

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: PHILIPPINES
Office: INTELLECTUAL PROPERTY OFFICE (IPOP HL)

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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 Philippine law, an invention is patentable if such is a technical solution of a problem in any field of human activity which is new, involves an inventive step and is industrially applicable. It may be, or may relate to, a product, or process, or an improvement of any of the foregoing. (Section 21 of Republic Act (R.A.) No 8293, as amended by RA No. 9502)

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.¹

- The following are exclusions from patentability (non-patentable inventions):

1. Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.

For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

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

2. Schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;

3. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods;

4. Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to micro-organisms and non-biological and microbiological processes.

Provisions under this subsection shall not preclude Congress to consider the enactment of a law providing sui generis protection of plant varieties and animal breeds and a system of community intellectual rights protection:

5. Aesthetic creations; and

6. Anything which is contrary to public order or morality. (Sec. 22, R.A. No. 8293 as amended by RA No. 9502)

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

- The following as the exclusive rights granted to a patentee:

(a) Where the subject matter of a patent is a product, to restrain, prohibit and prevent any unauthorized person or entity from making, using, offering for sale, selling or importing that product;

(b) Where the subject matter of a patent is a process, to restrain, prevent or prohibit any unauthorized person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale, or importing any product obtained directly or indirectly from such process.

Patent owners shall also have the right to assign, or transfer by succession the patent, and to conclude licensing contracts for the same. (Sec. 71, R.A. No. 8293, as amended by RA No. 9502)

However, even before the issuance of the letters patent (patent certificate) but after publication of the patent application, the applicant shall have all the rights of a patentee under Section 76 of RA No 8293 against any person who, without his authorization, exercised any of the rights conferred under Section 71 of said law in relation to the invention claimed in the published patent application, as if a patent had been granted for that invention: Provided, that the said person had

1) Actual knowledge that the invention that he was using was the subject matter of a published application; or

2) Received written notice that the invention that he was using was the subject matter of a published application being identified in the said notice by its serial number: Provided, That the action may not be filed until after the grant of a patent on the published application and within four (4) years from the commission of the acts complained of. (Section 42 of RA No 8293, as amended by RA No 9502)

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

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

² For example, extemporaneous preparation of prescribed medicines in pharmacies.

Section II: Private and/or non-commercial use

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

The owner of a patent has no right to prevent third parties from performing, without his authorization act/s such as making, using, selling, offering for sale, or importing the patented article/product which are done privately and on a non-commercial scale or for a non-commercial purpose, provided that such act does not significantly prejudice the economic interests of the owner of the patent (Section 72.2 of RA No 8293, as amended by RA 9502)

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):

An act is said to be done in private and on a non-commercial scale when it does not significantly prejudice the economic interests of the patent owner. The determination of this is on a case-by-case basis.

As provided under Section 72.2 of RA No 8293, as amended, the owner of a patent has no right to prevent third parties from performing, without his authorization act/s such as making, using, selling, offering for sale, or importing the patented article/product which are done privately and on a non-commercial scale or for a non-commercial purpose, provided that such act does not significantly prejudice the economic interests of the owner of the patent.

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:

[Footnote continued from previous page]

³ For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

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

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Section III: Experimental use and/or scientific research ⁴

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

The owner of a patent has no right to prevent third parties from performing, without his authorization act/s such as making, using, selling, offering for sale, or importing the patented article where the act/s consists of making or using exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or educational experimental use; (Section 72.3 of RA No 8293, as amended)

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

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

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

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

- The applicable law 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):

- The “experimental use” and/or “scientific research” must relate to the subject matter of the patented invention (Sec 72.3, RA 8293, as amended)

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:

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

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- seek an improvement to the patented invention
- invent around the patented invention
- other, please specify:

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

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

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

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

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

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

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

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

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

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Section IV: Preparation of medicines

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

The owner of a patent has no right to prevent third parties from performing, without his authorization act/s such as making, using, selling, offering for sale, or importing the patented article where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared (Section 72.5, R.A. No. 8293, as amended by R.A. No. 9502)

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

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

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

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

- A medical professional is entitled to use the exception.

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

- The applicable law does not provide for any limitations on the amount of medicines that can be prepared under the exception.

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):

- The medicine must be prepared in accordance with a medical prescription or acts concerning the medicine so prepared.

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):

- Notwithstanding Section 72 of RA 8293, as amended, any prior user, who, in good faith was using the invention or has undertaken serious preparations to use the invention in his enterprise or business, before the filing date or priority date of the application on which a patent is granted, shall have the right to continue the use thereof as envisaged in such preparations within the territory where the patent produces its effect. (Section 73 of RA No 8293, as amended)

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

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

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

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

- The prior user must be in good faith and was using the invention in his enterprise or business, before the filing date or priority date of the application on which a patent is granted. The prior user shall have the right to continue the use of the invention within the territory where the patent produces its effect.

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

- The applicable law does not provide for a remuneration to be paid to the patentee for the exercise of this exception.

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

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. The right of the prior user may only be transferred or assigned together with his enterprise or business, or with that part of his enterprise or business in which the use or preparations for use have been made. (Sec. 73.2 of RA No 8293, as amended)

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

- Yes
- No

If yes, please explain the conditions under which such use can continue to apply:

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

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

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

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

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

“Where the invention is used in any ship, vessel, aircraft, or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally: Provided, That such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines. (Sec 72.6 of RA 8293 as amended by RA 9502)

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

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

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

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45. The exception applies in relation to:

- ship, vessels, aircrafts, land vehicles.

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

- The applicable law applies such term as "temporarily or accidentally".

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):

- Yes. The invention must be used exclusively for the needs of the ship, vessel, aircraft, or land vehicle.

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):

- Yes. The applicable law prohibits the manufacturing and selling of the invention within the Philippines.

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):

The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 (making, using, offering for sale, selling or importing) of RA No 8293 in the case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product: Provided, That, in order to protect the data submitted by the original patent holder from unfair commercial use provided in Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Intellectual Property Office, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations necessary therein not later than one hundred twenty (120) days after the enactment of this law. Section 72.4 of RA No 8293, as amended)

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

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

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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:
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54. Who is entitled to use the exception? Please explain:
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55. The exception covers the regulatory approval of:
 any products
 certain products. Please describe which products: drugs and medicines

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):
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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):

However, as provided under RA 9502, the exhaustion regime is international only for drugs and medicines. (Section 72.1 of RA No 8293, as amended by RA No 9502)

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

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

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

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

- Yes
- No
- Uncertain

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

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

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

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Section IX: Compulsory licenses and/or government use

Compulsory licenses

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

A. Under Section 93 of RA No. 8293, as amended by RA No 9502, the Director General of the IPOPHL may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances:

1. National emergency or other circumstances of extreme urgency;
2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or

3. Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or
4. In case of public non-commercial use of the patent by the patentee, without satisfactory reason;
6. Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health.

B. Special Compulsory License

The Director General of the IPOPHL, upon the written recommendation of the Secretary of the Department of Health, shall, upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: Provided, That adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.

Under Section 92-A.2, a compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems, provided, that, a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement.

The right to grant a special compulsory license under Section 93-A shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippine laws, particularly Section 72.1 and Section 74 of RA No 8293, as amended. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws." – (Section 93-A of RA No 8293, as amended by RA No 9502)

C. Compulsory License Based on Interdependence of Patents. - If the invention protected by a patent, hereafter referred to as the "second patent," within the country cannot be worked without infringing another patent, hereafter referred to as the "first patent," granted on a prior application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

1. The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;
2. The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;
3. The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent; and
4. The terms and conditions of Sections 95, 96 and 98 to 100 of this Act. (Section 97 of RA No 8293, as amended)

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):

- The applicable law provides for the following ground for the grant of a compulsory license, namely: public health, non-working or insufficient working of the patented invention, national security, national emergency and/or extreme urgency, and judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive. (Section 93, RA No 8293, as amended)

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

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

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

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

Under Section 93 of RA No. 8293, as amended by RA No 9502, the Director General of the IPOPHL may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances: x x x

5. If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: Provided, That the importation of the patented article shall constitute working or using the patent; and

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?

“Sec. 94. Period for Filing a Petition for a Compulsory License. – 94.1. A compulsory license may not be applied for on the ground stated in Subsection 93.5 before the expiration of a period of four (4) years from the date of filing of the application or three (3) years from the date of the patent whichever period expires last.

“94.2. A compulsory license which is applied for on any of the grounds stated in Subsections 93.2, 93.3, 93.4, and 93.6 and Section 97 may be applied for at any time after the grant of the patent. (Sec. 94 of Ra No 8293, as amended by RA No 9502)

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):

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

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

SECTION 97 of RA No 8293, as amended provides:

"Section 97. Compulsory License Based on Interdependence of Patents. - If the invention protected by a patent, hereafter referred to as the "second patent," within the country cannot be worked without infringing another patent, hereafter referred to as the "first patent," granted on a prior application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

97.1. The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;

97.2. The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;

97.3. The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent; and

97.4. The terms and conditions of Sections 95, 96 and 98 to 100 of this Act.

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

Yes. Section 100 of Ra No. 8293, as amended provides:

SECTION 100. Terms and Conditions of Compulsory License. - The basic terms and conditions including the rate of royalties of a compulsory license shall be fixed by the Director of Legal Affairs subject to the following conditions:

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100.6. The patentee shall be paid adequate remuneration taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice

which was determined after judicial or administrative process, to be anti-competitive, the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration. (Sec. 35-B, R.A. No. 165a)

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:

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

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

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Government use

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

A Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where:

- (a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or
- (b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee is anti-competitive.
- (c) In the case of drugs and medicines, there is a national emergency or other circumstance of extreme urgency requiring the use of the invention or
- (d) public non-commercial use of the patent by the patentee without satisfactory reason;
- (e) the demand for the patented articles in the Philippines is not being met to an adequate extent and on reasonable terms as determined by the Secretary of the Department of Health. (Sec. 74 of RA No 8293, as amended by RA No. 9502)

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):

The following are grounds for the grant of government use of the patented article/product: nutrition and public health, national security, the development of other sectors, as determined by the appropriate agency of the government, so requires; or a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the use by the Government, or third person authorized by the Government subject, mutatis mutandis, to the conditions set forth in Sections 95 to 97 and 100 to 102 of RA No 8293, as amended. Please also find below sections 95 to 97 and 100 to 102 of the applicable law.

SEC. 95. Requirement to Obtain a License on Reasonable Commercial Terms

95.1. The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

95.2. The requirement under Subsection 95.1 shall not apply in the following cases:

(a) Where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;

(b) In situations of national emergency or other circumstances of extreme urgency;

(c) In cases of public non-commercial use.

95.3. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable.

95.4. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. (n)

SEC. 96. Compulsory Licensing of Patents Involving Semi-Conductor Technology

In the case of compulsory licensing of patents involving semi-conductor technology, the license may only be granted in case of public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive. (n)

SEC. 97. Compulsory License Based on Interdependence of Patents

If the invention protected by a patent, hereafter referred to as the "second patent," within the country cannot be worked without infringing another patent, hereafter referred to as the "first patent," granted on a prior application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

97.1. The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;

97.2. The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;

97.3. The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent; and

97.4. The terms and conditions of Sections 95, 96 and 98 to 100 of this Act. (Sec. 34-C, R.A. No. 165a)

SEC. 100. Terms and Conditions of Compulsory License

The basic terms and conditions including the rate of royalties of a compulsory license shall be fixed by the Director of Legal Affairs subject to the following conditions:

100.1. The scope and duration of such license shall be limited to the purpose for which it was authorized;

100.2. The license shall be non-exclusive;

100.3. The license shall be non-assignable, except with that part of the enterprise or business with which the invention is being exploited;

100.4. Use of the subject matter of the license shall be devoted predominantly for the supply of the Philippine market: Provided, That this limitation shall not apply where the grant of the license is based on the ground that the patentee's manner of exploiting the patent is determined by judicial or administrative process, to be anti-competitive.

100.5. The license may be terminated upon proper showing that circumstances which led to its grant have ceased to exist and are unlikely to recur: Provided, That adequate protection shall be afforded to the legitimate interest of the licensee; and

100.6. The patentee shall be paid adequate remuneration taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice

which was determined after judicial or administrative process, to be anti-competitive, the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration. (Sec. 35-B, R.A. No. 165a)

SEC. 101. Amendment, Cancellation, Surrender of Compulsory License

101.1. Upon the request of the patentee or the licensee, the Director of Legal Affairs may amend the decision granting the compulsory license, upon proper showing of new facts or circumstances justifying such amendment.

101.2. Upon the request of the patentee, the said Director may cancel the compulsory license:

(a) If the ground for the grant of the compulsory license no longer exists and is unlikely to recur;

(b) if the licensee has neither begun to supply the domestic market nor made serious preparation therefor;

(c) if the licensee has not complied with the prescribed terms of the license;

101.3. The licensee may surrender the license by a written declaration submitted to the Office.

101.4. The said Director shall cause the amendment, surrender, or cancellation in the Register, notify the patentee, and/or the licensee, and cause notice thereof to be published in the IPO Gazette. (Sec. 35-D, R.A. No. 165a).

SEC. 102. Licensee's Exemption from Liability

Any person who works a patented product, substance and/or process under a license granted under this Chapter, shall be free from any liability for infringement: Provided however, That in the case of voluntary licensing, no collusion with the licensor is proven. This is without prejudice to the right of the rightful owner of the patent to recover from the licensor whatever he may have received as royalties under the license. (Sec. 35-E, R.A. No. 165a)

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):

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

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

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

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

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

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

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Breeders' use of patented inventions

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

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

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

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

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

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

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

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Section XI: Other Exceptions and Limitations

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

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102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

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(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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

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In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

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(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

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103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

On 21 July 2015, RA 10667, also known as the Philippine Competition Act (the Competition Act) was signed into law. It came into effect on 8 August 2015, 15 days after its publication in the Government Gazette. It provides for a transitional period of two years for businesses to align structure, conduct, practice or act with the provisions of the Competition Act (Sec 53, RA 10667).

The Competition Act established the Philippine Competition Commission (Commission), which is an independent quasi-judicial body with primary jurisdiction to oversee the implementation and enforcement of the Competition Act and its rules and regulations.

Key aspects:

- Prohibits entities from entering into anti-competitive agreements
- Prohibits abuse of their dominant position by entities
- Sets out a framework for the compulsory notification of mergers and acquisitions where the value of the transaction exceeds PHP1 billion (approximately USD21.7 million)
- Prohibits mergers and acquisitions which substantially prevent, restrict or lessen competition
- Administrative fines and, in some cases, criminal penalties for breach of the law

The Competition Act defines a “dominant position” as a position of economic strength that an entity (or entities) hold, which makes it capable of controlling the relevant market independently from any, or a combination of any, competitors, customers, suppliers or consumers. The Competition Act sets out a list of conduct that is considered abuse, including:

- selling goods or services below cost with the object of driving competition out of the relevant market
- imposing barriers to entry or committing acts that prevent competitors from growing within the market in an anti-competitive manner except those that develop in the market as a result of or arising from a superior product or process, business acumen or legal rights or laws
- making a transaction subject to acceptance by the other parties of obligations which, by their nature or according to commercial usage, have no connection to the transaction
- setting prices or other terms or conditions that discriminate unreasonably between customers or sellers of the same goods or services
- making the supply of particular goods or services dependent upon the purchase of other goods or services from the supplier, which have no direct connection with the main goods or services to be supplied

- directly or indirectly imposing unfairly low purchase prices upon goods or services provided by marginalised service providers and producers
- directly or indirectly imposing an unfair purchase or selling price on competitors, customers, suppliers or consumers
- limiting production, markets or technical development, to the prejudice of consumers.

Provided that nothing in this Act shall prohibit or render unlawful the following:

- Permissible franchising, licensing, exclusive merchandising or distributor agreements such as those which give each party the right to unilaterally terminate the agreement.(Section 15 e1)
- Agreements protecting intellectual property rights, confidential information, or trade secrets. (Section 15 e2)
- Limiting production, markets or technical development to the prejudice of consumers, provided limitations that develop in the market as a result of or due to a superior product or process, business acumen or legal rights or law. (Section 15 i)

[End of Questionnaire]