Questionnaire on Exceptions and Limitations to Patent Rights

The answers to this questionnaire have been provided on behalf of:

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Office: Patent Office of the Republic of Latvia .....

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Section I: General

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term "applicable law" refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

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. 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.

(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 s. 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.

The s. 8(2) provides for exclusion from patentability of inventions in the field of medicine

(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.

The English version of the Patent Law which is currently available may be found at address: http://www.lrpv.lv/dl/pdf/pat_lik_en.pdf.....
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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]

1) discoveries, scientific theories, mathematic methods;

[1] This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

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.

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 Sec. 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 Sec.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.

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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.[3]

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. 20.1.....
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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.....
.....
.....

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2 For example, extemporaneous preparation of prescribed medicines in pharmacies.

3 For example, in some countries where patent rights extend to propagated or multiplicated material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

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):

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 [4]

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

Sec. 20.2.....
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12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None……...

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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

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[4] Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

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

N/a .....
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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. 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: .....

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

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

There is no further clarification of the exceptions 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
Both of the above
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 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 .....
.....
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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 .....
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.....

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 .....
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.....

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?

Yes
No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

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

None .....
.....
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Section V: Prior use

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

Sec. 22.....
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32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

None .....
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.....

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
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?

Yes
No

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
No

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.” .....
.....
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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.....
.....
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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 .....
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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:

any products
certain products. Please describe which products: medicinal products 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
Other. Please specify:……

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:

National
Regional
International
Uncertain, please explain.....

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?

Yes
No
Uncertain

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

.....
.....

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
Anti-competitive practices and/or unfair competition
Public health
National security
National emergency and/or extreme urgency
Dependent patents
Other, please specify: Overlapping rights of biotehcnological 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
No

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
No

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.

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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):

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: ……

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 .....
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.....

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

None .....
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.....

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.....
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.....

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."

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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 .....
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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 .....
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.....

Breeders' use of patented inventions

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

Sec. 19.5.....
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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 .....
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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 .....
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.....

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

None .....
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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." .....
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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 .....
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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 .....
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Section XI: Other Exceptions and Limitations

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

None .....
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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):

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(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:

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(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

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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?):

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(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

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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:

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[End of Questionnaire]