

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **Republic of Croatia**
Office: **State Intellectual property Office of the Republic of Croatia**

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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.

Patent Act (Official Journal Number 173/2003, 87/2005, 76/2007, 30/2009, 128/2010, 49/2011 and 76/2013) (Hereinafter referred as: Patent Act).

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.¹

According to the Patent Act the following is in particular not considered as inventions:

- 1. discoveries, scientific theories and mathematical methods**
- 2. aesthetic creations**

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

3. rules, instructions or methods for performing mental activities, playing games or doing business
 4. presentations of information
 5. computer programs
- (The above listed subject-matters and activities are excluded from patentability only to the extent to which a patent application or a patent relates to such subject-matter or activities as such.)

Furthermore, according to the Patent Act, patents shall not be granted in respect of:

1. animal and plant varieties
2. essentially biological processes for the production of plants or animals
3. diagnostic or surgical methods or methods of treatment practiced directly on the human or animal body, except for the products, in particular substances or compositions used in such methods
4. inventions relating to 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
5. inventions contrary to order public or morality, but not merely because such exploitation is prohibited by law or other regulation, in particular (specified by the Patent Act):
 - a) processes for cloning human beings;
 - b) processes for modifying the germ line genetic identity of human beings;
 - c) uses of human embryos for industrial or commercial purposes; and
 - d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes

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

According to article 2 of the Patent Act a patent is an exclusive right protecting a patent owner in the course of the economic exploitation of an invention. Further, article 58 of the Patent Act determines the exclusive rights acquired by a patent, and article 59 of the patent Act determines the exclusive rights acquired by a granted patent related to inventions in the field of biotechnology, in particular:

Article 58, paragraph (1) of the Patent Act: *“The patent owner shall be entitled to exploit the protected invention.”*

Article 58, paragraph (2) of the Patent Act: *“Any other person not having the patent owner’s consent shall be prohibited from:*

1. *making, offering for sale, selling, using, exporting or importing and stocking for such purposes, the product carried out according to the invention,*
2. *using the process which is the subject matter of the invention, or offering the use thereof,*
3. *offering for sale, selling, using, exporting or importing and stocking for such purposes, the product which is obtained directly from a process which is the subject-matter of the invention.”*

Article 58, paragraph (3) of the Patent Act: *“Any other person not having the patent owner’s consent shall be also prohibited from offering and supplying the product (substance, composition, part of the apparatus) constituting an essential element of the invention, to persons not entitled to exploit the said invention, if the offerer*

or the supplier knows or should have known from the circumstances of the case that such product is intended for putting into function the invention of another person.”

Article 59, paragraph (1) of the Patent Act: “If a biological material possessing specific characteristics as a result of the invention is protected by a patent, the exclusive rights referred to in Article 58, paragraphs (2) and (3) of this Law shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.”

Article 59, paragraph (2) of the Patent Act: “If a process that enables a biological material to be produced possessing specific characteristics as a result of the invention is protected by a patent, the exclusive rights referred to in Article 58, paragraphs (2) and (3) of this Law shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.”

Article 59, paragraph (3) of the Patent Act: “If a product containing or consisting of genetic information is protected by a patent, the exclusive rights referred to in Article 58, paragraphs (2) and (3) of this Law shall extend to all material, save as 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, in which the product is incorporated and in which the genetic information is contained and performs its function.”

With regard to the exclusive rights of the patent applicant, the Patent Act accords an exclusive right to the patent applicant if the patent application is published. Article 60, paragraph (1) of the Patent Act determines the exclusive rights conferred by a patent application, in particular:

Article 60, paragraph (1) of the Patent Act: “By the publication of the patent application in compliance with Article 35 of this Law, the patent applicant shall acquire temporary rights, on the basis of which reasonable compensation for damages may be claimed from any third party, which has exploited the invention within the period from the date of publication of the patent application and the date of publication of a mention of the grant of the patent contrary to Articles 58 and 59 of this Law, in a manner, that could be prohibited after the grant of the patent.”

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

- Private and/or non-commercial use;
- Experimental use and/or scientific research;
- Preparation of medicines;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;

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

X 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):

According to article 63, point (1) of the Patent Act the patent owner's exclusive right of exploitation of the invention shall not apply to acts in which the invention is exploited for private and non-commercial purposes.

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?

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

-

7. If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):

No definition

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

None

³ 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).

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

Yes

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

None

Section III: Experimental use and/or scientific research ⁴

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

According to article 63, point (2) of the Patent Act: “The patent owner’s exclusive right of exploitation of the invention shall not apply to acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, ...”

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

None

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

-

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

-

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

No

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

None

16. 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:

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

- 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):

According to article 63, point (2) of the Patent Act: “The patent owner’s exclusive right of exploitation of the invention shall not apply to acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, ...”

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

- A non-commercial purpose
- 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 distinction

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

None

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

Yes

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

None

Section IV: Preparation of medicines

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

According to article 63, point (3) of the Patent Act the patent owner's exclusive right of exploitation of the invention shall not apply to direct and individual preparation of a medicine in a pharmacy on the basis of an individual medical prescription and acts relating to the medicine so prepared.

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

None

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

-

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

-

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

Pharmacists are entitled to use the exception, when making the preparation in a Pharmacy on the basis of a medical prescription.

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

Yes

No

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

-

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

None

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

Yes

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

None

Section V: Prior use

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

Article 64 of the Patent Act

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

None

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

-

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

-

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

A patent shall have no effect against the person who had, prior to the filing date of the application, or prior to the date of granted priority exploited or manufactured, *in good faith and within her/his economic activities*, the product which is the subject-matter of the invention or, *had made real and serious preparations* for such exploitation of the invention in the Republic of Croatia.

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:

The prior user's right may be transferred or inherited only with the working process and production plant in which the exploitation of the invention has been prepared or has started.

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:

If the exploitation of the invention by a third party was in good faith, the "use" can continue for the purposes of their own business and needs related to it. (Article 57, paragraph (7) of the Patent Act)

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):

-

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

Yes

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

None

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

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

According to article 67 of the Patent Act the use of products made according to the protected invention in the construction or equipment of a vessel, aircraft or land vehicle belonging to any of the member States of the Paris Union or the World Trade Organization members shall not be considered to be the patent infringement where such transport means finds itself temporarily or accidentally in the territory of the Republic of Croatia, provided that the built-in product serves exclusively for the purposes of the said transport means.

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:

-

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

-

45. The exception applies in relation to:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

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

The applicable law applies the terms "temporarily" and "accidentally" but does not define them.

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

Yes, devices used exclusively for the purposes of the listed transport means

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

None

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

Yes

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

None

Section VII: Acts for obtaining regulatory approval from authorities

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

According to article 63 (2) of the Patent Act: "The patent owner's exclusive right of exploitation of the invention shall not apply to acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, including where such acts are necessary for obtaining registration or authorization for putting on the market a product being a human or a veterinary drug or a medical product."

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:

-

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

-

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

Any person

55. The exception covers the regulatory approval of:

any products

certain products. Please describe which products: **Human or a veterinary drug or a medical product**

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: **acts done for the purposes of research and development and for experiments necessary for obtaining registration or authorization for putting on the market a product being a human or a veterinary drug or a medical product**

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

None

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

Yes

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

None

Section VIII: Exhaustion of patent rights

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

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

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

Article 66 of the Patent Act

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:

-

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

-

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:

-

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):

Articles 67a to 69h of the Patent Act

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:

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

-

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

-

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):

According to article 68, paragraph (1) of the Patent Act the competent court in the Republic of Croatia may grant a compulsory license for lack or insufficiency of exploitation of a patent to any person filing a request for the grant of a compulsory license, or to the Government of the Republic of Croatia, if the patent owner has not exploited the invention protected by a patent in the territory of the Republic of Croatia on reasonable terms or has not made effective and serious preparations for its exploitation.

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

The applicable law does not specify whether the importation of a patented product constitute “working” of the patent.

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

Yes
 No

If yes, what is the time period? **A request for the grant of a compulsory license can be filed after the expiration of a period of four years as of the filing date of a patent application, or after the expiration of three years as of the date on which the patent was granted.**

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

Yes
 No

If yes, what are "legitimate reasons"? **The applicable law does not define the "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):

No

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

-

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

The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent

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

The patent owner has the right to remuneration, taking into account the economic value of the authorization and need to correct anti-competitive practice.

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

According to article 68, paragraph (6) of the Patent Act the court may grant a compulsory license if the exploitation of the patented invention is necessary in situations of extreme urgency (national security, public interest protection in the field of health, food supplying, environmental protection and improvement, specific commercial interest) or when it is necessary to remedy a practice determined after judicial or administrative process to be anticompetitive.

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

Unfortunately, data relating to this issue is not available

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

Yes

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

None

Government use

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

Articles 67a to 69 of the Patent Act

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?

-

(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:

According to article 68, paragraph (6) of the Patent Act: “The court may grant a compulsory license if the exploitation of the patented invention is necessary in situations of extreme urgency (national security, public interest protection in the field of health, food supplying, environmental protection and improvement, specific commercial interest)...”

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

Unfortunately, data relating to this issue is not available

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

Yes

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

None

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

Farmers’ use of patented inventions

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

Article 65, paragraph (3) of the Patent Act

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:

-

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

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92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

Article 65, paragraph (3) of the Patent Act: “ By way of derogation from Article 59 of this Law, the sale or any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the owner of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose, including making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.”

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

Yes

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

None

Breeders' use of patented inventions

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

Article 65, paragraph (2) of the Patent Act

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

None

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

-

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

-

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):

Article 65, paragraph (2) of the Patent Act: “By way of derogation from Article 59 of this Law the sale or other form of commercialization of plant propagating material to a farmer by the owner of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.”

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

Yes

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

None

Section XI: Other Exceptions and Limitations

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

None

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):

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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]