

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: PERU
Office: INVENTIONS AND NEW TECHNOLOGIES DIRECTORATE (DIN) OF THE
NATIONAL INSTITUTE FOR THE
DEFENSE OF COMPETITION AND INTELLECTUAL PROPERTY (INDECOPÍ)

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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.

A. The applicable legal standards are:

- (a) Decision 486 of the Commission of the Andean Community establishing the Common Industrial Property Regime;*
- (b) Legislative Decree 1075, approving complementary provisions to Decision 486 of the Commission of the Andean Community.*

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

A. Article 20 of Decision 486 of the Commission of the Andean Community establishes that the following shall not be patentable:

- (a) inventions, the commercial exploitation of which in the territory of the respective Member Country must necessarily be prevented so as to protect public order or morality. To that end, the commercial exploitation of an invention shall not be deemed to be contrary to public order or morality merely because said exploitation is prohibited or regulated by a legal or administrative provision;*
- (b) inventions, the commercial exploitation of which in the respective Member Country must necessarily be prevented in order to protect human or animal life or health or to preserve plants or the environment. To that end, the commercial exploitation of an invention shall not be deemed to be contrary to human or animal life*

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

or health or to the preservation of plants or the environment merely because said exploitation is prohibited or regulated by a legal or administrative provision;

(c) plants, animals and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes;

(d) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

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?

A. Article 52 of Decision 486 of the Commission of the Andean Community establishes that patents shall confer upon their holders the right to prevent third parties from carrying out any of the following acts without said holders' consent:

(a) where the subject matter of a patent is a product:

(i) manufacturing the product;

(ii) offering for sale, selling, or using the product; or importing it for these purposes; and,

(b) where the subject matter of a patent is a process:

(i) using the process; or,

(ii) carrying out any of the acts that are specified under paragraph a) above with respect to a product obtained directly through that process

In accordance with the relevant legislation, the publication of a patent application shall not confer exclusive rights upon the applicant.

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

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

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, grant, 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):

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

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

A. *Article 53(a) of Decision 486 of the Commission of the Andean Community establishes that patent holders may not exercise the right referred to in Article 52 of the Decision in respect of the following acts: (a) acts carried out in the private sphere and for non-commercial purposes.*

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

A. *Not applicable.*

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:

A. *Not applicable.*

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):

A. *The applicable law does not contain any definitions of the concepts “non-commercial”, “commercial” and/or “private”*

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):

A. *Not applicable.*

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:

A. *No amendments to the applicable law have so far been foreseen.*

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

A. *Not applicable.*

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

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

A. *Article 53(b) and (c) of Decision 486 of the Commission of the Andean Community establish that patent holders may not exercise the right referred to in the previous article with regard to the following acts:*

(b) acts carried out exclusively for experimental purposes with regard to the object of the invention patented;

(c) acts carried out exclusively for the purposes of teaching or scientific or academic research.

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

A. *Not applicable.*

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

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:

A. *Not applicable.*

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:

A. *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):

A. *The applicable law does not contain any definitions of the concept "experimental use".*

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: acts carried out exclusively for experimental purposes with regard to the object of the invention patented

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):

A. *Not applicable.*

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):

A. *Not applicable.*

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):

A. *Not applicable.*

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:

A. *No amendments to the applicable law have so far been foreseen.*

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

A. *Not applicable.*

Section IV: Preparation of medicines

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

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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):

A. *Not applicable.*

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):

A. *Not applicable.*

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:

A. *No amendments to the applicable law have so far been foreseen.*

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

A. *Not applicable.*

Section V: Prior use

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

A. Article 55 of Decision 486 of the Commission of the Andean Community establishes that: Without prejudice to the provisions concerning nullity of patents contained in the present Decision, the rights conferred by a patent may not be enforced against a third party who, in good faith and before the priority date or the filing date of the application as a result of which the patent was granted, was already using or exploiting the invention, or had already made effective and serious preparations for such use or exploitation. In such cases, the said third party shall have the right to start or continue using or exploiting the invention, but that right may only be assigned or transferred together with the business or company in which that use or exploitation is taking place.

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

A. Not applicable.

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:

A. Not applicable.

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):

A. The law does not define the scope of “use”, nor does it provide for any quantitative or qualitative limitations on the application of the “use” by prior user.

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

A. The law does not provide for a remuneration to be paid to the patentee.

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:

A. The right may only be assigned or transferred together with the business or company in which that use or exploitation is taking place (Article 55 of Decision 486 of the Commission of the Andean Community).

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:

A. *Not applicable.*

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):

A. *Not applicable.*

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:

A. *No amendments to the applicable law have so far been foreseen.*

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

A. *Not applicable.*

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):

A. *Article 53(d) of Decision 486 of the Commission of the Andean Community establishes that patentees may not exercise the right referred to in the previous article with regard to the following acts: (d) acts referred to in Article 5ter of the Paris Convention for the Protection of Industrial Property .*

Article 5ter of the Paris Convention establishes that: In any country of the Union the following shall not be considered as infringements of the rights of a patentee:
(i) the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel;
(ii) the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country.

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

A. *Not applicable.*

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:

A. *Not applicable.*

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):

A. Article 5ter of the Paris Convention uses the expressions "temporarily" and "accidentally" but does not provide definitions of said expressions.

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):

A. Under Article 5ter(i) of the Paris Convention devices are to be used exclusively for the needs of the vessel and in (ii) of the same Article it is stated that devices shall be used in the construction or operation of aircraft or land vehicles, or of accessories.

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):

A. Not applicable.

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:

A. No amendments to the applicable law have so far been foreseen.

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

A. Not applicable.

Section VII: Acts for obtaining regulatory approval from authorities

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

A. Article 39 of Legislative Decree 1075, approving complementary provisions for Decision 486 of the Commission of the Andean Community, establishes that without prejudice to the exclusivity rights of the patentee, a third person may use the material protected by said patent with the sole aim of generating the information necessary to support an application for approval for the commercialization of a pharmaceutical or agrochemical product in Peru. Any product produced in the light of the previous paragraph may only be manufactured, used, sold, offered for sale or imported in the national territory for the generation of information with the aim of complying with the requirements in terms of the approval of commercialization of the product once the term of the patent has expired. Likewise, the product may only be exported for the purposes of compliance with the requirements in terms of approval of commercialization in Peru.

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

A. Not applicable.

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:

A. *Not applicable.*

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

A. *In accordance with the applicable law, any third party may use the exception.*

55. The exception covers the regulatory approval of:

any products

certain products. Please describe which products: Pharmaceutical or agrichemical 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:

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):

A. *Not applicable.*

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:

A. *To date no amendments to the law are foreseen.*

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

A. *Not applicable.*

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):

A. *Article 54 of Decision 486 of the Commission of the Andean Community establishes that the patent shall not give the right to prevent third parties from carrying out commercial acts regarding a product protected by the patent once that product has been introduced onto the market in any country by the patentee, or by any other person authorized by or economically linked to the patentee.*

For the purposes of the previous paragraph, two persons shall be economically linked when one exercises a decisive influence, directly or indirectly, over the other with regard to the exploitation of a patent or when a third party can exercise such an influence over both persons.

When the patent protects biological material capable of reproducing itself, it shall not be extended to cover biological material obtained through reproduction, multiplication or propagation of the material introduced onto the market in accordance with the first paragraph, unless the reproduction, multiplication or propagation

was necessary to allow the use of the material for the purposes for which it was introduced onto the market and the material derived from such use is not used for the purposes of multiplication or propagation.

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

A. *Not applicable.*

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:

A. *Not applicable.*

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):

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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. *Articles 61-69 of Decision 486 of the Commission of the Andean Community establish the following:*

Article 61.- *Following a period of three years starting from the grant of a patent or of four years starting from the application for a patent, whichever is longer, the competent national office shall grant, on request by any interested party, a compulsory license mainly for the industrial manufacture of the product which is the subject of the patent, or for full use of the patented process, but only if, at the time of the request, the patent has not been worked in the manner specified in Articles 59 and 60, in the Member Country in which the license is sought, or if the exploitation of the invention has been suspended for more than one year.*

A compulsory license shall not be granted if the patentee is able to justify his inaction by legitimate reasons, including reasons of force majeure or unforeseeable circumstances, in accordance with the domestic provisions in effect in each Member Country.

A compulsory license shall be granted only if the applicant previously made efforts to obtain a contractual license from the patentee on reasonable commercial terms and conditions and such efforts were not successful within a reasonable period of time.

Article 62.- *The grant of the compulsory licenses referred to in the previous article shall be carried out following notification to the patentee, in order to allow him to put forward his arguments, should he see fit to do so, within the following 60 days.*

The competent national office shall specify the scope or extent of the license, and in particular shall specify the period for which it is granted, the subject of the license, the amount of the remuneration, and the conditions for the payment thereof. The remuneration must be appropriate in accordance with the individual circumstances of each case, the economic value of the authorization in particular being taken into account. Opposition to a compulsory license shall not prevent its exploitation or have any effect on any periods that may be ongoing. The filing of an objection shall not prevent the patentee, in the meantime, from collecting the remuneration specified by the competent national office concerning the part unaffected by the objection.

Article 63.- *At the request of the patentee or the licensee, the conditions governing the compulsory licenses may be changed by the competent national office when justified by new circumstances and, in particular, when the patentee grants another license on terms that are more favorable than the existing ones.*

Article 64.- *The licensee must exploit the invention within a period of two years starting from the date on which the license was granted, unless he is able to justify his inaction owing to reasons of unforeseeable circumstances or force majeure. Otherwise, at the patentee's request, the competent national office shall revoke the compulsory license.*

Article 65.- *Following the declaration by a Member Country of the existence of public interest, emergency, or national security considerations, and only for so long as those considerations exist, the patent may be subject to compulsory licensing at any time. In such a case, the competent national office shall grant the licenses that are applied for. The holder of the patent in question shall be notified as soon as is reasonably possible.*

The competent national office shall specify the scope or extent of the compulsory license and, in particular, the term for which it is granted, the subject matter of the license, and the amount of remuneration and the conditions for its payment.

The grant of a compulsory license for reasons of public interest shall not weaken the right of the patentee to continue working the patent.

Article 66.- *The competent national office may, either ex officio or at the request of a party, and after having obtained the consent of the national antitrust authority, grant compulsory licenses where practices are noted that affect free competition, especially where they constitute an abuse of a dominant position in the market by the patentee.*

The need to correct anti-competitive practices shall be taken into account when determining the amount of remuneration to be paid in such cases.

The competent national office shall refuse to revoke a compulsory license if the conditions which led to the grant of the license are likely to recur.

Article 67.- *The competent national office shall grant licenses at any moment, upon request by the holders of patents the working of which necessarily requires the use of another patent, if and when said patent holders have been unable to secure a contractual license for the other patent on reasonable commercial terms. Such licenses shall, without prejudice to the provisions of Article 68, be subject to the following conditions:*

(a) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(b) the holder of the first patent shall be entitled to a cross-license on reasonable terms to work the invention claimed in the second patent; and,

(c) the license authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 68.- *In addition to the provisions contained in the preceding articles, compulsory licenses shall be subject to the following provisions:*

(a) they shall be non-exclusive and sublicenses may not be granted in regard thereto;

(b) they shall be non-transferrable, except with the part of the business or goodwill which permits their industrial exploitation. This shall be evidenced in writing and registered with the competent national office, otherwise those licenses shall be devoid of any legal effect;

(c) they shall be liable, subject to adequate protection of the legitimate interests of the licensees, to be revoked if and when the circumstances which gave rise to them cease to exist and are unlikely to recur;

(d) their scope and duration shall be limited to the purposes for which they were granted;

(e) in the case of patents protecting semi-conductor technology, a compulsory license shall be authorized only for public non-commercial use or to remedy or rectify a practice declared by the competent national authority to be anti-competitive in accordance with Articles 65 and 66;

(f) they shall provide for payment of adequate remuneration according to the circumstances of each case, taking into account the economic value involved, without prejudice to the provisions contained in Article 66; and,

(g) they shall be used predominantly for the supply of the domestic market.

Article 69.- *Compulsory licenses that fail to comply with the provisions of this Chapter shall be devoid of any legal effect whatsoever*

Likewise, Article 40 of Legislative Decree 1075 establishes that upon prior declaration by Supreme Decree of the existence of grounds for public interest, emergency, or national security, that is, in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, and only while these grounds persist, a patent may at any moment be subject to compulsory licensing. In such a case, the requested licenses shall be granted. The holder of the patent subject to the licensing shall be notified as soon as it is reasonably possible to do so.

The competent National Directorate shall establish the scope or extent of the compulsory license, specifying in particular the term for which it is granted, the subject of the license, and the amount and conditions of the economic compensation.

The grant of a compulsory license shall not diminish the right of the holder of the patent to continue working the patent in question. Any decision relating to such a license shall be subject to judicial review.

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

A. *Not applicable.*

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:

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

A. *Not applicable.*

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):

A. *Not applicable.*

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):

A. *Not applicable.*

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?

A. *The time period is three years from the grant of the patent or four years from the patent application, whichever is longer.*

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"?

A. *The law provides for justification in the form of legitimate reasons, including reasons of force majeure or unforeseeable circumstances.*

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):

A. *The applicable law does not contain definitions of "reasonable terms and conditions" or "reasonable period of time".*

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):

A. *In accordance with the provisions of Article 66 of Decision 486, compulsory licenses may be granted when practices are noted that affect free competition, especially where they constitute an abuse of a dominant position in the market by the patentee.*

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:

A. *In accordance with the provisions of Article 67 of Decision 486, compulsory licenses may be granted at any moment, upon request by the holders of patents, the working of which necessarily requires the use of another patent, if and when said patent holders have been unable to secure a contractual license for the other patent on reasonable commercial terms. Such licenses shall be subject to the following conditions:*

- (a) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*
- (b) the holder of the first patent shall be entitled to a cross-license on reasonable terms to work the invention claimed in the second patent; and,*
- (c) the license authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.*

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:

A. *No provision is made*

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

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:

A. *The applicable law does not provide any definition of "national emergency" or "circumstances of extreme urgency".*

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

A. *No compulsory licenses have so far been granted.*

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

A. *No amendments to the applicable law have so far been foreseen.*

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

A. *Not applicable.*

Government use

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

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

Non-working or insufficient working of the patented invention

Refusal to grant licenses on reasonable terms

Anti-competitive practices and/or unfair competition

Public health

National security

National emergency and/or extreme urgency

Dependent patents

Other, please specify:

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

A. *Not applicable.*

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

A. *Not applicable.*

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:

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

A. *Not applicable.*

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):

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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):

A. *Not applicable.*

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:

A. *Not applicable.*

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:

A. *Not applicable.*

Breeders' use of patented inventions

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

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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

A. *Not applicable.*

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):

A. *Not applicable.*

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:

A. *Not applicable.*

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:

A. *Not applicable.*

Section XI: Other Exceptions and Limitations

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

A. *Not applicable.*

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):

A. *Not applicable.*

(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:

A. *Not applicable.*

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

A. *Not applicable.*

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

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

A. *Not applicable.*

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

A. *Not applicable.*

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:

A. *Not applicable.*

[End of Questionnaire]