

## Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Portugal .....

Office: Instituto Nacional da Propriedade Industrial – INPI  
(Portuguese Institute of Industrial Property).....

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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 standard is set in the Código da Propriedade Industrial – CPI (Industrial Property Code), articles 52 to 54. The CPI is the Portuguese statutory law regarding industrial property. You can find an English version in our web page, namely in [http://www.marcasepatentes.pt/files/collections/eng\\_US/1/Industrial%20Property%20Code%20%28Searchable%20PDF%29.pdf](http://www.marcasepatentes.pt/files/collections/eng_US/1/Industrial%20Property%20Code%20%28Searchable%20PDF%29.pdf) .**

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.<sup>1</sup>

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

**“Article 52 – Limitations on object**

**1 – The following are exceptions to the previous article:**

- a) Discoveries, scientific theories and mathematical methods;**
- b) Materials or substances already existing in nature and nuclear materials;**
- c) Aesthetic creations;**
- d) Schemes, rules or methods for intellectual acts, playing a game or doing business and computer programs, as such, with no contributions;**
- e) Presentations of information.**

**2 – (Revoked.)**

**3 – Paragraph 1 only excludes patentability if the object for which a patent is requested is limited to the elements mentioned in it.**

**Article 53 – Limitations on patent**

**1 – Inventions whose commercial exploitation is against the law or contrary to public policy, public health or morality are not patentable and their exploitation may not be considered as such due to the simple fact that it is forbidden by law or regulations.**

**2 – Under the previous paragraph, the following are not patentable:**

- a) Processes for cloning human beings;**
- b) Processes for modifying the germinal genetic identity of human beings;**
- c) The use of human embryos for industrial or commercial purposes;**
- d) Processes for modifying the genetic identity of animals which may cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.**

**3 – The following are also not patentable:**

- a) The human body, at the various stages of its formation and development and the simple decoding of one of its elements, including the discovery of a sequence or partial sequence of a gene, without prejudice to (1)(c) of the following article;**
- b) Plant and animal varieties and essentially biological processes for obtaining plants or animals;**
- c) Surgical or therapeutic methods for treating the human or animal body and diagnostic methods used on the human or animal body, though products, substances or compositions used in any of these methods may be patented.**

**Article 54 – Special cases of patentability**

**1 – The following may be patented:**

**a) A substance or composition included in the state of the art for use in a method referred to in paragraph (3)(c) of the previous article, on the condition that this use for any method mentioned therein is not included in the state of the art;**

**b) The substance or composition referred to in the previous paragraph for any other specific use in a method mentioned in paragraph (3)(c) of the previous article, provided that this use is not included in the state of the art;**

**c) A new invention that involves an inventive step and is susceptible of industrial application relating to any isolated element of the human body or produced in any other way by a technical process, including a sequence or partial sequence of a gene, even though the structure of this element is identical to that of a natural element, provided that the industrial application of a sequence or partial sequence of a gene is expressly observed and specifically described in the patent application;**

**d) An invention relating to plants or animals, if its technical feasibility is not confined to a particular plant variety or breed of animal;**

**e) A biological material isolated from its natural environment or produced on the basis of a technical process, even if it pre-exists in a natural state;**

**f) An invention relating to a microbiological process or other technical processes or products obtained by means of these processes.**

**2 – An essentially biological process for obtaining plants or animals is any process that consists wholly of natural phenomena, such as crossing or selection.**

**3 – A microbiological process is any process involving or performed upon or resulting in microbiological material.**

**4 – Biological material is any material that contains genetic information and is capable of reproducing itself or being reproduced in a biological system.”**

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 matter of exclusive rights granted with a patent is set forth in CPI, articles 101 to 104.

**“Article 101 – Rights conferred by patent**

**1 – A patent confers the exclusive right to exploit the invention anywhere in Portuguese territory.**

**2 – A patent also confers upon its holder the right to prevent others from manufacturing, offering, storing, commercializing or using a patented product or importing or possessing it for any of the aforementioned purposes without his consent.**

**3 – A patentee may oppose all acts constituting a violation of his patent, even if they merge with another patent with a later priority date, with no need to impugn titles or request annulment of patents with which this right merges.**

**4 – The rights conferred by a patent shall not exceed the scope defined by the claims.**

**5 – A patentee may ask the National Industrial Property Institute, on payment of a fee, to limit the scope of protection of the invention by altering the claims.**

**6 – If the examination shows that the request for limitation can be granted, the National Industrial Property Institute shall promote the publication of a notice of the alteration of the claims, otherwise the request shall be denied and the decision communicated to the requester.”**

Articles 102 to 104 CPI deal with limitation, exhaustion and non-opposability, respectively. For details, please see below the answers to other more specific questions.

We believe the extent of protection, as provided for by article 97 CPI, to be of relevance in this context.

**“Article 97 – Extent of protection**

**1 – The extent of the protection conferred by a patent shall be determined by the content of the claims and the description and drawings shall serve to interpret them.**

**2 – If a patent concerns a process, the rights conferred by it shall cover the products obtained directly by the patented process.**

**3 – The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.**

**4 – The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.**

**5 – The protection conferred by a patent of a product that contains or consists of genetic information shall extend to any material in which the product is incorporated, contained and performs its function, save as provided for in Article 53(3)(a).**

**6 – By way of derogation of paragraphs 3 to 5 of this article:**

**a) The sale or other form of commercialization of plant propagating material to a farmer by the holder of the patent, or with his consent for agricultural use, implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm;**

**b) The sale or any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.”**

Regarding publications, article 5 CPI, is the relevant provision.

**“Article 5 – Provisional protection**

**1 – An application for a patent, utility model or registration provisionally grants the applicant the right, as of its publication in the Industrial Property Bulletin, to the same protection as that granted by the right, to be considered in the calculation of any compensation.**

**2 – The provisional protection referred to in the previous paragraph is opposable, even before publication, by anyone who has been notified of the submission of the application and received the details of the case.**

**3 – Verdicts in suits brought on the basis of provisional protection cannot be delivered before the final granting or refusal of a patent, utility model or registration and the case shall be suspended at the end of the arguments.”**

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;<sup>2</sup>
- 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.<sup>3</sup>

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):

**The relevant provision is article 102 CPI, subheading a).**

#### **"Article 102 – Limitation of rights conferred by a patent**

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<sup>2</sup> For example, extemporaneous preparation of prescribed medicines in pharmacies.

<sup>3</sup> 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).

***The rights conferred by a patent do not extend to:***

***a) Acts performed in private and not for commercial purposes;***

***(...)***

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

**To our knowledge, there is no relevant case law on this matter.**

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

**Not to restrain the individual non-commercial activity, since it does not harm the right owner.**

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

**This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.**

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

**The CPI does not provide a definition for the concepts "non-commercial", "commercial" and/or "private", as well as it does not provide for a definition of invention nor for a definition of technical character an invention should have.**

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):

**To our knowledge, there is no relevant case law on this matter.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

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

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

The relevant provision is **article 102 CPI, subheading c).**

**“Article 102 – Limitation of rights conferred by a patent**

***The rights conferred by a patent do not extend to:***

***(...)***

***c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them;***

***(...)”***

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

**To our knowledge, there is no relevant case law on this matter.**

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

**To support R&D activities without IP restrictions, contributing this way to the innovation effort.**

**To ensure pharmaceutical companies wanting to produce a medicine which patent is about to expire the right to perform the required experiments before the patent’s expiration date in order to get government permission to produce them, so saving time.**

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

**This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention. However it only referred to “*Acts performed exclusively for trial or experimental purposes*”, the remaining text was only added in 2003.**

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:

**Our national law does not make any distinction concerning the nature of the organization conducting the experimentation or research.**

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

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):

**The applicable law does not provide any definition of the concepts “experimental use” and/or “scientific research”.**

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: .....

**Neither of the criteria is relevant.**

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

**Neither of the criteria is relevant.**

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

**To our knowledge, there are no relevant legal provisions nor case law on this matter.**

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):

**The applicable law does not make a distinction between “commercial” and “non-commercial” purpose.**



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):

**The applicable law does not provide any other criteria to be applied in determining the scope of the exception.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

#### ***Section IV: Preparation of medicines***

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

**The relevant provision is article 102 CPI, subheading b).**

#### ***“Article 102 – Limitation of rights conferred by a patent***

***The rights conferred by a patent do not extend to:***

***(...)***

***b) The preparation of medicinal products performed at the time and for individual cases on the basis of a doctor’s prescription at pharmaceutical laboratories or acts relating to the medicinal products prepared in this way;***

***(...)”***

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

**To our knowledge, there are no relevant legal provisions or case law on this matter.**

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

**Not to limit access to treatment and not to interfere with the relationship doctor/patient.**

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

**This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.**

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

**Anyone entitled to prepare this kind of medicinal products.**

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):

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

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):

**The applicable law does not provide any other criteria to be applied in determining the scope of the exception.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

***Section V: Prior use***

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

**Regarding prior use, the applicable provision is article 104 CPI. This article is directed at non-opposability.**

**"Article 104 – Non-opposability"**

**1 – The rights conferred by a patent are not opposable in the Portuguese territory before the date of the application or of priority, if it is claimed against someone who, in good faith, has learned of the invention by his own means and used it or made effective, serious preparations to use it.**

**2 – The previous paragraph does not apply if the knowledge is the result of unlawful or immoral acts against the patentee.**

**3 – The burden of proof lies with the person invoking the situations set forth in paragraph 1.**

**4 – Prior use or preparations therefore based on the information referred to in Article 57(1)(a) does not prejudice good faith.**

**5 – In the cases set forth in paragraph 1, the beneficiary has the right to pursue or commence use of the invention, within the limits of his prior knowledge, for his own business purposes, but may only transfer it in conjunction with the business establishment in which use is made.”**

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

**To our knowledge, there is no relevant case law on this matter.**

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

**Not to harm persons (inventors) who reached the same invention as described in the patent on their own at an earlier date.**

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

**This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.**

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 CPI does not provide for the scope of “use”, as well as it does not define the concepts “non-commercial”, “commercial” and/or “private”, as well as it does not provide for a definition of invention nor for a definition of technical character an invention should have.**

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

**The CPI does not provide for any such remuneration.**

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 applicable provision is article 104 CPI, paragraph 5, as transcribed above in the context of the answer to question 31.**

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:

**The relevant provision is set in article 8 CPI, regarding re-establishment of rights, namely paragraphs 6 and 7.**

**"Article 8 – Re-establishment of rights**

(...)

***6 – Applicants for or owners of rights that are re-established may not invoke them to a third party who, in good faith, in the period between the loss of the rights granted and the publication of the notice of re-establishment of the rights, has begun operation or sale of the object of the right or has made actual, serious preparations for its operation or sale.***

***7 – Third parties who may avail themselves of the provision in the previous paragraph may oppose the decision to re-establish rights of the applicant or owner within two months of the date of publication of the notice of re-establishment of the right."***

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):

**The CPI does not provide for other criteria to be applied in determining the scope of the exception regarding prior use.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

***Section VI: Use of articles on foreign vessels, aircrafts and land vehicles***

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

**The relevant provisions are set forth in article 102 CPI, subheadings d) to f).**

**“Article 102 – Limitation of rights conferred by a patent**

***The rights conferred by a patent do not extend to:***

***(...)***

***d) Use on board ships from other countries belonging to the Union[\*] or WTO of a patented invention in the hull, machinery, rigging, gear or other accessories of the ship, if they temporarily or accidentally enter the waters of the country, provided that said invention is used exclusively to serve the ship’s needs;***

***e) The use of a patented invention in the construction or operation of aircraft or land vehicles of other countries belonging to the Union[\*] or WTO or their accessories, if they temporarily or accidentally enter national territory;***

***f) The acts set forth in Article 27 of the Convention of 7 December 1944 concerning international civil aviation if they have regard to aircraft from another state to which the provisions of said article apply.”***

**[\*] “Union” stands for “Union for the Protection of Industrial Property”, established under the “Paris Convention of the Union for the Protection of Industrial Property” (Paris Convention of 20 March 1883 and its revisions).**

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

**To our knowledge, there is no relevant case law on this matter.**

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

**The binding of the Portuguese state to international treaties such as the Convention on International Civil Aviation signed on December 7, 1944.**

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

**This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.**

**Harmonization with article 5ter of the Paris Convention was intended.**

**In subheadings d) and e) of article 102 CPI, the mention to WTO was introduced in 2003, the current, although amended, CPI version. The earlier (revoked) 1995 CPI did not mention WTO.**

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):

**Yes, it applies such terms. Article 102 CPI, subheadings d) and e) do so. Please, read the answer to question 42, where the corresponding transcription of the law was made. There are no definitions for those terms.**

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):

**Yes, it provides for such restrictions.**

**In what vessels are concerned, article 102 CPI, subheading d) restricts the exception, as it is "(...) provided that said invention is used exclusively to serve the ship's needs", as already transcribed above in the context of the answer to question 42.**

**Regarding aircrafts and land vehicles, article 102 CPI, subheading e), states the exception to be restricted to "(...) the construction or operation (...)" of such aircrafts and land vehicles, as already transcribed above in the context of the answer to question 42.**

**The CPI does not provide corresponding provisions for spacecraft.**

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):

**The CPI does not provide for other criteria to be applied in determining the scope of the exception regarding use of articles on foreign vessels, aircrafts and land vehicles.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

***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 relevant provision is Article 102 CPI, subheading c).**

**“Article 102 – Limitation of rights conferred by a patent**

***The rights conferred by a patent do not extend to:***

***(...)***

***c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them;***

***(...)”***

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

**To our knowledge, there are no relevant legal provisions nor case law on this matter.**

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

**Not to extend the monopoly beyond its legal term.  
Please, read also the answer to question 13 (a).**

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

**This exception was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention. The part “(...) *including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them*” of article 102 CPI,**

subheading c), mentioned in the answer to question 51, was introduced in 2003. Before that, in the 1995 CPI, only the initial part “Acts performed exclusively for trial or experimental purposes (...)” was present.

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

**Any legal person that wishes to commercialize a patented product as soon as the respective patent expires.**

55. The exception covers the regulatory approval of:

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

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

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

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

**The applicable law does not provide any other criteria to be applied in determining the scope of the exception.**

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 our knowledge, there are no foreseen amendments to the current law on such matters.**

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

**The patentees do not agree with this exception and, especially in the pharmaceutical area, they try to prevent the obtaining of regulatory approvals setting up interim relief in the appropriate court. Court decisions are not unanimous regarding this issue.**

### **Section VIII: Exhaustion of patent rights**

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

- National



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

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

**The relevant provision is article 103 CPI. It applies to a patent valid in the Portuguese territory, be it a patent deriving from a Portuguese national application filing, a validated European patent or an international application filing.**

**“Article 103 – Exhaustion of rights**

***1 – The rights conferred by a patent do not allow its holder to forbid acts related to the products protected by it after its sale by the patentee or with his consent, in the European economic area.***

***2 – The protection referred to in Article 97(3) to 97(5) does not cover biological material obtained by propagation or multiplication of a biological material sold by the patentee or with his consent, in the European economic area, if the propagation or multiplication is the necessary result of the use for which the biological material was placed on the market, provided that the material obtained is not then used for further propagation or multiplication.”***

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

**To our knowledge, there is no relevant case law on this matter.**

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

**This limitation assures free circulation of products within the European Economic Area (EEA).**

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

**Paragraph 1 of article 103 CPI was introduced in the Portuguese statutory law in 1995 as a result of Portugal's accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention. The legal provision set forth in paragraph 2 of article 103 CPI was introduced in 2003 as a result of the transposition of Directive 98/44/EC on the legal protection of biotechnological inventions. It was absent from the 1995 (revoked) CPI.**

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):

**The CPI does not provide for such a provision.**

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

**To our knowledge, the applicable regime is considered adequate.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

### **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):

**The relevant CPI provisions are set forth in articles 107 to 112. Please find corresponding transcriptions just below.**

#### **“Article 107 – Compulsory licenses**

**1 – Compulsory licenses may be granted for a certain patent, in any of the following cases:**

- a) Lack or insufficient exploitation of a patented invention;**
- b) Dependency between patents;**
- c) Reasons of public interest.**

**2 – Compulsory licenses shall be non-exclusive and may only be transferred with the part of the company or establishment that exploits them.**

**3 – Compulsory licenses may only be granted if the potential licensee has made efforts to obtain a contractual license from the patentee on acceptable commercial conditions and said efforts have not been successful within a reasonable period of time.**

**4 – A compulsory license may be revoked without prejudice to the appropriate protection of the licensee’s legitimate interests if and when the circumstances that gave rise to it cease to exist or are not likely to occur again. The competent authority may re-examine the continuation of said circumstances on duly justified request.**

**5 – If a patent concerns semiconductor technology, compulsory licenses may only be granted for a non-commercial, public purpose.**

**6 – The patentee shall receive appropriate payment in each concrete case on the basis of the economic value of the license.**

**7 – A decision granting or denying payment is subject to judicial or arbitral appeal under Articles 48 to 50.**

**Article 108 – License due to failure to exploit the invention**

**1 – After the time limits referred to in Article 106(2) have expired, a patentee who, without a good reason or legal basis, does not exploit an invention, directly or under license, or does not do so in such a way as to meet national needs, may be obliged to grant a license for its exploitation.**

**2 – A patentee may also be obliged to grant an exploitation license for an invention if he ceases to exploit it for three consecutive years without a good reason or legal basis.**

**3 – Objective technical or legal reasons beyond the patentee's control and irrespective of his situation making the exploitation of the invention impossible or insufficient are considered good reason, but not economic or financial difficulties.**

**4 – For as long as a compulsory license remains in force, the patentee may not be obliged to grant another before the previous one is cancelled.**

**5 – A compulsory license may be cancelled if the licensee does not exploit the invention in such a way as to meet national needs.**

**Article 109 – Dependent licenses**

**1 – If it is not possible to exploit a patented invention, without prejudice to the rights conferred by a previous patent, and the two inventions are used for different industrial purposes, a license may only be granted if the first invention is essential to the exploitation of the second, and only in the part necessary for said exploitation, and the holder of the first patent is entitled to fair compensation.**

**2 – If inventions protected by dependent patents serve the same industrial purpose and a compulsory license is to be granted, the previous patentee may also demand a compulsory license for the previous patent.**

**3 – If an invention concerns a process for preparing a chemical, pharmaceutical or food product protected by a current patent, and whenever this process patent represents notable technical progress in relation to the previous patent, both the holder of the process patent and the holder of the product patent are entitled to demand a compulsory license for the other holder's patent.**

**4 – If the obtainer of a plant variety cannot obtain or exploit a plant securing right without infringing a prior patent, he may request a compulsory license for non-exclusive exploitation of the invention protected by the patent, provided that this license is necessary for the exploitation of the same plant variety, on payment of appropriate remuneration.**

**5 – Whenever a license of the type provided for in the previous paragraph is granted, the patentee is entitled to a reciprocal license on reasonable terms to use the protected variety.**

**6 – If the holder of a patent for a biotechnological invention is unable to exploit it without infringing a previous plant variety securing right, he may request a compulsory license for non-exclusive exploitation of the variety protected by the securing right on payment of an appropriate sum.**

**7 – Whenever a license of the type provided for in the previous paragraph is granted, the holder of the securing right is entitled to a reciprocal license on reasonable terms to use the protected invention.**

**8 – Applicants for the licenses referred to in paragraphs 4 and 6 must prove that:**

**a) They approached the patentee or plant securing right holder in vain to obtain a contractual license;**

**b) The plant variety or invention represents important technical progress of considerable economic interest in relation to the invention claimed in the patent or to the plant variety being protected.**

**9 – This article also applies whenever one of the inventions is protected by a patent and the other by a utility model.**

#### **Article 110 – Public interest**

**1 – A patentee may, in the public interest, be obliged to grant a license for the exploitation of his invention.**

**2 – There are considered to be reasons of public interest if the start, increase or generalization of the exploitation of the invention, or an improvement in the conditions of its exploitation, is of vital importance to public health or national defense.**

**3 – There are also considered to be reasons of public interest if failure to exploit or insufficient quality or quantity of exploitation is highly detrimental to the country's economic or technological development.**

**4 – The government shall be responsible for granting a license in the public interest.**

#### **Article 111 – Requests for compulsory licenses**

**1 – Compulsory licenses shall be requested from the National Industrial Property Institute. Applicants shall submit proof to justify their request.**

**2 – Requests for compulsory licenses shall be examined in the order in which they are submitted to the National Industrial Property Institute.**

**3 – On receiving a request for a compulsory license, the National Industrial Property Institute shall give the patentee two months in which to say anything he sees fit and to submit proof.**

**4 – The National Industrial Property Institute shall consider the parties' arguments and the guarantees of exploitation of the invention offered by the applicant for the compulsory license and decide, within two months, whether or not it should be granted.**

**5 – If it decides in favor, it shall give both parties one month to appoint an expert who, together with the expert appointed by the National Industrial Property Institute, shall agree, within two months, on the conditions of the compulsory license and the compensation to be paid to the patentee.**

#### **Article 112 – Notification of and appeal against grant or refusal of a license**

**1 – The National Industrial Property Institute shall inform both parties of the grant or refusal of a license and its exploitation conditions.**

**2 – Appeals may be lodged against the decision of the National Industrial Property Institute to grant or refuse the license, or only the conditions in which it has been granted, to the competent court under the terms of articles 39 et seq., within three months of the date of the notification referred to in the previous paragraph.**

**3 – A decision to grant shall only be effective after its confirmation and annotation at the National Industrial Property Institute, where the appropriate fees shall be paid as for an ordinary license.**

**4 – An extract of the registration referred to in the previous paragraph shall be published in the Industrial Property Bulletin.”**

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

**To our knowledge, there is no relevant case law on this matter.**

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

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

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

**To avoid abuse of the monopoly that is granted with a patent. To avoid obstacles to technological and economical development. To promote public health. To guarantee national security.**

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

**The provisions set forth in article 108 CPI, paragraphs 4 to 8, regarding plant varieties or biotechnological inventions, were introduced in 2003. The earlier (revoked) 1995 CPI did not provide for this.**

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):

**The applicable law is the one set forth in article 108 CPI. Please read its transcription, included in the answer to question 65. Also relevant in this context we believe to be the provisions of article 106 CPI.**

**“Article 106 – Obligation to exploit**

**1 – The patentee is obliged to exploit a patented invention directly or through a person authorized by him and to market the results obtained in order to fulfill the needs of the national market.**

**2 – Exploitation shall begin within four years of the date of the patent application or three years of the grant date, whichever is greater.**

**3 – It is possible to enjoy patent rights with no discrimination as to place of invention, the technological field or the fact that the products are imported from any country belonging to the European Union or WTO or produced locally.”**

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 in that sense constitutes “working” of a patent. The relevant legal provision is established in article 106 CPI, paragraph 3, as transcribed above in the context of the answer to question 69.**

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?

**The CPI does not provide for a time period, as such, to be respected before a compulsory license can be requested. Please read the transcription of article 107 CPI, paragraph 3, made in the context of the answer to question 65. Note that said provision only mentions a “(...) reasonable period of time”. Nevertheless, article 106 CPI, paragraph 2, does provide for time periods for the patented invention to be “worked”. Please read the corresponding transcription made in the context of the answer to question 69.**

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

- Yes  
 No

If yes, what are “legitimate reasons”?

**The applicable law is the one provided for by article 108 CPI, paragraph 3. Again, please read the transcription of said provision made in the context of the answer to question 65.**

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):

**The relevant provision is article 107 CPI, paragraph 3. Please read the corresponding transcription made in the context of the answer to question 65. The answer given to question 71 already addressed this matter. To our knowledge, there are no definitions in the relevant legal provisions nor in the case law.**

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):

**The CPI does not provide for the grant of compulsory licenses on such grounds.**

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:

**The relevant provisions are set forth in article 109 CPI. Please read the corresponding transcription made in the context of the answer to question 65.**

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:

**Yes, the law provides for a remuneration policy in such a context. The relevant provisions are the ones stated in article 107 CPI, paragraphs 6 and 7, article 109 CPI, paragraphs 1 and 4 to 7, and article 111 CPI, paragraph 5. Please read the corresponding transcriptions made in the context of the answer to question 65.**

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:

**The CPI does not provide for the grant of compulsory licenses on such grounds.**

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

**In our country one compulsory license was issued regarding plant protection products.**

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 our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

*Government use*

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

**Government use of patent rights in pursuing public interest is not specifically provided for in the CPI. Only article 105 CPI, as transcribed below, addresses state ownership of patent rights.**

**Article 105 CPI provides for loss and expropriation of a patent.**

**“Article 105 – Loss and expropriation of a patent**

***1 – Anyone who is liable for obligations undertaken in relation to third parties or whose patent is expropriated in the public interest may be deprived of a patent under the law.***

***2 – Any patent may be expropriated in the public interest on payment of fair compensation, if the need for dissemination of the invention or use by public bodies so requires.***

***3 – The Expropriation Code is applicable, with the necessary adaptations.”***

**Regarding public interest, the already mentioned and transcribed above provisions stated in articles 107 to 112 CPI on compulsory licensing include the pursuing of several forms of public interest, but without demanding any kind of ownership of patent rights by the state.**

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

**To our knowledge, there is no relevant case law on this matter.**

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: Public interest, as stated above in the answer to question 81.

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



**To pursue public interest.**

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

**Legal provisions for the pursuit of public interest through state ownership of patent rights have been essentially the same for decades.**

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:

**The CPI does not provide for the grant of government use on such grounds.**

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

**To our knowledge, the government has never used this exception.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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

**There have not been any challenges related to the practical implementation of this exception in our country.**

***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):

**The relevant provision is article 103 CPI, paragraph 2. It applies to a patent valid in the Portuguese territory, be it a patent deriving from a Portuguese national application filing, a validated European patent or an international application filing.**

**Please read the transcription made in the context of the answer giver to question 60.**

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

**To our knowledge, there is no relevant case law on this matter.**

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

**To avoid abuse of the monopoly that is granted with a patent, and to protect the farmers rights.**

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

**The legal provision set forth in paragraph 2 of article 103 CPI was introduced in 2003 as a result of the transposition of Directive 98/44/EC on the legal protection of biotechnological inventions. It was absent from the 1995 (revoked) CPI.**

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):

**To our knowledge, there is no relevant case law on this matter.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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:

**There have not been any challenges related to the practical implementation of this exception in our country.**

*Breeders' use of patented inventions*

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

**The relevant provision is article 103 CPI, paragraph 2. It applies to a patent valid in the Portuguese territory, be it a patent deriving from a Portuguese national application filing, a validated European patent or an international application filing.**

**Please read the transcription made in the context of the answer giver to question 60.**

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

**To our knowledge, there is no relevant case law on this matter.**

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

**To avoid abuse of the monopoly that is granted with a patent, and to protect the breeders' rights.**

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

**The legal provision set forth in paragraph 2 of article 103 CPI was introduced in 2003 as a result of the transposition of Directive 98/44/EC on the legal protection of biotechnological inventions. It was absent from the 1995 (revoked) CPI.**

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):

**To our knowledge, there is no relevant case law on this matter.**

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:

**To our knowledge, there are no foreseen amendments to the current law nor is there any on-going debate on such matters.**

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:

**There have not been any challenges related to the practical implementation of this exception in our country.**

#### ***Section XI: Other Exceptions and Limitations***

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

**To our knowledge, there is no other exceptions and limitations provided by our patent law.**

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):

**Not applicable.**

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

**Not applicable.**

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

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

**Not applicable.**

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

**Not applicable.**

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

**Referring to the answer given to question 81, specifically to the transcription of article 105 CPI included therein, namely to its paragraph 3, mention is made to the “Expropriation Code”, which is the Portuguese law regarding expropriations.**

[End of Questionnaire]