

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Germany
Office: Federal Ministry of Justice and for Consumer Protection /
German Patent and Trademark Office

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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.

Patents are granted for inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application (Sec. 1(1) Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 2 of the Act of 4 April 2016 (Federal Law Gazette I p. 558)).

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

- Discoveries, scientific theories and mathematical methods as such (Sec. 1(3) no. 1 Patent Act).
- Aesthetic creations as such (Sec. 1(3) no. 2 Patent Act).
- Schemes, rules and methods for performing mental acts, playing games or doing business as such (Sec. 1(3) no. 3 Patent Act).
- Programs for computers as such (Sec. 1(3) no. 3 and (4) Patent Act).
- Presentations of information as such (Sec. 1(3) no. 4 Patent Act).

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

- The human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene (Sec. 1a(1) Patent Act).
- Inventions the industrial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation (Sec. 2(1) Patent Act).
- Processes for cloning human beings and for modifying the germ line genetic identity of human beings (Sec. 2(2) no. 1, 2 Patent Act).
- Uses of human embryos for industrial or commercial purposes (Sec. 2(2) no. 3 Patent Act).
- 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 (Sec. 2(2) no. 4 Patent Act).
- Plant and animal varieties as well as essentially biological processes for the production of plants and animals and the plants and animals produced exclusively by such processes (Sec. 2a(1) no. 1 Patent Act)
- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. This shall not apply to products, in particular to substances or compositions, for use in one of these methods. (Sec. 2a(1) no. 2 Patent Act)

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?

*The proprietor of a patent has the exclusive right to use the patented invention (Sec. 9, first sentence, Patent Act). Any other person is prohibited from directly or indirectly using the patented products or processes in the absence of the consent of the proprietor of the patent (Sec. 9, second sentence, Patent Act, Sec. 10 Patent Act).
Under Sec. 33(1) Patent Act, the applicant is entitled to claim compensation as from the publication of his application.*

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

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

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the 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.).

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).

Section II: Private and/or non-commercial use

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

Sec. 11 no. 1 Patent Act: The effect of a patent shall not extend to acts done privately and for non-commercial purposes.

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?

Acts undertaken in the private sphere for non-commercial purposes are excluded from the effects of a patent, because patents are not intended for interventions in the private sphere.

(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):

Sec. 11 no. 2 Patent Act: The effects of a patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.

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?

Patents are meant to encourage technological progress. For this reason the effects of a patent do not extend to acts done for experimental purposes. The provision is intended to prevent patent protection from hindering research and technological development.

(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:

The limitation of the effects of the patent for acts done for experimental purposes applies to all experiments relating to the subject matter of the patented invention, irrespective of the aim of the experiment, and of the person or organisation conducting the experiment.

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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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

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

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):

Sec. 11 no. 2 Patent Act: acts done for experimental purposes relating to the subject matter of the patented invention.

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

- A non-commercial purpose
- A commercial purpose
- Both of the above
- The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

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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):

Sec. 11 no. 3 Patent Act: The effects of a patent shall not extend to the extemporaneous preparation in a pharmacy, for individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.

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

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

This provision is intended to facilitate the exercise of medical activities, since patents should not restrict the freedom of the doctor (physician) to prescribe medicines in the interest of health promotion. This is to allow doctors to prescribe medicines to their patients in the individual case, which are prepared in pharmacies, irrespective of possible patent rights. In addition, the provision is to supplement the prohibition of patent protection of methods for treatment of the human or animal body by surgery or therapy.

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

The above-mentioned objectives are mentioned in the explanatory statement to the draft law on the Community patent and on amending provisions in patent law (document of the Bundestag Bundestagsdrucksache 8/2087; p. 25) and the memorandum on the Convention for the European Patent for the Common Market (official gazette BIPMZ 1979, p. 325, 333).

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

The provision is intended to facilitate the prescription of medicines by doctors by way of exempting persons from the effect of the patent, who are directly involved in preparing and processing medicines in the individual case. It therefore concerns the activities of pharmacists and doctors.

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):

Sec. 11 no. 3 Patent Act does not contain explicit requirements concerning the admissible amount of medicines. However, the exemption from the effect of the patent only covers the "extemporaneous preparation for individual cases" (Sec. 11 no. 3 Patent Act). This is the amount which is required in one concrete individual case. The preparation of larger quantities of medicines for several patients is not covered by this provision.

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):

Sec. 12 Patent Act:

(1) The patent shall have no effect in respect of a person who, at the time the application was filed, had already begun to use the invention in Germany or had made the necessary arrangements for so doing. That person shall be entitled to use the invention for the needs of his own business in his own workshops or in the workshops of others. This entitlement may be inherited or sold only together with the business. Where the applicant or his legal predecessor has, before filing the application, disclosed the invention to others and, in so doing, has reserved his rights in the event of a patent being granted, a person learning of the invention as a result of this disclosure may not invoke measures referred to in the first sentence which he has taken within six months of the disclosure.

(2) If the proprietor of the patent is entitled to a right of priority, the earlier application shall be decisive and not the application referred to in subsection (1). However, this shall not apply to nationals of a foreign state which does not guarantee reciprocity in this respect if they claim priority of a foreign application.

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:

The purpose of the provision is to protect the economic status of possession of the prior user. It is intended to prevent the destruction of legitimately created values. Investments in existing facilities are not to be devalued by another person's later patent application.

(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):

The prior user can exploit the invention for his own enterprise. The Patent Act does not provide for explicit limitations of a quantitative or qualitative nature in respect of the admissible exercise of the right to continued use. However, according to a decision of the Bundesgerichtshof (German Federal Court of Justice, BGH, X ZR 32/99 – Biegevorrichtung, published in GRUR 2002, 231-234), the prior user is not allowed to further develop the prior use device if the development exceeds the scope of the previous use and interferes with the subject of the patented invention.

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:

The entitlement of the prior user to exploit the invention for the needs of his own business can only be inherited or transferred together with the business.

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:

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

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

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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):

*Sec. 11 no. 4, 5 Patent Act:
The effect of a patent shall not extend to:*

4. the use of the patented invention on board vessels of another State party to the Paris Convention for the Protection of Industrial Property in the body of such vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters to which the territorial scope of this Act extends, provided that the patented invention is used there exclusively for the needs of the vessel (Sec. 11 no. 4 Patent Act);

5. the use of the patented invention in the construction or operation of aircraft or land vehicles of another State party to the Paris Convention for the Protection of Industrial Property or the use of accessories for such aircraft or land vehicles, when these temporarily or accidentally enter the territory to which this Act applies. ,

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:

Sec. 11 no. 4 and no. 5 Patent Act correspond to the provision under Art. 5ter of the Paris Convention for the Protection of Industrial Property. They are intended to protect international traffic from impairments which might result from claiming patent rights.

(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):

The effect of a patent does not extend to the use of the subject matter of the patented invention on condition that the vessels, aircrafts or land vehicles temporarily or accidentally enter the territorial scope of this Act (Sec. 11 no. 4 and no. 5 Patent Act).

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):

Sec. 11 no. 4 Patent Act explicitly stipulates that the subject matter of the patented invention is used exclusively for the needs of the vessel.

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):

Sec. 11 no. 2b Patent Act stipulates that the effect of the patent does not extend to studies, experiments and the practical requirements resulting therefrom which are necessary for obtaining authorisation to place medicinal products on the market in the European Union, or which are necessary for obtaining authorisation to place medicinal products on the market in the member states of the European Union or in third countries.

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:

The purpose of the provision under Sec. 11 no. 2b Patent Act is to privilege the manufacturers of generic medicines. These manufacturers are allowed to carry out the use of the patent even before the term of protection ends under the condition that the use is necessary to obtain an authorisation for medicinal products.

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

Sec. 11 no. 2b Patent Act implements Article 10(6) of the amended Directive 2001/83/EC and Article 13(6) of the amended Directive 2001/82/EC into national law.

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

Manufacturers of medicaments, especially generic medicines.

55. The exception covers the regulatory approval of:

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

Medicaments.

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:.....

Studies, experiments and any practical requirements resulting therefrom, i.e. any use under the patent's scope of protection that is intended to meet the prerequisites of a privileged study or a privileged experiment (for example: production or importation of the still protected active substance intended to be used in the experiment).

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):

The scope of admissible use comprises studies, experiments and the practical requirements resulting therefrom, under the condition that they are necessary to obtain an authorisation for medicinal products. Therefore, a direct relation is required between the study, the experiment or its execution, on the one hand, and the authorisation sought, on the other hand.

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 and EU/EEA-wide (i.e. the goods protected by patent rights must have been marketed in the territory of a Member State of the European Union or a Contracting State to the Agreement on the European Economic Area)

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

Sec. 9b Patent Act contains a specific exhaustion provision applying to the propagation of biological material:

If the proprietor of the patent or a third party, with the consent of the proprietor of the patent, places on the market biological material which possesses specific characteristics as a result of the invention, in the territory of a Member State of the European Union or in a Contracting Party to the Agreement on the European Economic Area, and if further biological material is obtained from this biological material through propagation or multiplication, the effects of section 9 shall have no effect where the propagation or multiplication of the biological material was the purpose for which it was placed on the market. This shall not apply where the material obtained in this way is subsequently used for further propagation or multiplication.

There are no legal provisions on exhaustion governing other cases.

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

*e.g. decision of the Bundesgerichtshof (BGH, X ZR 61/98 – Karate, published in GRUR 2000, 299):
(1) Exhaustion of the rights conferred by a patent granted with effect in the Federal Republic of Germany occurs at any rate on principle, if the protected product has been placed on the market by the patent owner or with his consent in Germany, in a Member State of the European Community or a Contracting Party to the Agreement on the European Economic Area.
(2) Exhaustion constitutes an exception to the exclusive rights of the patent owner. The party invoking exhaustion has, on principle, the burden of demonstration and proof as to the preconditions.*

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

In the interest of the free movement of goods and trade, the patent should not give the owner the right to influence the trade with specific patent-protected objects forever, if these objects have been placed on the market by the patent owner or a third party with the owner's consent within a certain territory (Germany, EU, EEA). Once the patent owner has exercised his patent right by putting the protected object on the market himself or through a third party with his consent, there is no reason to give him further possibilities to

influence the future fate of the protected object. Rather, the exclusive right to dispose of the protected object lies with the lawful acquirer (in relation to the patent owner) (BGH, X ZR 61/98 – Karate, published in GRUR 2000, 299). In the event that the protected object is placed on the market in another Member State of the European Union by the patent owner or a third party with the owner's consent, the exhaustion of the patent right arises from Art. 34 of the Treaty on the Functioning of European Union according to which all quantitative restrictions on imports and all measures having equivalent effect are, on principle, prohibited between Member States.

The particular exhaustion rule of Sec. 9b Patent Act is to ensure that a person purchasing propagation material in the European Union or a Contracting Party to the Agreement on the European Economic Area, may in fact grow it since the material was bought for this purpose. Patent protection does not preclude the growing and exploitation. It should be noted, however, that this provision does not cover the later use of harvested material as seed.

(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):

Sec. 24 Patent Act:

(1) The non-exclusive authorisation to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence) where:

1. a licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions; and

2. the public interest calls for the grant of a compulsory licence.

(2) Where a licence seeker cannot exploit an invention for which he holds protection under a patent with a later filing or priority date without infringing a patent with an earlier filing or priority date, he shall be entitled, in respect of the proprietor of the patent with the earlier filing or priority date, to the grant of a compulsory licence from the proprietor of the patent if

1. the condition under subsection (1) no. 1 is fulfilled, and

2. his own invention demonstrates an important technological advance of substantial economic significance compared to that of the patent with the earlier filing or priority date.

The proprietor of the patent can require the licence seeker to grant him a cross-licence on reasonable terms and conditions for the use of the patented invention with the later filing or priority date.

(3) Subsection (2) shall apply mutatis mutandis where a plant breeder cannot obtain or exploit a plant variety right without infringing an earlier patent.

(4) A compulsory licence under subsection (1) may be granted for a patented invention in the field of semiconductor technology only where this is necessary to eliminate those anti-competitive practices pursued by the proprietor of the patent which have been established in court or administrative proceedings.

(5) Where the proprietor of the patent does not apply the patented invention in Germany or does not do so predominantly, compulsory licences in accordance with subsection (1) may be granted to ensure an adequate supply of the patented product on the German market. Import shall thus be equivalent to the use of the patent in Germany.

(6) The grant of a compulsory licence in respect of a patent shall be admissible only after the patent has been granted. The compulsory licence may be granted subject to limitations and made dependent on conditions. The extent and the duration of use shall be limited to the purpose for which the compulsory licence was granted. The proprietor of the patent shall be entitled to remuneration from the proprietor of the compulsory licence, such remuneration being equitable in the circumstances of the case and taking into account the economic value of the compulsory licence. Where, in relation to recurrent remuneration payments due in the future, there is a substantial change in the circumstances which governed the fixing of the amount of remuneration, each party shall be entitled to require a corresponding adjustment. Where the circumstances upon which the grant of a compulsory licence was based no longer apply and if their recurrence is improbable, the proprietor of the patent can require withdrawal of the compulsory licence.

Sec. 85 Patent Act

(1) In proceedings for the grant of a compulsory licence the claimant may, at his request, be permitted to use the invention on the basis of an injunction if he substantiates that the requirements under section 24 (1) to (6) are fulfilled and that there is an urgent need, in the public interest, for the immediate grant of the permission.

(2) The issue of the injunction may be made dependent on the fact that the person making the request provides a security due to the imminent threat of disadvantages arising for the party opposing the request.

(3) The Federal Patent Court shall take its decision on the basis of oral proceedings. The provisions set out in section 82 (3), second sentence, and in section 84 shall apply mutatis mutandis.

(4) Upon the withdrawal or rejection of the action for the issue of a compulsory licence (sections 81 and 85a), the effect of the injunction shall cease; a decision on costs may be amended if a party applies for the amendment within one month of the withdrawal or after the rejection has become effective.

(5) If the ordering of the injunction proves unjustified from the outset, the person making the request shall be obliged to compensate the party opposing the request for any damage which he suffered from the implementation of the injunction.

(6) The judgment awarding the compulsory licence may be declared provisionally enforceable upon request against or without provision of a security if this is in the public interest. If the judgment is set aside or amended, the person making the request shall be obliged to compensate the damage which the party opposing the request suffered from the enforcement.

Sec. 85a Patent Act

(1) The procedure in accordance with Article 5 point (c), Article 6, Article 10 (8) and Article 16 (1) and (4) of Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157 p. 1) shall be initiated by an action in accordance with section 81 (1), first sentence.

(2) Sections 81 to 85 shall apply mutatis mutandis in so far as the proceedings are not determined by Regulation (EC) No 816/2006.

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

Compulsory licences may also arise from cartel law. In its decision of May 6, 2009, Case No. KZR 39/06 – Orange Book Standard, published in IIC 2010, 269, the Federal Supreme Court ruled on a possible defence on the basis of cartel law:

“a) A defendant against whom an action has been filed on the basis of a patent may, in reply to the application for an injunction by the plaintiff who is the proprietor of the patent, raise the defence that the latter is abusing a market-dominant position by refusing to conclude a patent licence contract with the defendant on non-discriminatory and non-obstructive conditions. b) A patent holder, however, only acts abusively if the defendant has made him an unconditional offer to conclude a licence contract to which he remains bound and that the patent holder cannot refuse without infringing the prohibition on discrimination or obstruction, and if the defendant, if and as long as he is already using the subject matter of the patent, complies with those obligations that the licence contract to be concluded imposes on the use of the licenced object. c) If the defendant regards the patent holder’s licence requirements as abusively excessive or if the patent holder refuses to quantify the licence fee, the requirement of an unconditional offer is satisfied by an offer to conclude a licence contract under which the licensor shall specify the amount of the licence fee at this fair discretion.”

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 licences on reasonable terms

Note: in this case the public interest must, in addition, command the grant of a compulsory licence (Sec. 24(1) no. 2 Patent Act)

- Anti-competitive practices and/or unfair competition

Sec. 24(4) Patent Act contains a specific provision for compulsory licences in the area of semiconductor technology: in addition to the general requirements under subsection (1) (unsuccessful endeavour of the applicant for a licence and public interest) the compulsory licence must be required to remove an anti-competitive practice on the part of the patent owner that has been established in judicial or administrative proceedings.

Furthermore, there is, as stated above sub 66., an obligation to grant licences accruing from cartel law provisions (abuse of a dominant position - compare decisions of the Federal Supreme court of July 13, 2004, Case No. KZR 40/02 – Standard-Spundfass, published in GRUR 2004, 966 and of May 6, 2009, Case No. KZR 39/06 – Orange Book Standard, published in IIC 2010, 269).

- Public health
- National security
- National emergency and/or extreme urgency
- Dependent patents

Sec. 24(2) and (3) Patent Act; see comments on question 75

- Other, please specify:

Under Sec. 24(5) Patent Act, compulsory licences can be granted within the scope of subsection (1) to ensure an adequate supply of the patented product on the domestic market if the patent owner does not apply the patented invention or does not do so predominantly in Germany.

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

The provision of Sec. 24 Patent Act is intended to protect the public from any abuse of the exclusive right to which the patent owner is entitled.

(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 licences 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):

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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):

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

- Yes
- No

If yes, what is the time period?

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

- Yes
- No

If yes, what are “legitimate reasons”?

73. If the applicable law provides for the grant of compulsory licences on the ground of refusal by the patentee to grant licences 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):

Under Sec. 24(1) no. 1 Patent Act, a compulsory licence will only be granted if the patent owner refuses to allow another person to use the invention despite an offer for reasonable compensation.

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

See above comments on questions 66 and 67.

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

Under Sec. 24(2) Patent Act the applicant for a licence is entitled to request the grant of a compulsory licence with respect to the owner of the patent if the following requirements are met:
- dependent invention, i.e. the applicant for a licence is unable to exploit his later patented invention without infringing the earlier patent,
- the applicant for a licence has unsuccessfully endeavoured during a reasonable period of time to obtain from the patent owner consent to use the invention under reasonable commercial terms and conditions, and
- the invention of the applicant for a licence involves, in comparison with that under the patent of earlier date, an important technical advance of considerable commercial significance.
Sec. 24(2) Patent Act applies mutatis mutandis if a plant breeder cannot obtain or exploit a plant variety right without infringing an earlier patent (Sec. 24(3) Patent Act).

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

Under Sec. 24(6), 4th sentence, Patent Act the patent owner is entitled to remuneration from the holder of a compulsory licence that is equitable in the circumstances of the case and takes into account the economic value of the compulsory licence.
In the event of a significant change, with respect to recurrent remuneration payments that will become due in future, in the circumstances on which the determination of the amount of the remuneration was based, each party is entitled to require a corresponding adjustment (Sec. 24(6), 5th sentence, Patent Act).

77. If the applicable law provides for the grant of compulsory licences 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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78. Please indicate how many times and in which technological areas compulsory licences have been issued in your country:

The Federal Patent Court (BPatG) issued a compulsory licence only once, in 1991 (BPatG, 3 Li 1/90, published in GRUR 1994, 98-104). This compulsory licence was revoked subsequently by decision of the Bundesgerichtshof (BGH, X ZR 26/92– Polyferon, published in GRUR 1996, 190-195).

On August 31st 2016 the Federal Patent Court permitted to use an invention on the basis of an injunction (BPatG, 3 LiQ 1/16 (EP), GRUR 2017, 373-383. An appeal on points of law has been filed with the Federal Court of Justice against the injunction (X ZB 2/17). The main proceedings regarding the issuance of a compulsory licence are pending.

79. Is the applicable legal framework for the issuance of compulsory licences 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):

Sec. 13 Patent Act:

(1) The patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare. Further, it shall not extend to a use of the invention which is ordered in the interest of the security of the Federal Republic of Germany by the competent highest federal authority or by a subordinate authority acting on its instructions.

(2) The Federal Administrative Court shall be competent to hear an appeal from an order made pursuant to subsection (1) if the order was made by the Federal Government or by the competent highest federal authority.

(3) In the cases referred to in subsection (1), the proprietor of the patent shall be entitled to equitable remuneration from the Federal Republic of Germany. In the event of dispute as to its amount, recourse may be taken to the ordinary courts. A Federal Government order pursuant to subsection (1), first sentence, shall be communicated to the person entered in the Register as the proprietor of the patent (section 30 (1)) before the invention is used. Where the highest federal authority which issued an order or instruction in accordance with subsection (1), second sentence, obtains knowledge of a remuneration claim in accordance with the first sentence, this authority shall communicate this to the person registered as the proprietor of the patent.

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: public welfare

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

The provision allows to use the patented invention without the consent of the proprietor of the patent in favour of a higher-ranking public interest (public welfare, security).

(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:

Section 13 Patent Act has never been invoked by the German Federal Government.

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):

Sec. 9c Patent Act:

(1) Where plant propagating material is marketed by the proprietor of the patent or by a third party with the consent of the proprietor of the patent to a farmer for agricultural use, the latter shall, contrary to Sections 9, 9a and 9b, second sentence, be entitled to use the product of his harvest for propagation or multiplication by him on his own holding. Article 14 of Council Regulation (EC) No 2100/94, as amended, as well as the implementing rules adopted on that basis shall apply to the conditions and extent of this authorisation. Where claims arise therefrom for the proprietor of the patent, these claims are to be asserted pursuant to the implementing rules adopted on the basis of Article 14 paragraph 3 of Council Regulation (EC) No 2100/94.

(2) Where livestock or animal reproductive material are marketed to a farmer by the proprietor of the patent or by a third party with the consent of the proprietor of the patent, the farmer shall, contrary to Sections 9, 9a and 9b, second sentence, be entitled to use the livestock or the animal reproductive material for agricultural purposes. This entitlement shall also include making the livestock or other animal reproductive material available for the purposes of pursuing the farmer’s agricultural activity, but not the sale for the purpose or within the framework of a commercial reproduction activity.

(3) Sec. 9a (1) to (3) shall not apply to biological material obtained during agricultural activity by chance or in such manner as to be technically unavoidable. As a rule, a claim can therefore be brought on this ground against a farmer if he used the seeds or plants not subject to such patent protection.

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:

The objective is to allow the farmer to use a part of his harvest product again for planting even if the propagating material is patented, since the seeds are intended for agricultural use and were sold for this purpose. This applies mutatis mutandis to the reproduction of farm animals.

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

*- Sec. 9c(1) Patent Act: This provision implements Article 11(1) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ EC L 213 p. 13).
- Sec. 9c(2) Patent Act: This provision implements Article 11(2) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ EC L 213 p. 13).*

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):

Sec. 11 no. 2a Patent Act: The effect of a patent shall not extend to the use of biological material for the purpose of breeding, discovering and developing a new plant variety.

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:

Sec. 11 no. 2a Patent Act specifies the scope of the research exemption for breeding, discovering and developing new plant varieties on the basis of the declaration of the German delegation for the minutes in the Internal Market Council of 27 November 1997 (statement of reasons regarding the draft of an Act to implement the Directive on the legal protection of biotechnological inventions, document of the Bundestag BT-Drucksache 15/1709, p. 15). The provision shall ensure that breeding, discovering and development of new plant varieties is not unreasonably impeded by patent protection for biological material.

(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):

The provision establishes a research exemption for breeding, discovering and developing new plant varieties and includes any use of biological material for the indicated purposes. The terms "biological material" and "plant variety" are defined in Sec. 2a(3) nos. 1 and 4 Patent Act: Under Sec. 2a(3) no. 1 Patent Act, "biological material" means, for the purposes of this Act, any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. For the definition of the concept of "plant variety", Sec. 2a(3) no. 4 Patent Act refers to the Council Regulation (EC) no. 2100/94 of 27 July 1994 on Community plant variety rights (OJ EC L 227 p. 1), as amended.

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:

Sec. 11 no. 6 Patent Act: The effect of a patent shall not extend to the acts specified in Article 27 of the Convention on International Civil Aviation of 7 December 1944 (Federal Law Gazette 1956 II p. 411), where these acts concern the aircraft of another State to which this article shall apply.

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:

Sec. 11 no. 6 Patent Act takes account of the Convention on International Civil Aviation of 7 December 1944.

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

Art. 27 of the Convention on International Civil Aviation of 7 December 1944 provides for an exemption of seizure on the grounds of patent infringement if the construction, mechanism, parts, accessories or operation of the aircraft infringe a patent on occasion of an authorised entry or transit flight. This exemption also covers the storage of spare parts and spare equipment for the aircraft.

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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