

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Finland.....

Office: National Board of Patents and Registrations of Finland

Person to be contacted:

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Title:

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Note: Below the "Patents Act" refers to the Finnish Patents Act No. 550/67 of 15 December 1967, as last amended by Act No. 954/2010 of 12 November 2010

<http://www.prh.fi/en/patentit/lainsaadantoa/patenttilaki.html>

Section I: General

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.

Section 2(1) of the Finnish Patents Act:

Patents may only be granted for inventions which are new in relation to what was known before the date of filing of the patent application and which also differ essentially from them.

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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

Section 1 of the Patents Act:

- Discoveries, scientific theories and mathematical methods;
- Aesthetic creations:
- Schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- Presentations of information.
- Methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals,
- Plant or animal varieties.
- Essentially biological processes for the production of plants or animals.

Section 1 a of the Patents Act:

- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Section 1 b of the Patents Act:

- Inventions the commercial exploitation of which would be contrary to ordre public or morality. The following inventions, in particular, shall be considered unpatentable:
 - 1) processes for cloning human beings;
 - 2) processes for modifying the germ line genetic identity of human beings;
 - 3) uses of human embryos for industrial or commercial purposes;
 - 4) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

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

Section 1 of the Patents Act:

Anyone who has, in any field of technology, made an invention which is susceptible of industrial application, or his or her successor in title, is entitled, on application, to a patent and thereby to the exclusive right to exploit the invention commercially).

Section 3(1) and section 3(2) of the Patents Act):

The exclusive right conferred by a patent shall imply, with the exceptions stated below, that no one may exploit an invention, without the proprietor's consent, by:

- (1) making, offering, putting on the market or using a product protected by the patent, or importing or possessing such product for these purposes;

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

(2) using a process protected by the patent, or offering such process for use in this country if he knows or if it is evident from the circumstances that the use of the process is prohibited without the consent of the proprietor of the patent;

(3) offering, putting on the market or using a product obtained by a process protected by the patent or importing or possessing such product for these purposes.

A patent shall also confer on its proprietor the exclusive right to prevent any person not having his consent from supplying or offering to supply any person not entitled to exploit the invention with the means of working the invention in this country in relation to an essential element of the invention where such other person knows, or where it is evident from the circumstances, that the means are suitable and intended for working the invention. This provision shall not apply where the means are staple commercial products, except where such other person attempts to induce the receiver to commit any of the acts referred to in the first subsection of this section. For the purposes of this subsection, any person using the invention in a manner referred to in subsection (3), item (1), (2) or (4), shall not be regarded as entitled to exploit the invention.

Rights conferred by public patent application (Section 60 of the Patents Act): Where any person commercially exploits an invention which is the subject of a patent application after the application documents have been made available under Section 22, the provisions on patent infringement shall apply mutatis mutandis, if the application results in a patent. However, until a patent has been granted under Section 20, protection shall extend only to the subject matter disclosed both in the claims as worded when the application became available to the public and in the claims according to the patent. There shall be no liability to punishment, and damages arising from exploitation prior to the granting of the patent may be assessed only on the basis of Section 58 (2).

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

- x Private and/or non-commercial use;
- x Experimental use and/or scientific research;
- x Preparation of medicines;²
- 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.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

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).

parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

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

Section II: Private and/or non-commercial use

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

Section 3(3)(1) of the Patents Act:
Use which is not commercial

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

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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):

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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 ⁴

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

[Section 3\(3\)\(3\) of the Patents Act:](#)
[Use in experiments relating to the invention as such;](#)

12. 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?

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(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:

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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):

[Section 3\(3\)\(3\) of the Patents Act:](#)

[Use in experiments relating to the invention as such;](#)

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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

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:

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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):

Section 3(3)5 of the Patents Act:
Preparation in a pharmacy of a medicine prescribed by a physician in individual cases or treatment given with the aid of a medicine so prepared.....

24. 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:

Section 3(3)5 of the Patents Act:
Preparation in a pharmacy of a medicine prescribed by a physician in individual cases or treatment given with the aid of a medicine so prepared.

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

Yes
 No

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

Section 3(3)5 of the Patents Act:

Preparation in a pharmacy of a medicine prescribed by a physician in **individual** cases or treatment given with the aid of a medicine so prepared.....

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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):

Section 4 of the Patents Act:

Any person who, at the time the patent application was filed, was commercially exploiting the invention in this country may continue to do so, notwithstanding the grant of a patent, provided that the general nature of such previous exploitation is maintained and that the exploitation does not constitute an evident abuse in relation to the applicant or his predecessor in title. Such right of exploitation shall also be afforded, subject to the same conditions, to any person who has made substantial preparations for commercial exploitation of the invention in this country.

The right afforded under subsection (1) above can only be transferred to other parties together with the business in which it originated or in which exploitation was intended to take place.

32. 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:

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(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):

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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:

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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:

[Section 4\(2\) of the Patents Act:](#)

[The right afforded under subsection \(1\) above can only be transferred to other parties together with the business in which it originated or in which exploitation was intended to take place.](#)

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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:

Section 71 c of the Patents Act:

If a request under Section 71a or 71b is granted and if, as a result, the examination of a patent application that has been dismissed or rejected after becoming available to the public under Section 22 is resumed or a lapsed patent is reinstated, an announcement to that effect shall be made.

Any person who in good faith has begun to exploit an invention commercially in this country after expiration of the time limit for reinstating a dismissed application or after a rejection has become final or a patent has lapsed, but before such announcement is made, may nevertheless continue to exploit the invention provided he maintains the general nature of the exploitation. The right to exploit an invention shall be granted, on the same conditions, to anyone who has made substantial preparations for such exploitation in this country.

The right under subsection (2) above may only be transferred to another person together with the business in which it originated or in which exploitation of the invention was intended.

39. 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:

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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):

Section 5 and 5(1) of the Patents Act:

Notwithstanding the patent, an invention may be exploited on foreign vessels, aircraft or other means of transport for their own needs when temporarily entering Finland in regular traffic or otherwise.

The Government may decree that, notwithstanding the grant of a patent, spare parts and accessories for aircraft may be imported into the country and used here for the repair of aircraft belonging to a foreign State in which corresponding privileges are granted in respect of Finnish aircraft.

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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:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

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

[See question 42.](#)

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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):

[See question 42.](#)

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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):

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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:

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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):

Section 3(3)(4) of the Patents Act:

Examinations or experiments or measures arising from practical demands which are needed for an application to obtain a marketing authorisation for a medicinal product and which relate to the invention concerning that medicinal product.

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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: [See question 51](#)

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: [See question 51](#)

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

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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, please explain.....

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

[Section 3\(3\)\(2\) of the Patents Act:](#)

[The exclusive right shall not apply to:](#)

[Use of a patented product that has been put on the market within the European Economic Area by the proprietor of the patent or with his consent;](#)

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

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

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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):

[Sections 45 – 50 of the Patents Act:](#)

Section 45: Where three years have elapsed since the grant of the patent and four years have elapsed from the filing of the application, and if the invention is not worked or brought into use to a reasonable extent in Finland, any person who wishes to work the invention in Finland may obtain a compulsory licence to do so unless legitimate grounds for failing to work the invention may be shown. (22.12.1995/1695)

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

Section 46: The proprietor of a patent for an invention whose exploitation is dependent on a patent held by another person may obtain a compulsory licence to exploit the invention protected by such patent if deemed reasonable in view of the importance of the first-mentioned invention or for other special reasons.

The proprietor of a patent in respect of which a compulsory licence is granted under subsection (1) of this Section may obtain a compulsory licence to exploit the other invention unless there are special reasons to the contrary.

Section 46 a: Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

Applicants for the licence referred to in subsection 1 above must demonstrate that they have applied unsuccessfully to the holder of the patent to obtain a contractual licence and that the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent.

Provisions concerning the right of a patent holder to obtain a compulsory licence for the exploitation of a plant variety protected by plant breeder's right are laid down by the Act on Plant Breeders' Rights (No. 789/1992).

Section 47: In the event of considerable public interest, a person who wishes to exploit commercially an invention for which another person holds a patent may obtain a compulsory licence to do so.

Section 48: Any person who was commercially exploiting in this country an invention which is the subject of a patent application, at the time the application documents were made available under Section 22, shall, if the application results in a patent, be entitled to a compulsory licence for such exploitation, provided there are special reasons for this and also provided that he had no knowledge of the application and could not reasonably have obtained such knowledge. Such a right shall also be enjoyed, under corresponding conditions, by any person who has made substantial preparations for commercial exploitation of the invention in this country. Compulsory licences may also relate to the period of time preceding the grant of the patent.

Section 49: A compulsory licence may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner and in accordance with the terms of the licence who, before filing a claim for a compulsory licence, has made a

verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention. A compulsory licence shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. A compulsory licence may only be transferred to a third party together with the business in which it is exploited or was intended to be exploited.

Section 50: Compulsory licences shall be granted by a court of law, which shall also decide the extent to which the invention may be exploited and shall determine the remuneration to be paid and any other conditions under the licence. In the event of a substantial change in the circumstances, the court may, on request, revoke the licence or lay down new conditions.

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

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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:

68. (a) What are the public policy objectives for providing compulsory licenses in your country? 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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69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Section 45: Where three years have elapsed since the grant of the patent and four years have elapsed from the filing of the application, and if the invention is not worked or brought into use to a reasonable extent in Finland, any person who wishes to work the invention in Finland may obtain a compulsory licence to do so unless legitimate grounds for failing to work the invention may be shown. (22.12.1995/1695)

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

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

Section 45(2) of the Patents Act:

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

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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? 3 years from the grant of the patent and 4 years from the filing of the patent application.

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

Yes
 No

If yes, what are “legitimate reasons”? No definition.

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

Section 49: A compulsory licence may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner and in accordance with the terms of the licence who, before filing a claim for a compulsory licence, has made a verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention. A compulsory licence shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. A compulsory

licence may only be transferred to a third party together with the business in which it is exploited or was intended to be exploited.

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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):

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

Section 46: The proprietor of a patent for an invention whose exploitation is dependent on a patent held by another person may obtain a compulsory licence to exploit the invention protected by such patent if deemed reasonable in view of the importance of the first-mentioned invention or for other special reasons.

The proprietor of a patent in respect of which a compulsory licence is granted under subsection (1) of this Section may obtain a compulsory licence to exploit the other invention unless there are special reasons to the contrary.

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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:

Section 50: Compulsory licences shall be granted by a court of law, which shall also decide the extent to which the invention may be exploited and shall determine the remuneration to be paid and any other conditions under the licence. In the event of a substantial change in the circumstances, the court may, on request, revoke the licence or lay down new conditions.

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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:

Section 47: In the event of considerable public interest, a person who wishes to exploit commercially an invention for which another person holds a patent may obtain a compulsory licence to do so.

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

Not used.

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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:

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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):

Sections 75 and 76 of the Patents Act:

Section 75: If the country is at war or in danger of war, the Government may decree, where required by the public interest, that the right to a given invention shall be surrendered to the State or to another party designated by the Government. Reasonable compensation shall be paid for the right to the invention thus surrendered. If no agreement is reached on compensation with the party entitled to compensation, the court shall determine the compensation.

Where a party other than the State has availed itself of the right to an invention pursuant to subsection (1) above and if such party does not fulfill its obligations with regard to compensation, the State shall pay the compensation without delay on request by the party entitled to compensation.

Section 76: Special regulations shall apply to inventions of importance to the defense of the country.

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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:

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

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

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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:

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

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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:

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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):

Section 3b(1) of the Patents Act:

By way of derogation from the provisions of Section 3 a, subsections (1) to (3), the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Council Regulation (EC) No 2100/94 on Community plant variety rights.

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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):

Section 3b(2) of the Patents Act:

By way of derogation from the provisions of Section 3 a, subsections (1) to (3), the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

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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:

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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]