

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **Italy**

Office: **Italian Patent and Trade Mark Office**.....

Person to be contacted:

Name:

Title:

E-mail:

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Facsimile:

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.

They can constitute object of patent for invention the inventions of all fields of technology that are new and involve an inventive step and are susceptible of industrial application. (1st paragraph of article 45 industrial property code.¹ from now on Ipc)

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.²

Not be regarded as invention within meaning above, namely: a) discoveries, scientific theories and mathematical methods; b) scheme, rules and methods for performing

¹ [Decreto legislativo 10 febbraio 2005, n 30](#)

² This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

mental acts, playing games or doing business, end programs for computers; c) presentations of information. These subject-matter or activities shall exclude the patentability only to the extent to which a patent application or patent relates to such subject-matter or activities as such. (Paragraph 2, 3 article 45 Ipc)

They can't constitute object of patent a) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; b) plant or animal varieties or essentially biological processes for the production of animals or plants, including new plant variety, with reference to which the invention consist entirely in genetic modification of other plant variety, even if the same modification, is the outcome of genetic engineering process. These provisions shall not apply to micro biological processes and to products obtained through these process, as well as to products, in particular to substances or compositions, for use in any of these cited methods. (Paragraphs 4, 5, of article 45 Ipc)

They are not patentable the inventions the industrial whose exploitation would be contrary to "*ordre public*" and morality (article 50 Ipc)

Namely with reference to biotechnological invention (paragraph 5bis article 45 Ipc) are excluded from patentability a) The human body, from conception time and in the various stages of its formation and development, and the simple discovery of one of elements of body own, including the sequence or partial sequence of a gene, in order to guarantee that patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person end environment; b) inventions the commercial exploitation of which would be contrary to dignity of person, ordre public or morality; to protection of health, environment, and human and animal life, to conservation of plant and biodiversity and to prevention of serious prejudices to the environment, in compliance with principles contained in the article 27, paragraph 2 (TRIPS) . Such exclusion affect notably:

1. All technological processes for cloning human beings, any is the used technique, the highest stage of projected development of conferred organism and purposes of cloning;
2. the processes for modifying the germ line genetic identity of human beings;
3. all uses of human embryos enclosed therein the lines of staminal embryonal human cells;
4. processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;
5. the invention concerning protocols of genetic screening the exploitation of which conducts a discrimination or stigmatization of human person on the genetic, pathological, racial, ethnic, social and economic basis, or better having eugenic purposes and not diagnostic.

c) a mere DNA sequence, a partial sequence of a gene, used to produce a protein or part of a protein, unless indication and descriptions of a helpful function to valuation of industrial application requirement is provided and equivalent function is specifically claimed; each sequence is deemed as an independent sequence in patent law terms when sequences overlap only in parts which are not essential to the invention, (paragraph 1 article 81quinqies Ipc.)

Anyway is excluded by patentability every technical process employing embryonal human cells. (Paragraph 2 article 81 quinquies Ipc.)

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?

In compliance with article 66 Ipc the right granted with a patent consist of the exclusive faculty to carry out the invention and to profit from it in the State territory within and the provided conditions by the Code. Namely if the object of patent is a product, the patentee can forbid third, apart from his consent, to produce, to use, put on the market, to sell or to import the product to that purposes; if the object of patent is a process, the patentee can forbid third, apart from his consent, to apply process, as well as to use, put on the market, to sell or to import to that purpose the product, directly obtained with process.

With the publication of patent application the applicant can exercise the same rights of patent. (Paragraph 2nd article 53 Ipc)

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;³
- 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.⁴

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

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

³ For example, extemporaneous preparation of prescribed medicines in pharmacies.

⁴ For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

Section II: Private and/or non-commercial use

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

The effects of a patent shall not extend to acts done privately and for non-commercial purposes. letter a), paragraph 1, article 68 Ipc.

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

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

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

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

This exception was introduced by 1979 reform to comply with Community Patent Convention.

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

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

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

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

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Section III: Experimental use and/or scientific research ⁵

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

The effects of a patent shall not extend to acts done for experimental purposes
letters a) paragraph 1, article 68 Ipc.

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

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

They want avoid that patent system thought up to stimulate innovation works as
obstacle to innovation.

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

This exception (letter a) was introduced by 1979 reform to comply with Community
Patent Convention.

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:

Not

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”,
please provide those definitions by citing legal provision(s) and/or decision(s):

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

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- seek an improvement to the patented invention

⁵ Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

- 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 effects of a patent shall not extend to extemporary preparation, for unit, of drugs in the chemists on medical prescription, and to drugs like made provided they do not use active ingredients realized in industrial mode (letter c, paragraph 1 article 68 Ipc)

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

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

This provision is intended to facilitate the exercise of medical activities, since patents should not restrict the freedom of the doctor (physician) to prescribe drugs in the interest of health promotion. This is to allow doctors to prescribe drugs to their patients in the individual case, which are prepared in chemists, regardless of possible patent rights.

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

This exception, was introduced by 1979 reform to comply with Community Patent Convention. Attention! in Italy before the 1979 the drugs were considered unpatentable. The prohibition to use active ingredients realized in industrial mode has been introduced on 2005.

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

The law don't refer directly to who is reserved free use but it refers to preparation drug in the chemists on medical prescription

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):

The letter c) paragraph 1 article 68 Ipc does not explicit mention to admissible amount of drugs but only to "extemporary preparation, for unit, of drugs in the chemists by prescription", therefore this is the amount which is required in one concrete individual case

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):

in the preparation of drugs they forbid to use active ingredients realized in industrial mode.

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):

Anyone, in the course of twelve prior months to filing date of patent application or priority date, have done use in own firm of invention can continue to use it within of prior use. This faculty, is assignable only along with the firm where the invention is used. (Paragraph 3 article 68 Ipc)

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:

It is to safeguard the prior user about his economic status of possession. It is essential to avoid the legitimately created values are ruined. A later patent application cannot endanger prior user's investments.

- (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 law set out that prior user can continue use invention within prior use did by him in his firm.

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

The prior user don't have pay any remuneration for the exercise of the exception to 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

The prior user can assign this right only with assignment of firm where the invention is used

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

- Yes
 No

If yes, please explain what those conditions are:

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

- Yes
 No

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

Anyone has made serious and effective preparations or has begun use the patented invention in bona fides can carry it out gratuitous within prior use or in so far as they result from preparations. (letter a paragraph 6 article 193 Ipc)

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):

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

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

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

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45. The exception applies in relation to:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

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

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

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

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

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

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Section VII: Acts for obtaining regulatory approval from authorities

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

The effect of the patent does not extend to studies and experiments aimed to obtainment, in the foreign country also, a marketing authorization of drugs and to consequent practical requirements therein enclosed preparation and usage of pharmacologically active raw materials, to that strictly necessary.
(letter b, paragraph 1, article 68.)

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

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

The purpose of the provision is to privilege the manufacturers of generic drugs. These manufacturers are allowed to carry out the use of the patent even before the term of protection ends under the condition that the use is necessary to obtain an authorization for medicinal products.

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

Implementation, Article 10(6) of the amended Directive 2001/83/EC and Article of the amended Directive 2001/82/EC into national law.

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

Manufactures of medicaments, especially of generic drugs are entitled to use this exception

55. The exception covers the regulatory approval of:

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

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

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

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

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

The scope of admissible use comprises studies, experiments and any action to execute them, under the condition, that they are necessary to obtain an authorization for medicinal products or approval. Therefore, a direct relation is required between the study, the experiment or its execution, on the one hand, and the authorization or approval sought, on the other hand.

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

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

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Section VIII: Exhaustion of patent rights

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

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

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

The exclusive faculties granted by this code to holder of industrial property right are exhausted when the protected products by an industrial property right have been putted on the market by the holder or with his consent in the State territory or in the territory of a member State of European community or European Economic Area. (Article 5 paragraph 1 Ipc.)

This holder's powers limitation however is not applied when rightful motives subsist so as holder himself opposes to further marketing of products, namely when their condition is modified or altered after their putting in the market. (Article 5 paragraph 2 Ipc.)

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:

They intend to avoid that monopoly can compromise certainty of trade, being used *ad nutum* by the holder to obstruct further marketing of protected product .

(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):

Lapsed three years from the granting patent date or four years from filling application date, if this term expires later than prior in case Patentee or his successor, directly or through one or more licensees, has not carried out the patent invention producing in the territory of the State or importing objects, produced in a Member States of European Union or of European economic Area or in a State member of World-wide organization of the commerce, or rather he has carried out it in a measurement such to result in serious disproportion with the needs of Country, a compulsory license can be granted for not exclusive use of same invention in favour of every person concerned which applies for it. (Article 70, paragraph 1 Ipc)

The compulsory license can equally be granted in the event that implementation of invention have been for further three years, suspended or reduced in a measurement such to result in serious disproportion with the needs of Country, (Article 70, paragraph 2 Ipc)

Compulsory license is not granted if loss or insufficient implementation is due to grounds beyond patentee's will or of his successor. Lack of financial resources and in case the same product is diffused abroad, the lack of request in the internal market of patented product or obtained with patented process, not are encompassed among these grounds (Article 70 paragraph 3 Ipc)

Granting of compulsory license does not relieve patentee or his successor from the burden of implementation. The patent lapsed if the invention is not carried on within two years from the granting date of the first compulsory license or it have been in a measurement such to result in serious disproportion with the needs of Country, (Article 70 paragraph 4 Ipc)

A compulsory license can be granted if the patent invention cannot be exploited without prejudice of rights relative to a patent granted on under prior application. In this case, license can be granted to later patent's holder in necessary measure as exploiting invention, provided that constitutes, with regard to of object earlier patent, an important technical progress of remarkable economic account. (Article 71 paragraph 1 Ipc)

Compulsory license is assigned only jointly to patent on dependent invention. Patentee on primary invention have right granting of a compulsory license on reasonable terms on patent of dependent invention (Article 71 paragraph 2 Ipc)

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

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

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

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

They will avoid that patentee can abuse of exclusive position vested to him by patent rights towards the public.

- (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):

Patentee or his successor, directly or through one or more licensees, has not carried out the patent invention producing in the territory of the State or importing objects, produced in a Member States of European Union or of European economic Area or in a State member of World-wide organization of the commerce, or rather he has carried out it in a measurement such to result in serious disproportion with the needs of Country,

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):

Yes, if the imported patented products are realized in a Member States of European Union or of European economic Area or in a State member dell' World-wide organization of the commerce,

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? Three years from the granting date or four years from the filling date if this delay fall later the previous. Past three years in the case of suspension or reduction.

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"? The law affirms "Compulsory license is not granted if loss or insufficient implementation is due to grounds beyond patentee's will or of his successor". But it specifies "Lack of financial resources and in case the same product is diffused abroad, the lack of request in the internal market of patented product or obtained with patented process, not are encompassed among these grounds"

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:

Under the law compulsory licenses on the ground of dependent patents, can be granted to holder of posterior patent to the extent that is necessary exploiting invention, provided that constitutes, with regard to of object earlier patent a important technical progress of remarkable economic importance

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

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

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

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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):

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

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

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

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

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

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85. If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

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

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

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

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Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

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

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

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

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

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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):

Point 1. Breeder's Right

the breeder's authorization is required for following affected acts in respect of the propagating material of the protected variety: (a) production or reproduction (multiplication), (b) conditioning for the purpose of propagation, (c) offering for sale, selling or other marketing, (d) exporting or importing, (e) stocking for any of the purposes mentioned above. (see paragraph 1 article 107 Ipc)

the breeder's authorization is required for this affected acts in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating materials of the protected variety unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material. (see paragraph 2 article 107 Ipc)

Point 2. Breeder's Right extend

(a) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety, (b) varieties which are not clearly distinguishable from the protected variety in accordance with requirement of distinctness and (c) varieties whose production requires the repeated use of the protected variety. (see paragraph article 107)

The "Breeder's exemption"

Breeder's Right does not extend effected acts for the purpose to breeding other varieties as well as, where these not are variety listed in point 2 ,acts of which to point 1 affected in respect such other variety

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

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

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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:

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[End of Questionnaire]