

## Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Thailand  
Office: Department of Intellectual Property

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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.

According to Section 5 of the Patent Act of Thailand 1979, a patent may be granted only for an invention in respect of which the following conditions are satisfied: (1) the invention is new; (2) it involves an inventive step; and (3) it is capable of industrial application.

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>

According to Section 9, the following inventions are not protected under the Patent Act:  
(1) naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants;  
(2) scientific or mathematical rules or theories;

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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.

- (3) computer programs;
- (4) methods of diagnosis, treatment or cure of human and animal diseases;
- (5) inventions contrary to public order, morality, health or welfare.

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

Section 36 of the Patent Act 1979 stipulates the exclusive rights of the patent owner as follows;

- (1) where the subject matter of a patent is a product, the right to produce, use, sell, have in the possession for sale, after for sale or import the patented product;
- (2) where the subject matter of a patent is a process, the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

According to Section 35 bis of the Patent Act, any act in violation of Section 36 committed before the grant of a patent shall not be deemed to be an infringement of the patentee's rights unless the act is in respect of the invention under the pending application already published under Section 28, the person so acting knowing of the filing of the patent application or having been informed in writing that a patent application has been filed for the invention, in which case the applicant shall be entitled to damages from the infringer. A complaint for such damages shall be filed with the court after the patent is granted.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):
- Private and/or non-commercial use;
  - Experimental use and/or scientific research;
  - Preparation of medicines;<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;
  - 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

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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).

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

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

**Section II: Private and/or non-commercial use**

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

[In Thailand, there is no statutory exclusion for private and non-commercial use](#)

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

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

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

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

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

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

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

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**Section III: Experimental use and/or scientific research <sup>4</sup>**

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

Section 36 : No other person except the patentee shall have following rights:

(1) where the subject matter of a patent is a product, the right to produce, use, sell, have in the possession for sale, after for sale or import the patented product;

(2) where the subject matter of a patent is a process, the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

The preceding paragraph shall not apply to:

(1) any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner;

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

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

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

This exception was revised twice by the Patent Act (No.2) B.E. 2535 and the Patent Act (No.3) B.E. 2542.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

No distinction

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

No definition

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- seek an improvement to the patented invention
- invent around the patented invention
- other, please specify: ... for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

- Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
- Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- Both of the above

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

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

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

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):

The Patent Act provided that the experimental exception shall not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.

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

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

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**Section IV: Preparation of medicines**

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

Section 36 : No other person except the patentee shall have following rights:

(1) where the subject matter of a patent is a product, the right to produce, use, sell, have in the possession for sale, after for sale or import the patented product;

(2) where the subject matter of a patent is a process, the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

The preceding paragraph shall not apply to:

...

(3) the compounding of a drug specifically to fill a doctor's prescription by a professional pharmacist or medical practitioner, including any act done to such pharmaceutical product;

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

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

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

This exception was first introduced in the Patent Act (No.2) B.E. 2535.

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

a professional pharmacist or medical practitioner

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

- Yes
- No

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

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

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

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

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**Section V: Prior use**

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

Section 36 : No other person except the patentee shall have following rights:  
(1) where the subject matter of a patent is a product, the right to produce, use, sell, have in the possession for sale, after for sale or import the patented product;  
(2) where the subject matter of a patent is a process, the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

The preceding paragraph shall not apply to:

.....

(2) the production of the patented product or use of the patented process, provided that the producer or user, in good faith and without knowing or having no reasonable cause to know about the patent application, has engaged in the production or has acquired the equipment therefore prior to the date of filing of the patent application in Thailand, Section 19 bis not applicable hereto;

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

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

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

This exception was revised twice by the Patent Act (No.2) B.E. 2535 and the Patent Act (No.3) B.E. 2542.

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

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

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

- Yes  
 No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

- Yes  
 No

If yes, please explain what those conditions are:

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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:

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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):

According to Section 36 Paragraph 2 (2), in order to gain the benefit of the exception, that person must produce or use in good faith and without knowing or having no reasonable cause to know about the patent application.

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

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

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

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

Section 36 : No other person except the patentee shall have following rights:

(1) where the subject matter of a patent is a product, the right to produce, use, sell, have in the possession for sale, after for sale or import the patented product;

(2) where the subject matter of a patent is a process, the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

The preceding paragraph shall not apply to:

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(5) the use of a device forming the subject of a patent in the body of a vessel or other accessories of a vessel of a country party to an international convention or agreement on patent protection to which Thailand is also party, when such a vessel temporarily or accidentally enters the waters of Thailand, provided that such a device is used there exclusively for the needs of the vessel;

(6) the use of a device forming the subject of a patent in the construction or other accessories of an aircraft or a land vehicle of a country party to an international convention or agreement on patent protection to which Thailand is also party, when such aircraft or land vehicle temporarily or accidentally enters Thailand;

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

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

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

This exception was introduced in the Patent Act (No.3) B.E. 2542.

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):

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

According to Section 36 paragraph 2(5), a device must be used exclusively for the needs of the vessel but there is no restriction on the case of aircrafts and land vehicles.

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

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

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

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

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

Section 36 : No other person except the patentee shall have following rights:

(1) where the subject matter of a patent is a product, the right to produce, use, sell, have in the possession for sale, after for sale or import the patented product;

(2) where the subject matter of a patent is a process, the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

The preceding paragraph shall not apply to:

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(4) any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term;

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

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

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

This exception was introduced by the Patent Act (No.2) B.E. 2535.

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

Those who wish to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term.

55. The exception covers the regulatory approval of:

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

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: any act concerning an application for drug registration

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

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

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

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**Section VIII: Exhaustion of patent rights**

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

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

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

Section 36 : No other person except the patentee shall have following rights:

(1) where the subject matter of a patent is a product, the right to produce, use, sell, have in the possession for sale, after for sale or import the patented product;

(2) where the subject matter of a patent is a process, the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

The preceding paragraph shall not apply to:

...

(7) the use, sale, having in possession for sale, offering for sale or importation of a patented product when it has been produced or sold with the authorization or consent of the patentee.

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

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

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

This exception was introduced in the Patent Act (No.3) B.E. 2542.

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):

**PART V**

**LICENSES OF RIGHT COMPULSORY LICENSES AND GOVERNMENT USE**

Section 45 Any patentee may, in accordance with the rules and procedures as prescribed in the Ministerial Regulations, apply to the Director-General for an entry to be made in the register to the effect that any other person may obtain a license.

At any time after an entry has been made, the Director-General shall grant a license under the patent to any person who applies for such a license on such conditions, restrictions and royalty terms as agreed upon by the patentee and the applicant. If the patentee and the applicant cannot agree within the period as prescribed by the Director-General, the Director-General shall grant a license on such conditions, restrictions and royalty terms as he deems appropriate.

Any of the parties may appeal the decision of the Director-General made under the preceding paragraph to the Board within thirty days from the receipt of the decision. The decision of the Board shall be final.

The application for and grant of a license under the second paragraph shall comply with the rules and procedures as described by the Ministerial Regulations.

Where an entry is made pursuant to the first paragraph, the annual fees in respect of the patent after the date of the entry shall be reduced as prescribed by a Ministerial Regulations, by at least one half of the annual fees which would be payable if the entry had not been made.

Section 46<sup>(1)</sup> At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows:

(1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or

(2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

Whether it is an application under (1) or (2), the applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedures prescribed in the Ministerial Regulations.

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<sup>(1)</sup> as revised by the Patent Act (No.3) B.E. 2542

Section 47<sup>(1)</sup> If the working of any claim in a patent is likely to constitute an infringement of a claim in a patent of any other person, the patentee, desiring to exploit his own patent, may apply to the Director-General for a license under the patent of the other person under the following criteria:

- (1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;
- (2) the patentee shall be entitled to a cross-license on reasonable terms;
- (3) the applicant shall not assign his right in the license to other persons except with the assignment of his patent.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedures prescribed by the Ministerial Regulations.

Section 47 bis<sup>(2)</sup> If the working of any claim in the patent having obtained a license under Section 46 is likely to constitute an infringement of a claim in a patent of any other person, the applicant for a license under Section 46 may apply to the Director-General for a license under the patent of the other person under the following criteria:

- (1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;
- (2) the applicant shall not assign his right in the license to other persons.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having purposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedure prescribed by the Ministerial Regulations.

Section 48<sup>(1)</sup> Where a compulsory license is granted under Section 46, 47 or 47 bis , the patentee shall be entitled to remuneration.

The licensee under Section 38 shall be entitled to remuneration where a compulsory license is granted under 46, 47 or 47 bis, provided that he has the exclusive right to grant licenses to other persons. In such circumstances, the patentee shall not be entitled to such remuneration.

Section 49<sup>(2)</sup> In an application for a license made under Section 46, 47 or 47 bis, the applicant shall set forth the amount of remuneration, the conditions for the exploitation of the patent and the restrictions on the rights of the patentee and the exclusive licensee under paragraph 2 of Section 48, and a request for a license. In the application for a license under Section 47, the applicant shall also offer a license under his patent to the other party.

Where an application for a license is filed pursuant to Section 46, 47 or 47 bis, the competent officer shall notify the applicant the patentee and the exclusive licensee under paragraph 2 of Section 48 of the date on which the application shall be considered. The patentee and the exclusive licensee shall be furnished with a copy of the application.

In the consideration of an application for a license under the preceding paragraph, the competent officer may require the applicant, the patentee or the exclusive licensee under paragraph 2 of Section 48 to appear before him to give any statement, or to hand over to him any

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<sup>(1)</sup> as revised by the Patent Act (No.3) B.E. 2542

<sup>(2)</sup> as revised by the Patent Act (No.3) B.E. 2542

<sup>(1)</sup> as revised by the Patent Act (No.3) B.E. 2542

<sup>(2)</sup> as revised by the Patent Act (No.3) B.E. 2542

document or any other item. When the application has been considered by the competent officer and the Director-General has made his decision, the applicant, the patentee and the exclusive licensee shall be notified of the decision.

The decision of the Director-General made under the preceding paragraph is appealable to the Board within sixty days of receipt of the notice.

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

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67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security
- National emergency and/or extreme urgency
- Dependent patents
- Other, please specify: .....

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

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

This exception was revised twice by the Patent Act (No.2) B.E. 2535 and the Patent Act (No.3) B.E. 2542.

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):

According to Section 46, the ground of “non-working” or “insufficient working” will be granted if the patentee unjustifiably fails to exercise his legitimate rights as follows:

(1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or

(2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.



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

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.....

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

- Yes
- No

If yes, what is the time period? [At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later.](#)

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

- Yes
- No

If yes, what are “legitimate reasons”? .....

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

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

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:

[According to section 47, the conditions that dependent patents must meet are as follow;](#)  
[\(1\) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;](#)  
[\(2\) the patentee shall be entitled to a cross-license on reasonable terms;](#)  
[\(3\) the applicant shall not assign his right in the license to other persons except with the assignment of his patent.](#)

The applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

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:

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

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:

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

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

Never

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

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.....

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

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.....  
.....

*Government use*

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

Section 51<sup>(2)</sup> In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the

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<sup>(2)</sup> as revised by the Patent Act (No.3) B.E. 2542

patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 46 bis and 47.

In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis.

Section 52<sup>(3)</sup> During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay.

The patentee may appeal the order or the amount of remuneration to the court within sixty days from the receipt of the order.

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

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

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security
- National emergency and/or extreme urgency
- Dependent patents
- Other, please specify: for the preservation or realization of natural resources or the environment, any other public service

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

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

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

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.....  
.....

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<sup>(3)</sup> as revised by the Patent Act (No.3) B.E. 2542

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:

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

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

Since 2006, the Ministry of Public Health of Thailand announced the use of Compulsory Licensing (CL) under the government use provisions on 9 patented drugs; 2 antiretroviral drugs (Efavirenza and Lopinavir+Ritonavir), an antiplatelet drug (Clopidigrel), a lung cancer drug with generic name Erlotinib and trade name Tarceva®, a breast cancer drug with generic name Letrozole and trade name Femara®, a lung and breast cancer drug with generic name Docetaxel and trade name Taxotere®, a medication for chronic leukemia with generic name Imatinib and trade name Glivec®.

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):

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

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

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

(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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.....  
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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:

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

*Breeders' use of patented inventions*

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

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

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

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

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

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

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

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

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):

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

- (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?):

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

- (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]