

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: FRANCE.....
Office: National Institute of Industrial Property (INPI).....

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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.

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The French Intellectual Property Code specifies three conditions of patentability, which are the same for all fields of technology that are the subject of a patent application (novelty, inventive step and industrial applicability).....

Article L611-10 of the Intellectual Property Code (CPI) specifies the conditions of patentability: “In all fields of technology, new inventions which involve an inventive step and are industrially applicable shall be patentable”.

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

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French law specifies what is not considered to be an invention and what is excluded from patentability.

Article L611-10(2) of the CPI states: "The following shall not be considered to be inventions:

(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) plans, principles and methods in the exercise of intellectual activities, games or the field of economic activities and computer programs; (d) presentations of information;

Article L611-16 of the CPI states: "Methods of surgical or therapeutic treatment of the human or animal body and the diagnostic methods applied to the human or animal body shall not be patentable. This provision shall not apply to products, in particular substances or compositions, for the implementation of one of these methods";

Article L611-17 of the CPI states: "Inventions, the commercial working of which would be contrary to the dignity of the human person, *ordre public* or good manners, whereby this contrary nature cannot result solely from the fact that such working is forbidden by a legislative or regulatory provision, shall not be patentable".

Article L611-18 of the CPI states: "The human body, at the different stages of its constitution and its development, and also the simple discovery of one of its elements, including the total or partial sequence of a gene, may not constitute patentable inventions. Only an invention constituting the technical application of a function of an element of the human body may be patent-protected. This protection covers the element of the human body only to the extent necessary for carrying out and working this particular application. Such application must be detailed in specific and precise terms in the patent application. The following shall, *inter alia*, not be patentable: (a) processes for cloning of human beings; (b) processes for modifying the genetic identity of human beings; (c) the uses of human embryos for industrial or commercial purposes; (d) the total or partial sequences of a gene taken as such".

Article L611-19 of the CPI states: "The following shall not be patentable (1) animal breeds; (2) plant varieties as defined in Article 5 of Council Regulation (EC) No 2100/94, of July 27, 1994, on Community plant variety rights; (3) essentially biological processes for obtaining plants and animals; processes which require exclusively natural phenomena such as crossing or selection shall be considered such; (4) processes for modifying the genetic identity of animals, such that they cause suffering in those animals without substantive medical usefulness for humanity or animals, and also animals produced by such processes".

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

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

According to Article L611-1 of the CPI, the patent shall confer on its owner or his successors in title a direct or indirect exclusive right of working. Article L613-1 of the CPI specifies that: “The exclusive right of working mentioned in Article L.611-1 shall take effect from the time the application is filed,”

The exclusive right of working conferred by the patent allows its owner to prohibit a number of acts performed without his consent. Article L613-3 states, for this purpose, that: “In the absence of the consent of the patent owner, the following shall be forbidden: (a) the manufacture, offer, marketing, use or also the import or retention for the above purposes of the product which is the subject of the patent; (b) the use of a process which is the subject of the patent or, where the third party knows or where the circumstances make it obvious that the use of the process is forbidden without the consent of the patent owner, the offer of its use on French territory; (c) the offer, marketing or use, or also the import or retention for the above purposes of the product obtained directly by the process which is the subject of the patent”.

Article L613-4 of the CPI also states that: “(1) In the absence of the consent of the patent owner, the delivery or offer of delivery, on French territory, to a person other than those entitled to work the patented invention, of the means of carrying out, on such territory, of the invention relating to an essential element thereof, shall also be forbidden, where the third party knows or where the circumstances make it obvious that these means are suitable and intended for such performance...”.

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 prescribed and acts concerning medicines;²
- Prior use by a person who, in good faith, was in possession of the invention, before the filing date (priority date);
- Use of articles on foreign vessels, aircrafts and land vehicles;
- Acts for obtaining regulatory approval from authorities;
- Exhaustion of patent rights;
- Compulsory licensing and/or government use;
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³

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

² For example, extemporaneous preparation of prescribed medicines in pharmacies.

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

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

Section II: Private ~~and/or~~ non-commercial use

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

Article L613-5 of the CPI states that “The rights conferred by the patent shall not extend to: (a) the acts performed in a private context **and** for non-commercial purposes...”

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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:

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

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

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

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

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

YES.....

No changes to legislation are planned.
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10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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

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

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Article L613-5 states that: "The rights conferred by the patent shall not extend to...(b) the acts performed for experimental purposes, which relate to the subject matter of the patented invention";

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The exception for the purposes of scientific research does not exist in French legislation.

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?

In keeping with Article L613-5 of the CPI, the aim of acts performed for experimental purposes shall be to verify the technical interest of the invention, to measure the scope thereof or to improve it and not to seek the commercial impact of the product or process.
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation ~~or research~~ (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

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

French legislation does not make a distinction regarding the nature of the body conducting the experimentation or research.
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15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

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

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- ~~determine the validity of the claims~~
- seek an improvement to the patented invention
- ~~invent around the patented invention~~
- other, please specify:

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 the subject matter of the patented invention ~~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):

The exception given to the patent monopoly by Article L613-5(b) of the CPI shall be assessed strictly and may apply only to the experimental acts, the aim of which is to

participate in the verification of the technical interest of the invention or its development in order to advance knowledge, and not to commercially-oriented acts.

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

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

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No legislative changes planned.....
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22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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The Law of February 26, 2007 introduced a specific exception for the bioequivalence tests in the field of medicines with a view to promoting the generic medicines found in Article L613-5(d) of the CPI: *"the rights conferred by patents shall not extend to: the studies and tests required with a view to obtaining marketing of a medicine, and also for the acts necessary for their production and obtaining the authorization"*. This provision shall allow exemption for the marketing authorization and the acts necessary for obtaining it from the range of acts constituting infringement of a patent.
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Section IV: Preparation of medicines

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

Article L613-5 of the CPI states that: "The rights conferred by the patent shall not extend to: (c) the extemporaneous preparation of medicines or that done by unit in pharmacies, on medical prescription, or to the acts concerning the medicines thus prepared".

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:

Exception in the interest of public health (specific preparations in pharmacies).....
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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:

Pharmacists and doctors who may continue to carry out their specific preparations (the article of the Law specifies that these are medicines prepared in pharmacies and on medical prescription).....
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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):

Article L613-5 of the CPI specifies that this exception applies to the extemporaneous preparations of medicines and those by unit in pharmacies.
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28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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

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

As far as we are aware, there have been no challenges in the application of this exception.
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Section V: Prior use personal possession

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

Article L613-7 of the CPI states that: "Any person who, in good faith, on the filing or priority date of a patent, was, on the territory where this book applies, in possession of the invention which is the subject of the patent, shall have the right, in a personal capacity, to work the invention, despite the existence of the patent".....

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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:

This exception stems from the first applicant system and allows the inventor of a non-patented invention which he has kept secret since a date prior to the filing of the application of a third party relating to the same invention, to be able to continue working the invention personally after the filing of the patent. The benefit of the prior personal possession shall prevent any infringement action on the part of the patent owner

The possession must relate to the technology even covered by the patent and the invention must be known completely. The earlier holder must act in good faith.

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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):

Article L613-7 of the CPO specifies that the holder of the invention shall have the possibility to work it freely or to assign it until the filing or priority date of the patent application and that, from that date, he shall retain only the right to work it personally;

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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:

There is no provision for the payment of such remuneration. The earlier holder of an invention which he has not patented shall retain only a right of personal working not subject to remuneration for the benefit of the patent owner.
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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

Article L613-7 of the CPI specifies that: "the right recognized by this Article may be transferred only with the goodwill of the firm or part of the firm to which it is attached".

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

- Yes
- No

If yes, please explain what those conditions are:

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

- Yes
- No

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

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

The earlier holder must act in good faith and the possession must be certain, unambiguous and on French territory.....
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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 changes to legislation are planned.
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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 L613-5(e) of the CPI states that: "The rights conferred by the patent shall not extend to the objects intended to be launched in the extra-atmospheric space introduced onto French territory". Article *5ter* of the Paris Convention shall also apply.

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

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

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

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45. The exception applies in relation to:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

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

Article *5ter* of the Paris Convention refers to the criteria "temporarily or accidentally".

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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):

Article 5^{ter} of the Paris Convention limits the exception to the use on board vessels of means which are the subject of the patent in the body of the vessel, and also to the use of the means that are the subject of the patent in the construction or operation of aircraft or land vehicles, or accessories of such vehicles.....

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

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

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

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Section VII: Acts for obtaining regulatory approval from authorities

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

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Article L613-5(d) of the CPI states: "The rights conferred by the patent shall not extend to the studies and tests required with a view to obtaining a marketing authorization for a medicine, or also to the acts necessary for them to be carried out or the authorization to be obtained.

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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:

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This exception aims to facilitate the marketing of generic medicines. This exception allows generic medicine industries to begin the procedure with a view to a marketing authorization involving, *inter alia*, clinical trials without waiting for the monopoly on the patented product to expire. However, the working of generic medicines may only occur once the period of patent protection has expired.
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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

The person requesting the marketing authorization.
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55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products: 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: Studies and tests with a view to obtaining a marketing authorization and acts necessary for producing and obtaining the marketing authorization.....

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:

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

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Section VIII: Exhaustion of patent rights

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

- National
- Regional (European Economic Area)
- International
- Uncertain, please explain.....

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

Article L613-6 of the CPI specifies that “the rights conferred by the patent shall not extend to the acts concerning the product covered by the patent, performed on French territory, after the product has been commercialized in France or on the territory of a State party to the Agreement on the European Economic Area by the patent owner or with his express consent”.

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

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

The exercise of the right in patents is restricted for the sake of the free circulation of goods on the territory of the European Union (EU). Once the owner of a patent has placed in circulation the product patented on the territory of one of the EU countries, he can no longer oppose the circulation of this product on the territory of the other countries of the EU by invoking the rights he holds in such 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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62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- Yes
- No
- Uncertain

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

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

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

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Section IX: Compulsory licenses and/or government use

Compulsory licenses

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

Article L613-11 of the CPI states that: “any public or private legal person may, upon expiry of a period of three years following the grant of a patent, or four years from the application filing date, obtain a compulsory license for the patent, subject to the conditions provided in the following articles, if at the time of the request, and in the absence of legitimate reasons, the patent owner or his successor in title: (a) has not begun to work or make effective and serious preparations to work the invention which is the subject of the patent on the territory of a Member State of the European Economic Community or of another State party to the Agreement on the European Economic Area; (b) has not marketed the product which is the subject of the patent in sufficient quantity to satisfy the needs of the French market. The same is true when the working provided for in (a) above or the marketing provided for in (b) above has been abandoned for more than three years. For the application of this Article, the import of products that are the

subject of patents manufactured in a State party to the Agreement Establishing the World Trade Organization shall be considered working of the patent”.

Article L613-15 of the CPI states that: “the owner of a patent infringing an earlier patent may not work his patent without the authorization of the owner of the earlier patent; that owner may not work the later patent without the authorization of the owner of the later patent. Where the owner of a patent may not work it without infringing an earlier patent owned by a third party, the Regional Court may grant him a license to work the earlier patent to the extent necessary for working the patent of which he is the owner and insofar as this invention represents, in relation to the earlier patent, significant technical progress and is of considerable economic interest. The license granted to the owner of the later patent may be transferred only with that patent”.

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Article L613-16 of the CPI states that: “If the interest of public health so requires and in the absence of an amicable agreement with the patent owner, the Minister for Industrial Property may, at the request of the Minister for Public Health, subject, by decree, to the *ex officio* license regime, under the conditions specified in Article L613-17, any patent granted for: (a) a medicine, medical device, an *in vitro* medical diagnostic device, or a related therapeutic product; (b) the process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product; (c) an *ex vivo* diagnostic method. The patents for these products, processes or methods of diagnosis may be subject to the *ex officio* license regime in the interest of public health only when these products, or products resulting from these processes, or these methods are made available to the public in an insufficient quantity or quality, or at abnormally high prices, or when the patent is worked in conditions contrary to the interest of public health, or constituting anti-competitive practices following an administrative or court decision made final. Where the license aims to remedy a practice declared anti-competitive or in case of emergency, the Minister for Industrial Property shall not be obliged to seek an amicable agreement”.

Article L613-19 of the CPI states that: “the State may obtain, *ex officio*, at any time, for the needs of national defense, a license to work an invention which is the subject of a patent application or of a patent, whether this working is done by the State itself or on its behalf.”

Article L613-19-1 specifies that: “If the subject of the patent is an invention in the field of semi-conductor technology, a compulsory or *ex officio* license may be granted only for a use for public non-commercial purposes or to remedy a practice declared anti-competitive following court or administrative proceedings”.

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: needs of the national economy

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

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The patentee's monopoly may be restricted by economic or social imperatives of general interest, which are considered more important.....
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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):

.....
No legal definition.
.....

70. Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

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In accordance with French legislation, the import of a patented product or a product manufactured using a patented process constitutes an act of "working" of the patent (see Article L613-3 of the aforementioned CPI in question 2). As a result, the grant of compulsory licenses for "non-working" or "insufficient working" cannot be obtained in the case of import of a patented product or a product manufactured using a patented process.
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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? Three years after the grant of a patent, or four years from the application filing date.

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"? No legal definition.....

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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In French patent legislation, two provisions envisage the possibility of granting compulsory licenses to combat anti-competitive uses:

.....
The first provision envisages *ex officio* licenses in the interest of national public health, declared by decree of the Minister for Intellectual Property for a number of patents (in particular medicines, medical equipment, production or manufacturing processes) on the assumption that the patent is worked in conditions considered to constitute anti-competitive practices. Article L613-16 of the CIP specifies that:
"If the interest of public health so requires and in the absence of an amicable agreement with the patent owner, the Minister for Industrial Property may, at the request of the Minister for Public Health, subject, by decree, to the ex officio license regime, under the conditions specified in Article L613-17, any patent granted for: (a) a medicine, medical device, an in vitro medical diagnostic device, or a related therapeutic product; (b) the process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product; (c) an ex vivo diagnostic method. The patents for these products, processes or methods of diagnosis may be subject to the ex officio license regime in the interest of public health only when these products, or products resulting from these processes, or these methods are made available to the public in an insufficient quantity or quality, or at abnormally high prices, or when the patent is worked in conditions contrary to the interest of public health, or constituting anti-competitive practices following an administrative or court decision made final. Where the license aims to remedy a practice declared anti-competitive or in case of emergency, the Minister for Intellectual Property shall not be obliged to seek an amicable agreement"

The second provision applies specifically to patents relating to an invention in the field of semi-conductor technology and states that an *ex officio* license may be granted to remedy practices declared to be anti-competitive following administrative or court proceedings. Article L613-19-1 states that *"If the subject matter of the patent is an invention in the field of semi-conductor technology, a compulsory or ex officio license may*

be granted only for a use for public non-commercial purposes or to remedy a practice declared anti-competitive following court or administrative proceedings”.

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 L613-15 of the CPI states that: “the owner of a patent infringing an earlier patent may not work his patent without the authorization of the owner of the earlier patent; that owner may not work the later patent without the authorization of the owner of the later patent. Where the owner of a patent may not work it without infringing an earlier patent owned by a third party, the Regional Court may grant him a license to work the earlier patent to the extent necessary for working the patent of which he is the owner and insofar as this invention represents, in relation to the earlier patent, significant technical progress and is of considerable economic interest. The license granted to the owner of the later patent may be transferred only with that patent”.

.....
.....

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

.....
No.
.....

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:

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

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

.....
According to the information available, no case relating to public health has been recorded.....
.....

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:

.....
In France, recourse is very rarely had to compulsory license mechanisms. The existing provisions appear to be satisfactory.....
.....

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

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

Government use

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

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

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

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

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: national defense

.....

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

.....

These provisions refer to cases where:

- the working of the patent would be contrary to the interest of public health (products which are not made available to the public in a reasonable quantity, prices too high);
- the working of the patent would be contrary to the interest of the national economy.

.....

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

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

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:

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

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

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

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:

.....
No amendments to legislation are envisaged.
.....

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 L613-5-1 of the CPI states that: "By way of exception to the provisions of Articles L613-2-2 and L613-2-3, the sale or any other act of marketing of plant reproduction material by the patent owner, or with his consent, to a farmer for agricultural working purposes implies for the farmer authorization to use the product of his harvest for reproduction or propagation by himself on his own holding. The conditions of such use shall be those which are provided for in Article 14 of Council Regulation (EC) No 2100/94 of July 27, 1994 on Community plant variety rights".

Article L613-5-2 of the CPI states that: "By way of exception to the provisions of Articles L613-2-2 and L-613-2-3, the sale or any other act of marketing of breeding animals or animal reproduction material by the patent owner, or with his consent, to a farmer, implies for the farmer authorization to use, where appropriate for remuneration, protected livestock for an agricultural use. This authorization shall involve making the animal or animal reproduction material available for the continuation of his agricultural activity, but shall exclude sale as part of a commercial reproduction activity".

Article L613-5-3 of the CPI states that: “The rights conferred by Articles L613-2-2 and L613-2-3 shall not extend to the acts performed with a view to creating or discovering and developing other plant varieties”.

.....

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

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

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

.....
Articles L613-5-1 and L613-5-2 of the CPI introduce into patent law the “farmer or breeder’s privilege”, which constitutes the rule linking the monopoly and the plant and animal reproduction laws. This provision allows farmers to re-use, on certain conditions, the product of the harvest from protected seeds, without infringing the right in a patent or in a plant breeder’s certificate.....

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

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

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

.....
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.....

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

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

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:

.....
.....

.....
Breeders' use of patented inventions

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

.....
Article L623-25(2) of the CPI states that: "Subject to the provisions of Article L623-4, the use of the variety protected as a source of initial variation with a view to obtaining a new variety shall not constitute an infringement of the rights of the owner of a breeder's certificate".

Article L623-4 of the CPI states that: "Any plant variety may be the subject of a title called "plant variety certificate", which shall confer on its owner an exclusive right to produce, introduce into the territory where this chapter applies, sell or offer for sale any or part of the plant, or all elements of plant reproduction or propagation of the variety under consideration and the varieties resulting therefrom by means of hybridization where their reproduction requires the repeated use of the initial variety. State Council decrees shall make the provisions of the previous paragraph gradually applicable to the different plant species, depending on the development of scientific knowledge and means of control. The same decrees shall determine, for each of the plant species, the elements of the plant to which the breeder's right relates".

Article L613-15-1 of the CPI states that "Where a breeder may not obtain or work a plant breeder's right without infringing an earlier patent, he may request the grant of a license for this patent to the extent that this license is required for working the plant variety to be protected and insofar as the variety constitutes, in relation to the invention claimed in this patent, significant technical progress and is of considerable economic interest. Where such a license is granted, the patent owner shall obtain, on equitable conditions, on a request submitted to the court, the grant of a reciprocal license for using the protected variety. The provisions of Articles L613-12 to L613-14 shall apply".

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

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

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

.....
Article L613-15-1 introduces a compulsory license procedure, as an exception to the patent monopoly, with a view to encouraging patent owners to grant a license voluntarily.
.....

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

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

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):

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

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:

.....
The implementation of the compulsory license provided for in Article L613-15-1 is exceptional.....
.....

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:

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

Section XI: Other Exceptions and Limitations

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

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.....
.....

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

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

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

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

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.....
.....

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

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.....

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

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

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

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

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.....
.....

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

.....
National and European competition law sanctions the misuse of IP rights, as soon as such use is likely to be covered by the provisions relating to anti-competitive practices, in particular as part of unlawful agreements and abuse of dominant position.
.....

[End of Questionnaire]