

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

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

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Office: Patent 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.

[Under the Japanese Patent Act, an “Invention” is defined as a highly advanced creation of technical ideas utilizing the laws of nature \(Article 2\), and also required to be industrially applicable \(main paragraph of Article 29\). Moreover, the legal standard to determine patentability includes so called novelty and inventive step \(Article 29 \(1\) and \(2\)\).. .....](#)

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>

[Notwithstanding Article 29, any invention that is liable to injure public order, morality or public health shall not be patented \(Article 32\). .....](#)

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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.

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 68 of the Japanese Patent Act stipulates that a patentee shall have the exclusive right to work the patented invention as a business.

Pursuant to Article 2(3) of the Japanese Patent Act, "working" of an invention means the following acts:

- (i) in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof;
- (ii) in the case of an invention of a process, the use thereof; and
- (iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process.

- .....  
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;<sup>2</sup>
  - ✓ 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;
  - ✓ Compulsory licensing and/or government use;
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.<sup>3</sup>

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.).

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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 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):

Article 68 of the Japanese Patent Act stipulates that A patentee shall have the exclusive right to work the patented invention as a business; provided, however, that where an exclusive license regarding the patent right is granted to a licensee, this shall not apply to the extent that the exclusive licensee is licensed to exclusively work the patented invention.

.....  
.....

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

.....  
.....  
.....

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

Although it was presupposed in defunct Article that the effect of patent right was extended to, not only enforcement of the patented invention as business, but also to individual homely enforcement, that was considered to be excessive regarding the social actual condition. ....

.....

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

.....  
.....  
.....

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

.....  
.....  
.....

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):

.....  
.....  
.....

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

No amendment for changing the legal framework of the exception has been scheduled..

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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 69(1) of the Japanese Patent Act stipulates that a patent right shall not be effective against the working of the patented invention for experimental or research purposes.....  
.....
12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
- .....  
.....  
.....
13. (a) What are the public policy objectives for providing the exception?  
It is intended to promote further inventive activities among the public. ....  
.....
- (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:
- .....  
.....  
.....
14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:
- The Japanese Patent Act does not make a distinction concerning the nature of the organization conducting the experimentation or research. ....  
.....
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):
- .....  
.....  
.....
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

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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.

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):

.....  
.....  
.....

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):

.....  
.....  
.....

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:

[No amendment for changing the legal framework of the exception has been scheduled.](#)  
.....  
.....

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 69 (3) of the Japanese Patent Act stipulates that a patent right for the invention of a medicine (refers to a product used for the diagnosis, therapy, treatment or prevention of human diseases, hereinafter the same shall apply in this paragraph) to be manufactured by mixing two or more medicines or for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.....

.....

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

Taking into account an act of preparing medicine by a physician or a dentist has a social mission with a particular purpose of helping citizens, when becoming patients, recover their health, it is considered inappropriate for the effect of a patent right to extend to an act of preparing medicine. Yet, it is interpreted that medicine itself is generally deemed to be prepared by a medicine manufacturer with a patent license granted, and legally sold by a physician or a dentist. ....

.....

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

.....  
.....  
.....

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

Article 69 (3) of the Japanese Patent Act stipulates that a patent right for the invention of a medicine (refers to a product used for the diagnosis, therapy, treatment or prevention of human diseases, hereinafter the same shall apply in this paragraph) to be manufactured by mixing two or more medicines or for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.....

.....

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

- Yes
- No

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

.....  
.....  
.....

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

.....  
.....  
.....

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 amendment for changing the legal framework of the exception has been scheduled..

.....  
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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 79 of the Japanese Patent Act stipulates that a person who, without knowledge of the content of an invention claimed in a patent application, made an invention identical to the said invention, or a person who, without knowledge of the content of an invention claimed in a patent application, learned the invention from a person who made an invention identical to the said invention and has been working the invention or preparing for the working of the invention in Japan at the time of the filing of the patent application, shall have a non-exclusive license on the patent right, only to the extent of the invention and the purpose of such business worked or prepared. ....

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

.....

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

If the first-to-file system is strictly applied, it is not necessarily be fair that a party which had been working the same invention prior to the filing of a patent application by another party should be precluded from working the same invention of the patent right, just because the party was slightly behind in filing an application. Therefore, even if such a policy is applied, there remains a need to adjust the interests of the patent owner and any party already working the invention in question prior to the patent application.

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

.....

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

Article 79 of the Japanese Patent Act stipulates that a person who, without knowledge of the content of an invention claimed in a patent application, made an invention identical to the said invention, or a person who, without knowledge of the content of an invention claimed in a patent application, learned the invention from a person who made an invention identical to the said invention and has been working the invention or preparing for the working of the invention in Japan at the time of the filing of the patent application, shall have a non-exclusive license on the patent right, only to the extent of the invention and the purpose of such business worked or prepared.

Pursuant to Article 2(3) of the Japanese Patent Act, "working" of an invention means the following acts:

- (i) in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof;
  - (ii) in the case of an invention of a process, the use thereof; and
  - (iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process.
- .....

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

The Japanese Patent Act does not provide for a remuneration to be paid to the patentee for the exercise of the exception.....

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:

Article 94(1) of the Japanese Patent Act stipulates that except for a non-exclusive license granted by an award under Article 83(2), 92(3), 92(4) or 93(2) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, a non-exclusive license may be transferred only where the business involving the working of the relevant invention is also transferred, where the consent of the patentee (or, in the case of non-exclusive license on the exclusive license, the patentee and the exclusive licensee) is obtained and where the transfer occurs as a result of general succession including inheritance.

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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:

Article 176 of the Japanese Patent Act stipulates that where a patent right pertaining to an invalidated patent or a patent right pertaining to the invalidated registration of an extension of the duration thereof has been restored through a retrial or where the establishment of a patent right or the extension of the duration of a patent right with respect to a patent application or an application for registration of an extension of the duration of a patent right refused by a trial decision has been registered through a retrial, and where a person has, without knowledge, been working the invention in Japan or has, without knowledge, been making preparations therefore, after the trial decision became final and binding but before the registration of the demand for a retrial, such person shall have a non-exclusive license on the patent right, to the extent of the invention and the purpose of such business worked or prepared. ....  
.....

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):

Article 80(1) of the Japanese Patent Act stipulates that a person falling under any of the following items, who is doing a business working an invention in Japan or preparing such business, before the registration of a request for a trial for patent invalidation, without knowledge that the patent falls under any of the paragraphs of Article 123(1), shall have a non-exclusive license regarding the invalidated patent right or the exclusive license existing at the time of the invalidation, only to the extent of the invention and the purpose of such business worked or prepared:

- (i) the original patentee in the case where one of two or more patents granted for the same invention has been invalidated;
- (ii) the original patentee in the case where, after a patent has been invalidated, a patent is granted to the person who is entitled to obtain a patent for the same invention; and
- (iii) in the case referred to in items (i) and (ii), a person that, at the time of the registration of the request for a trial for patent invalidation, has an exclusive license regarding the patent right to be invalidated, or a non-exclusive license effective under Article 99(1) regarding the patent right or an exclusive license on the patent right.

Article 81 of the Japanese Patent Act stipulates that where a design right with regard to an application for a design registration filed on or before the date of filing of a patent application is in conflict with the patent right with regard to the patent application, the original holder of design right shall, upon expiration of the duration of the design right, have a non-exclusive license on the said patent right or on the exclusive license actually existing at the time of expiration of the duration of the design right, limited to the extent of the original design right. ....

Article 82(1) of the Japanese Patent Act stipulates that where a design right with regard to an application for a design registration filed on or before the date of filing of a patent application is in conflict with the patent right with regard to the patent application, a person who, at the time of expiration of the duration of the design right, actually owns the exclusive license on the design right, or a non-exclusive license having effect under

Article 99(1) of the Patent Act as applied under Article 28(3) of the Design Act on the design right or on the exclusive license shall, upon expiration of the duration of the design right, have a non-exclusive license on the patent right or on the exclusive license actually existing at the time of expiration of the duration of the design right, limited to the extent of the original right.

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 amendment for changing the legal framework of the exception has been scheduled.

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

**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 69 (2) (i) of the Japanese Patent Act stipulates that A patent right shall not be effective against the following products:  
(i) vessels or aircrafts merely passing through Japan, or machines, apparatus, equipment or other products used therefor

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

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

It is for substantial validity and correspondence with the Paris Convention.

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

45. The exception applies in relation to:

Vessels

- ✓ Aircrafts
- Land Vehicles
- Spacecraft

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

Article 69 (2) (i) of the Japanese Patent Act stipulates that A patent right shall not be effective against the following products:  
(i) vessels or aircrafts merely passing through Japan, or machines, apparatus, equipment or other products used therefor.....  
.....

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):

Article 69 (2) (i) of the Japanese Patent Act stipulates that A patent right shall not be effective against the following products:  
(i) vessels or aircrafts merely passing through Japan, or machines, apparatus, equipment or other products used therefor  
.....

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):

.....  
.....  
.....

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:

No amendment for changing the legal framework of the exception has been scheduled.  
.....  
.....

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 69(1) of the Japanese Patent Act stipulates that a patent right shall not be effective against the working of the patented invention for experimental or research purposes.....  
.....  
.....

.....

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

.....  
Second Petty Bench of the Supreme Court  
Decided on April 16, 1999 (Case No. 153(ju) of 1998) (Minshu 53 (4) 627)  
<Summary of Decision> .....  
In a case where a person holds a patent right of a chemical substance or a medicine having said chemical substance as active ingredient, it is appropriate to interpret the following act falls into Article 69 (1) of the Japanese Patent Act, and thus is not deemed patent infringement; for the purpose of production and sale, to file an application prescribed in Article 14 of Pharmaceutical Affairs Act for an approval for its production, within the term of the patent right, the third party produces a chemical substance or medicine within the technical scope of patented invention, and by using it conducts a study required to obtain a material which should be attached to the above-mentioned application.

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

If it is not allowed to conduct a clinical study required for an approval for production of generic medications within the term of the patent right, substantially speaking, the third party cannot use said patented invention freely even after the term of the patent right is expired.  
Moreover, a patent right holder can ensure financial benefit by an exclusive license of patented invention. ....

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

.....  
.....  
.....

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

.....  
.....  
.....

55. The exception covers the regulatory approval of:

- any products
- ✓ certain products. Please describe which products: .....Medicines, agrichemicals.....

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

- ✓ Making
- ✓ Using
- Selling
- Offering for sale
- Import
- Export
- Other. Please specify:.....

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

.....  
.....  
.....

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:

No amendment for changing the legal framework of the exception has been scheduled..

.....  
.....

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

.....  
.....  
.....

**Section VIII: Exhaustion of patent rights**

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

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

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

From Decision of Third Petty Bench Supreme Court on July 1, 1997  
(BBS Supreme Court case)

As for assignment of patented products in Japan, it was ruled that "in a case where a patent right holder or its licensee assigned to a patented product in Japan, it should be interpreted that the patent right of said patented product is exhausted since the purpose thereof is deemed to be achieved, and the effects of the patent right no longer extend to acts such as use, assignment, or lease of said patented product." As shown in this court decision, the national exhaustion doctrine is applied in Japan. In the meantime, as for assignment of patented products overseas, it was ruled that "in a case where a patent holder in Japan or a person deemed to be equal thereto assigned a patented product overseas, it should be interpreted that the patent right holder is not allowed to execute his/her patent right in Japan, except that for an assignee, an agreement was made between a patent holder and the assignee that the areas for sale or use of the patented product excludes Japan, and that for the third party to whom the patented product was assigned by the assignee and subsequent acquirer, above-mentioned agreement was made between an assignee and said third party or acquirer, and it is explicitly indicated on the patented product. Therefore, the internationally applied exhaustion principle is not applied in Japan. ....

.....

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

.....  
.....  
.....

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

It is to harmonize between protection of invention and public benefit, as well as to coordinate between product distribution in international trade and a right of patentee.....

.....

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

.....

.....

.....

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- Yes
- No
- Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

.....  
.....  
.....

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

At present, there is no court decision to overrule the above decision. ....  
.....

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

.....  
.....  
.....

**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 83 of the Japanese Patent Act stipulates that, (1) Where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan, a person intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license; provided, however, that this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed.  
(2) Where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Commissioner of the Patent Office for an award.

Article 92 of the Japanese Patent Act stipulates that, (1) Where a patented invention falls under any of the cases as provided in Article 72, the patentee or exclusive licensee may request the other person under the said Article to hold consultations to discuss granting a nonexclusive license to work the patented invention or a non-exclusive license on the utility model right or the design right.  
(2) The other person under Article 72 who is requested to hold consultations under the preceding paragraph may request the patentee or exclusive licensee requesting such consultations to hold consultations to discuss granting a nonexclusive license to the extent of the patented invention that the said patentee or exclusive licensee intend to work with a non-

exclusive license on the patent right, on the utility model right or on the design right granted through consultations.

(3) Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (1), the patentee or the exclusive licensee may request the Commissioner of the Patent Office for an award.

(4) Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (2) and where a request for an award is filed under the preceding paragraph, the other person under Article 72 may request the Commissioner of the Patent Office for an award only within the time limit for the submission of a written answer by the said other person designated by the Commissioner of the Patent Office under Article 84 as applied mutatis mutandis under paragraph (7).

(5) In the case of paragraph (3) or (4), the Commissioner of the Patent Office shall not render an award to the effect that a non-exclusive license is to be granted where the granting of the non-exclusive license will be unreasonably prejudicial to interest of the other person under Article 72, the patentee or the exclusive licensee.

(6) In the case of paragraph (4), in addition to the case provided for in the preceding paragraph, the Commissioner of the Patent Office shall not render an award ordering a non-exclusive license to be granted if an award ordering a non-exclusive license to be granted is not rendered with respect to the request for an award under paragraph (3).

(7) Articles 84, 85(1) and 86 through 91-2 shall apply mutatis mutandis to the award under paragraph (3) or (4)

Article 93 of the Japanese Patent Act stipulates that, (1) Where the working of a patented invention is particularly necessary for the public interest, a person(s) intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license.

(2) Where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Minister of Economy, Trade and Industry for an award.

(3) Articles 84, 85(1) and 86 through 91-2 shall apply mutatis mutandis to the award under the preceding paragraph.

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: ...Where the working of a patented invention is particularly necessary for the public interest (Article 93).....

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

It is to balance the right of the patent holder and the purpose to the development of industry, or for the benefit of the public. ....

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

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

Article 83 of the Japanese Patent Act stipulates where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan.....

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):

Article 83 of the Japanese Patent Act stipulates that, (1) Where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan, a person intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license; provided, however, that this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed.

Pursuant to Article 2(3) of the Japanese Patent Act, "working" of an invention means the following acts:

- (i) in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof;
- (ii) in the case of an invention of a process, the use thereof; and
- (iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process.

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

- Yes
- No

If yes, what is the time period?

3 years or longer (however, this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed). .....

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"?

Article 85 (2) of the Japanese Patent Act stipulates where there is a reasonable ground for failing to properly work the patented invention. ....

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):

There are no provisions to grant compulsory license simply due to refusal to grant license. However, as a condition to request for arbitrary license in Article 83 and 92 of the Japanese Patent Act, it is required that granting license is refused or licensing consultations cannot be initiated (Article 92 (3) (7))

.....

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

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.....  
.....

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

In a case where a person cannot work his/her own patented invention without working other's patented invention, the person can request the patent right holder or exclusive licensee to hold consultations on the grant of a non-exclusive license thereon. Yet, if no agreement is reached or no consultation is possible, the person can request for arbitration decision of Commissioner of the Japan Patent Office. Yet, in a case where the grant of a non-exclusive license would unduly injure the other person or the patent right holder, the Commissioner of the Patent Office cannot render an arbitration decision ordering a non-exclusive license to be granted.....

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

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.....  
.....

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

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.....

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

There were some cases where arbitration decisions were requested. Yet, in any of these cases, the request was withdrawn before arbitration decision was made, and there have been no cases where non-exclusive license was granted by arbitration decision.

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 amendment for changing the legal framework of the exception has been scheduled..

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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):

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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):

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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:

.....  
.....  
.....

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

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

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

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.....

*Breeders' use of patented inventions*

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

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

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

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.....

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

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.....  
.....

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

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

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

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**Section XI: Other Exceptions and Limitations**

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

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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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.....  
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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]