

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: SRI LANKA
Office: INTELLECTUAL PROPERTY OFFICE OF SRI LANKA

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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.

Novelty, inventive step and industrial application (Intellectual Property Act No. 36 of 2003 Section 63)

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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

*The following, notwithstanding they are inventions, are not be patentable –
(a) discoveries, scientific theories and mathematical methods ;*

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

(b) plants, animals and microorganisms other than transgenic microorganisms and an essentially biological process for the production of plants and animals other than non-biological and microbiological processes ;

(c) schemes, rules or methods for doing business, performing purely mental acts or playing games;

(d) methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body; provided however, any product used in any such method shall be patentable;

(e) an invention which is useful in the utilization of special nuclear material or atomic energy in an atomic weapon;

(f) any invention, the prevention within Sri Lanka of the commercial exploitation of which is necessary to protect the public order, morality including the protection of human, animal or plant life or health or the avoidance of serious prejudice to the environment. (S. 62(3) of the Intellectual Property Act No. 36 of 2003)

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

Rights to use, assign and license the patent/protected technology.

The national patent applications are examined and published where the invention is patentable.

Upon publication, any interested party can challenge the proposed grant of patent. If no objection is raised during the prescribed period, the patent is granted.

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

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

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

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).

exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

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

Section II: Private and/or non-commercial use

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

The protected rights extend only to acts done for industrial or commercial purposes and in particular do not extend to acts done only for the purpose of scientific research. (S.86(1)(i) of the Intellectual Property Act No. 36 of 2003)

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

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

Promote creativity while protecting the rights of the patent holder

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

Hanzard (Records of Parliamentary Debates) dated 23.07.2003. The purposes of introduction of the new law in 2003 were the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment

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

Not defined

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

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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:

No study done. But, probably due to the existing level of R & D activities in the country, the exception has not been practically tested.

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:
No information available.

Section III: Experimental use and/or scientific research ⁴

11. If the exception is contained in statutory law, please provide the relevant provision(s):
The protected rights extend only to acts done for industrial or commercial purposes and in particular do not extend to acts done only for the purpose of scientific research. (S.86(1)(i) of the Intellectual Property Act No. 36 of 2003)

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

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13. (a) What are the public policy objectives for providing the exception?
Promote creativity while protecting the rights of the patent holder

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

Hazard (Records of Parliamentary Debates) dated 23.07.2003. The purposes of introduction of the new law in 2003 were the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment

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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):

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

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):

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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
- *Not yet interpreted by an authoritative court.*

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):

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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:

So far no complaints from R & D Institutions to the IP Office.

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

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Section IV: Preparation of medicines

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

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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:

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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:

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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?

- 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):

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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:

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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):

Where a person at the filing date or, where applicable, the priority date, of the patent application, was in good faith making the product or using the process in Sri Lanka which is the subject of the invention claimed in such application or had in good faith made serious preparations in Sri Lanka towards the making of the product or using the process.(S.87(1) of the Intellectual Property Act of 2003).

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

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

Promote creativity while protecting the rights of the patent holder.

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

Hazard (Records of Parliamentary Debates) dated 23.07.2003. The purposes of introduction of the new law in 2003 were the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment

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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):

Not so far defined by an authoritative court.

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

No.

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

- Yes
 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 cannot be assigned or transmitted except as part of the business of the prior user (.S.87(1) of the intellectual Property Act of 2003).

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

- Yes
 No

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

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:

Not known.

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

Not known.

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

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

The protected rights do not extend to the presence or use of products on foreign vessels, aircraft, spacecraft, or land vehicles which temporarily or accidentally enter the waters, airspace or territory of Sri Lanka.(S.86(1)(iii) of the IP Act of 2003)

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

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

To honor our international obligations

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

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45. The exception applies in relation to:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

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

Yes. No definitions available

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

No..

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

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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:

Not known to the IP Office.

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

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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):

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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:

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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:

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55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which 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):

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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:

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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:

- National
- Regional
- International

Uncertain

The protected rights do not extend to acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under license. (S.86(1)(iv) of the IP Act). The issue whether these provisions cover both national and international exhaustion needs the interpretation of court.

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

The protected rights do not extend to the acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under license. (S. 86 (1)(iv) of the Intellectual Property Act)

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

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

Consumer protection

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

Hazard (Records of Parliamentary Debates) dated 23.07.2003. One of the purposes of the introduction of the new law 2003 was to safeguard consumer interests.

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):

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

Not yet practically tested.

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

So far not really tested the provisions

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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):

Section 86(2) of the Intellectual Property Act

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

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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):

- 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:Nutrition and development of the vital sections of the national economy

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

Consumer protection

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

Hazard (Records of Parliamentary Debates) dated 23.07.2003. One of the purposes of the introduction of the new law in 2003 was to safeguard consumer interests.

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

Not so far

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

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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?

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”?

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

Not given by the statute or any case

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

Not given specifically

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

Where the application is for the exploitation of the patent (the second patent) which cannot be exploited without infringing another patent (the first patent), the following conditions shall apply:

- *the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*
- *the owner of the first patent shall be entitled to a cross license on reasonable terms to exploit the invention claimed in the second patent; and*
- *the exploitation authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent. (S. 86(2)(g) of the IP Act).*

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

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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:

Not explained. It is a matter for the court to decide

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

Not yet.

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

Not yet practically tested.....
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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):

Director-General may grant a compulsory license where he has satisfied himself of the existence of a national emergency or any other circumstances of extreme urgency or in case of public non-commercial use for the purpose such as national security, nutrition, health or for the development of other vital sections of the national economy. (S. 86 (2)(c) of the Intellectual Property Act)

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

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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
- National security
- National emergency and/or extreme urgency
- Dependent patents
- Other, please specify: for the development of other sections. Nutrition and development of the vital sections of the national economy
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84. (a) What are the public policy objectives for providing government use in your country?

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

Hanzard (Records of Parliamentary Debates) dated 23.07.2003. One of the purposes of the introduction of the new law 2003 was to safeguard consumer interests.

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

Not so far.

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

Not so far.

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

Not so far.

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

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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):

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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):

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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:

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(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):

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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:

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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:

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Breeders' use of patented inventions

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

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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):

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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:

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(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:

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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:

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Section XI: Other Exceptions and Limitations

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

The exclusive patent rights shall not preclude a licensee from exploiting the patented invention. (S.86 (1)(ii) of the IP Act.)

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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]