

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **Brazil**
Office: **Ministry of External Relations**

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Section I: General

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term “applicable law” refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

....According to Law n. 9.279 of 14 May 1996, an invention is patentable if it satisfies the requirements of novelty, inventive step, and industrial application.

Moreover, the applicant shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and shall also indicate the best mode for carrying out the invention

Those standards are applicable to all fields of technology.

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

Article 10 of Law n. 9.279 of 14 May 1996 establishes that the following are not considered to be inventions or utility models:

I – discoveries, scientific theories, and mathematical methods;

II – purely abstract conceptions;

III – commercial, accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles or methods;

IV – literary, architectural, artistic and scientific works, or any aesthetic creation;

V – computer programs per se;

VI – presentation of information;

VII – rules of games;

VIII – surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animal body; and

IX – all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.

Besides that, Article 18 of the Law also establishes that the following are not patentable:

I – anything contrary to morals, standards of respectability and public security, order and health;

II – substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus; and

III – all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability – novelty, inventive step and industrial application – and which are not mere discoveries.

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

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

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?

According to Article 42 of Law n. 9.279 of 14 May 1996, a patent confers to its rightholder the right to prevent a third party from, without his consent, producing, using, offering for sale, selling or importing for these purposes:

I – a product that is the object of the patent;

II – a process or a product directly obtained by a patented process.

The publication of a patent application does not grant a right to the applicant, since it is a right contingent on the grant of the patent by the National Institute of Industrial Property. Nonetheless, Article 44 of Law n. 9.279 provides to the rightholder the right to obtain compensation for the unauthorized exploitation of the subject matter of the patent, including exploitation that occurred between the date of publication of the application and that of the grant of the patent.

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".

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).

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

Section II: Private and/or non-commercial use

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

Article 43, Paragraph I, of Law n. 9.279.

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?

.....The exception intends to establish a reasonable balance of interests between right holders and society at large. The Brazilian Legislation provides for an exception which does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties, in order to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

(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):

There is no such definition.

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):

There is no other criterion.

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:

The Brazilian Government is carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system.

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):

Article 43, Paragraph II, of Law n. 9.279 of 14 May 1996.

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?

The patent system aims at stimulating research and innovation by providing a framework which ensures that the benefits of inventions accrue to society as a whole. In light of this fact, the purpose of this exception is to limit the rights granted by a patent in order to allow the development of scientific or technological research, thereby striking the right balance between rightholders' and third parties' interests while fostering the advancement of the society.

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

(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:

There is no such definition.

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):

There are no such definitions.

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:

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):

There is no other criterion.

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:

The Brazilian Government is carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system.

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

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Section IV: Preparation of medicines

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

Article 43, Paragraph III, of Law n. 9.279 of 14 May 1996.

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:

.....It is fundamental to establish the right balance of interests between rightholders and users of intellectual property rights as well as to protect public interests by setting limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with its normal exploitation and do not unreasonably harm the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Therefore, the exception is considered to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

(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:

Law n. 9.279 establishes that the preparation is to be carried out by a qualified professional.

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

Yes

No

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

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

There are no other criteria.

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:

Yes.

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

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Section V: Prior use

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

Article 45 of Law n. 9.279 of 14 May 1996.

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:

The prior use exception relates to the principle of acquired rights, which aims at avoiding unnecessary burden on good faith users who had been exploiting the invention before the date of deposit or priority of the patent application. Furthermore, this principle is found in the Brazilian Constitution under Article 5, which establishes the fundamental rights.

(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):

There is no such definition and the law does not provide for quantitative or qualitative limitations.

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

No, it does not.

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

Yes

No

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

Yes

No

If yes, please explain what those conditions are:

Article 45, Paragraph 2, of Law n. 9.279 provides that the right thus conferred may be assigned only by transfer or leasing, together with the business of the undertaking or the part thereof that has direct relation with the exploitation of the subject matter of the patent.

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):

Article 45 of Law n° 9.279 provides that a person who, in good faith, prior to the date of filing or of priority of a patent application, had been exploiting its object in Brazil will be guaranteed the right to continue the exploitation, without charge, in the previous form and conditions.

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):

The Paris Convention, revised in Stockholm in 1967, was ratified in Brazil by the Decree n. 635/1992, which provides that, among others, Article 5ter of the Convention is to be duly executed as provided therein, therefore being part of the Brazilian statutory law.

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:

The Paris Convention already provides that such an exception shall not affect negatively the rightholder.

(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

By analogy, one might consider that the exception also applies to spacecrafts.

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):

There are no such definitions.

- 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):

No, it does not.

- 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):

There is no other criterion.

- 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:

Yes.

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

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Section VII: Acts for obtaining regulatory approval from authorities

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

Article 43, Paragraph VII, of Law n. 9.279 of 14 May 1996.

- 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 legislation aims at avoiding the extension of patent terms beyond twenty years from the filing date, as pointed by the World Trade Organization panel “Canada – Patent Protection of Pharmaceutical Products” (DS114), thus establishing a reasonable balance of interests between rightholders and users of intellectual property rights, as well as protecting public interests.

(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:

Non-authorized third parties regarding patented inventions whose acts aim exclusively at producing information, data and test results to obtain regulatory approval to market, in Brazil or any other country, in order to exploit and commercialize the patented product after its term of protection has expired in Brazil.

55. The exception covers the regulatory approval of:

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

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: Acts performed by non-authorized third parties regarding patented inventions which aim exclusively at the production of information, data and test results to seek approval to market, in Brazil or any other country, in order to exploit and commercialize the patented product after its term of protection has expired.

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):

See answers to questions 54 to 56.

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:

.....The Brazilian Government is carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system.

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):

Article 43, Paragraph IV, of Law n. 9.279 of 14 May 1996.

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):

Article 42 of Law n. 9.279 also establishes the rightholder's right to prevent a third party from, without his consent, importing a product that is object of the patent, or a process or a product directly obtained by a patented process.

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):

Decree n. 3.201 of 6 October 1999 and Articles 68 to 74 of Law n. 9.279 of 14 May 1996.

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

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

Non-working or insufficient working of the patented invention

Refusal to grant licenses on reasonable terms

Anti-competitive practices and/or unfair competition

Public health

National security

National emergency and/or extreme urgency

Dependent patents

Other, please specify:

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

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

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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):

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

Yes

No

If yes, what is the time period?

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:

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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):

Decree n. 3.201 of 6 October 1999 and Articles 68 to 74 of Law n. 9.279 of 14 May 1996.

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:

Since the enactment of Law n. 9.279, one compulsory license in the pharmaceutical area was issued.

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):

There is no such exception.

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):

Article 43, Paragraph V, of Law N. 9.279 of 14 May 1996.

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:

It is fundamental to stimulate the research and development of new plant varieties in order to establish a reasonable balance of interests between rightholders and users of intellectual property rights, as well as to protect public interests.

- (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):

.....The non-commercial use of the subject matter of a patent related to living material by third parties is allowed as an initial source of variation or propagation to obtain other products.

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:

Yes.

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:

Article 43, Paragraph VI, of Law n. 9.279 of 14 May 1996.

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):

Article 43, Paragraph VI, of Law n° 9.279 provides that rights conferred by a patent do not apply to third parties who, in the case of patents related to living matter, use, place in circulation or commercialize a patented product that has been introduced lawfully onto the market by the patentee or his licensee, provided that the patented product is not used for commercial multiplication or propagation of the living matter in question.

- (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?):

Yes.

- (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:

The Brazilian Competition Law (Law n. 8.884 of 11 June 1994), in Article 24, Paragraph IV, Item a, provides for the possibility of recommending the compulsory license of a patent to the competent authorities as a penalty for the infraction against the economic order. Furthermore, Articles 20 and 21 of the Law establish several acts that may be considered violation to the economic order.

[End of Questionnaire]