

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Romania

Office: State Office for Inventions and Trademarks.....

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Section I: General

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

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

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

According to the article 7 paragraph (1) of the Romanian Patent Law no. 64/1991 as republished in 2007, a patent shall be granted for any invention having as subject matter a product or a process, in any technological field, provided that it is new, involves an inventive step and is susceptible of industrial application.

The law includes provisions on biotechnological inventions in paragraph (2) of the same article:

Inventions in the field of biotechnology shall be patentable if they relate to:

- a) biological material which is isolated from its natural environment or produced by any technical process, even if it previously occurred in nature;
- b) plants or animals, if the technical feasibility of the invention is not limited to a particular plant variety or animal breed;
- c) a microbiological process or other technical process or a product, other than a plant variety or animal breed, obtained by means of said process;
- d) an element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.

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Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.¹

Articles 8 and 9 of the law provide the exclusions and exceptions from patentability:

Art. 8 - The following in particular shall not be considered as inventions, within the meaning of Art. 7:

- a) discoveries, scientific theories and mathematic methods;
- b) aesthetic creations;
- c) schemes, rules and methods for performing mental acts, playing games or doing business, as well as computer programs;
- d) presentations of information.

The provisions of paragraph 1 shall exclude the patentability of the subject-matters or activities referred to therein, only to the extent to which the patent application or patent relates to such subject-matter or activities as such.

Art. 9 - Patents shall not be granted under this Law in respect of:

- a) inventions the exploitation of which would be contrary to public order or morality, including inventions harmful to the health or life of persons, animals or plants, and which are likely to seriously harm the environment, provided that such exception from patentability shall not depend merely on the fact that exploitation is prohibited by a legal provision;
- b) plant varieties and animal breeds, as well as the essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes or products obtained thereby;
- c) the inventions having as a subject-matter the human body in its various stages of formation and development, as well as the mere discovery of one of its elements, including the sequence or partial sequence of a gene;
- d) methods of treatment concerning the human or animal body, by surgery or therapy and methods of diagnosis applied to human or animal body.

The provisions of paragraph 1 d) shall not apply to products, in particular substances or compositions to be used in any such method.

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

The article 32 of the law provides the exclusive rights granted with a patent:
Art. 32 (1) The patent shall confer on its owner an exclusive right of exploitation throughout its entire duration.

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

It is prohibited to perform the following acts without the owner's consent:
a) manufacturing, using, offering for sale, selling or importing for the purpose of using, offering for sale or selling, where the subject-matter of the patent is a product;

b) using the process and using, offering for sale, selling or importing for those purposes the product directly obtained by the patented process, where the subject-matter of the patent is a process.

In addition, the publication of the patent application accords provisional the same exclusive rights to the patent applicant, pursuant to article 33 of the law.

Art. 33 Starting from the date of its publication under Art. 23, paragraphs 1-3, the patent application shall provisionally confer on the applicant the protection laid down in Art. 32.

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3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- X Private and/or non-commercial use;
- X Experimental use and/or scientific research;
- Preparation of medicines;²
- X Prior use;
- X Use of articles on foreign vessels, aircrafts and land vehicles;
- Acts for obtaining regulatory approval from authorities;
- X Exhaustion of patent rights;
- X Compulsory licensing and/or government use;
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³

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

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

Section II: Private and/or non-commercial use

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

Art. 34 - The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

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).

c) performing any of the acts referred to in Art. 32, paragraph 2 exclusively privately and for non-commercial purposes; production or, as the case may be, use the invention exclusively privately 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?

Inventions might be created for improvement of private life, but their commercialization is up to their creator. Patents shall not intervene in private life.

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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):

These terms are not defined in the law

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

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

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

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Section III: Experimental use and/or scientific research ⁴

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

Art. 34 - The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

e) use of the subject-matter of the patented invention for exclusively non-commercial experimental purposes.....

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

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

The public policy encourages innovation and technological progress by means of the patents. Especially for research and development, the effects of the patent do not extend to acts done for experimental purposes.

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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.

The Romanian law does not provide any distinction in the limitation of the effects of patents for acts done for experimental purposes. Consequently, *ubi lex non distinguit nec nos distinguere debemus*.

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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):

These definitions are not provided in the patent law.
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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 or relating to the patented invention (“research on”)
- Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- Both of the above

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

. The exception is related to the experimental use, of the subject matter of the patented invention
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18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

- A non-commercial purpose
- A commercial purpose
- Both of the above
- The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

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

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

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

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Section IV: Preparation of medicines

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

The exception is not provided in the law.....
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24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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

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

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

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

- Yes
- No

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

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

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

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

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Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):
Art. 34 - The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

b) performing any of the acts referred to in Art. 32, paragraph 2 by a person who has applied the subject-matter of the patent or that of the patent application, as published, or has taken real and effective steps towards producing or exploiting said subject-matter in good faith on the territory of Romania, independently of the owner of the patent and before the regular national filing concerning the invention has been effected or before the recognized priority date; in that case the invention may continue to be exploited

by that person to the same extent as on the date of the regular national filing or recognized priority, but the right of use may not be transferred otherwise than with the assets of that person or the part of the said assets assigned to the exploitation of the invention.

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

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

The provision is intended to protect the investments of a person done in good faith on the territory of Romania and to avoid the abuse of right.....

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

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34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

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The Patent Law provides only that the invention may continue to be exploited by that person to the same extent as on the date of the regular national filing or recognized priority.
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35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

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

Yes
 No

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

Yes
 No

If yes, please explain what those conditions are:

The right of use may not be transferred otherwise than with the assets of that person or the part of the said assets assigned to the exploitation of the invention. That means a transfer with the business. Although the law provides for the transfer of rights, the meaning of the transfer is restricted only to the assignment and inheritance.....
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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:

There is another provision in the law for this exception:

Art. 34 - The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

f) exploitation in good faith or taking real and effective steps towards exploiting the invention by third parties in the interval between the patent owner’s loss of rights and the reinstatement of the patent; in that case, the invention may continue to be exploited by that person to the same extent as on the date of publication of the mention of reestablishment of rights, but the right of use may

not be transferred otherwise than with the assets of the person exploiting the invention or the part of said assets assigned to the exploitation of the invention;

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

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

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

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

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

Art. 34 - The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

a) exploitation of inventions in the construction and the operation of land vehicles or aircrafts and aboard vessels or in devices used in the operation thereof that belong to States party to international treaties and conventions concerning inventions to which Romania is also a party, when the vehicles, crafts or vessels enter the territory of Romania, either temporarily or accidentally, provided that such exploitation is exclusively for the needs of the vehicles, crafts or vessels;

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

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44. (a) What are the public policy objectives for providing the exception? Please explain:
The provision in the Romanian patent law corresponds to the provision under Art. 5ter of the Paris Convention for the Protection of Industrial Property. The protection of the international traffic from against claiming patent rights is envisaged.

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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:

- X Vessels
- X Aircrafts
- X Land Vehicles
- Spacecraft

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

The applicable law applies the terms "temporarily and accidentally", but the definition thereof is not provided in the legal provisions.

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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):

The provision in the Patent law explicitly stipulates that the subject matter of the patented invention is used exclusively for the needs of the vessel.

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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):

There is no express provision in the Romanian Patent law in relation with acts for obtaining regulatory approval from authorities. In the case of obtaining an authorization to put a medicine or a plant protection product on the market the exception is applied.

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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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(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:

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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):
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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 (EU and EEA)
 - International
 - Uncertain, please explain.....

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

Art. 34 - The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

d) marketing or offering for sale within the territory of the European Union of specimens of the product constituting the subject-matter of the invention that have been previously sold 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 interest of the free movement of goods and trade.

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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):

Art. 46 - Upon request by any interested person, the Court of Bucharest may grant a compulsory license after 4 years have elapsed from the patent application filing date or after 3 years have elapsed from the grant of the patent, whichever period expires later.

The provisions of paragraph 1 shall only apply where the invention has not been exploited or has been insufficiently exploited on the territory of Romania, and the patent owner cannot justify his inaction and where no agreement has been reached with him regarding the conditions and commercial methods for applying the invention.

The Court of Bucharest shall authorize the compulsory license, provided that it considers, based on given circumstances, that, in spite of all efforts made by the interested person, no agreement could be reached within a reasonable time period.

Besides the cases referred to in paragraph 2, a compulsory license may be authorized by the Court of Bucharest:

- a) in national emergency cases;
- b) in other cases of extreme emergency;
- c) in cases of public use for non-commercial purposes.

The grant of the compulsory license, for one of the reasons provided under paragraph 4, shall not require the fulfilment of the conditions mentioned under paragraph 2. Nevertheless, the licensee shall inform the applicant or patent owner about the authorization given by the Court, within the shortest delay.

In cases of public use for non-commercial purposes, the Government or third parties authorized by the Government, if they know or have demonstrable reasons to know that a valid patent is or will be used by the Government or the third parties, shall inform the patent owner accordingly, within a reasonable time.

In cases where a patent cannot be exploited without infringing the rights conferred by other patent granted for an application having a prior regular national filing date, a compulsory license for exploiting the second patent may only be authorized if the following additional conditions are cumulatively fulfilled:

- a) the invention claimed in the second patent involves an important technical advance of considerable economic significance as compared with the invention in the first patent;
- b) the owner of the first patent is entitled to a cross-license on reasonable terms for using the invention claimed in the second patent;
- c) the use authorized in respect of the first patent shall be non-transferable, except for the transfer of the second patent.

Art. 47 - Compulsory licenses shall be non-exclusive and shall be granted by the Court of Bucharest, under specific conditions regarding their extent and duration, as well as the amount of royalties to which the right holder is entitled, established in accordance to the commercial value of the granted licenses.

Beneficiaries of the compulsory license can also be the Government or third parties authorized by the Government.

Compulsory licenses shall be authorized mainly for supplying the market.

The extent and duration of compulsory licenses shall be limited to the purposes for which they have been authorized. In case of the inventions in the semiconductor technology field, the license shall be granted only for public non-

commercial purposes or to remedy a practice declared as anti-competitive, as a result of a judiciary or administrative procedure.

When the owner of a plant variety patent cannot exploit the patent without infringing a prior patent, he may request a compulsory license for the invention protected by said patent.

When the owner of a patent relating to a biotechnological invention cannot exploit the patent without infringing a prior plant variety patent, he may request a compulsory license for the exploitation of the plant variety protected by said patent.

Where a compulsory license is authorized for remedying an anti-competitive practice, the provisions of Art. 46, paragraphs 3 and 4 and Art. 47, paragraph 3 shall not be applicable.

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

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

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

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

To protect the public against the abuse of exclusive right of the patent owner

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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):

The definition of the terms is not provided but the Patent law provides that that the invention has not been exploited or has been not enough exploited in Romania and the patent owner cannot justify his inaction and where no agreement has been reached with him regarding the conditions and commercial methods for applying the invention.

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

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

Yes
 No

If yes, what is the time period? After 4 years have elapsed from the patent application filing date or after 3 years have elapsed from the grant of the patent, whichever period expires later.

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

Yes
 No But the patent owner can justify his inaction in front of the Court, and the Court may decide upon its legitimacy.

If yes, what are “legitimate reasons”?

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

See answer no. 71

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 law does not provide for explicitly, but the Court may decide on the existence of an anti-competitive practice and may grant a compulsory license.

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75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

According to article 46 paragraph (7) and to article 47 paragraphs (5) and (6):

Art. 46 (7) In cases where a patent cannot be exploited without infringing the rights conferred by other patent granted for an application having a prior regular national filing date, a compulsory license for exploiting the second patent may only be authorized if the following additional conditions are cumulatively fulfilled:

- a) the invention claimed in the second patent involves an important technical advance of considerable economic significance as compared with the invention in the first patent;
- b) the owner of the first patent is entitled to a cross-license on reasonable terms for using the invention claimed in the second patent;
- c) the use authorized in respect of the first patent shall be non-transferable, except for the transfer of the second patent.

Art. 47

(5) When the owner of a plant variety patent cannot exploit the patent without infringing a prior patent, he may request a compulsory license for the invention protected by said patent.

(6) When the owner of a patent relating to a biotechnological invention cannot exploit the patent without infringing a prior plant variety patent, he may request a compulsory license for the exploitation of the plant variety protected by said patent.

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

Compulsory licenses shall be non-exclusive and shall be granted by the Court of Bucharest, under specific conditions regarding their extent and duration, as well as the amount of royalties to which the right holder is entitled, established in accordance to the commercial value of the granted licenses.

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

Yes, the law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, but the terms are not defined in the patent law.

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

As far as the State Office for Inventions and Trademarks knows, there have been issued no compulsory licenses in Romania up to now.

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

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

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Government use

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

The law provides for that beneficiaries of the compulsory license can also be the Government or third parties authorized by the Government

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

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.....

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

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security

National emergency and/or extreme urgency
Dependent patents
Other, please specify:

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

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.....
.....

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

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.....

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

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

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

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

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

Farmers' use of patented inventions

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

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

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

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.....

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

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.....

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

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

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

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.....

Breeders' use of patented inventions

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

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

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.....

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

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.....

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

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.....

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

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

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

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Section XI: Other Exceptions and Limitations

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

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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):

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.....

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

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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?):

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- (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:

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[End of Questionnaire]