

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **SPAIN**.....
Office: **SPANISH PATENT AND TRADEMARK OFFICE**.....

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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 used is Law No. 11/1986 of March 20, 1986, on Patents (hereinafter, Law on Patents), in Title II (Articles 4 to 9).
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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

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

Pursuant to the Law on Patents (Articles 4 and 5), the exclusions from patentability are:

Article 4.

4. In accordance with the above paragraphs, the following are not considered inventions, in particular:

- (a) discoveries, scientific theories and mathematical methods;**
- (b) literary or artistic works or any other esthetic creation, as well as scientific works;**
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and computer programs; and**
- (d) presentations of information.**

Methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are industrially applicable.

Article 5. The following may not be the subject matter of a patent:

1. Inventions whose commercial exploitation would be contrary to public order or morality, without considering such working an invention solely because it is prohibited by a law or regulation. In particular, the following shall not be considered patentable under the provisions of the preceding paragraph:

- (a) procedures for cloning human beings;**
- (b) procedures for modifying the germ line genetic identity of human beings;**
- (c) uses of human embryos for industrial or commercial purposes; and**
- (d) procedures for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical or veterinary benefit to human beings or animals, and animals resulting from such procedures.**

2. Plant varieties and animal breeds. However, inventions that have plant or animal subject matter shall be patentable provided that the technical viability of the invention is not limited to a specific plant variety or animal breed.

3. Essentially biological procedures for the production of plants or animals. For this purpose, essentially biological procedures shall mean those consisting entirely of natural phenomena such as crossing or selection. The provision of the preceding paragraph shall not affect the patentability of inventions whose subject matter is a microbiological process or any other technical process or a product obtained from such processes.

4. The human body, in the various stages of its formation or development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene. However, an isolated element of the human body or obtained by other means through a technical process, including the total or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a total or partial sequence of a gene must be disclosed in the patent application.

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

The exclusive rights granted by a patent are indicated in Articles 50 and 51 of the Law on Patents and are the following:

Article 50.

1. A patent shall give its owner the right to prevent any third party from undertaking the following acts without his consent:

(a) manufacturing, offering for sale, putting on the market or using the product that is the subject matter of the patent or importing or possessing the product for one of the above-mentioned purposes;

(b) making use of a process that is the subject matter of a patent or offering such use when the third party is aware, or the circumstances make it obvious, that use of the process without the consent of the patent owner is prohibited; and

(c) offering for sale, putting on the market or using the product directly obtained by the process that is the subject matter or importing or possessing the said product for any of the above-mentioned purposes.

2. Where the subject matter of a patent is a biological material that, as a result of the invention, has specific properties, the rights conferred by the patent shall extend to any biological material derived from the patented biological material by propagation or multiplication, in an identical or divergent form and possessing those same characteristics.

3. Where the subject matter of a patent is a process for the production of a biological material that, as a result of the invention, has specific characteristics, the rights conferred by the patent shall extend to biological material directly obtained through that patented process and to any other biological material obtained through propagation or multiplication, in an identical or divergent form and possessing those same characteristics.

4. Where the subject matter of a patent is a product containing or consisting of genetic information, the rights conferred by the patent shall extend, without prejudice to the provisions of Article 4.5, to all material in which the product is incorporated and in which the genetic information is contained and performs its functions.

Article 51.

1. A patent shall also entitle its owner to prevent a third party from handing over or offering to hand over to unauthorized persons without his consent elements related to an essential part of the invention to be used for putting into effect, when the third party knows, or the circumstances make it obvious, that such elements are capable of putting the invention into effect and are to be used for that purpose.

2. The provisions set out in the preceding paragraph shall not apply when the elements referred to are products commonly found on the market, unless the third party incites the person handing over to commit acts prohibited in the preceding article.

The rights conferred by the publication of a patent are defined in Article 59:

1. A patent application shall, from the date of its publication, confer on its owner provisional protection consisting of the right to require reasonable remuneration appropriate to the circumstances from any third party who, between the date of that publication and that of the announcement that the patent has been granted, has made use of the invention in a manner that would have been prohibited had the patent already been granted.

2. That provisional protection shall also apply before the application's publication to any person informed of the filing of the application and its contents.

3. Where the subject matter of the patent application consists of a process concerning a microorganism, provisional protection shall only commence when the microorganism has been made available to the public.

4. Patent applications shall have none of the effects provided for in the preceding paragraphs when they have been or are considered to have been withdrawn or when they have been rejected as a result of a final 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;²
- Prior use;
- Use of articles on foreign vessels, aircrafts and land vehicles;
- Acts for obtaining regulatory approval from authorities;
- Exhaustion of patent rights;
- Compulsory licensing and/or government use;
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³

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

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, 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 52 of the Law on Patents

The rights conferred by a patent shall not extend to:

1. (a) acts carried out in private and not for any commercial purpose;

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).

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

Not applicable.

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

These are not considered as acts of exploitation of the patent and, therefore, do not affect the content of the right of the patent. One of the objectives is teaching and in that field, patents may be used without fear of infringing them.

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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):

Such concepts are not defined in the law.

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):

No other provisions exist.

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 legal framework is considered adequate since no amendments to the law are foreseen.

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

No problems have been encountered in relation to its implementation.....
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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 52 of the Law on Patents

1. The rights conferred by a patent shall not extend to:

(b) acts carried out for experimental purposes related to the subject matter of the patented invention, in particular studies and trials for obtaining generic medicine authorization, in Spain or elsewhere, and the resulting practical requirements, including preparing, obtaining and using the active substance for such purposes.

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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?

This limitation is expected to contribute to the ultimate goal of technological innovation, thereby guaranteeing that patent rights do not stifle research, by expressly authorizing that the subject matter of the patented invention may be used during its period of validity, as a starting point for scientific research and development, all for the benefit of society and technological progress.

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

This Article of the Law on Patents was amended by Law No. 29/2006, of July 26, 2006, on the Guarantees and Rational Use of Medicines and Healthcare Products. This Law, in turn, incorporates Directive No. 2004/27/CE, of March 21, 2004. This amendment introduced into Spanish law the so-called "Bolar clause or provision", according to which, no infringement of patent rights shall be sought for working the patent for experimental purposes for studies and trials required for authorizing generic medicines.

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

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:

No distinction is made in this regard.

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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):

Such concepts are not defined in the law. However, following the above-mentioned amendment, for the purpose of clarification, this is exemplified by “the studies and the tests carried out to obtain authorization for generic medicines, either in Spain or abroad, and the subsequent practical requirements, including preparation, obtaining and use of the active element for such purposes”......

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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: carry out the studies and tests required for authorizing generic medicines

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:

The legal framework is considered adequate. No amendment is foreseen.

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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:

Prior to the amendment of 2006, doubts had been expressed concerning the limitation of the patent right in the prior precept of the Law on Patents (which referred only to acts carried out for experimental purposes related to the subject matter of the patented invention) including studies and trials designed for the authorization of generic medicines. To clarify this scope and to transpose the above-mentioned European Directive No. 2004/27/CE, Article 52.1(b) has been amended and includes the following sentence "in particular the studies and the tests carried out to obtain authorization for generic medicines, either in Spain or abroad, and the subsequent practical requirements, including preparation, obtaining and use of the active element for such purposes".

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Section IV: Preparation of medicines

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

Art. 52.1(c) of the Law on Patents:

The rights conferred by the patent shall not extend to the extemporaneous preparation of medicines in pharmacies carried out individually in making up a prescription and acts related to the medicines thus prepared;

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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:

The objective is to provide patients with access to medicines prescribed by medical professionals and capable of being prepared in a pharmacy. That is, on the one hand, healthcare reasons are protected and on the other, such acts are considered as not impairing the usual working of the patent subject matter.

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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:

Article 52.1(c) of the Law on Patents refers to medicines prepared in pharmacies. Therefore, it may be understood that pharmacists are entitled to use the exception on the pharmacy premises.

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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):

Pursuant to Article 52.1(c) of the Law on Patents, the exception is limited to one medicine and based on its preparation being done according to a medical prescription.

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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:

The legal framework is considered adequate since no amendment is expected.

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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:

No challenges have been encountered in relation to its implementation.

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Section V: Prior use

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

This limitation is provided for under Article 54 of the Law on Patents, according to which:

1. the owner of a patent shall not have the right to prevent persons who, in good faith, prior to the date of priority of the patent, had worked the patented invention in Spain or had made serious and concrete preparations to work said invention, from continuing or commencing its working or from preparations in the same manner as before in such a way as to meet the reasonable needs of their enterprises. This right to work the invention shall only be transferable with the enterprise.

2. the rights conferred by the patent shall not extend to acts related to a product protected by it after the product has been put on the market by the person who enjoys the right to work the invention mentioned in the preceding paragraph.

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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:

The aim is to reconcile the interests of the patent owner with those of a prior user acting in good faith. In this manner, the prior user is allowed to continue using or working the invention, albeit under more restrictive conditions than if he were the owner of a patent.

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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:
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34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

The scope of “use” is defined by its working in the form in which it has been carried out until then or for which serious and concrete preparations have been undertaken. Therefore, the prior user shall be permitted to continue to work the invention in the same manner or according to the preparations which had been undertaken until then or for the form in which preparations had been carried out. However, in both cases, this is restricted to such working having been carried out sufficiently to meet the reasonable needs of the enterprise.

Good faith is required of the prior user: the beneficiary of the right of prior use must be a third party who carried out the same invention as the patent owner prior to the patent owner, with no links or contact with the patent owner and having kept the invention secret. There shall be no good faith where the invention had been misappropriated or knowledge of the results obtained by the inventor had been acquired unfairly.

The working of or preparations to work the invention must have been carried out prior to the priority date of the application.

The invention should not have been disclosed prior to the priority date as a result of working the invention or of preparations to work it.

There must be an identity, at least as regards the relevant elements of the invention and technical development stage of the invention must have been similar.

The preparations or working must have been carried out in the territory of Spain.
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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:

No.
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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:

The right may only be transferred with the enterprise to which it belongs.

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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:

Where a patent which has been restored following notice of its forfeiture, restoration shall be granted without prejudice to the rights conferred by forfeiture (Article 117 of the Law on Patents).

Where a time limit is not observed before the Spanish Patent and Trademark Office, resulting in the loss of the right (for instance, the resulting of a refusal to grant a patent), the patent may be reinstated. However, the patent owner may not enforce his patent before good faith third parties who have begun working with the subject matter of the invention in the period between the loss of rights and the notice of restoration (Article 25 of Law No. 17/2001, of December 7, 2001, on Trademarks, applicable to patents under the Seventh Additional Provision).

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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:

No amendments to the law are expected in this regard......

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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):

Article 52.1 The rights conferred by the patent shall not extend to:

(d) use of the subject matter of a patented invention on board vessels of countries of the Paris Union for the Protection of Industrial Property, in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter Spanish waters, provided that the subject matter of the invention is used exclusively for the needs of the vessel;

(e) use of the subject matter of the patented invention in the construction or operation of aircraft or land vehicles of countries that are members of the Paris Union for the Protection of Industrial Property, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter Spanish waters; and

(f) acts provided for in Article 27 of the Convention of December 7, 1944, on International Civil Aviation, when such acts relate to aircraft of a State to which the provisions of the said Article apply, which establishes that:

(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 grounds 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;

(b) 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;

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

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

The objective of these exceptions is to facilitate the free transit of international means of transportation, without being constrained by the existence of patent rights in force......
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

The direct predecessor of this law is Article 5ter of the Paris Convention......
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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):

The law applies the terms "temporarily" or "accidentally" but does not define them.
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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):

As regards vessels, these are indicated as places where the subject matter of the patent is employed: On the body of the vessel, on the machinery, tackle, gear and additional accessories......
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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):

As regards vessels, it is stipulated that patent rights remain exempted exclusively for the needs of the vessel. Also, as regards other aircraft or land vehicles, these are exempt when they temporarily or accidentally enter the territory of Spain. Aircraft may only transit the territory of Spain when authorized......
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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:

Yes, since no amendments to the law are expected.....
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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):

Article 52.1(b) of the Law on Patents:

The rights conferred by a patent shall not extend to acts carried out for experimental purposes which refer to the subject matter of the patented invention, in particular studies and trials carried out to obtain authorization for generic medicines, either in Spain or abroad, and the subsequent practical requirements, including preparation, obtaining and use of the active element for such purposes.

This paragraph was added to Article 52.1(b), which initially only stated: the rights conferred by the patent shall not extend to acts carried out for experimental purposes related to the subject matter of the patented invention; however, Law No. 29/2006, of July 26, 2006, on Guarantees and Rational Use of Medicines and Healthcare Products, under the Second Additional Provision, added the mention of studies and trials carried out to obtain authorization for generic medicines.

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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:

Promoting the marketing of generic medicines once the patent has lapsed, since if manufacturers of generic medicines were prevented from starting to prepare and obtain approval for a generic medicine, it would delay putting generic medicines on the market, which in effect would amount to prolonging the term of protection once the patent expired.

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

As already indicated under question 13(b), this Article of the Law on Patents was amended by Law No. 29/2006, of July, 26, 2006, on Guarantees and Rational Use of Medicines and Healthcare Products. In turn, this law incorporates Directive No. 2004/27/CE, of March 21, 2004. This amendment included in our legislation the so-called "Bolar clause or provision", according to which, no infringement of patent rights shall be sought for working the patent for experimental purposes for studies and trials required for authorizing generic medicines.

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

This is not specified; it means any natural or legal person seeking the authorization of generic medicines.

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55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products: **Generic medicines.**

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

- Making
- Using
- Selling
- Offering for sale
- Import
- Export
- Other. Please specify: **The law refers to studies and trials and the resulting practical requirements (to obtain authorization of generic medicines), including those providing for use, preparation and obtaining.**

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

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

Yes. No amendments to the law are expected.

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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:

There has been some debate on whether the amendment to Article 52.1(b) of the Law on Patents No. 11/1986 of March 20, 1986, on the Guarantees and Rational Use of Medicines and Healthcare Products, implementing Directive 2004/27/CE of the European Parliament and the Council of March 31, 2004, amending Directive 2001/83/CE of the European Parliament and the Council of November 6, 1983, has retroactive effect or not. The Explanatory Memorandum of Law No. 29/2006 states that the only effects of this introduction are for clarification purposes and that this is covered by the previous text of Article 52.1(b), which establishes that patent rights shall not extend to acts carried out for experimental purposes. However, Ruling No. 424/2010 of the Supreme Court, a chamber of the Civil Courts, of June 30, 2010, states that prior to the entry into force of Law No. 29/2006, the provision of samples to public health authorities was not covered by the "experimental use exemption".

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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):

Articles 52(2) and (3) of the Law on Patents:

(2) The rights conferred by the patent shall not extend to acts relating to a product protected thereby once that product has been put on the market in the territory of a Member State of the European Community by the patent owner or with his consent.

(3) The rights conferred by the patent shall not extend to acts relating to biological material derived from the protected biological material, which is the subject of the patent, by propagation or multiplication, once this has been put on the market on the territory of a Member State of the European Union by the patent owner or with his consent, when the propagation or multiplication is the necessary result of the use for which the biological material was marketed, provided that the material obtained is not subsequently used for new propagation or multiplication.

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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:

The aim of this exemption is that once the product has been legally marketed, its buyer may use or return it for free sale without his acts entailing an infringement of patent rights. The aim thus is to prevent the owner of a patent invoking his right to limiting later marketing of the protected products to observance of an imposed price or other clauses which restrict free competition.

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

The inclusion of this exemption in the Law on Patents stems from European Community case law, initiated by the rulings of the European Court of Justice of October 31, 1974 (C-15/74, Sterling Drug), July 14, 1981 (C-178/80, Merck) and July 9, 1985 (C-19/84, Pharmon).

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

- Yes
 No
 Uncertain

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

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

Yes.

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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 licenses are governed by Chapter II of Title IX of the Law on Patents. Specifically, Article 86 establishes:
Where a particular patent is not the subject of the offer of *ex-officio* licenses and where one of the following situations exists, a compulsory license may be granted:**

- (a) failure or insufficiency of working of the patented invention;
- (b) export necessities;
- (c) dependency of patents; or between patents and plant variety rights;
- (d) existence of reasons of public interest for the grant.

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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: **For reasons of public interest.**

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

Public interest is put before the exclusive rights of private scope which are granted by the patent.

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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):

“Sufficient working” is considered to be that which is able to satisfy the demand of the national market.

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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):

Yes. Importation from one of the Member Countries of the World Trade Organization (WTO) is considered to be “working”.

Article 83 of the Law on Patents states that:

The owner of a patent shall be obliged to work the patented invention either himself or through a person authorized by him, by implementing it in Spain or on the territory of a Member of the World Trade Organization in such a manner that the working is sufficient to satisfy the demand of the national market.

This Article was amended by Law No. 66/1997, of December 30, 1997, on Fiscal, Administrative and Social Measures, to comply with the provisions of the TRIPS Agreement.

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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?

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Four years from the filing of a patent application or three years from publication in the Official Industrial Property Gazette, whichever expires later.

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"?

Article 87(2) of the Law on Patents considers that legitimate reasons are deemed to be "objective difficulties of a legal and technical nature, independent of the will and circumstances of the owner of the patent, which make working of the invention impossible or prevent its working from being more extensive than it is".

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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:

Article 89 of the Law on Patents stipulates that:

(1) Where it is not possible to work the invention protected by a patent without harming the rights conferred by an earlier patent or plant variety right, the owner of the subsequent patent may at any time require the granting of a non-exclusive compulsory license for the earlier patent subject matter or variety subject to the plant variety right in return for payment of an appropriate fee.

(2) Where a plant variety right cannot be obtained or exploited without harming the rights conferred by a previous patent, the breeder may apply for a compulsory non-exclusive license for working the invention protected by the patent, in return for the payment of an appropriate fee.

(3) Where the subject matter of a patent is a process to obtain a chemical or pharmaceutical substance protected by a patent in force, both the owner of the patent for the process and the owner of the patent for the product shall have the right to obtain a non-exclusive compulsory license for the patent of the other party.

(4) Compulsory license applicants, referred to in the preceding paragraphs, should demonstrate:

(a) that the invention or variety represents significant technical progress of considerable economic importance as regards the invention claimed in the earlier patent or in the variety protected by a prior plant variety right; and

(b) that they have tried, without success in a reasonable time limit, to obtain from the owner of the patent or of the prior plant variety right, a contractual license set out in reasonable terms and conditions.

(5) When, according to the provisions of this Article, a cross-license is granted, the owner of the patent or of the prior plant variety right shall also have the right to

request the issue, under reasonable conditions, of a cross-license to use the invention or the variety protected by the patent or subsequent plant variety right.

(6) The cross-license shall be awarded only with the content required to work the invention protected by a patent, or of the variety protected by the plant variety right concerned, and shall remain without effect by declaring that one of the titles on which the cross-licensing depends is invalid or has expired.

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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:

Article 101(2) of the Law on Patents states that the license shall provide for adequate remuneration according to the particular circumstances of each case, due regard being had to the economic importance of the invention.

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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:

Under Spanish law, mention is made of reasons of "public interest": Reasons of public interest are invoked when:

- the increase or generalization of working of the invention, or improvement of the conditions in which it is being worked, are of paramount importance for public health or national defense; and
- failure to work or insufficient quality or quantity of working leads to serious prejudice for Spain's economic or technological development.

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

No compulsory licenses have been issued on the basis of legislation in force in Spain.

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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:

Yes. No amendments to the law are envisaged.

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

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Government use

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

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

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

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

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

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

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

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

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

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

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

Farmers' use of patented inventions

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

Article 53 of the Law on Patents stipulates:

1. Notwithstanding the provisions of Article 50, the sale, or any other form of marketing of plant reproduction material carried out by the owner of the patent or with his consent given to a farmer for his farm, shall grant the right of the farmer to use the product of his harvest for later propagation or reproduction by the farmer on his farm. The scope and arrangements of this exception shall correspond to the provision of Article 14 of the Council Regulation (CE) 2100/94, of July 27, 1994, on Community Plant Variety Rights.

2. Notwithstanding the provisions of Article 50, the sale or any other form of marketing of farmed animals or animal reproduction material carried out by the owner of the patent or with his consent to a farmer or cattle breeder, shall require providing them with the authorization to use the protected livestock for agricultural or breeding purposes. This shall include providing livestock or other animal reproduction material so that the farmer or breeder may continue with his farming or breeding activity, but not the sale in the context of a commercial reproduction activity or for such purposes. The scope and arrangements of this exception shall correspond to those established in Law.

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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:

For the purposes of developing and protecting agricultural and livestock production, the free use of seeds obtained from plant or animal reproduction material acquired by the farmer is permitted; this use resembles the use of protected inventions in a private capacity and not for commercial purposes, since its use remains restricted specifically to the needs of agricultural or livestock breeding activities.

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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):

The scope of the farming exception is stipulated in Article 14 of the Council Regulation (CE) 2100/94, of July 27, 1994, on Community Plant Variety Rights, under which:

“1. Notwithstanding Article 13 (2), and for the purposes of safeguarding agricultural production, farmers are authorized to use for propagating purposes in the field, on their own holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right.” Under Paragraph 2 of this Article, agricultural plant varieties are cited as applicable for this exception.

In relation to the scope of the agricultural exception, Article 53 of the Law on Patents provides for the scope to be established in Law; however, such legal development is still to occur.

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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:

Yes. No amendments to the law are envisaged.

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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:

- **Procedural limitation;**
- **Dependence of patents;**
- **Lawfulness of working;**
- **Existence of a legal monopoly in the subject matter of a patent; and**
- **Secret patents.**

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

- (i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):
 - **Procedural limitation: under Article 55 of the Law on Patents, the owner of a patent shall have no right to invoke this limitation to defend himself against acts directed against him for infringement of other patents which have an earlier priority date than his.**
 - **Dependence of patents: under Article 56 of the Law on Patents, the fact that the invention protected by patent may not be worked without using the invention protected by a prior patent belonging to a different owner shall not invalidate that patent. In such a case, neither the owner of the prior patent may work the later patent during its lifetime without the consent of its owner, nor may the owner of the later patent work either patent during the lifetime of the prior patent, without the consent of the owner of the prior patent or without a compulsory license.**
 - **Lawfulness of working: in general, Article 57 of the Law on Patents provides that "a patented invention may not be worked in any form contrary to the Law, morality or public order or public health, and its working shall be subject in all cases to the prohibitions and restrictions, whether temporary or permanent, established or to be established by the legal provisions".**
 - **Existence of a legal monopoly in the subject matter of a patent: Article 58 governs a series of limitations for those cases in which a patent is granted for an invention whose subject matter concerns a legal monopoly. However,**

currently legal monopolies are prohibited and so this Article may be abrogated *de facto*.

- **Secret patents:** Article 119 of the Law on Patents states that the Ministry of Defense may order the Spanish Patent and Trademark Office to decree the secret processing of a patent application, in which case the applicant or the owner must abstain from any act which might disclose the invention to unauthorized persons. Nonetheless, the Ministry of Defense, at the owner's request, may authorize acts leading to full or partial working of the subject matter of the application or the patent, indicating the conditions by which such acts are bound.

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

- **Procedural limitation:** to prevent the practice of so-called "blanket patents";
- **Dependence of patents:** to allow the working of a later valid patent but in a relationship of dependence with a prior patent belonging to another owner;
- **Lawfulness of working:** to prevent the working of the patent being contrary to the Law and established morality;
- **Existence of a legal monopoly in the subject matter of a patent:** respecting the legally-permitted monopolies; and
- **Secret patents:** to put the interests of the Defense of the State before the individual interests of the applicant.

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

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?):

Yes. No amendments to the law are envisaged.

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

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

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[End of Questionnaire]