

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: *Republic of Moldova*

Office: *The State Agency on Intellectual Property*

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Section I: General

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

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

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

Law on the protection of inventions No. 50/2008 of the Republic of Moldova can be found at: http://www.agepi.md/pdf/lege/lege-prot-inv_en.pdf

According to the Art.6 of the national Law 50/2008 on the protection of inventions:

(1) A patent shall be granted for any invention having as subject a product or a process, in all fields of technology, provided that such invention is new, involves an inventive step and is susceptible of industrial application.

(4) Inventions in the field of biotechnology shall be deemed patentable if they concern:

a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

- b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;*
- c) a microbiological process or other technical process, or a product obtained by means of such a process other than a plant or animal variety;*
- d) an element isolated from the human body or otherwise produced by means of 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.*

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

According to the Art.6 of the national Law 50/2008 on the protection of inventions:

(2) The following shall not be regarded as inventions within the meaning of paragraph (1):

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

(3) The provisions of paragraph (2) shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a patent application or patent relates to such subject-matter or activities as such.

According to the Art.7 (1) of the national Law 50/2008 on the protection of inventions patents shall not be granted in respect of:

- a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, including those harmful for human, animal or plant life or health, and which are likely to cause serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by a clause;*
- b) plant or animal varieties;*
- c) essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;*
- d) inventions concerning the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;*

(2) Patents shall not be granted within the meaning of paragraph 1(a) in respect of biotechnological inventions which, in particular, concern the following:

- a) processes for cloning human beings;*

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

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

Article 12. Subject-Matter Protected by a Short-Term Patent for Invention

(1) A short-term patent for invention shall be granted for any invention which is new, involves an inventive step and is susceptible of industrial application.

(2) An invention shall be considered as involving an inventive step within the meaning of paragraph (1) if it gives a technical or practical advantage.

(3) Additionally to Article 7, short-term patents for invention shall not be granted in respect of inventions concerning:

- a) biological material;*
- b) chemical or pharmaceutical substances and/or processes.*

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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?

According to the Art.20 of the Law 50/2008 on the protection of inventions

(1) A patent shall confer on its owner an exclusive right to exploit the invention for the entire term thereof.

(2) The patent shall confer on its owner, in accordance with paragraph (1), the right to prevent third parties from performing, without his authorization, on the territory of the Republic of Moldova, the following acts:

- a) manufacture, offering for sale, selling, use, importing or stocking for these purposes of the protected product;*
- b) the using of a process which is the subject-matter of the patent or, where the third party knows, or it is obvious in the circumstances, that the process cannot be used without the consent of the patent owner, offering of the process for use;*
- c) offering for sale, selling, use, importing or stocking for such purposes of the product obtained directly by a process which is the subject-matter of the patent.*

According to the Article 21 "Prohibition of Indirect Exploitation of an Invention" of the Law 50/2008 on the protection of inventions

(1) A patent shall confer on its owner, in addition to the right conferred in accordance with Article 20, the right to prevent third parties not having his consent from supplying or offering to supply, on the territory of the Republic of Moldova, a person, other than a party entitled to exploit the patented invention, with means relating to an essential element of that invention, for carrying out the invention, when the third party knows, or it is obvious in the circumstances, that those means are suitable and intended for carrying out that invention.

(2) The provisions of paragraph (1) above shall not apply when the supplied or offered means are staple commercial products, except when the supplier or offerer deliberately incites his client to commit the acts prohibited by Article 20 paragraph (2).

(3) *Persons performing acts referred to in Article 22 paragraph (1) letter a) and b) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph (1) above.*

*According to the Art.19 of the Law 50/2008 on the protection of inventions
(1) A patent application shall, from the date of its publication and up to grant of the patent, provisionally confer upon the applicant the protection provided for by Article 20 paragraph (2).*

(2) Any natural or legal person who exploits the invention during the period referred to in paragraph (1) above shall be required, after grant of a patent, to pay a reasonable monetary compensation to the owner. The amount of such compensation shall be determined by agreement between the parties, taking account of the good faith of the person who exploited the invention, or by the court, where it cannot be determined by amicable arrangement.

(3) The effects of the patent application referred to in paragraph (1) shall be considered to be null and void when the patent application has been withdrawn by the applicant and when it has been withdrawn or refused in accordance with the provisions of this Law.

(4) The above provisions shall not apply to short-term patents.

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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;*
- X *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;*
- X *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):

*According to the Art. 22 of the Law 50/2008 on the protection of inventions
(1) The rights conferred by a patent shall not extend to:
a) acts done privately and on a non-commercial scale;
(2) The use referred to in paragraph (1) above shall be allowed, provided that it does not unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In the contrary case, the patent owner is entitled to an adequate compensation for the injury suffered because of the unauthorized exploitation of the invention.*

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

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

Do not restrict the private and non-commercial use of inventions in order to contribute to the dissemination of the patent information

The public policy objectives for providing the exception is to:

- 1. Promote research*
- 2. Avoid abuse of rights in cases of non-commercial (private) use*
- 3. Contribute to the dissemination of the patent information*
- 4. Provide a mechanism to use a patented invention in case that it is not utilized by the owner and the late refuses to grant a license*
- 5. Provide a mechanism to use a patented invention in force majeure situation which endanger public security and/or health.....*

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

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):

No applicable law defines the concepts “non-commercial”, “commercial” and/or “private” and there are no court decisions regarding this issue. However, in the case that national legislation does not contain certain provisions, general principles contained in international treaties will be applied. In that way, in ruling such a case a court would conduct itself by provisions of the TRIPS Agreement and Paris Convention for industrial property protection.....

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

No other criteria are provided in the applicable law. In the absence of such provisions, court will take into consideration any other acceptable legal sources in order to decide on a case regarding exceptions and limitations

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:

No amendments are foreseen

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

No challenges have been encountered as far as we know.....

Section III: Experimental use and/or scientific research ⁴

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

*According to the Art. 22 of the Law 50/2008 on the protection of inventions
(1) The rights conferred by a patent shall not extend to:
b) acts done for experimental purposes relating to the subject-matter of the patented invention;*

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

.....

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

Do not restrict scientists and researchers in using inventions in order to conduct researches and contribute to the dissemination of the patent information

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

.....

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

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

The applicable law does not make a distinction between persons conducting experimentation or research

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):

No applicable law defines the concepts "experimental use" and/or "scientific research" and there are no court decisions regarding this issue. However, in the case that national legislation does not contain certain provisions, general principles contained in international treaties will be applied. In that way, in ruling such a case a court would conduct itself by provisions of the TRIPS Agreement and Paris Convention for industrial property protection

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: *any actions which can be viewed as experimentation or research.....*

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")

X *Both of the above*

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

.....

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:

- X *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):

Applicable law does not contain definitions of those terms, as it is considered unnecessary in the case of commonly accepted meaning of a term.

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):

None.

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:

No amendments of the law are foreseen......

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

None

Section IV: Preparation of medicines

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

According to the Art. 22 of the Law 50/2008 on the protection of inventions:

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

c) extemporaneous preparation once-only, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;
.....

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

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

Do not restrict the use of medicine in individual cases in order to improve access to medicines.
.....

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

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

The pharmacists are entitled to use the exception.

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

X Yes
No

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

It must be an extemporaneous once-only preparation, in a pharmacy.

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):

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:

At the moment the applicable legal framework of the exception is considered adequate. No amendments to the law are foreseen

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

No challenges or court cases were registered in relation to the practical use of this exception.

Section V: Prior use

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

Art. 25 of the Law 50/2008 on the protection of inventions:

(1) Any person who in good faith, before the filing date, or, where priority is claimed, the priority date of the application on which the patent is granted and within the territory of the Republic of Moldova was using the invention or was making effective and serious preparations for such use, shall be personally entitled, for the purposes of his enterprise or business, to continue such use or to use the invention within the limits and/or extent envisaged in such preparations, without having to pay a royalty and on condition that he does not extend the volume of production existent or planned at the day of filing or of the priority.

(2) The right of prior user referred to in paragraph (1) may only be transferred during the user's lifetime or by hereditary or testamentary succession together with his enterprise or business, or with that part of his

enterprise or business in which the use or preparations for use have been made.

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

.....

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

The public policy objectives for providing the exception is to permit another person who independently developed the same invention as the invention protected by patent and started it's use prior to filling date of the patented invention to continue it's use in the same amount without paying royalty .

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

.....

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

The applicable law defines the scope of "use" for it's own enterprise/business. Also, the applicable law limits the use of the invention to the existing amount of production before the filling date or priority date or to the amount planned for which serious and real preparations were made.

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

No, it doesn't.

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

X 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?

X Yes
No

If yes, please explain what those conditions are:

According to the Art. 25(2) of the Law 50/2008 on the protection of inventions the right of prior user may only be transferred during the user's lifetime or by hereditary or testamentary succession together with his enterprise or business, or with that part of his enterprise or business in which the use or preparations for use have been made.

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?

X Yes
No

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

According to the Art. 92(5) of the Law 50/2008 on the protection of inventions any person who has in good faith used or made effective and serious preparations for using an invention which is the subject of a published patent application or a patent in the period between the loss of any patent rights and publication of the mention of re-establishment of those rights, may without payment of any compensation and within the limits of the existing volumes continue such use in the course of his business or for the needs thereof.....

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):
.....

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:

At the moment the applicable legal framework of the exception is considered adequate. No amendments to the law are foreseen

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

None.....

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):

According to the Art. 22 (1) d) e) of the Law 50/2008 on the protection of inventions:

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

d) use of the subject-matter of a patented invention on board of any foreign vessel of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party which temporarily or accidentally enters the waters of the Republic of Moldova, provided that the invention is used exclusively for the needs of the vessel;

e) use of the subject-matter of the patented invention in the construction or operation of foreign aircraft or land vehicle or other means of transport of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party, or in the manufacture of spare parts for such vehicles when such means of transport temporarily or accidentally enter the territory of the Republic of Moldova.

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

.....

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

The public policy objective for providing the exception was to exclude patent infringement cases when means of transport temporarily or accidentally enter the territory of the Republic of Moldova. Another public policy objective was to harmonize national legislation with international treaties in the field of intellectual property.

.....

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

.....

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):

Applicable law does not contain definitions of those terms, as it is considered unnecessary in the case of commonly accepted meaning of a term.

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):

According to the Art. 22 (1) d) e) of the Law 50/2008 on the protection of inventions the invention shall be used exclusively for the needs of the vessel;

According to the Art. 22 (2) of the Law 50/2008 on the protection of inventions the use shall be allowed, provided that it does not unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In the contrary case, the patent owner is entitled to an adequate compensation for the injury suffered because of the unauthorized exploitation of the invention.....

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):

.....

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:

At the moment the applicable legal framework of the exception is considered adequate. No amendments to the law are foreseen

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

None.....

Section VII: Acts for obtaining regulatory approval from authorities

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

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

.....

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

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

.....

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

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):

.....

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:

.....

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

.....

Section VIII: Exhaustion of patent rights

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

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

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

Article 23. Exhaustion of Rights

(1) The rights conferred by a patent shall not extend to acts concerning the patented product insofar as such acts are performed on the territory of the Republic of Moldova, after that product has been so put on the market in the Republic of Moldova by the patent owner or with his express consent.

(2) The protection referred to in Article 24 paragraphs (5) - (7) shall not extend to biological material obtained by propagation or multiplication of a biological material put on the market or offered for sale on the territory of the Republic of Moldova by the patent owner or with his consent, when the multiplication or propagation necessarily results from the use for which the biological material has been so put on the market, provided that the material obtained is not subsequently used for other propagation or multiplication.

(3) By way of derogation from Article 24 paragraphs (5) – (7), the sale or other form of commercialization of the plant propagating material to a farmer by the owner of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.

(4) By way of derogation from Article 24 paragraphs (5) – (7), the sale or other form of commercialization of breeding stock or other animal reproductive material to a farmer by the owner of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose, with the exception of breeding holdings; this includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity.

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

.....

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

Do not restrict the use of inventions that are on the market in order to contribute to the dissemination of the information about patented product

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

.....

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):

.....

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

.....

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

.....

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 28. Compulsory License

(1) If after the expiration of a period of 4 years from the day of filing of the patent application or 3 years from the grant of the patent, whichever is later, the patent owner has not exploited the patent in the territory of the Republic of Moldova or if he has not undertaken serious and effective preparations for such purpose, the courts may grant a compulsory license, on request, to any interested person. No distinction shall be made between the domestic products or imported products for the purposes of establishing the fact of the lack of exploitation or insufficient exploitation of the patent.

(2) A compulsory license shall be granted solely where the proposed user has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived in the cases

referred to in paragraph (3) below. In such cases, the patent owner shall be notified as soon as reasonable practicable.

(3) A compulsory license may be granted in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

(4) In the case of semiconductor technology, a compulsory license may only be granted for public non-commercial use or to remedy a practice, determined after judicial or administrative process to be anti-competitive.

(5) A compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

(6) The respective methods and procedures for the implementation of principles contained in this article are laid down in the Regulations.

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

-
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:

- 1. Unblock the use of an invention in case that there's real and reasonable interest from third parties to use the invention, and the patent holder groundlessly refuses to grant a license and doesn't use the invention himself.*
 - 2. Public interest in case of national emergency or other circumstances of extreme urgency, especially cases concerning public health.*
 - 3. Cross license in cases of dependent patents directly linked to obtain a better technical result*
-

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

.....

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):

.....

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):

.....

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 the expiration of a period of 4 years from the day of filing of the patent application or 3 years from the grant of the patent, whichever is later.

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

Yes
 No

If yes, what are “legitimate reasons”?

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):

.....

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):

According to the Art. 28(4) of the Law 50/2008 on the protection of inventions, in the case of semiconductor technology, a compulsory license may only be granted for public non-commercial use or to remedy a practice, determined after judicial or administrative process to be anti-competitive.....

According to the Art. 29(1) of the Law 50/2008 on the protection of inventions, at the time of grant of a compulsory license to exploit the patent under Article 28 above, the court shall specify the types of use covered by such license and the terms and conditions to be observed. The following conditions shall apply:

d) any such use shall be authorized predominantly for the supply of the domestic market, except where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive;

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 the Art. 28 of the Law 50/2008 on the protection of inventions a compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

.....

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:

According to the Art. 29 of the Law 50/2008 on the protection of inventions the license holder shall pay the patent owner an adequate remuneration, taking into account the economic value of the authorization and, eventually, the need to remedy an anti-competitive practice.

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:

According to the Art.1(2) of the Law 93/2007 on Civil Protection Service and Extreme Situations, extreme situation is defined as interruption of normal life and activity of the population at an objective or in a region as a result of accidents, disasters, natural or socio-biological calamities which resulted or could result with human and economic losses.

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

Compulsory licenses have never been issued in our country.....

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:

At the moment legal framework for the issuance of compulsory licenses is considered adequate to meet the objectives sought. However, in the light of the new TRIPS provisions (art.31bis) will be necessary to amend national legislation in order to meet new TRIPS standards laid down in art.31bis

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):

There aren't separate provisions on Government use. However, compulsory license can be issued including to the government.

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:

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

.....

(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:

.....

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

.....

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):

According to the Art. 23(3) of the Law 50/2008 on the protection of inventions, the sale or other form of commercialization of the plant propagating material to a farmer by the owner of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.

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:

Do not restrict the use of inventions by farmers

(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):

.....

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):

According to the Art. 23(2) of the Law 50/2008 on the protection of inventions, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not

extend to biological material obtained by propagation or multiplication of a biological material put on the market or offered for sale on the territory of the Republic of Moldova by the patent owner or with his consent, when the multiplication or propagation necessarily results from the use for which the biological material has been so put on the market, provided that the material obtained is not subsequently used for other propagation or multiplication.....

According to the Art. 28(5) of the Law 50/2008 on the protection of inventions, a compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

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:

Do not restrict the use of inventions for breeding purposes

(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:
.....
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:

.....
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:
.....

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

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

(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:
.....

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:
.....

[End of Questionnaire]