

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **Chile**
Office: **National Institute of Industrial Property (INAPI)**.....

Person to be contacted:

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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.

The legal standard which establishes the requirements for determining whether an invention is patentable is Law No. 19.039 on Industrial Property of 1991, amended by Law No. 19.996 of 2005 and Law No. 20.160 of 2007.

Articles 33, 35 and 36 of Law No. 19.039 state that the requirements of patentability are novelty, inventive step and industrial applicability respectively.

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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. Articles 37 and 38 of Law No. 19.039 establish the exclusions from patentability and non-patentable subject matter.

“Article 37. The following shall not be considered an invention and shall be excluded from the patent protection provided by this Law:

(a) discoveries, scientific theories and mathematical methods.

(b) plants and animals, except for microorganisms which satisfy the general requirements of patentability. Plant varieties shall enjoy protection only in accordance with Law No. 19.342 on Rights of Breeders of New Varieties of Plants. Also not patentable are essentially biological procedures for the production of plants and animals, except for microbiological procedures. For these purposes, an essentially biological procedure is that which consists entirely of natural phenomena such as crossing and selection.

(c) Economic, financial, commercial, business or simple monitoring and supervision systems, methods, principles or plans; and those referring to purely mental or intellectual activities, or games.

(d) Methods of surgical or therapeutic treatment for the human or animal body, as well as methods of diagnosis applied to the human or animal body, apart from products intended to put one of these methods into practice.

(e) The new use, change of form, change of dimensions, change of proportions or change of materials for articles, objects or elements known and used for specific purposes. Without prejudice to the above, an invention eligible for protection may be constituted by the new use of known articles, objects or elements, provided that said new use resolves a technical problem without a previous equivalent solution, meets the requirements referred to in Article 32 and requires a change in the dimensions, proportions or materials of the known article, object or element in order to obtain the above solution to said technical problem. The new claimed use shall be proven by means of experimental evidence in the patent application.

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

(f) Part of living beings as they are found in nature, natural biological processes, the biological material existing in nature or that which may be isolated, including a genome or germoplasm. However, the procedures which use one or more of the above biological materials and the products directly obtained thereby may be eligible for protection, provided that they satisfy the requirements established in Article 32 of this Law, that the biological material is appropriately described and that the industrial application thereof is explicitly included in the patent application.”

“Article 38. Inventions whose commercial working shall necessarily be prevented in order to protect ordre public, State security, morality and good customs, the health or life of persons or animals, or in order to preserve plants or the environment, shall not be patentable, provided that such an exclusion is not made merely because a legal or administrative provision exists, which prohibits or regulates said working.”

2. Article 8 of Law No. 20.120 on Scientific Research on Human Beings, their Genomes, and Prohibiting Human Cloning also establishes non-patentable material.

“Article 8. Knowledge of the human genome shall be the common property of humanity. Consequently, no person may acquire or establish ownership thereof or of part thereof. Knowledge of the structure of a gene and complete or partial DNA sequences shall not be patentable.

The biotechnology processes derived from knowledge of the human genome, as well as the products obtained directly therefrom, and diagnostic or therapeutic processes, shall be patentable according to the general rules.”

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?

1. Article 49 of Law No. 19.039 establishes the exclusive rights conferred by a patent.

“Article 49. The owner of a patent shall enjoy exclusivity in producing, selling or marketing, in any form, the product or subject matter of the invention and, in general, carrying out any other type of commercial working thereof.

In process patents, the protection covers the products obtained directly by said process.

The scope of the protection granted by the patent or the patent application shall be determined by the content of the claims. The patent specification and the drawings shall be used to interpret the claims.

The patent right shall extend to the whole of the national territory up to the day when the period for grant of the patent expires.

The patent shall not confer the right to prevent third parties from marketing the product protected by the patent, whether they have been acquired lawfully after that product has been legally introduced into the trade of any country by the patent owner or by a third party, with the consent of that owner.

The patent shall not confer the right to prevent third parties from importing, exporting, manufacturing or producing the subject matter protected by a patent for the purpose of obtaining the registration or health authorization of a pharmaceutical product. The above shall not entitle said products to be marketed without the patent owner's authorization."

2. Article 4 of Law No. 19.039 establishes the publication of an extract of the application in the Official Gazette, following acceptance for processing.

"Article 4. Once an application for registration has been filed and accepted for processing, the publication of an extract thereof in the Official Gazette shall be compulsory, in the form and within the time periods determined by the regulations. Publication errors which, in the view of the Head of the Department, are not substantive, may be corrected by means of a decision laid down in the respective file. In case of substantive errors, the Head of the Department shall order a new publication, which shall be made within the period of 10 days, beginning from the date of the relevant decision."

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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;[□]
- 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.[□]

For example, extemporaneous preparation of prescribed medicines in pharmacies.

For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers

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.).

Section II: Private and/or non-commercial use

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

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[Footnote continued from previous page]

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).

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

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

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

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

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

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

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

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Section III: Experimental use and/or scientific research

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

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

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

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

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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:

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

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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
- invent around the patented invention
- other, please specify:

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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):

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

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

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

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

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

- Yes
- No

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

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

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

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

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Section V: Prior use

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

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

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

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

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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):

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

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

- Yes
- No

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

- Yes
- No

If yes, please explain what those conditions are:

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

- Yes
- No

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

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

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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):

Law No. 19.039 does not establish this exception. However, Chile is party to the Paris Convention and Chicago Convention on International Civil Aviation, which envisage these exceptions.

Paris Convention: Article 5ter

Patents: *Patented Devices Forming Part of Vessels, Aircraft, or Land Vehicles*

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.

Chicago Convention: Article 27

Exemption from seizure on patent claims

(a) While engaged in international air navigation, any authorized entry of aircraft of a contracting State into the territory of another contracting State or authorized transit across the territory of such State with or without landings shall not entail any seizure or detention of the aircraft or any claim against the owner or operator thereof or any other interference therewith by or on behalf of such State or any person therein, on the ground that the construction, mechanism, parts, accessories or operation of the aircraft is an infringement of any patent, design, or model duly granted or registered in the State whose territory is entered by the aircraft, it being agreed that no deposit of security in connection with the foregoing exemption from seizure or detention of the aircraft shall in any case be required in the State entered by such aircraft.

The provisions of paragraph (a) of this Article shall also be applicable to the storage of spare parts and spare equipment for the aircraft and the right to use and install the same in the repair of an aircraft of a contracting State in the territory of any other contracting State, provided that any patented part or equipment so stored shall not be sold or distributed internally in or exported commercially from the contracting State entered by the aircraft. The benefits of this Article shall apply only to such States, parties to this Convention, as either (1) are parties to the International Convention for the Protection of Industrial Property and to any amendments thereof; or (2) have enacted patent laws which recognize and give adequate protection to inventions made by the nationals of the other States parties to this Convention.

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 basis of this exception is the same as for the treaties where it is established. This exception seeks not to limit the transfer of goods and services that are not intended for trade in the country in question.....

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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 final paragraph of Article 49 of Law No. 19.039 establishes this exception.

“The patent shall not confer the right to prevent third parties from importing, exporting, manufacturing or producing the subject matter protected by a patent for the purpose of obtaining the registration or health authorization for a pharmaceutical product. The above shall not entitle those products to be marketed without the authorization of the patent owner.”

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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 aim of this rule, which has its source in the international treaties negotiated by Chile, is to incorporate flexibilities in the patent regime and to avoid the time for protection thereof being extended owing to the procedures necessary to obtain the health registration of a drug.....

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

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

The third importer, exporter, manufacturer or producer of the subject matter protected by a patent, with the aim of obtaining the registration or health authorization for a pharmaceutical product......
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55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products: **Pharmaceutical products**
The final paragraph of Article 49 of Law No. 19.039 refers expressly only to "pharmaceutical products."

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

- Making
- Using **in order to obtain registration or health authorization for a pharmaceutical product**
- Selling **With the patent owner's authorization**
- Offering for sale
- Import
- Export
- Other. Please specify:...**Production of the invention patented in order to obtain the registration or health authorization for a pharmaceutical product.**.....

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):

National legislation does not envisage other criteria......
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58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

To date, the exception has been considered to meet the objective. Without prejudice thereto, this Article, together with all IP legislation, is being revised with a view to possible reform.

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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):

Article 49(5) of Law No. 19.039 establishes the international exhaustion:

“Article 49. The patent shall not confer the right to prevent third parties from marketing the patent protected product, which such parties have acquired lawfully after that product has been lawfully introduced into the market of any country by the right owner or by a third party with the owner’s consent.”

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

This exception is based originally on the rulings concerning anti-trust commissions, which have now been replaced by the Court of Free Competition. There was a period in which the anti-monopoly bodies assumed powers to deal with such cases. Since said bodies are

responsible for ensuring compliance with the standards designed to avoid conduct that harms free competition, they applied reasoning specific to the problems of parallel imports, and systematically sanctioned those industrial property rights holders who exercised the exclusive rights stemming therefrom in an abusive manner.

One example is the 1993 Ruling No. 886 of the Central Prevention Commission, which refers rather to marks, but is fully applicable to patents, which states that “the owner of a trademark that refers to articles or products of a certain manufacture may not lawfully oppose the trade of another person in genuine or authentic articles of the same origin, since the Law on Industrial Property prohibits trade in articles protected by a mark, that do not correspond to those that are lawful. The exclusive distributor of a foreign product may not prevent importers that acquire the same product also abroad from marketing it in the country.”

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

The aim of the rule was to establish the limits on the exercise of the industrial property rights with the aim of achieving balance in the system and promoting competition......

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

In legislative debates, it has been stated that parallel imports provide a balance between the industrial property right holders and, on the other hand, the rights of citizens, which are safeguarded before industrial property rights by the parallel imports mechanism, thus avoiding possible rights abuse......

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The exhaustion of the right may be national or international according to the geographical scope which it covers. In making use of the freedom of choice which the TRIPS Agreement provides in this respect, Chile opted for the second formula, and so the intellectual property right owner which has disposed of it in different territories, at different prices, may not prevent any person from importing from where the product is cheapest and introducing it into a market where its value is higher......

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):

There is no express rule on the matter within industrial property legislation.

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

To date, the exception has been considered to meet the objective. Without prejudice thereto, this article, together with all IP legislation, is being revised with a view to possible reform.

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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):

Compulsory (non-voluntary) licenses are enshrined in Articles 51 to 51bis D of Law No. 19.039.

Article 51. A decision shall be taken on a non-voluntary license application in the following cases:

- (1) Where the patent owner has engaged in conduct or practices declared contrary to free competition, in direct relation to the use or**

working of the patent in question, according to a firm or final decision of the Court of Free Competition.

(2) Where, for reasons of public health, national security, non-commercial public use, or national emergency or others of extreme urgency, declared by the competent authority, the grant of said licenses is justified.

(3) Where the aim of the non-voluntary license is to work a later patent that cannot be worked without infringing a previous patent. The grant of non-voluntary licenses for dependent patents shall be subject to the following rules:

(a) The invention claimed in the later patent shall include a technical advance of considerable economic significance with respect to the invention claimed in the first patent.

(b) The non-voluntary license for working the previous patent may be transferred only with the later patent.

(c) The owner of the earlier patent may, in the same circumstances, obtain a non-voluntary license on reasonable terms and conditions for working the invention claimed in the later patent.

As regards semi-conductor technology, the license may be granted only for non-commercial public purposes or to rectify the practice declared contrary to competition.”

“Article 51 bis A. A person who requests a non-voluntary license shall provide proof that he requested previously from the patent owner a contractual license, and that he could not obtain such a license on reasonable terms and conditions, and within a reasonable period of time. This requirement shall not be imposed with respect to the clause contained in Article 51(2) of this Law. Nor shall this requirement be imposed where the aim of the non-voluntary license is to put an end to practices considered contrary to competition.”

“Article 51 bis B. The application for the grant of a non-voluntary license shall constitute a request and shall contain all the requirements of Article 254 of the Code of Civil Procedure. The following shall deal with such an application:

(1) In the case of Article 51(1), the Court of Free Competition, in accordance with the procedure provided for in Law No. 19.911.

(2) In the case of Article 51(2), the Head of the Industrial Property Department, in accordance with the procedure for nullity of patents established in this Law. In addition, on the basis of a reasoned decision, for the purposes of settling a particular incident, the Head may have

temporary access to the request. This decision shall remain in force as long as the facts which substantiated it persist or until a final ruling is handed down.

(3) In the case of Article 51(3), the civil judge, according to the rules of competition of the Code of Civil Procedure and in accordance with the summary procedure.”

“Article 51 bis C. The competent authority shall take a decision on the application for a non-voluntary license, depending on the circumstances specific thereto.

Where said ruling is positive, the Court of Free Competition, the Head of the Department or the civil judge, as the case may be according to Article 51(1), (2) or (3), shall, on the one hand, fix the duration and scope of the license, limiting it for the purposes for which it was granted and, on the other, the amount of the remuneration that the licensee shall pay periodically to the patent owner. The license granted by this procedure shall be non-exclusive and may not be assigned, other than with that part of the firm that owns the patent.”

“Article 51 bis D. The non-voluntary license may be left without effect, either total or partial, subject to the licensee’s legitimate interests, if the circumstances which gave rise thereto have disappeared and are not likely to recur. The Court of Free Competition, the Head of the Department or the civil judge shall, according to the case and subject to consultation with the competent authority as appropriate, be authorized to examine, on the basis of a reasoned request, whether such circumstances continue to exist.

An application for withdrawal of a non-voluntary license shall not be accepted if the circumstances which gave rise to the issue thereof are likely to be repeated. Similarly, the Court of Free Competition, the Head of the Department or the civil judge may, as the case may be, at the request of an interested party, amend a non-voluntary license where new facts or circumstances so justify, in particular when the patent owner has issued contractual licenses on more favorable conditions than those granted for the beneficiary of the non-voluntary license.

In the non-voluntary license application proceedings, in the cases provided for in Article 51(1) and (3), the Department shall be heard before a ruling is handed down.”

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:

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

The aim behind this rule is to provide the industrial property system with balance, by providing tools that limit the right where committed higher interests exist.

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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):

In accordance with the provisions of Articles 51(1), 51 bis B(1) and 51 bis of Law No. 19.039, the competent entity for issuing a compulsory license based on anti-competitive practices is the Court of Free Competition, in accordance with the procedure established in Law No. 19.911.

It is the responsibility of the Court of Free Competition to determine in which cases a compulsory license should be granted owing to anti-competitive practices.

Article 51 bis C states: "The competent authority shall take a decision on the non-voluntary license application based on the circumstances specific thereto."

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:

Article 51(3) of Law No. 19.039 establishes the possibility of compulsory licenses for "dependent patents".

Article 51. A decision shall be taken on a non-voluntary license application in the following cases:

(3) Where the aim of the non-voluntary license is to work a later patent that may not be worked without infringing an earlier patent. The grant of non-voluntary licenses for dependent patents shall be subject to the following rules:

(a) The invention claimed in the later patent shall include a technical advance of considerable economic significance with respect to the invention claimed in the first patent.

(b) The non-voluntary license for working the earlier patent may be transferred only with the later patent.

(c) The owner of the earlier patent may, in the same circumstances, obtain a non-voluntary license on reasonable conditions to work the invention claimed in the later 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:

The second subparagraph of Article 51 bis C establishes that the authority competent to issue the license shall fix the amount of the remuneration to be paid periodically by the licensee to the patent owner. However, rules of general conduct for fixing the amount of the remuneration are not established.

“Article 51 bis C. The competent authority shall take a decision on the application for a non-voluntary license, depending on the circumstances specific thereto.

Where said ruling is positive, the Court of Free Competition, the Head of the Department or the civil judge, as the case may be according to Article 51(1), (2) or (3), shall, on the one hand, fix the duration and scope of the license, limiting it for the purposes for which it was granted and, on the other, the amount of the remuneration that the licensee shall pay periodically to the patent owner. The license granted by this procedure shall be non-exclusive and may not be assigned, other than with that part of the firm that owns the patent.”
.....

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:

Article 51(2) of Law No. 19.039 does not define the concepts of “national emergency” or “circumstances of extreme urgency”. In Chile, compulsory licenses based on said cases have not been granted.

“Article 51. A decision may be taken on a non-voluntary license application in the following cases:

(2) Where for reasons of public health, national security, non-commercial public use, or national emergency or others of extreme urgency, declared by the competent authority, the grant of said licenses shall be justified.”

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

Compulsory licenses have not been issued in Chile.....

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:

To date, the rule has been considered to meet the objective. Without prejudice thereto, this Article, together with all IP legislation, is being revised with a view to possible reform.

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

To date, cases have not been submitted, for which reason practical problems in the implementation thereof cannot be identified......

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):

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

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

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

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

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

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

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Section XI: Other Exceptions and Limitations

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

Article 51(2) of Law No.19.039 establishes as a cause for the grant of a compulsory license "non-commercial public use".....
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"Article 51. A decision may be taken on a non-voluntary license application in the following cases:

(2) Where for reasons of public health, national security, non-commercial public use, or national emergency or others of extreme urgency, declared by the competent authority, the grant of said licenses shall be justified.".....

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):

The legal source is Article 51(2) of the aforementioned Law No. 19.039.....

.....

- (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:

The basis for this case of the grant of a compulsory license is the same as with respect to the earlier ones; providing the system with balance to allow the right to be limited in order to favor higher interests in the cases where this is necessary.

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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:

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

To date, the exception has been considered to meet the objective. Without prejudice thereto, this article, together with all IP legislation, is being revised with a view to possible reform.

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

To date, there have been no cases allowing problems of practical implementation to be determined.

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[English translation by WIPO]

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]