

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

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

Country: Sweden.....  
Office: Ministry of Justice, Division for Intellectual Property and Transport Law.....

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**Section I: General**

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

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

- 1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

**The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837) Article 1, 1 st paragraph, 1a, 1b 2<sup>nd</sup> paragraph and article 2, .....**  
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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.<sup>1</sup>

**Article 1, 2<sup>nd</sup> paragraph SPA (a discovery, scientific theory or mathematical method, an artistic creation, a scheme, rule or method for intellectual activities, for playing games or for doing business or a computer program, or a presentation of information), Article 1 a (plant and animal varieties, an essentially biological processes for the production of plants and**

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

animals), Article 1 b The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837) (The human body in the various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence of a gene or a partial sequence of a gene), Article 1 c SPA (invention the commercial exploitation of which would be contrary to public order or morality, *inter alia*, processes for cloning of human beings, processes for modifying the germ line genetic identity of human beings, the use of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit for men or animals.) Article 1 d SPA (process for surgical or therapeutic treatment or for diagnostics that is to be used on men or animals.).

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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?

**Article 3 The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837): The exclusive right conferred by a patent implies that no one is entitled, without the consent of the holder of the patent, to make use of the invention by manufacturing, offering, putting on the market or using a product protected by the patent or import or possess such a product for those purposes, making use of a process that is protected by the patent, or, if he or she knows, or it is from the circumstances obvious, that the process must not be used without the consent of the holder, offering it for use in Sweden, offering, putting on the market, or using a product prepared by a process protected by the patent or importing, or possessing the product for these purposes.**

**The exclusive right also implies that no one may, without the consent of the holder of the patent, exploit the invention by offering or supplying to a person who is not entitled to exploit the invention with such means for carrying out the invention in Sweden that relate to an essential element of the invention, if the person offering or supplying the means knows or it is obvious from the circumstances, that the said means are suited and intended for use in the carrying out of the invention.**

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

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

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

<sup>3</sup> For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers of harvested plant material or of

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):

**Article 3, 2<sup>nd</sup> The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837)  
paragraph p 1: "From the exclusive right are excluded the following acts: 1.  
exploitation that is not commercial,..."**

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[Footnote continued from previous page]

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).

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 <sup>4</sup>**

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

**Article 3, 2<sup>nd</sup> paragraph, p. 3 SPA: "From the exclusive right are excluded the following acts:...use of the invention for experiments that relate to ..... the invention itself..."**

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

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

**Facilitate research activities and the development of technology and peer control of the functioning of the patented invention.**

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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:

**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):

**It does not**.....  
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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:

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

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):

**Article 3, 2<sup>nd</sup> paragraph, p. 3 SPA: "From the exclusive right are excluded the following acts:...use of the invention for experiments that relate to ..... the invention itself..."**

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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:

**Yes**.....  
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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):

**Article 3, 2<sup>nd</sup> paragraph, p 5 SPA: "From the exclusive right are excluded the following acts:...preparation in pharmacies of medicines in ..... accordance with a prescription by a physician in an individual case or acts relating to ..... medicines prepared in such cases..."**

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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:

**Enable personal at pharmacies, in an individual case, to prepare medicine according in accordance with a prescription by a physician without being exposed to the risk of infringing a patent.....**

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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:

**Personnel at pharmacies .....**

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

x Yes  
No

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



**It only provides extemporaneous preparation for individual cases** .....

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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):

**See answers above**.....

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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:

**No amendments foreseen in the near future but the exception is not used since preparation of medicines do not takes place at pharmacies in Sweden** .....

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

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**Section V: Prior use**

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

**Article 4 of the SPA: Anyone who, at the time when the application for a patent was filed, was exploiting the invention commercially in this country may, notwithstanding the patent, continue such exploitation while retaining its general character, if the exploitation did not constitute an evident abuse in relation to the applicant or his predecessor in title. The right to such exploitation shall also be due to anyone who has made substantial preparations for commercial use of the invention in this country.**

**The right under the first Paragraph may be transferred to others only together with the business where it originated or where the exploitation was intended to take place.**

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

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

**To allow use in good faith before the application date as long as no abuse can be considered. It is reasonable and provide for economic benefits to the society as a whole.....**

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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):

**See above cited article of SPA "...the exploitation did not constitute an evident abuse in relation to the applicant or his predecessor in title.."** .....

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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:

**No** .....

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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:

**see above cited article of SPA: The right under the first Paragraph may be transferred to others only together with the business where it originated or where the 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:

**This is regulated in Article 74 of the SPA. The general idea is: Under certain circumstances the processing of a patent application that has been dismissed or rejected can be resumed, or a patent that has lapsed can be considered maintained. In such cases an announcement shall be made. If anyone, after the expiry of the time limit for restoration of the dismissed application, after the decision on rejection has gained legal force, or after the patent has lapsed, but before the said announcement has been made, has begun in good faith to exploit the invention commercially he may, notwithstanding the patent, continue such exploitation while retaining the general character of the exploitation. Such a right shall also be granted on corresponding conditions to anyone who has made substantial preparations for commercial exploitation of the invention.**

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

**See answer above (38)** .....

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:

**No amendments foreseen** .....

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

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

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

**Article 5 (SPA). Notwithstanding the existence of a patent, an invention may be used on a foreign vessel, aircraft, or other foreign means of transport for its own needs, when it temporarily enters this country in regular traffic or otherwise.**

**The Government may prescribe that, notwithstanding the existence of a patent, spare parts and accessories may be imported into this country and used here for the repair of an aircraft from a foreign country where corresponding privileges are granted to Swedish aircraft (Act 1977:700).**

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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:

**Facilitate international transportation (Implementation of article 5 ter in the Paris Convention)** .....

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

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45. The exception applies in relation to:

- x Vessels
- x Aircrafts
- x Land Vehicles
- x Spacecraft

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

**See answer above (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 answer above (42) "...for its own needs, when it temporarily enters this country in regular traffic or otherwise"** .....

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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:

**Yes**.....

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

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**Section VII: Acts for obtaining regulatory approval from authorities**

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

**Article 3 2<sup>nd</sup> paragraph, 4 p: "From the exclusive right are excluded the following acts... studies, tests, examination activities and practical measures that refer to a reference medicine to the extent that these are necessary for obtaining a approval for the sale of a medicine pursuant to Article 8 a of the Act (1992:859) on Medicinal Products or for other proceedings for approval based on Article 10. 4 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as last amended by Directive 2004/27/EC, of the European Parliament and of the Council, or Article 13.1 – 13.5 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code**

**Relating to Veterinary Medicinal Products, as last amended by Directive 2004/28/EC of the European Parliament and the Council,”**

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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:

**Implementation of EU directives 2004/27 and 2004/28** .....  
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54. Who is entitled to use the exception? Please explain:

**Anyone**.....  
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55. The exception covers the regulatory approval of:

any products  
x certain products. Please describe which products: **reference  
medicine** .....

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

Making  
Using  
Selling  
Offering for sale  
Import  
Export  
x Other. Please specify: **Acts necessary to obtain marketing clearance for medicinal product, e.g. studies, tests, examination activities and practical measures See above (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:

Yes.....  
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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
- x Regional
- International
- Uncertain, please explain.....

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

**Article 3 2<sup>nd</sup> paragraph 2 p SPA** .....  
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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:

**Common internal market in the European Union. A regional exhaustion regime has been determined by the EU Court of Justice and ensure the free trade between member states of the European Union**

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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:

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

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**Section IX: Compulsory licenses and/or government use**

*Compulsory licenses*

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

**Article 45 – 50 The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837)....**  
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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):

**Article 45 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). A compulsory license for the use of an invention in Sweden may be granted if**  
**1. three years have passed from the granting of the patent and four years from the filing of the patent application,**  
**2. the invention is not used to a reasonable extent in Sweden, and**  
**3. there is no acceptable reason for the non-use of the invention.**

**For the purposes of the application of the first Paragraph, Item 2, use of an invention equals importation of the invention to Sweden from a State within the European Economic Area or a State or a territory that is party to the Agreement Establishing the World Trade Organization (WTO). (Act 2004:159).**

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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):

**See above answer to question nr 69, 2<sup>nd</sup> paragraph of Article 45**

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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? **Three years from the granting of the patent and four years from the filing of the patent application, Article 45 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837)** .....

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"? **"there is no acceptable reason for the non-use of the invention", Article 45 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837)** .....

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

**See above answer to question 69** .....

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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):

**It does not**.....

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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:

**Article 46 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). A holder of a patent for an invention of which the exploitation is depending on a patent that belongs to someone else may be granted a compulsory license to exploit the invention protected by the other patent. Such a license may be granted only if the applicant proves that the first-mentioned invention constitutes a significant technical progress of considerable economic interest compared with the other invention.**

**If a compulsory license is granted pursuant to the first Paragraph, the holder of the patent for which a compulsory license has been granted is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the other invention. (Act 2004:159).**

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

**Article 50 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). A compulsory license is granted by a Court which also decides to what extent the invention may be exploited and determines the remuneration and other terms for the license. When substantially changed circumstances call for it, the Court may, upon request, revoke the license or establish new conditions for it.**

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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:

**Article 47 of the The Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). If a public interest of extreme importance so requires, anyone who desires to make commercial use of an invention for which another party holds a patent may obtain a compulsory license to that effect.**

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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 since the current patent act was introduced in 1968** .....

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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:

**No amendments foreseen**.....  
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80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

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*Government use*

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

**No exception**.....  
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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):

**Article 3 b 1<sup>st</sup> paragraph of the Swedish Patents Act (Swedish Statute Book, SFS, 1967:837). Where the holder of the patent or someone with his consent assigns plant propagating material to a farmer for agricultural use, the farmer may, notwithstanding Articles 3 and 3 a, use the product of the harvest for propagation or multiplication in his own agricultural activity. The extent of, and the conditions for, this exception from the exclusive right of the holder of the patent are contained in Article 14 of the Council Regulation (EC) No 2100/94 of 27 July, 1994 on the Community Plant Variety Right and the Implementing Regulations issued pursuant to that Article.**

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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:

**Implementation of EU directive 98/44 for the Legal Protection of Biotechnological Inventions.**.....  
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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):

**See the above given answer to question nr 89** .....  
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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):

**Article 3 b 2<sup>nd</sup> paragraph of the Swedish Patents Act (Swedish Statute Book, SFS, 1967:837)Where the holder of the patent or someone with his consent assigns breeding stock or other animal reproductive material to a farmer, the farmer may, notwithstanding Articles 3 and 3 a, use the livestock or other animal reproductive material for agricultural purposes within his agricultural activity. The farmer may, however, not sell protected breeding stock or other material within the framework, or for the purpose, of a commercial reproduction activity.**

**The right of the farmer under the second Paragraph must not be exercised to an extent wider than what is reasonable taking into account the needs of the farmer and the interests of the patent holder. (Act 2004:159).**.....  
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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:

**Implementation of EU directive 98/44 for the Legal Protection of Biotechnological Inventions.** .....

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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):

**See above provided answer to question nr 95** .....

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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]