee.

(2) Where a plant variety right cannot be obtained or exploited without harming the rights conferred by a previous patent, the breeder may apply for a compulsory non-exclusive license for working the invention protected by the patent, in return for the payment of an appropriate fee.

(3) Where the subject matter of a patent is a process to obtain a chemical or pharmaceutical substance protected by a patent in force, both the owner of the patent for the process and the owner of the patent for the product shall have the right to obtain a non-exclusive compulsory license for the patent of the other party.

(4) Compulsory license applicants, referred to in the preceding paragraphs, should demonstrate:

(a) that the invention or variety represents significant technical progress of considerable economic importance as regards the invention claimed in the earlier patent or in the variety protected by a prior plant variety right; and

(b) that they have tried, without success in a reasonable time limit, to obtain from the owner of the patent or of the prior plant variety right, a contractual license set out in reasonable terms and conditions.

(5) When, according to the provisions of this Article, a cross-license is granted, the owner of the patent or of the prior plant variety right shall also have the right to request the issue, under reasonable conditions, of a cross-license to use the invention or the variety protected by the patent or subsequent plant variety right.

(6) The cross-license shall be awarded only with the content required to work the invention protected by a patent, or of the variety protected by the plant variety right concerned, and shall remain without effect by declaring that one of the titles on which the cross-licensing depends is invalid or has expired.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Article 101(2) of the Law on Patents states that the license shall provide for adequate remuneration according to the particular circumstances of each case, due regard being had to the economic importance of the invention.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Under Spanish law, mention is made of reasons of “public interest”: Reasons of public interest are invoked when:

- *the increase or generalization of working of the invention, or improvement of the conditions in which it is being worked, are of paramount importance for public health or national defense; and*
- *failure to work or insufficient quality or quantity of working leads to serious prejudice for Spain’s economic or technological development.*

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

No compulsory licenses have been issued on the basis of legislation in force in Spain.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. No amendments to the law are envisaged.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81.-88.

[Note from the Secretariat: the applicable law of Spain does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions

Farmers’ use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 53 of the Law on Patents stipulates:

1. Notwithstanding the provisions of Article 50, the sale, or any other form of marketing of plant reproduction material carried out by the owner of the patent or with his consent given to a farmer for his farm, shall grant the right of the farmer to use the product of his harvest for later propagation or reproduction by the farmer on his farm. The scope and arrangements of this exception shall correspond to the provision of Article 14 of the Council Regulation (CE) 2100/94, of July 27, 1994, on Community Plant Variety Rights.

2. Notwithstanding the provisions of Article 50, the sale or any other form of marketing of farmed animals or animal reproduction material carried out by the owner of the patent or with

his consent to a farmer or cattle breeder, shall require providing them with the authorization to use the protected livestock for agricultural or breeding purposes. This shall include providing livestock or other animal reproduction material so that the farmer or breeder may continue with his farming or breeding activity, but not the sale in the context of a commercial reproduction activity or for such purposes. The scope and arrangements of this exception shall correspond to those established in Law.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

For the purposes of developing and protecting agricultural and livestock production, the free use of seeds obtained from plant or animal reproduction material acquired by the farmer is permitted; this use resembles the use of protected inventions in a private capacity and not for commercial purposes, since its use remains restricted specifically to the needs of agricultural or livestock breeding activities.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The scope of the farming exception is stipulated in Article 14 of the Council Regulation (CE) 2100/94, of July 27, 1994, on Community Plant Variety Rights, under which:

"1. Notwithstanding Article 13 (2), and for the purposes of safeguarding agricultural production, farmers are authorized to use for propagating purposes in the field, on their own holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right."

Under Paragraph 2 of this Article, agricultural plant varieties are cited as applicable for this exception.

In relation to the scope of the agricultural exception, Article 53 of the Law on Patents provides for the scope to be established in Law; however, such legal development is still to occur.

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes. No amendments to the law are envisaged.

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Spain does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

*Procedural limitation;
Dependence of patents;
Lawfulness of working;
Existence of a legal monopoly in the subject matter of a patent; and
Secret patents.*

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

Procedural limitation: under Article 55 of the Law on Patents, the owner of a patent shall have no right to invoke this limitation to defend himself against acts directed against him for infringement of other patents which have an earlier priority date than his.

Dependence of patents: under Article 56 of the Law on Patents, the fact that the invention protected by patent may not be worked without using the invention protected by a prior patent belonging to a different owner shall not invalidate that patent. In such a case, neither the owner of the prior patent may work the later patent during its lifetime without the consent of its owner, nor may the owner of the later patent work either patent during the lifetime of the prior patent, without the consent of the owner of the prior patent or without a compulsory license.

Lawfulness of working: in general, Article 57 of the Law on Patents provides that "a patented invention may not be worked in any form contrary to the Law, morality or public order or public health, and its working shall be subject in all cases to the prohibitions and restrictions, whether temporary or permanent, established or to be established by the legal provisions".

Existence of a legal monopoly in the subject matter of a patent: Article 58 governs a series of limitations for those cases in which a patent is granted for an invention whose subject matter concerns a legal monopoly. However, currently legal monopolies are prohibited and so this Article may be abrogated de facto.

Secret patents: Article 119 of the Law on Patents states that the Ministry of Defense may order the Spanish Patent and Trademark Office to decree the secret processing of a patent application, in which case the applicant or the owner must abstain from any act which might disclose the invention to unauthorized persons. Nonetheless, the Ministry of Defense, at the owner's request, may authorize acts leading to full or partial working of the subject matter of the application or the patent, indicating the conditions by which such acts are bound.

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

- *Procedural limitation: to prevent the practice of so-called "blanket patents";*
- *Dependence of patents: to allow the working of a later valid patent but in a relationship of dependence with a prior patent belonging to another owner;*
- *Lawfulness of working: to prevent the working of the patent being contrary to the Law and established morality;*
- *Existence of a legal monopoly in the subject matter of a patent: respecting the legally-permitted monopolies; and*
- *Secret patents: to put the interests of the Defense of the State before the individual interests of the applicant.*

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

(iv) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

Yes. No amendments to the law are envisaged.

(v) if there have been any challenges encountered in the practical implementation of the exception in your country:

[Note from the Secretariat: response was not provided.]

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

[Note from the Secretariat: response was not provided.]

Country: SRI LANKA
Office: Intellectual Property Office of Sri Lanka

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Novelty, inventive step and industrial application (Intellectual Property Act No. 36 of 2003 Section 63)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The following, notwithstanding they are inventions, are not be patentable –

- (a) discoveries, scientific theories and mathematical methods ;*
- (b) plants, animals and microorganisms other than transgenic microorganisms and an essentially biological process for the production of plants and animals other than non-biological and microbiological processes ;*
- (c) schemes, rules or methods for doing business, performing purely mental acts or playing games;*
- (d) methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body; provided however, any product used in any such method shall be patentable;*
- (e) an invention which is useful in the utilization of special nuclear material or atomic energy in an atomic weapon;*
- (f) any invention, the prevention within Sri Lanka of the commercial exploitation of which is necessary to protect the public order, morality including the protection of human, animal or plant life or health or the avoidance of serious prejudice to the environment. (S. 62(3) of the Intellectual Property Act No. 36 of 2003)*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

*Rights to use, assign and license the patent/protected technology.
The national patent applications are examined and published where the invention is patentable. Upon publication, any interested party can challenge the proposed grant of patent. If no objection is raised during the prescribed period, the patent is granted.*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The protected rights extend only to acts done for industrial or commercial purposes and in particular do not extend to acts done only for the purpose of scientific research. (S.86(1)(i) of the Intellectual Property Act No. 36 of 2003)

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided]

6. (a) What are the public policy objectives for providing the exception?

Promote creativity while protecting the rights of the patent holder

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Hanzard (Records of Parliamentary Debates) dated 23.07.2003. The purposes of introduction of the new law in 2003 were the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment.

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

Not defined

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided]

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No study done. But, probably due to the existing level of R & D activities in the country, the exception has not been practically tested.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

No information available.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

*The protected rights extend only to acts done for industrial or commercial purposes and in particular do not extend to acts done only for the purpose of scientific research.
(S.86(1)(i) of the Intellectual Property Act No. 36 of 2003)*

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided]

13. (a) What are the public policy objectives for providing the exception?

Promote creativity while protecting the rights of the patent holder

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Hazard (Records of Parliamentary Debates) dated 23.07.2003. The purposes of introduction of the new law in 2003 were the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No

15.-17.

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

*The commercial intention of the experimentation and/or research is not relevant
Not yet interpreted by an authoritative court.*

19.-20.

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

So far no complaints from R & D Institutions to the IP Office.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23-30.

[Note from the Secretariat: the applicable law of Sri Lanka does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Where a person at the filing date or, where applicable, the priority date, of the patent application, was in good faith making the product or using the process in Sri Lanka which is the subject of the invention claimed in such application or had in good faith made serious preparations in Sri Lanka towards the making of the product or using the process. (S.87(1) of the Intellectual Property Act of 2003).

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

Promote creativity while protecting the rights of the patent holder.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Hazard (Records of Parliamentary Debates) dated 23.07.2003. The purposes of introduction of the new law in 2003 were the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Not so far defined by an authoritative court.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The prior user's right cannot be assigned or transmitted except as part of the business of the prior user (.S.87(1) of the intellectual Property Act of 2003).

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

If yes, please explain the conditions under which such use can continue to apply:

N/A

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Not known.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Not known.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The protected rights do not extend to the presence or use of products on foreign vessels, aircraft, spacecraft, or land vehicles which temporarily or accidentally enter the waters, airspace or territory of Sri Lanka.(S.86(1)(iii) of the IP Act of 2003).

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

To honor our international obligations

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes. No definitions available

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

No.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Not known to the IP Office.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Sri Lanka does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Uncertain

The protected rights do not extend to acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under license. (S.86(1)(iv) of the IP Act). The issue whether these provisions cover both national and international exhaustion needs the interpretation of court.

If the exception is contained in statutory law, please provide the relevant provision(s):

The protected rights do not extend to the acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under license. (S. 86 (1)(iv) of the Intellectual Property Act)

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Note from the Secretariat: response was not provided

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

Consumer protection

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Hanzard (Records of Parliamentary Debates) dated 23.07.2003. One of the purposes of the introduction of the new law 2003 was to safeguard consumer interests.

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Not yet practically tested.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

So far not really tested the provisions

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 86(2) of the Intellectual Property Act

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Consumer protection

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Hazard (Records of Parliamentary Debates) dated 23.07.2003. One of the purposes of the introduction of the new law in 2003 was to safeguard consumer interests.

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Not so far

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

71.-72.

[Note from the Secretariat: response was not provided.]

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Not given by the statute or any case

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

Not given specifically

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Where the application is for the exploitation of the patent (the second patent) which cannot be exploited without infringing another patent (the first patent), the following conditions shall apply:

- the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*
- the owner of the first patent shall be entitled to a cross license on reasonable terms to exploit the invention claimed in the second patent; and*
- the exploitation authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent. (S. 86(2)(g) of the IP Act).*

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

[Note from the Secretariat: response was not provided.]

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Not explained. It is a matter for the court to decide.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Not yet.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Not yet practically tested.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Director-General may grant a compulsory license where he has satisfied himself of the existence of a national emergency or any other circumstances of extreme urgency or in case of public non-commercial use for the purpose such as national security, nutrition, health or for the development of other vital sections of the national economy. (S. 86 (2)(c) of the Intellectual Property Act).

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency*

84. (a) What are the public policy objectives for providing government use in your country?

Consumer protection

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Hazard (Records of Parliamentary Debates) dated 23.07.2003. One of the purposes of the introduction of the new law 2003 was to safeguard consumer interests.

85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Not so far.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

Not so far.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Not so far.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

89-100.

Note from the Secretariat: the applicable law of Sri Lanka does not provide exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Section XI: Other Exceptions and Limitations

101-103.

[Note from the Secretariat: the applicable law of Sri Lanka does not provide other exceptions and limitations.]

Country: SWEDEN
Office: Ministry of Justice, Division for Intellectual Property and Transport Law

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837) Article 1, 1 st paragraph, 1a, 1b 2nd paragraph and article 2.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Article 1, 2nd paragraph SPA (a discovery, scientific theory or mathematical method, an artistic creation, a scheme, rule or method for intellectual activities, for playing games or for doing business or a computer program, or a presentation of information), Article 1 a (plant and animal varieties, an essentially biological processes for the production of plants and animals), Article 1 b The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837) (The human body in the various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence of a gene or a partial sequence of a gene), Article 1 c SPA (invention the commercial exploitation of which would be contrary to public order or morality, inter alia, processes for cloning of human beings, processes for modifying the germ line genetic identity of human beings, the use of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit for men or animals.) Article 1 d SPA (process for surgical or therapeutic treatment or for diagnostics that is to be used on men or animals.).

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Article 3 The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837): The exclusive right conferred by a patent implies that no one is entitled, without the consent of the holder of the patent, to make use of the invention by manufacturing, offering, putting on the market or using a product protected by the patent or import or possess such a product for those purposes, making use of a process that is protected by the patent, or, if he or she knows, or it is from the circumstances obvious, that the process must not be used without the consent of the holder, offering it for use in Sweden, offering, putting on the market, or using a product prepared by a process protected by the patent or importing, or possessing the product for these purposes.

The exclusive right also implies that no one may, without the consent of the holder of the patent, exploit the invention by offering or supplying to a person who is not entitled to exploit the invention with such means for carrying out the invention in Sweden that relate to an

essential element of the invention, if the person offering or supplying the means knows or it is obvious from the circumstances, that the said means are suited and intended for use in the carrying out of the invention.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

*Article 3, 2nd The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837)
paragraph p 1: "From the exclusive right are excluded the following acts:*

- 1. exploitation that is not commercial,..."*

5.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 3, 2nd paragraph, p. 3 SPA: "From the exclusive right are excluded the following acts:...use of the invention for experiments that relate to the invention itself..."

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

Facilitate research activities and the development of technology and peer control of the functioning of the patented invention.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

It does not

16.

[Note from the Secretariat: response was not provided.]

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)

Research and/or experimentation must be conducted with or using the patented invention (“research with”)

Please explain by citing legal provision(s) and/or decision(s):

Article 3, 2nd paragraph, p. 3 SPA: “From the exclusive right are excluded the following acts:...use of the invention for experiments that relate to the invention itself...”

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

The commercial intention of the experimentation and/or research is not relevant

19.-20.

[Note from the Secretariat: response was not provided.]

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 3, 2nd paragraph, p 5 SPA: "From the exclusive right are excluded the following acts: ...preparation in pharmacies of medicines in accordance with a prescription by a physician in an individual case or acts relating to medicines prepared in such cases..."

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

25. (a) What are the public policy objectives for providing the exception? Please explain:

Enable personal at pharmacies, in an individual case, to prepare medicine according in accordance with a prescription by a physician without being exposed to the risk of infringing a patent.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Personnel at pharmacies

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

It only provides extemporaneous preparation for individual cases.

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

See answers above.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments foreseen in the near future but the exception is not used since preparation of medicines do not takes place at pharmacies in Sweden.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 4 of the SPA: Anyone who, at the time when the application for a patent was filed, was exploiting the invention commercially in this country may, notwithstanding the patent, continue such exploitation while retaining its general character, if the exploitation did not constitute an evident abuse in relation to the applicant or his predecessor in title. The right to such exploitation shall also be due to anyone who has made substantial preparations for commercial use of the invention in this country.

The right under the first Paragraph may be transferred to others only together with the business where it originated or where the exploitation was intended to take place.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

To allow use in good faith before the application date as long as no abuse can be considered. It is reasonable and provide for economic benefits to the society as a whole.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

See above cited article of SPA “...the exploitation did not constitute an evident abuse in relation to the applicant or his predecessor in title..”

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

See above cited article of SPA: The right under the first Paragraph may be transferred to others only together with the business where it originated or where the exploitation was intended to take place.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

This is regulated in Article 74 of the SPA. The general idea is: Under certain circumstances the processing of a patent application that has been dismissed or rejected can be resumed, or a patent that has lapsed can be considered maintained. In such cases an announcement shall be made. If anyone, after the expiry of the time limit for restoration of the dismissed application, after the decision on rejection has gained legal force, or after the patent has lapsed, but before the said announcement has been made, has begun in good faith to exploit the invention commercially he may, notwithstanding the patent, continue such exploitation while retaining the general character of the exploitation. Such a right shall also be granted on corresponding conditions to anyone who has made substantial preparations for commercial exploitation of the invention.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

See answer above (38).

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments foreseen.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 5 (SPA). Notwithstanding the existence of a patent, an invention may be used on a foreign vessel, aircraft, or other foreign means of transport for its own needs, when it temporarily enters this country in regular traffic or otherwise.

The Government may prescribe that, notwithstanding the existence of a patent, spare parts and accessories may be imported into this country and used here for the repair of an aircraft from a foreign country where corresponding privileges are granted to Swedish aircraft (Act 1977:700).

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

44. (a) What are the public policy objectives for providing the exception? Please explain:

Facilitate international transportation (Implementation of article 5 ter in the Paris Convention).

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

See answer above (42).

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

See answer above (42) "...for its own needs, when it temporarily enters this country in regular traffic or otherwise".

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 3 2nd paragraph, 4 p: "From the exclusive right are excluded the following acts... studies, tests, examination activities and practical measures that refer to a reference medicine to the extent that these are necessary for obtaining a approval for the sale of a medicine pursuant to Article 8 a of the Act (1992:859) on Medicinal Products or for other proceedings for approval based on Article 10. 4 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as last amended by Directive 2004/27/EC, of the European Parliament and of the Council, or Article 13.1 – 13.5 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products, as last amended by Directive 2004/28/EC of the European Parliament and the Council,"

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

53. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of EU directives 2004/27 and 2004/28

54. Who is entitled to use the exception? Please explain:

Anyone

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: reference medicine

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: Acts necessary to obtain marketing clearance for medicinal product, e.g. studies, tests, examination activities and practical measures, See above (51).

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Yes

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Regional

If the exception is contained in statutory law, please provide the relevant provision(s):

Article 3 2nd paragraph 2 p SPA

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

Common internal market in the European Union. A regional exhaustion regime has been determined by the EU Court of Justice and ensure the free trade between member states of the European Union.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Yes

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 45 – 50 The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837).

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 45 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). A compulsory license for the use of an invention in Sweden may be granted if

1. *three years have passed from the granting of the patent and four years from the filing of the patent application,*
2. *the invention is not used to a reasonable extent in Sweden, and*
3. *there is no acceptable reason for the non-use of the invention.*

For the purposes of the application of the first Paragraph, item 2, use of an invention equals importation of the invention to Sweden from a State within the European Economic Area or a State or a territory that is party to the Agreement Establishing the World Trade Organization (WTO). (Act 2004:159).

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

See above answer to question nr 69, 2nd paragraph of Article 45

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three years from the granting of the patent and four years from the filing of the patent application, Article 45 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837)

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

“there is no acceptable reason for the non-use of the invention”, Article 45 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837).

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

See above answer to question 69.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

It does not.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Article 46 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). A holder of a patent for an invention of which the exploitation is depending on a patent that belongs to someone else may be granted a compulsory license to exploit the invention protected by the other patent. Such a license may be granted only if the applicant proves that the first-mentioned invention constitutes a significant technical progress of considerable economic interest compared with the other invention.

If a compulsory license is granted pursuant to the first Paragraph, the holder of the patent or which a compulsory license has been granted is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the other invention. (Act 2004:159).

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Article 50 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). A compulsory license is granted by a Court which also decides to what extent the invention may be exploited and determines the remuneration and other terms for the license. When substantially changed circumstances call for it, the Court may, upon request, revoke the license or establish new conditions for it.

77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Article 47 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). If a public interest of extreme importance so requires, anyone who desires to make commercial use of an invention for which another party holds a patent may obtain a compulsory license to that effect.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Not used since the current patent act was introduced in 1968.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments foreseen.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Government use

81.-88.

[Note from the Secretariat: the applicable law of Sweden does not provide exceptions related to government use..]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 3 b 1st paragraph of the Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). Where the holder of the patent or someone with his consent assigns plant propagating material to a farmer for agricultural use, the farmer may, notwithstanding Articles 3 and 3 a, use the product of the harvest for propagation or multiplication in his own agricultural activity. The extent of, and the conditions for, this exception from the exclusive right of the holder of the patent are contained in Article 14 of the Council Regulation (EC) No 2100/94 of 27 July, 1994 on the Community Plant Variety Right and the Implementing Regulations issued pursuant to that Article.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of EU directive 98/44 for the Legal Protection of Biotechnological Inventions.

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

See the above given answer to question nr 89.

93.-94.

[Note from the Secretariat: response was not provided.]

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 3 b 2nd paragraph of the Swedish Patents Act (Swedish Statute Book, SFS, 1967:837) Where the holder of the patent or someone with his consent assigns breeding stock or other animal reproductive material to a farmer, the farmer may, notwithstanding Articles 3 and 3 a, use the livestock or other animal reproductive material for agricultural purposes within his agricultural activity. The farmer may, however, not sell protected breeding stock or other material within the framework, or for the purpose, of a commercial reproduction activity.

The right of the farmer under the second Paragraph must not be exercised to an extent wider than what is reasonable taking into account the needs of the farmer and the interests of the patent holder. (Act 2004:159).

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

[Note from the Secretariat: response was not provided.]

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of EU directive 98/44 for the Legal Protection of Biotechnological Inventions.

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

See above provided answer to question nr 95.

99.-100.

[Note from the Secretariat: response was not provided.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Sweden does not provide other exceptions and limitations.]

Country: TURKEY
Office: Turkish Patent Institute

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Under the Turkish Patent Decree law, an invention which is novel, which surpass the State-of-the-Art and which is applicable in industry shall be protected by patents.(Art 5)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

According to the article 6 of the Turkish Patent Decree Law, non-Patentable subject matter and Inventions are given below.

Article 6 :

The following, not being inventions as of their nature, shall remain outside the scope of this present Decree-Law :

- a/ Discoveries, scientific theories, mathematical methods;*
- b/ Plans, methods, schemes/rules for performing mental acts, for conducting business/trading activity, and for playing games.*
- c/ Literary and artistic works, scientific works, creations having an esthetic characteristic, computer programs.*
- d/ Methods involving no technical aspect, for collecting, arranging, offering/presenting and transmitting information/data.*
- e/ Methods of diagnosis, therapy and surgery applying to human or animal body.*

The provision under the paragraph one, subparagraph (e) of this present Article, shall apply neither to the products and compositions (per se) used in connection with these methods nor to their process of manufacturing.

Patent shall not be granted for inventions in respect of following subject matter.

- a/ Inventions whose subject matter is contrary to the public order or to morality as is generally accepted.*
- b/ Plant and animal varieties/species or processes for breeding/plant or animal varieties/species, based mainly on biological grounds.*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Scope of Right Conferred By a Patent is given below according to the article 73 of the Turkish Patent Decree Law,

Article 73 :

The holder of a patent shall benefit from the right it confers without differentiating between the place of the invention, its field of technology and whether the concerned products are imported or of domestic production.

The holder of a patent is entitled to prevent following actions by third parties performed without permission:

a/ Production, sale, use, or importation of patented products or keeping them in possession for purposes other than for personal needs;

b/ Use of a process that is the subject matter of the patent;

c/ Offers made by third persons to others for the use of a patented process of which the use is known or should be known to be prohibited;

d/ Putting to sale or making use or importing or keeping in possession for any such purpose other than for personal needs of products directly obtained through the patented process.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Experimental use and/or scientific research;

Preparation of medicines;

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

Acts for obtaining regulatory approval from authorities;

Exhaustion of patent rights;

Compulsory licensing and/or government use;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Art 75 (a) of the Turkish Patent Decree Law, acts of any non industrial or non commercial purpose and limited to private ends/aims; shall remain outside the scope of rights conferred by a patent :

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

6.

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

No definition

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

None

9.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Art 75(b) of the Turkish Patent Decree Law provide that acts for experimental purposes shall remain outside the scope of rights conferred by a patent .

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

13.

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The Turkish Patent Decree Law does not make any distinction concerning the nature of the organization conducting the experimentation or research

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

None

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

Other, please specify: (every acts for non commercial experimental purposes, very broad definition without any restriction)

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Research and/or experimentation must be conducted with or using the patented invention ("research with")

Please explain by citing legal provision(s) and/or decision(s):

There is no further clarification of the exceptions provided.

There are no criteria relevant to the determination of the scope of the exception

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose

19. If the applicable law makes a distinction between "commercial" and "non-commercial" purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

No legal provision explaining these terms by providing their definitions.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

No further criteria applied.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No further amendments are foreseen.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Art 75(c) of the Turkish Patent Decree Law provide that preparations of medicines in pharmacies involving no mass production and carried out solely in making up a prescription and acts related to the medicines thus prepared shall remain outside the scope of rights conferred by a patent.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None.

25.

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

No definition regarding the entitled person to use the exception.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment is foreseen.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

According to Article 77 :

The applicant or patent owner shall not have the right against any person who works the invention or has made serious and effective preparations to work the said invention in the country in a good faith between the date of filing of the application and the date of priority, if any, to prevent them to continue to work the subject of the patent in the same manner as before or to commence to work as of the preparations made to these effect. However, continuing to work the subject matter of the patent or working as of the preparations made to these effects may only be to the extent necessary for meeting the reasonable needs of their enterprise. Such right to work the invention may only be transferable with the enterprise.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

None.

33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

According to the Art 77, continuing to work the subject matter of the patent or working as of the preparations made to these effects may only be to the extent necessary for meeting the reasonable needs of their enterprise.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

The Turkish Patent Decree law does not provide for a remuneration to be paid to the patentee for the exercise of the exception.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes.

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes.

If yes, please explain what those conditions are:

According to Art 77, such right to work the invention shall only be transferable with the enterprise.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Only be to the extent necessary for meeting the reasonable needs of their enterprise. No legal decision.

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendment is foreseen..

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 75(d) of the Turkish Patent Decree Law provide that patent right shall not be effective against the following products:

d- Use of patented invention in the manufacture or operation of ships or spaceships or airplanes or land transportation vehicles of countries signatory of the Paris Convention or for satisfying the needs of these, provided that said vehicles happen to be, temporarily or accidentally, within the boundaries of the Republic of Turkey;

Article 75(e) of the Turkish Patent Decree Law provide that patent right shall not be effective against the following products:

Where acts provided under Article 27 of the International Convention for Civil Aviation dated December 7, 1944 are related to an aircraft of a State, the provisions of this present Article shall apply likewise to said aircrafts.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

None.

44. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of Paris Convention Art. 5

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes, temporarily or accidentally

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, According to article 75(d) of The Turkish Patent Decree Law the patented product must be used in the manufacture or operation of ships, spaceships, airplanes, land transportation vehicles or for the needs of the vessels.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None.

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

[Note from the Secretariat: response was not provided.]

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None.

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

*Article 75(f) of the Turkish Patent Decree Law provide that patent right shall not be effective against the following products:
f-Acts for experimental purpose relating to the subject matter of the invention subjected to market approval including the market approval of medicines and the tests and experiments required therefore.*

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None.

53.

[Note from the Secretariat: response was not provided.]

54. Who is entitled to use the exception? Please explain:

No special provision defining the entitled party.

55. The exception covers the regulatory approval of:

Certain medicinal products.

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

Other. Please specify: Acts necessary to obtain marketing approval for medicinal products, e.g., experimental studies and tests

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments are foreseen.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

*According to the Turkish Patent decree Law Article 76 :
Rights conferred by a patent shall not extend to acts committed with regard to a product under patent protection after said product has been put to sale in Turkey by the right holder of the patent or with his consent.*

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Article 99 :

Compulsory license is (to be) granted where no offer for licensing offer has been made and where any one of the following situations/conditions materializes:

- 1. Failure to put to use/work the patented invention in accordance with Article 96;*
- 2. Dependency of subject matter of patents as mentioned in Article 79.*
- 3. On grounds of public interest as mentioned in Article 103 (including public health and national security)*

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None.

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention

Public health

National security

Dependent patents

Other, please specify: Where the working of a patented invention is particularly necessary for the public interest.

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of TRIPS Agreement

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Article 96 of the Turkish Patent Decree Law

The patentee or the person authorized by him is under obligation to put to use/work, the invention under patent protection. The obligation to put to use/work must be realized within

three years as from the date of publication in the relevant bulletin of the announcement related to the issue of the patent.

Market conditions are (to be) taken into consideration when/for assessing use/working. Article 100 of the Turkish Patent Decree Law

Any interested person may after the expiration of the period foreseen in Article 96, request the granting of a compulsory license on the grounds that the patent, at the time of the request, was not put to use or that the delay in the use thereof was not due to justifiable/legitimate reasons or that the use thereof had been suspended during an uninterrupted period of more than 3 years without justifiable/legitimate reason.

Technical or economic or legal reasons of an objective nature shall be deemed to constitute legitimate excuses for the inability to put the patent to use. The reasons accepted to be in the nature to constitute obstacles for using/working the patented invention are those which are beyond the control and will of the patentee.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, the importation of a patented product constitutes working of the patent according to the art 40 of the implementing Regulations .

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes.

If yes, what is the time period?

Within 3 years as from the date of publication of the mention of the grant of the patent or a patented invention is not sufficiently and continuously worked for more than 3 years in Turkey.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

Technical or economic or legal reasons of an objective nature shall be deemed to constitute legitimate excuses for the inability to put the patent to use. The reasons accepted to be in the nature to constitute obstacles for using/working the patented invention are those which are beyond the control and will of the patentee. (Art. 100).

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

No.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

According to the art 101, where the patented invention can not be put to use without infringing the rights conferred by a prior patent, the latter patentee, by bringing evidence that his patent, with reference to the prior patent will serve a different industrial purpose or achieves significant technical improvement, may request the court to grant license for using the patent of prior date.

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

According to the art 110, The decision to grant the compulsory license shall include the following:

The scope, the fee, the term of the license, the guarantee produced by the licensee, the date when the use is to commence and the measures for an effective and serious use of the patent.

According to the art 114:

In case of a compulsory license the patentee shall be paid an economically reasonable fee. The license fee shall be determined especially by taking into consideration the economic importance of the invention.

Request for modifying the terms/conditions

Article 118 :

The licensee or the patentee may request from the court to modify the fee or the terms/conditions of compulsory license on grounds of events occurring, at a later date, and justifying such modification. Especially, when the patentee has subsequently concluded a contractual license, under conditions, more favourable compared to those of the compulsory license, confers the right to request such modification.

Where the licensee seriously violate his obligations arising from the compulsory license or where he continuously fails to fulfill them, the court may, upon request of the patentee cancel the license, without prejudice to patentee's right for compensation of damages.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

No specific definition for "national emergency" or "circumstances of extreme urgency".

There are definitions for "public interest" and "national defense or public health" in Art. 103 on Compulsory license on grounds of Public Interest

Article 103 :

Situations where the non use of the invention or its insufficient use in terms of quality and quantity, causes serious damage to the country's economic or technical development shall be deemed to also involve public interest.

The concerned Ministry proposes to the Council of Ministers to issue a decree pertaining to the grant of compulsory license. In case, where the use of the invention is important for national defense or public health, the proposal is prepared jointly by the concerned ministry, and the Ministry of National Defense or the Ministry of Health.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Only 1 compulsory license has been issued in Turkey. Technological area of the relevant invention is mechanical engineering (IPC Class: F16B13 (Dowels or other devices fastened in walls or the like by inserting them in holes made therein for that purpose)). The compulsory license was granted on the grounds that the failure to put to use/work the patented invention in accordance with Article 96. In other words, the patentee had not put to use/work, the invention under patent protection within three years as from the announcement related to the issue of the patent.

79.-80.

[Note from the Secretariat: response was not provided.]

Government use

81.-88.

[Note from the Secretariat: the applicable law of Turkey does not provide exceptions related to government use.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Turkey does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Turkey does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of Turkey does not provide other exceptions and limitations.]

Country: UKRAINE
Office: State Service for Intellectual property of Ukraine (SIPS)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

An invention meets the patentability requirements provided that it is new, involves an inventive step and is industrially applicable.

A utility model meets the patentability requirements provided that it is new and industrially applicable.

(Paragraphs 1 and 2 of Article 7 of Law of Ukraine “On the Protection of Rights to Inventions and Utility Models” (further – Law)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

According to this Law, the legal protection shall not extend to such technology objects:

- plant varieties and animal breeds;*
- processes of the reproduction of plants and animals that are biological in its basis and do not belong to non-biological and microbiological processes;*
- topographies of integrated circuits;*
- results of art constructing.*

(Paragraph 3 of Article 6 of Law)

Not recognized as inventions (utility models) is the meaning of point 1.2 of these Rules:

- discoveries, scientific theories ta mathematical methods;*
- methods of intellectual, economical, organizational and commercial activities (planning, financing, supplying, stock-taking, crediting, forecasting, rationing etc.);*
- rules of performing physical exercises, games, competitions, auctions;*
- plans and schemes of planning constructions, buildings, territories;*
- signs (traffic signs, routes, codes, types etc.), itineraries, instructions;*
- computer programs;*
- forms of representation of information (e.g. in table form, diagrams, graphics, acoustic signals, words spelling, visual demonstrations, books, audio- and videodiscs).*

(Point 2.5 Rules for patent and utility model application making and filing)

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

*A patent shall give the exclusive right to the owner of a patent to use an invention (utility model) at his own discretion if such a use does not infringe rights of other owners of patents.
(Paragraph 2 of Article 28 of Law)*

*The patent shall give to his owner the exclusive right to forbid other persons to use an invention (utility model) without his permission, excluding the cases when according to this Law such a use is not considered to be the infringement of rights granted by a patent.
(Paragraph 5 of Article 28 of Law)*

The data on the application for a patent for an invention, which were published according to Article 16 of this Law, shall provide the temporary legal protection for the applicant in the volume of a patent claims in consideration of which the said data were published.

*After publication of the data on the application, the applicant shall have the right to obtain a compensation for damages from a person, which really knew, or received a notification written in Ukrainian with the indication of the application number about the publication of the data on the application for an invention used by this person without the applicant permission.
The applicant shall obtain the said compensation only after obtaining a patent.
(Paragraphs 1 and 2 of Article 21 of Law)*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use;*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of the patented invention (utility model) shall not be considered to be the infringement of rights deriving from a patent provided that it is used:

...

*without any commercial purpose;
(Paragraph 2 of Article 31 of Law)*

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

To limit exclusive right of the owner to forbid use of the invention without permission if such use is non-commercial.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of the patented invention (utility model) shall not be considered to be the infringement of rights deriving from a patent provided that it is used:

...

*for scientific or experimental purposes;
(Paragraph 2 of Article 31 of Law)*

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

To stimulate development of science e.g. to allow using some methods of researching, diagnostics, testing without permission of owner while scientific experiment is carried on.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

determine how the patented invention works
determine the scope of the patented invention
determine the validity of the claims
seek an improvement to the patented invention
invent around the patented invention
other, please specify: Any

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention
("research on")
Research and/or experimentation must be conducted with or using the patented invention
("research with")

Please explain by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

Commercial and non-commercial purposes

19.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23.-30.

[Note from the Secretariat: the applicable law of Ukraine does not provide exceptions related to the preparation of medicines.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Any person, which has honestly used a technology (technical) solution identical to the claimed invention (utility model) or has made considerable and serious preparations for such a use in the interests of its activity with the commercial purpose before the date of filing the application for granting a patent on the invention (utility model) with the Office or, if the priority has been claimed, before the priority date, shall have the right to extend this use free of charge or to use an inventions (utility model) as it was foreseen by the mentioned preparation (the right of previous use).
(Paragraph 1 of Article 31 of Law)

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

33. (a) What are the public policy objectives for providing the exception? Please explain:

To limit exclusive right of the owner to forbid use of the invention without permission to person who invented and used invention but didn't patented it in time.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The following shall be considered to be the use of an invention (utility model):

- manufacturing a product with the use of a patented invention (utility model), the use of this product, an offer of a product for the market, including an offer via the Internet, selling, import (coming-in) and other its introduction into the commercial circuit as well as storing a product for defined purposes;*
- the use of a process protected by a patent or an offer of a process for the use in Ukraine, provided that the person offering a process shall know that the use of a process without the permission of the patent owner is prohibited or, considering the circumstances, it is obvious.*

(Paragraph 2 of Article 28 of Law)

The right of previous use shall be restricted by the volume of the use of a solution identical to the claimed invention, which it was on the date of filing of the application with the Office. The right of previous use of the design may be transferred to another person only together with the enterprise or business practice, or with the part of the enterprise or business practice, in which the solution identical to the claimed invention (utility model) had been used or a considerable and serious preparation to such a use had been made.

(Paragraph 1 of Article 31 of Law)

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No (within the boundaries of prior use)

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

*The right of previous use of the design may be transferred to another person only together with the enterprise or business practice, or with the part of the enterprise or business practice, in which the solution identical to the claimed invention (utility model) had been used or a considerable and serious preparation to such a use had been made.
(Paragraph 1 of Article 31 of Law)*

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

No

39.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The use of the patented invention (utility model) shall not be considered to be the infringement of rights deriving from a patent provided that it is used:

...

*in a construction or during the exploitation of a transportation means of a foreign state that temporarily or occasionally is situated at any sea, air, or at the territory of Ukraine, provided that an invention (utility model) is used exclusively for the operation of the said transportation means;
(Paragraph 2 of Article 31 of Law)*

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes (See 42). No definitions.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes (See 42).

48.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of Ukraine does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

International

If the exception is contained in statutory law, please provide the relevant provision(s):

The introduction of a product that has been manufactured with the use of the patented invention (utility model) into the commercial circuit by any person, which has obtained a product without violation of the patent owner rights, shall not be considered to be the infringement of rights deriving from a patent.

*The product manufactured with the use of the patented invention (utility model) shall be considered to be obtained without the violation of the patent owner rights provided that this product has been manufactured by the patent owner and (or) after manufacturing has been introduced into the commercial circuit by the patent owner or other person according to the special permission (license) of the patent owner.
(Paragraph 3 of Article 31 of Law)*

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

Please explain your answer by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

63.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

See below

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents*

68.

[Note from the Secretariat: response was not provided.]

69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

If an invention (utility model), excluding a secret invention (utility model) is not used or is inadequately used in Ukraine within 3 years from the date of publishing the data on granting a patent or from the date when the use of an invention (utility model) has been terminated, any person who wishes and is ready to use an invention (utility model) may appeal to the court for granting the right to use an invention (utility model) provided that the owner of rights has rejected the conclusion of the license agreement.

If the patent owner does not prove that the fact of nonuse of an invention (utility model) is caused by important reasons, the court shall make a decision on granting the permission to

an interested person to use an invention (utility model) and define the volume of its use, the term of the permission, the amount and procedure of remunerating the patent owner. In this case, the right of the patent owner to grant permissions to use an invention (utility model) shall not be restricted.

(Paragraph 1 of Article 30 of Law)

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, the importation constitutes “working” of the patent

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

*3 years from the date of publishing the data on granting a patent or from the date when the use of an invention (utility model) has been terminated
(Paragraph 1 of Article 30 of Law)*

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes (by court decision)

If yes, what are “legitimate reasons”?

Any that court decided to be such

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The CL on the ground of anti-competitive practice can be granted only in relation to semiconductor technology by the decision of a relevant body of the state power;

(Paragraph 3 of Article 30 of Law).

Also see answer to question 81.

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

*The patent owner shall be obliged to grant the permission (license) to use an invention (utility model) to the owner of the patent that has been granted later provided that an invention (utility model) of the latter is intended for other purpose or has significant technical and economical advantages and may not be used without infringement of the rights of the owner the patent that has been granted earlier. The permission shall be granted in the volume that is necessary for the use of an invention (utility model) by the owner of the patent that has been granted later. In this case, the owner of the patent that has been granted earlier shall have the right to obtain on acceptable conditions a license to use an invention (utility model) that is protected by the patent that has been granted later.
(Paragraph 2 of Article 30 of Law).*

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

*In this case, the owner of the patent that has been granted earlier shall have the right to obtain on acceptable conditions a license to use an invention (utility model) that is protected by the patent that has been granted later.
(Paragraph 2 of Article 30 of Law).*

77.-80.

[Note from the Secretariat: response was not provided.]

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

With the purpose to protect the health of population, ecological safety and other public interests, the Cabinet of Ministers of Ukraine may permit the use of the patented invention (utility model) by a defined person without the consent of the patent (declarative patent) owner provided that this owner has groundlessly rejected granting a license for the use of an invention (utility model).

In this case:

- 1. the permission for such a use shall be granted with consideration of specific circumstances;*
- 2. the volume and the duration of such a use shall be determined by purpose of the granted permission and, in the case of semiconductor technology this shall be purely noncommercial use by bodies of the state power or implementing an anticompetition practice by the decision of a relevant body of the state power;*
- 3. the permission for such a use shall not deprive the patent owner of the right to grant permissions for the use of an invention (utility model);*
- 4. the right to such a use shall not be transferred excluding the case when it is transferred together with the part of the enterprise or business practice in which this use is carried out;*
- 5. the use shall be permitted mainly for providing the internal market needs;*
- 6. the notification concerning the grant of the permission for the use of an invention (utility model) shall be sent to the patent owner at the first opportune moment;*

7. the permission for the use shall be revoked in case of discontinuance of circumstances under which this permission has been granted;

*8. an adequate compensation in accordance with an economic value of an invention (utility model) shall be paid to the patent owner.
(Paragraph 3 of Article 30 of Law).*

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Public health
National security
National emergency and/or extreme urgency*

84.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of Ukraine does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of Ukraine does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

See 102.

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

The use of an invention with the commercial purpose by any person, which has obtained a product manufactured with the use of the patented invention, but could not

know that this product has been manufactured or introduced into the commercial circuit with the violation of the rights granted by the patent, shall not be considered to be the infringement of rights deriving from a patent. Meanwhile, after receiving the relevant notification from the owner of rights, the said person shall terminate the use of a product or pay the relevant compensation to the owner of rights. The amount of the said compensation shall be determined according to laws or by an agreement between the parties. The court shall resolve any disputes on the amounts and the procedure of paying compensation.

(Paragraph 4 of Article 31 of Law).

- (ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

- (iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

In addition, in relation to each exception and limitation, please explain:

- (i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

[Note from the Secretariat: response was not provided.]

- (ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

[Note from the Secretariat: response was not provided.]

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

[Note from the Secretariat: response was not provided.]

Country: UNITED KINGDOM
Office: UK Intellectual Property Office (UK IPO)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The standard for patentability is set out by s.1(1) of the Patents Act 1977 (as amended):

1(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –

- (a) the invention is new;*
- (b) it involves an inventive step;*
- (c) it is capable of industrial application;*
- (d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below;*

...

'Invention' is defined by s.125(1) as 'that specified in a claim of the specification of the application or patent... as interpreted by the description and any drawings'. Section 1(2) defines certain things which are not regarded as inventions. Sections 1(3) and 4A define classes of inventions for which a patent will not be granted.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The exclusions from patentability are set out in Sections 1(2), 1(3) and 4A of the Patents Act:

1(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of –

- (a) a discovery, scientific theory or mathematical method;*
- (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;*
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;*
- (d) the presentation of information;*

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.

(3) A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

(4) *For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.*

...

4A(1) *A patent shall not be granted for the invention of-*

- (a) a method of treatment of the human or animal body by surgery or therapy, or*
- (b) a method of diagnosis practised on the human or animal body.*

(2) *Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method.*

(3) *In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.*

(4) *In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art.*

Exclusions under s.1(2)

*The list of exclusions under s.1(2) is not to be considered exhaustive. Each category has its own legal precedents. However, the preferred method when examining patent applications for excluded matter is to follow the four step test set out by the Court of Appeal in *Aerotel/Macrossan* [2007] RPC 7 which sets out how an examiner should approach the issue and provides a framework for making any decision.*

The four steps are:

1 *Construe the claim;*

What does the claim mean and what is its scope?

2 *Identify the actual or alleged contribution;*

This can be summarised by asking what the inventor has really added to the stock of human knowledge? It will take into account the problem being solved and how the invention works. It will also consider to some extent the common general knowledge though should not be confused with identifying the inventive step. Any assessment of the contribution must be based on the context of the claim as a whole and not its individual integers.

3 *Ask whether it falls solely within excluded subject matter;*

Having identified the contribution is it excluded under one or more of the exclusions listed in Section 1(2) of the Act.

4 *Check whether the actual or alleged contribution is actually technical in nature.*

This step is included to ensure that an invention is technical and not something for which we would not normally grant a patent.

Interpretation of the fourth step should also consider the judgement in Oneida Indian Nation [2007] EWHC 954 (Pat). In that case the fourth step does not need to be applied if an application has failed at the third.

Taking each category in turn, the applicable case law is as follows:

Discovery, scientific method

*Hickton's Application [1909] 26 RPC 339
Genentech [1989] RPC 147
Tate & Lyle Technology v Roquette Frères [2010] FSR 1*

Mathematical Methods

*Gales Application [1991] RPC 305
Vicom/Computer-related invention [1987] 1 OJEPO 14 (T0208/84)*

Literary, dramatic, musical or artistic work or any other aesthetic creation

ITS Rubber [1979] RPC 318

Scheme, rule or method of performing a mental act

*Fujitsu [1997] RPC 608
Halliburton [2005] EWHC 1623 (Pat)*

Playing a Game

*Shopalotto [2006] RPC 7
IGT [2007] EWHC 1341
Patents Act 1977: Patentability of games [2006] RPC 8*

Method of doing Business

*Merrill Lynch [1989] RPC 561
Aerotel/Macrossan [2007] RPC 7*

Computer Program

*Aerotel/Macrossan [2007] RPC 7
Symbian [2009] RPC 1
Astron Clinica [2008] RPC 14
AT&T/Cvon [2009] EWHC 343 (Pat)
Gemstar v Virgin [2010] RPC 10
Vicom/Computer-related invention [1987] 1 OJEPO 14 (T0208/84)*

Symbian makes it clear that a computer program may be patentable if it makes a 'technical contribution'.

AT&T sets out five signposts that indicate if a computer program makes the required technical contribution – only one of the signposts needs to be answered in the affirmative. The signposts are:

- i) *Whether the claimed technical effect has a technical effect on a process which is carried on outside the computer;*
- ii) *Whether the claimed technical effect operates at the level or the architecture of the computer; that is to say whether the effect is produced irrespective of the data being processed or the application being run;*
- iii) *Whether the claimed effect results in the computer being made to operate in a new way;*
- iv) *Whether there is an increase in the speed or reliability of the computer;*
- v) *Whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented;*

Presentation of Information

Gemstar v Virgin [2010] RPC 10
Autonomy [2008] EWHC 146 (pat)
Townsend's Application [2004] EWHC 482

Further details of the case law may be found in section 1 of the Manual of Patent Practice.

Medical inventions

Methods of treatment by therapy or surgery, or methods of diagnosis performed directly on the human or animal body are excluded from patentability under s.4A(1), which corresponds to Art.53(c) of the EPC 2000. UK practice in interpreting this exclusion is governed by a variety of decisions of the UK courts (binding on our practice) and the EPO Boards of Appeal (strongly persuasive). For example, the UK Court of Appeal decision in Unilever (Davis's) Application [1983] RPC 21 confirmed that the definition of 'therapy' includes both curative and prophylactic treatments (such as vaccination), and the exclusion applies equally to treatment of humans and veterinary treatment of animals. Our practice on the interpretation of 'methods of diagnosis practised on the human or animal body' is based on the decision of the EPO Enlarged Board of Appeal in G 01/04 Diagnostic methods OJEP 2006, 334. Therefore, methods are only excluded if they include all the steps leading towards the identification of a condition, and thereby make it possible to decide on a particular course of treatment. Moreover, diagnostic methods are only excluded if they are practised on the human or animal body; in vitro diagnostic methods (e.g. genetic or immunological tests performed on isolated blood samples) are not excluded.

Section 4A(1) does not prevent the patenting of materials or compositions used in such methods, as stated in s.4A(2).

In addition, 'first medical use' claims of the type 'substance X for the use in therapy' are regarded as novel if the substance has not previously been used in any method excluded under s.4A(1); as set out in s.4A(3) (equivalent to Art.54(4) EPC).

Moreover, s.4A(4) (equivalent to Art. 54(5) EPC) allows for the protection of further, specific uses of known substances or compositions; i.e. 'second medical use' claims of the type 'substance X for use in the treatment of disease Y'.

Following the decision of the Court of Appeal in Actavis v Merck [2008] RPC 26, a second medical use claim may be distinguished from the prior art solely by a new and inventive dosage regime. The UK IPO no longer allows 'Swiss-type' second medical use claims of the form 'the use of substance X in the manufacture of a medicament to treat substance Y',

following the EPO Enlarged Board of Appeal decision in G 02/08 ABBOTT RESPIRATORY/Dosage regime [2010] 10 OJEPO 456.

Biotechnological inventions

Schedule A2 to the Patents Act 1977 (which implements articles 1-11 of EC Directive 98/44/EC on the legal protection of biotechnological inventions) states that an invention is not excluded from patentability solely on the grounds that it concerns either a product consisting of or containing biological material, or a process by which biological material is produced, processed or used. However, Sch.A2 states that the following are not patentable inventions:

- (a) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;*
- (b) processes for cloning human beings;*
- (c) processes for modifying the germ line genetic identity of human beings;*
- (d) uses of human embryos for industrial or commercial purposes;*
- (e) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;*
- (f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.*

Schedule A2 also states that inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. Moreover, notwithstanding part (a) above, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. Where the invention resides in a whole or partial gene sequence, the industrial application of the sequence must be disclosed in the application as filed.

Following the EPO Enlarged Board of Appeal decision in G 02/06 WARF/ Use of embryos [2009] 5 OJEPO 306, the UK IPO issued a Practice Notice on 4 February 2009 setting out our practice on the patentability of inventions involving human embryonic stem cells. The UK IPO will not grant patents for processes of obtaining stem cells from human embryos, but will continue to grant patents for inventions involving human embryonic stem cells provided that, at the filing or priority date, the invention could be obtained by means other than the destruction of human embryos.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Rights granted with a patent

Infringement is covered by sections 60 to 71 of the Patents Act. The acts that constitute infringement of a patent are set out by s.60(1) and (2):

60(1) Subject to the provision of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say –

- (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;*
- (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;*
- (c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.*

(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

Sections 60(1) and (2) correspond to articles 25 and 26 of the Community Patent Convention.

Section 61 gives the proprietor of a patent the right to bring civil proceedings in the court in respect of any act alleged to infringe the patent. The claims that may be made in such proceedings are set out by s.61(1):

61(1) Subject to the following provisions of this Part of this Act, civil proceedings may be brought in the court by the proprietor of a patent in respect of any act alleged to infringe the patent and (without prejudice to any other jurisdiction of the court) in those proceedings a claim may be made –

- (a) for an injunction or interdict restraining the defendant or defender from any apprehended act of infringement;*
- (b) for an order for him to deliver up or destroy any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;*
- (c) for damages in respect of the infringement;*
- (d) for an account of the profits derived by him from the infringement;*
- (e) for a declaration or declarator that the patent is valid and has been infringed by him.*

Section 61(2) provides that the court cannot both award damages and order an account of profits in respect of the same infringement.

If the proprietor and the alleged infringer agree to do so, they may refer the question of infringement to the Comptroller to be determined in proceedings before the UK IPO (s.61(3)). However, the powers of the Comptroller are more limited than those of the court and the proprietor may only claim the reliefs mentioned in s.61(1)(c) and (e) in such proceedings.

Rights conferred by publication

Section 69(1) provides that, from publication of the application until grant, the applicant has the same right to bring proceedings for an act of infringement as he would have had if the patent had been granted on the day of publication. However, the right is subject to the following conditions set out in s.69(2):

69(2) *The applicant shall be entitled to bring proceedings by virtue of this section in respect of any act only –*

(a) after the patent has been granted; and

(b) if the act would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent, but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.

Section 69(3) requires the court or the comptroller to reduce the amount of damages awarded if it is considered that it would not have been reasonable to expect from the application as published that a patent conferring protection against the infringing act would be granted.

Section 69 corresponds to article 34 of the Community Patent Convention.

Rights of co-owners and exclusive licensees

Where there are two or more joint proprietors, each of the proprietors has the right to bring proceedings under sections 61 and/or 69 without the concurrence of the others, although the others must be made parties to the proceedings (s.66(2)).

An exclusive licensee has the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence, although the proprietor must be made a party to the proceedings (s.67).

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

*Private and/or non-commercial use;
Experimental use and/or scientific research;
Preparation of medicines;
Prior use;
Use of articles on foreign vessels, aircrafts and land vehicles;
Acts for obtaining regulatory approval from authorities;
Exhaustion of patent rights;
Compulsory licensing and/or government use;
Exceptions and limitations related to farmers' and/or breeders' use of patented
Inventions*

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions". Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(a) of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

(a) it is done privately and for purposes which are not commercial;

Section 60(5)(a) corresponds to article 27(a) of the Community Patent Convention (CPC) of 1975 (which never came into force).

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

6. (a) What are the public policy objectives for providing the exception?

It should be possible to carry out minor activities without hindrance by the threat of patent infringement.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The Patents Act 1977 was intended (inter alia) to implement the CPC and s.60(5)(a) implements article 27(a) of the CPC.

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

*These terms are not defined in statute but there is case law providing guidance on their interpretation. In *Smith, Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 513, the court considered that the word ‘privately’ in s.60(5)(a) includes commercial and non-commercial situations; is not synonymous with ‘secret’ or ‘confidential’; and is used as the opposite of ‘publicly’, denoting an act done for the person’s own use. In interpreting the meaning of ‘purposes which are not commercial’, the purposes of the act must be considered: there would be infringement if the purposes include any commercial ones in addition to the non-commercial ones. Experiments done for legal proceedings in the High Court or the UK IPO are not considered to be done for a ‘commercial’ purpose.*

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

Section 60(6) provides that a person who does an act falling within the exception under s.60(5)(a) is not treated as a ‘person entitled to work the invention’ for the purposes of s.60(2). It follows that acts of contributory infringement under s.60(2) do not fall within the exception under s.60(5)(a). It may therefore be an infringing act under s.60(2) to supply a person with material for carrying out an act falling within the scope of s.60(5)(a).

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is considered adequate and there are no plans to change it.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

In Smith, Kilne & French v. Evans [1989] FSR 513 and McDonald v. Graham [1994] RPC 407 at 431 it was considered that where there is a dual purpose to the activities carried out and one of these activities is commercial in nature then the defence of private use will not apply.

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(b) of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

...

(b) it is done for experimental purposes relating to the subject-matter of the invention;

Section 60(5)(b) corresponds to article 27(b) of the Community Patent Convention.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

N/A

13. (a) What are the public policy objectives for providing the exception?

Scientific progress should not be hindered by the threat of patent infringement.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The origin of the UK experimental use exception lies in the CPC. Section 60(5)(b) of the Patents Act 1977 is almost identical to the equivalent provisions in Article 27 of the CPC.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

There is no distinction concerning the nature of the organisation in statute or case law. In Monsanto Co v Stauffer Chemical Co and another [1985] RPC 515, the Court of Appeal considered that the exception may cover acts which have a commercial end in view. It follows that the exception may apply to commercial organisations.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The statute contains no definition of ‘experimental purposes’ but there is case law providing guidance on its interpretation.

In Monsanto Co v Stauffer Chemical Co and another (above) it was held that trials carried out in order to discover something unknown, or to test a hypothesis, or in order to find out whether something which is known to work in specific conditions will work in different conditions can fairly be regarded as experiments. However, trials carried out in order to demonstrate to a third party that a product works or in order to amass information to satisfy a third party, whether a customer or a body regulating the safety etc of such products, that the product works as its maker claims are not to be regarded as acts done "for experimental purposes".

In CoreValve v Edwards Lifesciences [2009] EWHC 6 Pat Ct, the court applied the principle established by the German Supreme Court in Klinische Versuche (Clinical Trials) I [1997] RPC 623:

An act for experimental purposes which is related to the subject-matter of the invention and therefore legitimate can exist if a patented pharmaceutically active substance is used in clinical trials with the aim of finding whether and, where appropriate, in what form the active substance is suitable for curing or alleviating certain other human diseases.

However, the court in CoreValve v Edwards Lifesciences considered that there must be an outward limit to that principle, and held that application of the principle should involve the consideration of whether the immediate purpose of the transaction is to generate revenue. The clinical trials in question were not considered to be exempted under s.60(5)(b) since one of the purposes of the trials was to 'generate immediate revenue of a substantial character'. It follows that commercial factors must be considered in determining whether the exception applies.

In Smith, Kline & French Laboratories Ltd v Evans Medical Ltd [1989] FSR 513, it was held that experiments for the purposes of litigation are exempted under s.60(5)(b) if they relate to the subject matter of the invention found in the claims of the patent alleged to be infringed, in the sense of having a real and direct connection with it.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

Other, please specify: The law does not require the purpose of the experiment to fall into any specific category. The relevant case law is set out in answer to question 15.

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

[Note from the Secretariat: response was not provided.]

Please explain by citing legal provision(s) and/or decision(s):

Section 60(5)(b) requires that the act must be done for experimental purposes 'relating to the subject matter of the invention'. Beyond that, the law contains no requirement to consider the above criteria in determining the scope of the exception.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

*A non-commercial purpose
A commercial purpose*

In Monsanto Co v Stauffer Chemical Co and another (above) it was held that the exception can cover experimental work having a commercial purpose, but not all trials for a commercial purpose fall within the exception. Furthermore in CoreValve v Edwards Lifesciences (above) it was held that the exception did not apply since one of the purposes of the experiments was to 'generate immediate revenue of a substantial character'

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

There is no distinction in statute. The case law sets out no clear distinction but requires commercial factors to be considered in determining whether the exception applies. For a discussion of the case law see answers to questions 14, 15 and 18.

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Section 60(6) provides that a person who does an act falling within the exception under s.60(5)(b) is not treated as a 'person entitled to work the invention' for the purposes of s.60(2). It follows that associated acts of contributory infringement under s.60(2) do not fall within the exception under s.60(5)(b). It may therefore be an infringing act under s.60(2) to supply a person with material for carrying out the experimental work.

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The experimental use provision was the subject of a 2008 UK consultation by the UK IPO. The purpose of this consultation was to seek evidence on the effect of the patent research exception and to identify the extent of stakeholder concerns on this aspect of UK patent law. This consultation was in response to a number of reports that concluded that clarification or restructuring of the research exception was needed. In particular it was noted that the lack of case law in this area leads to uncertainty over the scope of the experimental use exception. No conclusive evidence was provided in the consultation responses to indicate that the experimental use exception was restricting research in the UK. The absence of clear evidence did not support a change of legislation. The consultation did provide evidence in two areas which do not strictly concern the experimental use exception in the UK:- risk of patent infringement during clinical trials and use of patented plant material by plant variety breeders; these issues are the subject of further investigation and monitoring, consecutively, in the UK.

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

See 21.

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(c) of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

...

(c) it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;

Section 60(5)(c) corresponds to article 27(c) of the Community Patent Convention.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

25. (a) What are the public policy objectives for providing the exception? Please explain:

Pharmacists should be free to make individual medical preparations as prescribed by a doctor without threat of patent infringement.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The Patents Act 1977 was intended (inter alia) to implement the CPC and s.60(5)(c) implements article 27(c) of the CPC.

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

There is no relevant case law but the wording of the statute indicates that the exception covers pharmacists.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

Section 60(6) provides that a person who does an act falling within the exception under s.60(5)(c) is not treated as a 'person entitled to work the invention' for the purposes of s.60(2). It follows that associated acts of contributory infringement under s.60(2) do not fall within the exception under s.60(5)(c). It may therefore be an infringing act under s.60(2) to supply a person with material for preparation of a medicine.

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is considered adequate and there are no plans to change it.

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We are not aware of any significant challenges.

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 64 of the Patents Act:

64(1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention –

- (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or*
- (b) makes in good faith effective and serious preparations to do such an act, has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.*

64(2) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may –

- (a) authorise the doing of that act by any partners of his for the time being in that business, and*
- (b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.*

64(3) Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

N/A

33. (a) What are the public policy objectives for providing the exception? Please explain:

The exclusion exists to ensure prior users are treated fairly with respect to patent holders.

Section 2(1) of the Patents Act 1977 states that 'An invention shall be taken to be new if it does not form part of the state of the art'. When the Act came into force it deprived a secret prior user of his right to sue a patent holder for grounds of invalidity. To counter this deprivation it was thought only just to accord a right to continue his use, thus a secret prior user may continue his use without being sued on grounds of infringement subject to Section 64.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The 1949 Act granted no protection to a prior user whose prior use began before the priority date of the invention; however, secret prior use was grounds for revocation, and was thus protected.

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 64 protects a person who in the UK before the priority date of the invention does in good faith an act which would constitute infringement of the patent or who makes in good faith effective and serious preparations to do such an act (s.64(1)). Therefore, in order for the prior use exception to apply, the act in question must constitute infringement of the patent. The recipients of products disposed of in exercise of rights conferred by s.64(1) or (2) are protected under s.64(3).

In Lubrizol Corporation v Esso Petroleum Co. Ltd. [1998] RPC 727 the Court of Appeal affirmed (at page 770) that the protection afforded by s.64 to the prior user is not strictly limited to acts identical to those which were performed before the priority date but ‘cannot be a right to manufacture any product, nor a right to expand into other products’. The Court of Appeal upheld the view of the Patents Court that ‘if the protected act has to be exactly the same (whatever that may mean) as the prior art then the protection given by the section would be illusory. The section is intended to give practical protection to enable a man to continue in substance what he was doing before’. In the event, two customer trials by the defendant in the UK of small samples imported from the US with a view to possible later manufacture in the UK but with no decision yet made, were held, although serious, not to be ‘effective’ preparations to do an infringing act. The Court of Appeal amplified (at page 785) that it is not ‘sufficient to show that the serious preparations, if pursued to finality, will have the requisite effect’.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No.

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

The right may not be licensed but, if the act of prior use or preparations therefor occurred in the course of a business, the prior user may assign or transmit the right, or authorise the doing of the act, under the specific conditions set out by s.64(2).

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes.

If yes, please explain what those conditions are:

The conditions are set out by s.64(2) (see answer to question 31).

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes – these situations are covered by similar provisions in sections 20B and 28A of the Patents Act.

If yes, please explain the conditions under which such use can continue to apply:

Where a terminated application has been reinstated under s.20A following termination of the application, the rights of third parties are as set out under s.20B:

20B(4) If the application has been published under section 16 above before its termination and, after the termination and before publication of notice of the request for its reinstatement, a person –

(a) began in good faith to do an act which would have constituted an infringement of the rights conferred by publication of the application if the termination had not taken place, or

(b) made in good faith effective and serious preparation to do such an act, he has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the reinstatement of the application and the grant of the patent; but this right does not extend to granting a licence to another person to do the act.

(5) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (4) above may –

(a) authorise the doing of that act by any partners of his for the time being in that business, and

(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

(6) Where a product is disposed of to another in exercise of a right conferred by subsection (4) or (5) above, that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the applicant.

(6A) The above provisions apply in relation to the use of a patented invention for the services of the Crown as they apply in relation to infringement of the rights conferred by publication of the application for a patent (or, as the case may be, infringement of the patent).

Similar provisions exist under s.28A to cover the situation where a lapsed patent has been restored under s.28:

28A(4) If after it was no longer possible for the patent to be so renewed, and before publication of notice of the application for restoration, a person –

(a) began in good faith to do an act which would have constituted an infringement of the patent if it had not expired, or

(b) made in good faith effective and serious preparations to do such an act, he has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the restoration of the patent; but this right does not extend to granting a licence to another person to do the act.

(5) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (4) may –

(a) authorise the doing of that act by any partners of his for the time being in that business, and

(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

(6) Where a product is disposed of to another in exercise of the rights conferred by subsection (4) or (5), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.

(7) The above provisions apply in relation to the use of a patent for the services of the Crown as they apply in relation to infringement of the patent.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is considered adequate and there are no plans to change it.

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

*See explanation of *Lubrizol Corporation v Esso Petroleum Co. Ltd.* [1998] RPC 727 in answer to question 34.*

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(d)-(f) of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

...

(d) it consists of the use, exclusively for the needs of a relevant ship, of a product or process in the body of such a ship or in its machinery, tackle, apparatus or other accessories, in a case where the ship has temporarily or accidentally entered the internal or territorial waters of the United Kingdom;

(e) it consists of the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing the United Kingdom (including the air space above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle;

(f) it consists of the use of an exempted aircraft which has lawfully entered or is lawfully crossing the United Kingdom as aforesaid or of the importation into the United Kingdom, or the use or storage there, of any part or accessory for such an aircraft;

Section 60(7) defines the terms used in s.60(5)(d)-(f):

60(7) In this section –

"relevant ship" and "relevant aircraft, hovercraft or vehicle" mean respectively a ship and an aircraft, hovercraft or vehicle registered in, or belonging to, any country, other than the United Kingdom, which is a party to the Convention for the Protection of Industrial Property signed at Paris on 20 March 1883 or which is a member of the World Trade Organisation; and

"exempted aircraft" means an aircraft to which section 89 of the Civil Aviation Act 1982 (aircraft exempted from seizure in respect of patent claims) applies.

Section 60(5)(d)-(f) corresponds to article 27(d)-(f) of the Community Patent Convention.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

44. (a) What are the public policy objectives for providing the exception? Please explain:

The movement of foreign vessels, etc, should not be hindered by the threat of patent infringement.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The Patents Act 1977 was intended (inter alia) to implement the CPC and s.60(5)(d)-(f) implement article 27(d)-(f) of the CPC.

45. The exception applies in relation to:

Vessels (the statute refers to 'ships' rather than 'vessels')

Aircrafts

Land Vehicles (the statute refers to 'vehicles' rather than 'land vehicles')

Hovercraft are also specifically mentioned in s.60(5)(e)

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes – the words 'temporarily' and 'accidentally' are used in section 60(5)(d) and (e). These terms are not defined in statute but the meaning of 'temporarily' was considered by the courts in Stena Aktiebolag v Irish Ferries Ltd [2002] RPC 50 and [2003] RPC 36 CA. The case concerned a high-speed catamaran used to provide a regular ferry service between Eire and the UK, with three or four crossings being made each day. The vessel's home port was in

Dublin, but it spent around three hours in UK territorial waters on each crossing. The vessel's superstructure was found to fall within the scope of the claimant's patent, and the claimant argued that the vessel's regular and frequent crossings took it outside the scope of s.60(5)(d) because 'temporarily' should be interpreted as 'on isolated occasions or casually'. The court rejected this argument, stating that the primary purpose of the word 'temporarily' was to distinguish between vessels which were engaged in essentially internal operations, and those which travelled between countries. Regard was to be had for the intention of the vessel's operator; on each crossing, the intention was for the vessel to enter and then leave UK territorial waters, and the fact that each crossing was repeated frequently did not alter the fact that each entry into UK waters was designed to be short-lived. The court therefore held that s.60(5)(d) applied and so infringement had not occurred.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 60(5)(d) specifies that the use must be 'exclusively for the needs of a relevant ship'. In Stena Aktiebolag v Irish Ferries Ltd (above), the court rejected an argument that the defence in s.60(5)(d) was restricted only to 'machinery, tackle, apparatus or other accessories' associated with the vessels and held that a purposive construction made clear that s.60(5)(d) applied as much to vessels as a whole as to any parts used on them.

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The framework is considered adequate and there are no plans to change it.

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We are not aware of any significant challenges.

Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(i) of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

...

(i) it consists of -

(i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or

(ii) any other act which is required for the purpose of the application of those paragraphs.

Section 60(7) defines the terms used in s.60(5)(i):

60(7) In this section –

...

"Directive 2001/82/EC" means Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products as amended by Directive 2004/28 of the European Parliament and of the Council;

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by Directive 2002/98/EC of the European Parliament and of the Council, by Commission Directive 2003/63/EC, and by Directives 2004/24/EC and 2004/27/EC of the European Parliament and of the Council.

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

53. (a) What are the public policy objectives for providing the exception? Please explain:

Generic medicines should be in competition with patented medicines as soon as the relevant period of protection has expired

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Section 60(5)(i) implements article 13 paragraph 6 of Directive 2001/82/EC on veterinary medicinal products and article 10 paragraph 5 of Directive 2001/83/EC on medicinal products for human use.

54. Who is entitled to use the exception? Please explain:

Section 60(5)(i)(i) provides that the exception applies to those carrying out studies, tests and trials on generic medicinal products to show that the generic product is bioequivalent to an approved patented product where these acts are required to obtain marketing authorisation. Section 60(5)(i)(ii) provides that the exception also applies to any other act required for the purpose of such studies, tests and trials. This suggests that manufacturers and suppliers of materials for such studies, tests and trials would also be covered by the exception.

55. The exception covers the regulatory approval of:

Certain products. Please describe which products: Veterinary medicinal products and medicinal products for human use which fall within the scope of the Directives mentioned in s.60(5)(i).

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

The following acts would appear to be allowed in principle if carried out for the purposes of a study, test or trial falling within the scope of s.60(5)(i):

*Making
Using
Selling
Offering for sale
Import*

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to the law are foreseen.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We are not aware of any significant challenges.

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

*National
Regional*

If the exception is contained in statutory law, please provide the relevant provision(s):

A regional exhaustion doctrine applies within the EEA under articles 34 and 36 of the Treaty on the Functioning of the European Union (the 'EU Treaty').

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

*The UK also has a doctrine of implied licence, which functions as an exhaustion doctrine. This doctrine was established in *Betts v Willmott* (1871) LR 6 Ch App 239 where it was held that, on selling a patented product, the patentee transfers with the goods a licence for the purchaser to sell or use the article. The principle applies regardless of whether the first sale is made in the UK or elsewhere.*

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

Balancing patent holders' rights with freedom of trade.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

See 60.

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

Yes (National law)

No (Regional law)

Please explain your answer by citing legal provision(s) and/or decision(s):

The regional exhaustion doctrine cannot be overridden since it derives from article 28 of the EU Treaty which prohibits restrictions on imports between Member States.

Since the national exhaustion doctrine is one of implied licence, it can be overridden if the patentee imposes conditions on the use/re-sale of the product when it is first sold. Such conditions place a limitation on the grant of the licence to deal with the patented product and apply to all those who buy the product with knowledge of them. These principles were set out in National Phonograph Company v Menck (1911) 28 R.P.C. 229 Pat Ct ; Incandescent Gas Light v Brogden (1899) 16 R.P.C. 179 ; and Dunlop v Longlife Battery [1958] R.P.C. 473.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Yes.

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

We are not aware of any significant challenges.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 48-54 of the Patents Act are concerned with the grant of compulsory licences.

Also applicable is the EU Compulsory Licensing Regulation (Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems). Section 128A of the Patents Act sets out how certain provisions of the Act apply to EU compulsory licences and applications for such licences.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Under sections 48-54, the grounds that apply are dependent on whether or not the proprietor of the patent is a 'WTO proprietor' i.e. is a national of, or is domiciled in, a country which is a member of the World Trade Organisation, or has a real and effective industrial or commercial establishment in such a country. The grounds for patents owned by WTO proprietors and non-WTO proprietors are set out by s.48A(1) and s.48B(1) of the Patents Act respectively.

48A(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are-

(a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;

(b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms-

(i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or

(ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;

(c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

...

48B(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are-

(a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;

(b) where the patented invention is a product, that a demand for the product in the United Kingdom-

(i) is not being met on reasonable terms, or

(ii) is being met to a substantial extent by importation from a country which is not a member State;

(c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked-

(i) where the invention is a product, by the importation of the product from a country which is not a member State,

(ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;

(d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms-

(i) a market for the export of any patented product made in the United Kingdom is not being supplied, or

(ii) the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered, or

(iii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;

(e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

...

The Compulsory Licensing Regulation provides for the availability of a compulsory licence for anyone who wishes to make a specific patented pharmaceutical product solely in order to export it to a developing country with a particular health problem.

*Non-working or insufficient working of the patented invention (s.48B(1)(a))
Refusal to grant licenses on reasonable terms (s.48A(1)(b) and s.48B(1)(d))
Anti-competitive practices and/or unfair competition (s.50A and s.51)
Public health (Compulsory Licensing Regulation)
Dependent patents (s.48A(1)(b)(i) and s.48B(1)(d)(ii))
Other, please specify: See s.48A(1)(a), (c) and s.48B(1)(b)-(c), (e).*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Sections 48-54

The objective is to prevent the monopoly conferred by the patent working against the public interest.

The Patents Act 1977 provides for the granting of compulsory licences as a way of correcting or remedying problems where certain conditions in the market are not being met or where licences are available but only under unreasonable terms.

It could also be argued that the existence of the compulsory licensing provisions acts as an incentive for parties to negotiate and agree voluntary licensing agreements rather than go through what is, essentially, inter partes litigation in order to attempt to obtain a compulsory

licence. If so, it can be said that the existence of the provisions also acts to prevent or repress anti-competitive behaviour.

Compulsory Licensing Regulation

The Regulation implements the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). It was implemented as part of wider European and international action to address public health problems faced by least developed countries and other developing countries⁶.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Sections 48-54

Section 22 of the Patents, Designs and Trade Marks Act 1883 gave the Board of Trade the power to order the grant of compulsory licence where:

- (a) The patent was not being worked in the UK; or
- (b) The reasonable requirements of the public with respect to the invention were not satisfied; or
- (c) Any person was prevented from working or using the invention of which he was possessed.

The jurisdiction of the Board of Trade was subsequently passed to the Judicial Committee of the Privy Council, and then court by subsequent patent Acts in the early 20th century.

The 1949 Patent Act allowed for the grant of compulsory licences in two categories:

- (a) In respect of any patent where there had been inadequate working or oppressive conduct by the patentee
- (b) Where the invention was concerned with food, medicine, or surgical or curative device.

The 1977 Patents Act re-enacted the 1949 Act in this area, save for the omission of the provision relating to food, medicine and surgical/ curative devices; however, the European Court held that the UK may not grant compulsory licences where demand for a patented product is satisfied by imports from other European member states. Additionally, it was held that the UK may not grant compulsory licences to permit a licensee to import products from outside the EC if the patentee works the invention in another member State, but not if he works in in the UK. The aim of this being to prevent discrimination against a patentee who decides to manufacture in another member State of the EC.⁷

Compulsory Licensing Regulation

See <http://eur-lex.europa.eu/en/index.htm> for further information.

⁶ For further information see Regulation (EC) No 816/2006 which can be found on <http://eur-lex.europa.eu/en/index.htm>.

⁷ For a fuller discussion of the legislative history see Thorley, S; Miller, R; Burkill, G; Birss, C; Terrell on the law of patents, (2000), Sweet & Maxwell.

69. If the applicable law provides for the grant of compulsory licenses on the ground of “nonworking” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Section 48B(1)(a) refers to whether an invention is being ‘commercially worked’ or ‘so worked to the fullest extent possible’. These terms are not defined in statute but decisions of the UK IPO have provided guidance on how s.48B(1)(a) is to be interpreted.

In Enviro-Spray Systems Inc’s Patents [1986] RPC 147, the hearing officer declined to attempt a formal definition of ‘commercial working’ but saw no reason to depart from its plain and ordinary meaning – ‘as far as manufactures are concerned, the expression is... clearly satisfied by the straightforward manufacture of goods for the purposes of trade’. He also observed that working can be commercial and yet not be exploiting the invention to the full, so manufacture on a scale too small to fully meet demand can still constitute commercial working.

In Kamborian’s Patent [1961] RPC 403 (also a decision of the UK IPO), the hearing officer considered that the fullest extent to which an invention may be worked can be expressed as ‘the highest rate of production which is practicable and necessary substantially to meet the demand’. In order to succeed in showing that this ground applies, the applicant for the compulsory licence must provide ‘evidence to show what the demand for the invention might reasonably be expected to be, and how far short, if at all, production under the patent falls, as far as is practicable to supply it’.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

In effect, yes, under the conditions set out by s.48B(3), which provides that a compulsory licence cannot be granted in respect of the ground mentioned in s.48B(1)(a) if demand in the UK is being met by importation of the patented invention from a member State of the European Economic Area (EEA) where the invention is being commercially worked.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Three years from the date of grant of the patent (s.48(1)). This time period applies to all applications for a compulsory licence.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

Section 48B(2) allows an application on the ground mentioned in s.48B(1)(a) to be stayed to allow sufficient time for the patentee to ‘commercially work’ the invention if ‘it appears to the

comptroller that the time which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to allow the invention to be so worked'.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

There is no definition of 'reasonable terms' in statute but section 48A.03 of the Manual of Patent Practice gives the following guidance:

What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.

Furthermore, in Brownie Wireless Co Ltd's Applications 46 RPC 457, the court considered the best test of whether a royalty is reasonable is: how much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay?

74. If the applicable law provides for the grant of compulsory licenses on the ground of anticompetitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

Sections 50A and 51 of the Patents Act allow the Competition Commission, the Secretary of State or a Government Minister to apply for a compulsory licence if patent abuse is a factor contributing to an anti-competitive situation. Section 50A allows the Competition Commission or the Secretary of State to apply to the comptroller to take action following a merger or market investigation to remedy, mitigate or prevent a competition matter that cannot be dealt with in any other way under the Enterprise Act. Section 51 makes provision for Government Ministers to apply to the comptroller to take action in response to a report by the Competition Commission 'that a person was engaged in an anti-competitive practice which operated or may be expected to operate against the public interest' or 'that a person is pursuing a course of conduct which operates against the public interest' (s.51(1)). Applications under s.50A or 51 must involve 'conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences', or 'a refusal by the proprietor to grant licences on reasonable terms' (s.50A(1)(c) and 51(3)).

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

The conditions are set out in s.48A(1)(b)(i) and s.48B(1)(d)(ii) (see answer to question 67).

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Different provisions apply for WTO and non-WTO proprietors. For WTO-proprietors, s.48A(6)(c) entitles the proprietor to 'remuneration adequate in the circumstances of the

case, taking into account the economic value of the licence' whereas s.50(1)(b) provides that non-WTO proprietors are entitled to 'reasonable remuneration having regard to the nature of the invention'.

In the decision of the UK IPO in Montgomerie Reid's Application (BL O/145/83) (decided under the 'reasonable remuneration' criterion) it was held that the royalty to be paid for a compulsory licence under s.48 should be one which would be negotiated between a willing licensor and a willing licensee.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

N/A

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

No compulsory licences have been issued under sections 48-54 in the last 10 years. Very few applications for compulsory licences are received (estimated to be less than one per year on average since the Patents Act 1977 came into force).

Similarly, the UK IPO has received no applications for EU compulsory licences.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to the law are foreseen.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

We are not aware of any significant challenges.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 55-59 of the Patents Act concern Crown use of patented inventions. Section 122 concerns the Crown's right to sell forfeited articles.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

National emergency and/or extreme urgency (s.59)

Other, please specify: Section 55(1) provides that certain acts are exempt from infringement if they are done in the UK by a government department, or any person authorised in writing by a government department, 'for the services of the Crown'.

According to s.56(2), 'for the services of the Crown' includes –

- (a) the supply of anything for foreign defence purposes;*
- (b) the production or supply of specified drugs and medicines; and*
- (c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient.*

Section 122 provides that nothing in the Patents Act affects the Crown's right to dispose of or use articles forfeited under the customs and excise laws. The Crown is therefore exempted from infringement for the sale or use of goods seized under the customs and excise laws.

84. (a) What are the public policy objectives for providing government use in your country?

Government departments should not be fettered by the existence of patents in the discharge of their functions.

- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Powers to use a patented invention, without the permission of the proprietor of the patent go back to 1883. Proposals to limit the powers were rejected by the Banks Committee (1970).

85. If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Section 59 has the effect of extending the Crown use provisions under s.55 'during any period of emergency'. Section 59(3) defines the meaning of 'period of emergency' as follows':

any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.

Section 59(4) requires that the draft of an Order under s.59(3) must be approved by each House Of Parliament. To date, no Order under s.59(3) has ever been made.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

We do not keep records of this as the UK IPO does not generally get involved in Crown use matters - the relevant government department negotiates directly with the proprietor of the patent. However, it is our understanding that the Crown use provisions are invoked very rarely because the government prefers to negotiate a licence like any other party would. It seems likely that the need to determine and pay compensation for Crown use is a factor in deciding to take a conventional licence.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

We have not consulted our users about the Crown use provisions recently but we are not aware of any problems with the provisions.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

See 87.

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented Inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(g) of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

...

(g) it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use;

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

The exception originates from EU Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. For further information see Directive 98/44/EC which can be found on <http://eur-lex.europa.eu/en/index.htm>.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

See <http://eur-lex.europa.eu/en/index.htm> for further information.

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The exception under s.60(5)(g) applies where plant propagating material has been sold to a farmer by the proprietor of the patent, or with his consent, for agricultural use. It allows the farmer to subsequently use the product of his harvest from such material for further propagation or multiplication of the plant on his own land without infringing the patent. Section 60(6A) imposes restrictions on the exception and sets out conditions which apply

when an otherwise infringing act falls within the scope of s.60(5)(g). These restrictions and conditions are set out in Schedule A1 to the Patents Act. Paragraph 2 of Schedule A1 provides that s.60(5)(g) applies only to certain specified varieties of plant species and groups. The conditions which apply where an otherwise infringing act falls within the scope of sub-section (5)(g) include (i) the requirement that a farmer (other than a 'small farmer') must pay equitable remuneration to the proprietor (which must, however, be less than the farmer would have paid for buying more plant propagating material from the proprietor); and (ii) certain specified information must be supplied by the farmer and by the proprietor, on request from the other.

Schedule A1 is not reproduced here but may be viewed on the UK IPO's website at: <http://www.ipo.gov.uk/patentsact1977.pdf>.

The scope of 'sale' in s.60(5)(g) is clarified in s.60(6C):

60(6C) In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation.

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to the law are foreseen.

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

We are not aware of any significant challenges.

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(h) and of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

...

(h) it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

The exception originates from EU Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. For further information see Directive 98/44/EC which can be found on <http://eur-lex.europa.eu/en/index.htm>.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

See <http://eur-lex.europa.eu/en/index.htm> for further information.

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The exception under s.60(5)(h) applies where breeding stock or other animal reproductive material has been sold to a farmer by the proprietor of the patent, or with the proprietor's consent. The farmer may subsequently use the animal or animal reproductive material for an agricultural purpose without infringing the patent. There is no equivalent to Schedule A1 for s.60(5)(h) and thus the exception applies to all varieties of animal. However, s.60(6B) makes clear that the farmer is not allowed to sell any animals or animal reproductive material derived from his 'agricultural use' of the original animal or material as part of a commercial reproduction activity:

60(6B) For the purposes of subsection (5)(h), use for an agricultural purpose –

(a) includes making an animal or animal reproductive material available for the purposes of pursuing the farmer's agricultural activity; but

(b) does not include sale within the framework, or for the purposes, of a commercial reproduction activity.

The scope of 'sale' in s.60(5)(h) is clarified in s.60(6C):

60(6C) In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation.

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to the law are foreseen.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

We are not aware of any significant challenges.

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Section 60(3) provides an exception from contributory infringement for those who supply or offer to supply a staple commercial product.

102. In relation to each exception and limitation, please indicate:

- (i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

60(3) Subsection (2) above shall not apply to the supply or offer of a staple commercial product unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above.

Subsection (2) relates to contributory infringement and subsection (1) relates to primary infringement.

- (ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Section 60(3) corresponds to paragraph 2 of article 26 of the CPC.

- (iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

There is no definition of 'staple commercial product' but in Pavel v Sony BL CC/14/93 the Patents County Court construed the term as a product of the kind needed every day and generally obtainable. It was also noted that the product should be one generally available when the specification was published.

In addition, in relation to each exception and limitation, please explain:

- (i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

No amendments are foreseen.

- (ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

We are not aware of any significant challenges.

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

Articles 101 and 102 of the EU Treaty provide prohibitions on anti-competitive practices within the EU which place limitations on the scope of licensing agreements.

The Competition Act 1998 provides similar prohibitions applicable within the UK.

References

The Manual of Patent Practice (1 July 2011 update).

The CIPA Guide to the Patents Act 6th Ed, 2009, Sweet and Maxwell, London.

The CIPA Guide to the Patents Act 6th Ed 1st Supplement, 2010, Sweet and Maxwell, London.

Thorley, S; Miller, R; Burkill, G; Birss, C; Terrell on the law of patents, (2000), Sweet & Maxwell, London.

Country: UNITED REPUBLIC OF TANZANIA
Office: Business Registrations and Licensing Agency (BRELA)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and/or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

- (i) *Novelty*
- (ii) *Inventive step*
- (iii) *Applicability as provided for under section 8 of the Patents Act.*

The provisions of section 7 (2) of the Patents (Registration) Act Cap. 217 R.E. 2002 provides for exclusion from patentable inventions.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

Plants and animals varieties
Methods for treatment
Discoveries, scientific and mathematical theories
Mere presentation of information
Schemes, rules or method for doing business

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Exclusive exploitation of the invention.
The provisions of section 35 and 36 of the Patents (Registration) Act Cap 217 R.E. 2002 so provides.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;
Experimental use and/or scientific research;
Use of articles on foreign vessels, aircrafts and land vehicles;
Exhaustion of patent rights;
Compulsory licensing and/or government use;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

The provisions of section 38 of the Act limit the rights of the patentee to acts done for scientific research. Patent rights do not extend to scientific research or acts related thereto.

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

6. (a) What are the public policy objectives for providing the exception?

An inference may be drawn from the preamble of the Patents (Registration) Act Cap 217R.E. 2002 in respect of facilitation to acquisition of technology on fair terms

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

Section 37 of the Act provides for the scope of protection to be determined by the terms of the claims in a patent document.

- 9.-10.

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The provisions of section 38 of the Patent Act are an exception in that the rights of the patentee cannot extend to acts done on scientific research.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

13. (a) What are the public policy objectives for providing the exception?

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No, it doesn't.

15.-17.

[Note from the Secretariat: response was not provided.]

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

*A non-commercial purpose
A commercial purpose*

19.-22.

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Methods for treatment are excluded from patentable inventions in terms of the provisions of section 7 (2) (a) of the Patents Act.

24.-25.

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

Doctors are most likely to use the exception in so far as prescription of medication is concerned.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

No

28.-30.

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31.-33.

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

No

35.-41.

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights under the patent shall not extend to the use of articles on an aircraft, land vehicles or vessels of other countries as provided for under the provisions of section 38 (3) of the Act.

43.-44.

[Note from the Secretariat: response was not provided.]

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles*

46.-50.

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

[Note from the Secretariat: the applicable law of the United Republic of Tanzania does not provide exceptions related to acts for obtaining regulatory approval from authorities.]

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

National

If the exception is contained in statutory law, please provide the relevant provision(s):

The provisions of section 38 (2) of the Patent Act in respect of articles which have been put on the market by the patentee or with his consent.

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

61.

[Note from the Secretariat: response was not provided.]

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

No

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

[Note from the Secretariat: response was not provided.]

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

The provisions of sections 53, 54 and 55 of the Patents Act provide for compulsory licences and government use under section 62. An exception is provided for under section 53 (3) of the Act.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 53(3)

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Non-working or insufficient working of the patented invention
Refusal to grant licenses on reasonable terms
Anti-competitive practices and/or unfair competition
Public health
National security*

*National emergency and/or extreme urgency
Dependent patents*

68.-69.

[Note from the Secretariat: response was not provided.]

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

The provisions of section 53(1) (c) of the Patents Act to the effect that the working of the patented invention in the United Republic of Tanzania is being hindered by or prevented by the importation of the patented product.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes

If yes, what is the time period?

Four(4)years(section 53(1) of the Act.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes

If yes, what are “legitimate reasons”?

Depending on the prevailing circumstances that shall be determined by the court under section 53(3) of the Act.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

[Note from the Secretariat: response was not provided.]

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

Section 53(1)(c)

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

- (i) Serves industrial purposes (section 54 of the Act)*
- (ii) Constitute substantial technical progress in relation to that last mentioned invention*

(iii) *If the two (patents) inventions serves the same purpose*

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Equitable remuneration in circumstances of a case at hand as provided for under the provisions of section 62 (3) of the Act.

77.-79.

[Note from the Secretariat: response was not provided.]

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

Insufficiency or no capacity on the part of local industries to produce generic pharmaceutical products should a compulsory licence be issued against a patented invention.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Where a vital public interest requires and or justifies issuance of a compulsory license by Government for Government use in terms of section 62(1).

Where the patentee prefers to appeal against the amount of remuneration fixed by the Registrar of Patents, such appeal shall not suspend the exploitation of the patented invention as provided for under section 62 (1) of the Act.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

*Public health
National security
National emergency and/or extreme urgency*

84.-88.

[Note from the Secretariat: response was not provided.]

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

[Note from the Secretariat: the applicable law of the United Republic of Tanzania does not provide exceptions related to farmers' use of patented inventions.]

Breeders' use of patented inventions

95.-100.

[Note from the Secretariat: the applicable law of the United Republic of Tanzania does not provide exceptions related to breeders' use of patented inventions.]

Section XI: Other Exceptions and Limitations

101.-103.

[Note from the Secretariat: the applicable law of the United Republic of Tanzania does not provide other exceptions and limitations.]

Office: EURASIAN PATENT OFFICE (EAPO)

Section I: General

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

Eurasian Patent Convention (EAPC)

Patent Regulations under Eurasian Patent Convention (adopted by the Administrative Council of the EAPO at its second (1st ordinary) session on December 1, 1995, with further amendments and additions)

"The Eurasian Office shall grant a Eurasian patent for any invention that is new, involves an inventive step and is industrially applicable." (Art. 6 EAPC).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The following shall not, as such, be recognized as inventions as implied in Rule 3(1) of the Regulations, inter alia:

- *discoveries;*
- *scientific theories and mathematical methods;*
- *presentation of information;*
- *methods of economic organization and management;*
- *symbols, schedules and rules;*
- *methods for performing mental acts;*
- *algorithms and computer programs;*
- *topographies of integrated circuits;*
- *projects and plans for structures and buildings and for land development;*
- *solutions concerning solely the outward appearance of manufactured goods and aimed at satisfying aesthetic requirements.*

The above-listed subject matter shall not be recognized as inventions in those cases where a Eurasian application or a Eurasian patent are directly pertinent to any of the above-listed subject matter as such;

Eurasian patents shall not be granted for:

- *plant varieties and animal breeds;*
- *topology of integrated circuits;*
- *inventions, the commercial use of which it is essential to prevent, for the purposes of protecting public order or morality, including the protection of the life and health of people and animals or the protection of plants, or in order to prevent serious damage being caused to the environment. In that regard, such use may not be considered such, solely on the grounds that it is forbidden by the legislation of one or more Contracting States. (Rule 3 par. (3) and (4) of Patent Regulations).*

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

EAPC, Art. 9:

“ (1) The owner of a Eurasian patent shall have the exclusive right to use, and also to authorize the use or prohibit others from using, the patented invention.

(2) The owner of a Eurasian patent may assign or license his rights.

(3) After an application for the grant of a Eurasian patent (hereinafter referred to as “the Eurasian application”) has been published, the applicant shall enjoy provisional protection in conformity with the national legislation of the Contracting States.”

Patent Regulations, R. 17:

“The following acts shall constitute an infringement, within the meaning of Article 13(1) of the Convention, of said patent owner's exclusive right:

- *the making, use, importing, offering for sale, sale or any other form of marketing or storage for that purpose, of a product protected by a Eurasian patent;*
- *the use of a process protected by a Eurasian patent or the offering thereof for such use;*
- *the use, importing, offering for sale, sale or any other form of marketing or storage for that purpose, of a product directly obtained by a process protected by a Eurasian patent.”*

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

Private and/or non-commercial use;

Experimental use and/or scientific research;

Preparation of medicines;

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

Exhaustion of patent rights;

Compulsory licensing and/or government use;

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other

parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI “Other Exceptions”.

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

Patent Regulations, R. 19:

“The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

- *use for private non-profit-making purposes”.*

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

6.

[Note from the Secretariat: response was not provided.]

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

No definition

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

None

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to change the legal framework of the exception are foreseen

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section III: Experimental use and/or scientific research

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Patent Regulations, R. 19:

“The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

- *use for scientific research and experimental purposes*".

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

13.

[Note from the Secretariat: response was not provided.]

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

Regulated under the national laws of Contracting States

15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

No definition

16.-19.

[Note from the Secretariat: response was not provided.]

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to change the legal framework of the exception are foreseen

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Patent Regulations, R. 19:

"The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

- *use for the extemporaneous preparation, in a pharmacy, of a medicine on a medical prescription*".

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

25. (a) What are the public policy objectives for providing the exception? Please explain:

Protection of the human health, assurance of the access to medicines

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

- *Pharmacists making the preparation in the pharmacy of the medicines on a medical prescription*
- *Doctors and physicians making the medical prescription*

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

Yes

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

“use for the extemporaneous preparation, in a pharmacy, of a medicine on a medical prescription”

28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to change the legal framework of the exception are foreseen

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Patent Regulations, R. 20:

“(1) Any natural person, legal entity, or organization assimilated thereto, which in good faith, before the filing date of the application or, where priority has been established, before the priority date of the invention, has been using an identical solution on the territory of a Contracting State, or has made the necessary preparations for such use, shall retain the right to proceed with that use free of charge, provided that the scope thereof is not increased.

The right of the prior user may only be transferred to another natural person, legal entity, or assimilated organization, together with the production unit in which the identical solution has been used, or the necessary preparations for the use thereof have been made.

(2) The right of the prior user shall apply only on the territory of the Contracting State in which such prior use has occurred.”

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

33. (a) What are the public policy objectives for providing the exception? Please explain:

In the patent system “first-to-file” it is important to respect a balance between the patent owner interest and the rights of the person who earlier created and used a similar technical solution.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Defined under the national laws of Contracting States

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

According to the provisions of national laws of Contracting States

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

Yes

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes

If yes, please explain what those conditions are:

The right of the prior user may be only transferred together with the production unit in which the invention has been used or the necessary preparations for the use thereof have been made.

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes

If yes, please explain the conditions under which such use can continue to apply:

Patent Regulations, R. 20¹:

“(1) Any natural person, legal entity or organization assimilated thereto, which in good faith has begun to use the invention or an identical solution on the territory of a Contracting State, or has made the necessary preparations for such use, during the period between the date on which the right to the Eurasian application published in accordance with Article 15(4) of the Convention or the Eurasian patent granted have lapsed, and the date of publication of the information on the restoration, pursuant to Rules 39(1) and 39(2) of the Regulations, of the rights to the Eurasian application or Eurasian patent, shall retain the right to proceed with the use of this invention or solution identical thereto free of charge, provided that the scope thereof is not increased.

The right of the subsequent user may only be transferred to another natural or legal person, or organization assimilated thereto, together with the production unit in which the invention or identical solution has been used, or the necessary preparations for the use thereof have been made.

(2) The right of the subsequent user shall apply only on the territory of the Contracting State where the subsequent use has taken place and the legislation of which provides for such a right.”

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to change the legal framework of the exception are foreseen

41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Patent Regulations, R. 19:

“The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

- *use in the construction or operation of means of transportation of a member State of the Paris Union for the Protection of Industrial Property that is not a Contracting State, when such means of transportation temporarily or accidentally enter the territory of the Contracting State, provided that the invention is used exclusively for the needs of said means of transportation”.*

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

44. (a) What are the public policy objectives for providing the exception? Please explain:

[Note from the Secretariat: response was not provided.]

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Implementation of the Art. 5ter of the Paris Convention

45. The exception applies in relation to:

*Vessels
Aircrafts
Land Vehicles
Spacecraft*

46. In determining the scope of the exception, does the applicable law apply such terms as “temporarily” and/or “accidentally” or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes, “temporarily or accidentally”

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, “provided that the invention is used exclusively for the needs of said means of transportation”. (Patent Regulations, R.19).

48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

None

49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to change the legal framework of the exception are foreseen

50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

[Note from the Secretariat: response was not provided.]

Section VII: Acts for obtaining regulatory approval from authorities

51.-59.

No provisions

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

Uncertain, please explain. According to the provisions of national laws of Contracting States

If the exception is contained in statutory law, please provide the relevant provision(s):

Patent Regulations, R. 19:

"The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

- use of a product after this product has been marketed by the patent owner himself or with his consent in a Contracting State where the Eurasian patent is valid and in which the product in question was marketed."*

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

To respect a balance between the rights of patent owner and the public benefit and to coordinate the international trade

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[Note from the Secretariat: response was not provided.]

62.-64.

[Note from the Secretariat: response was not provided.]

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

EAPC, Art. 12:

“ (1) Compulsory licenses for the use of a Eurasian patent by third parties may be granted in conformity with the Paris Convention for the Protection of Industrial Property by the competent authority of a Contracting State with effect in the territory of that State.

(2) A decision to grant a compulsory license may be contested in the courts or other competent authorities of the contracting State in the territory of which the compulsory license has been granted.”

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

[Note from the Secretariat: response was not provided.]

67.-80.

According to the provisions of national laws of Contracting States.

Government use

81.-88.

According to the provisions of national laws of Contracting States.

Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-94.

According to the provisions of national laws of Contracting States.

Breeders' use of patented inventions

95.-100.

According to the provisions of national laws of Contracting States.

Section XI: Other Exceptions and Limitations

101.-103.

None

[End of Annex II and of document]