

## **Questionnaire on Exceptions and Limitations to Patent Rights**

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

Country: Republic of Poland  
Office: Patent Office of the Republic of Poland

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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.

#### **Article 24 of the Act – Industrial Property Law (“IPL”) stipulates that:**

“Patents shall be granted – regardless of the field of technology – for any inventions which are new, which involve an inventive step and which 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.<sup>1</sup>

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<sup>1</sup> This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

Pursuant to **Article 28** of IPL:

*The following in particular shall not be regarded as inventions within the meaning of Article 24:*

- (i) discoveries, scientific theories and mathematical methods,*
- (ii) aesthetic creations,*
- (iii) schemes, rules and methods for performing mental acts, doing business or playing games,*
- (iv) creations, whose incapability of exploitation may be proved under the generally accepted and recognized principles of science,*
- (v) programs for computers,*
- (vi) presentations of information.*

Pursuant to **Article 29**:

- 1. Patents shall not be granted for:*
  - (i) inventions whose exploitation would be contrary to public order or morality; the exploitation shall not be deemed to be so contrary merely because it is prohibited by law,*
  - (ii) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof,*
  - (iii) methods for treatment of the human or animal body by surgery or therapy or diagnostic methods applied on human or animal bodies; this provision shall not apply to products, and in particular to substances or compositions applied in diagnostics or treatment.*
- 2. The process for the production of plants or animals, referred to in section (1)(ii), is essentially biological if it consists entirely of natural phenomena such as crossing or selection.*

*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.*

Pursuant to **Article 93<sup>2</sup>** *The following, in particular, shall be considered as biological inventions eligible for patent protection:*

- (i) inventions, the subject of which is biological material which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature,*
- (ii) elements 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,*
- (iii) inventions which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety.*

*2. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.*

**Article 93<sup>3</sup>**

*1. 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.*

*2. The following, in particular, shall be considered as biotechnological inventions, whose exploitation would be contrary to Public order or morality within the meaning of Article 29(1)(i), or with public morality:*

- (i) processes for cloning human beings,*
- (ii) processes for modifying the germ line genetic identity of human beings,*
- (iii) uses of human embryos for industrial or commercial purposes,*
- (iv) 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?

*In accordance with Articles 63 and 66:*

*1. A patent shall confer the exclusive right to exploit the invention, for profit or for professional purposes, throughout the territory of the Republic of Poland. The patent holder shall have the right to prevent any third party not having his consent from exploiting his invention for profit or for professional purposes by way of performing the acts consisting of:*

*(i) making, using, offering, putting on the market a product that is the subject matter of the invention, or importing the product for such purposes, or*

*(ii) employing a process that is the subject matter of the invention, as well as using, offering, putting on the market or importing for such purposes the product directly obtained by that process*

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

- X Private and/or non-commercial use;
- X Experimental use and/or scientific research;
- X Preparation of medicines;<sup>2</sup>
- X Prior use;
- X Use of articles on foreign vessels, aircrafts and land vehicles;
- X Acts for obtaining regulatory approval from authorities;
- X Exhaustion of patent rights;
- X Compulsory licensing and/or government use;
- X Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.<sup>3</sup>

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.).

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<sup>2</sup> For example, extemporaneous preparation of prescribed medicines in pharmacies.

<sup>3</sup> For example, in some countries where patent rights extend to propagated or multiplied 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).

**Section II: Private and/or non-commercial use**

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

**Article 66 (1) Industrial Property Law states that:**

The patent holder shall have the right to prevent any third party not having his consent from exploiting his invention for profit or for professional purposes by way of performing the acts consisting of:

- (i) making, using, offering, putting on the market a product that is the subject matter of the invention, or importing the product for such purposes, or
- (ii) employing a process that is the subject matter of the invention, as well as using, offering, putting on the market or importing for such purposes the product directly obtained by that process.

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

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

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

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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**

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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):

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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:

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

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**Section III: Experimental use and/or scientific research <sup>4</sup>**

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

**Article 69 (1) (iii) Industrial Property Law states that:**

The following shall not be considered acts of infringement of a patent:  
Employing of an invention for search and experimental purposes, for the evaluation thereof, analysis or teaching.

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

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

**Lack of such an exception would render impossible developing of science and technology**

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

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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:

**Commercial use of the invention is exception. Commissioned research with the use of the invention is probably not allowed.**

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<sup>4</sup> 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):

**No such definitions in the Polish law**

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

X other, please specify: **for the evaluation of an invention, analysis 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”)

X Both of the above

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

**Article 69 (1) (iii) Industrial Property Law states that:**

The following shall not be considered acts of infringement of a **patent:**

**Employing of an invention for search and experimental purposes**, for the evaluation thereof, analysis or teaching.

- .....
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):

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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):

**For the evaluation of an invention, analysis or teaching.**

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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 amendments to 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:

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**Section IV: Preparation of medicines**

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

**Article 69 (1) (v) Industrial Property Law states that:**

The following shall not be considered acts of infringement of a patent:  
The extemporaneous preparation of a medicine in a pharmacy on a physician's prescription.

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

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

**Not making impossible individual treatment**

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

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

**Doctors, pharmacists only a medicine on a physician's prescription.**

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.....

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

X Yes  
No

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

**On a physician's prescription**

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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):

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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 to the law 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:

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**Section V: Prior use**

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

**Article 71 Industrial Property Law states that:**

1. Any person who, on the date according to which the priority for the grant of a patent is determined, has exploited the invention on the territory of the Republic of Poland in good faith, may continue to exploit it in his enterprise free of payment to the extent to which he had previously exploited the invention. This right shall also belong to a person who at the same date had already made substantial preparations for the exploitation of the invention.

2. The rights referred to in paragraph (1) shall, at the request of the person concerned, be recorded in the Patent Register. The rights may be transferred to another party only together with the enterprise.

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

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

**Not to make impossible continuing exploitation of a patented invention by a party who has not been aware of the existence of the patent.**

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

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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):

**Use of the invention in good faith (good faith of the user comes from either his developing of the same invention independently of the holder of the patent, or the user's believe that he can freely use a given technical solution)**

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

**See above Article 71**

**May continue to exploit it in his enterprise free of payment**

**Article 284 (vii) Industrial Property Law states that:**

The following cases, in particular, shall be decided in civil law procedure in accordance with the general principles of law:

vii) for ascertainment of the right to exploit an invention,

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

X 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?

X Yes  
No

If yes, please explain what those conditions are:

**Article 71 (2) Industrial Property Law states that:**

The rights referred to in paragraph (1) shall, at the request of the person concerned, be recorded in the Patent Register. The rights may be transferred to another party only together 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?

Yes  
No

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

**Article 75**

1. Any person who, acting in good faith, was granted or acquired the patent subsequently transferred to the entitled person under Article 74, or, being in good faith, acquired a license and has exploited the invention for at least one year before a proceeding for the transfer of the patent has been instituted, or within that period has made substantial preparations necessary for exploiting the invention, may, subject to payment in favour of the entitled person of compensation at the amount as determined, continue to exploit that invention in his enterprise to the extent to which he had exploited it at the date of institution that proceeding.

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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):

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

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**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 (1) (i) Industrial Property Law states that:**

The following shall not be considered acts of infringement of a patent:

The exploitation of an invention concerning means of transport or their parts or accessories, temporarily located on the territory of the Republic of Poland, or concerning articles which are in transit through its territory.

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

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

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

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45. The exception applies in relation to:

- X Vessels
- X Aircrafts
- X Land Vehicles
- X 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):

**Means of transport temporarily located on the territory of the Republic of Poland, or concerning articles which are in transit through its territory**

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

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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):

**Article 69 (1) (iv) Industrial Property Law states that:**

The following shall not be considered acts of infringement of a patent:  
The exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorization, being, due to the intended use thereof, requisite for certain products to be allowed for putting them on the market, in particular those being pharmaceutical products.

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

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.....

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

**Faster introduction of generics on the market**

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

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.....

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

**The enterprise that wants to register a new medicine.....**

.....

55. The exception covers the regulatory approval of:

any products

X certain products. Please describe which products: **medical products**

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

X Making

X 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):

**Article 69 ( 5) Industrial Property Law states that:**

Grant of the registration or the authorization referred to in paragraph (1)(iv) shall be without prejudice to civil liability for putting on the market of a product without the patent holder's consent, where such consent is required.

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 foreseen.....**

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

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**Section VIII: Exhaustion of patent rights**

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

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

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

**Article 70 (1) Industrial Property Law states that:**

The rights conferred by a patent shall not extend to acts concerning a product embodying the invention or manufactured by means of the invention, consisting in particular of its offering for sale or further putting on the market, if that product has been put on the market on the territory of the Republic of Poland by the patent holder or with his consent.

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

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

**Ensuring the supply of medicine .....**

.....

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

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.....  
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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?

- X Yes
- No
- Uncertain

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

**Article 70 (2) Industrial Property Law states that:**

A patent shall neither be considered infringed by an act of importation into the territory of the Republic of Poland or other acts referred to in paragraph (1) in respect of a product that has earlier been put on the market on the territory of the European Economic Area by the patent holder or with his consent.

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

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

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### **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 82 Industrial Property Law states that:**

- 1.The Patent Office may grant authorization to exploit a patented invention of another person (a compulsory license), where:
  - (i) it is necessary to prevent or eliminate a state of national emergency, in particular in the field of defense, public order, the protection of human life and health, as well as the protection of natural environment, or
  - (ii) it has been established that the patent has been abused within the meaning of Article 68, or
  - (iii) it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) prevents, by refusing to conclude a license contract, the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case, the holder of the earlier patent may demand that an authorization be given to him for the exploitation of the invention that is the subject matter of the dependent patent (cross- license).
- 2.The grant of a compulsory license for the exploitation of an invention in the case referred to in paragraph (1) (iii) shall be conditional upon ascertainment that the exploitation of the invention that is the subject matter of the dependent patent, where the both inventions concern the same subject matter, involves an important technical advance of considerable economic significance. In case of an invention concerning semi- conductor technology, a compulsory license may only be granted to counteract unreasonable anti- competitive practices.
- 3.Where the Patent Office finds that the patent is abused within the meaning of Article 68, it may decide that a compulsory license may be applied for and shall announce this in "Wiadomości Urzędu Patentowego".
- 4.A compulsory license may be granted, if the applying party is able to prove that it has earlier made, in good faith, efforts to obtain a license. This requirement may be waived in the case of a compulsory license to be granted for the purpose of preventing or eliminating a state of national emergency or where it is announced that a compulsory license may be applied for.
- 5.Where it is announced that a compulsory license may be applied for, waiver of the requirement referred to in paragraph (4) shall not be applicable in respect of applications for the grant of a license submitted after the expiration of a period of one year counted from the date of that announcement.
- 6.The provision of paragraph (1)(iii) shall apply accordingly, where a plant breeder is

not able to exercise his right to the protected plant variety or demands a cross-license to be granted to him by the patent holder.

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

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

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

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

**See the text of Article 82 above and Article 68 (1) below**

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

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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 68 (1)( 2) Industrial Property Law states that:**

1. The patent holder or the licensee may not abuse his rights, in particular by preventing the invention from being exploited by a third party, if such exploitation is necessary for the purpose of meeting home market demands and is particularly dictated by public interest considerations, and consumers are supplied with the product in insufficient quantity or of inadequate quality, or at excessively high prices.

2.Preventing third parties from exploiting the invention within a period of three years from the date of the grant of the patent shall not be considered the abuse of rights, referred to in paragraph (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):

*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?

X Yes  
No

If yes, what is the time period? **3 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?

Yes  
X No

If yes, what are "legitimate reasons"? .....

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 Article 68 (1) above .....

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:

**Article 82 Industrial Property Law states that:**

1.The Patent Office may grant authorization to exploit a patented invention of another person (a compulsory license), where:

(i) (...)

(ii) (...)

(iii) it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) prevents, by refusing to conclude a license contract, the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case, the holder of the earlier patent may demand that an

authorization be given to him for the exploitation of the invention that is the subject matter of the dependent patent (cross- license).

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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:

**Article 84**

1. The person exploiting the invention under a compulsory license shall be obliged to pay a royalty to the patent holder.

2. The Patent Office shall determine the scope and duration of a compulsory license, the detailed terms and conditions of its exercise, as well as the amount, in proportion to the market value of the license, of the royalty and the manner and time limits of payment.

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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 does not define those two concepts and their scope of application**

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

Once – mining industry .....

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 foreseen**.....  
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.....

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

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.....

*Government use*

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

**Article 69 (1) (ii) Industrial Property Law states that:**

The exploitation of an invention for national purposes, to a necessary extent, without the exclusive right, where it is has been found indispensable to prevent or eliminate a state of emergency relating to vital interests of the State, in particular to security or public order

**Article 69 (4) Industrial Property Law states that:**

The person whose invention is exploited for national purposes shall have the right to compensation payable from the State budget funds at an amount corresponding to the market value of the license.

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

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.....

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
- X National security
- X National emergency and/or extreme urgency
- Dependent patents
- X Other, please specify: **vital interests of the State**

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

Not to expose the nation to or liquidation of disastrous situations

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

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

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 those 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:

No single case 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:

**YES, no amendments to the law 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:

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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):

***In accordance with Article 93<sup>5</sup>***

*1. The protection conferred by a patent shall not extend to biological material obtained by means of a single act of propagation or multiplication of biological material placed on the market by the holder of the patent or with his consent, where the propagation or multiplication necessarily results from the application of the biological material.*

*2. Any party who has acquired or otherwise obtained the patented biological material from the holder of a patent or with his consent for agricultural use, shall be authorized to use it for propagation or multiplication on his own farm, the extent and conditions of this derogation being the same as provided for the use, without the plant breeder's consent, of plant propagating material of the plant variety protected under the provisions of the act of 26 June 2003 on the legal protection of plant varieties (JL No 137, text 1300, of 2006 No 126, text 877 and of 2007 No 99, text 662).*

*3. The provision of paragraph (2) shall apply accordingly to breeding stock or other animal reproductive material.*

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

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.....  
.....

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

**New plant varieties are registered in accordance with the regulations of the Seed Act**

.....  
.....

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

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

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):

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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 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:

.....  
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*Breeders' use of patented inventions*

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

See **Article 93<sup>5</sup>**

Additionally, **Article 82** stipulates that:

1. The Patent Office may grant authorization to exploit a patented invention of another person (a compulsory license), where:

[ (i)-(ii)],

(iii) it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) prevents, by refusing to conclude a license contract, the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case, the holder of the earlier patent may demand that an authorization be given to him for the exploitation of the invention that is the subject matter of the dependent patent (cross-license).

6. The provision of paragraph (1)(iii) shall apply accordingly, where a plant breeder is not able to exercise his right to the protected plant variety or demands a cross-license to be granted to him by the patent holder.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

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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:

Not to make impossible developing of agriculture industry .....

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

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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):

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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 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:

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**Section XI: Other Exceptions and Limitations**

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

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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):

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

- (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:

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

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

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

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?):

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

- (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]