

Section 1: General

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

The Law on Inventions, Utility model Registration (LPUMR); Art. 6. (1) Patents shall be granted for inventions in any field of technology, which are new, involve an inventive step and are susceptible of industrial application.

Art. 6. (2) The following shall not be regarded as inventions:

- 1. discoveries, scientific theories and mathematical methods;*
- 2. artistic work results;*
- 3. schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers;*
- 4. presentation of information.*

(3) The provisions of paragraph (2) shall apply to the subject matter referred to only to the extent that legal protection is sought for the subject matter as such.

(4) The human body at the different stages of its formation and development, as well as the mere discovery of an element thereof, including the sequence or partial sequence of a gene, may not represent a patentable invention. An element isolated from the human body or otherwise obtained through a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of such element is identical with 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

The Law on Inventions, Utility model Registration (LPUMR), Art. 7 Patents shall not be granted for:

- 1. inventions the commercial use of which would be contrary to social order or morality, including:*
 - (a) methods of cloning human beings;*
 - (b) methods of altering the genetic identity of human embryo;*
 - (c) use of human embryos for industrial or commercial purposes;*
 - (d) methods of modifying the genetic identity of animals, where this may cause them suffering without any substantial use from a medical point of view for humans or animals, as well as of animals obtained by such methods;*
 - 2. methods for treatment of the human or animal body by therapy or surgery, as well as diagnostic methods practised on the human or animal body. This shall not apply to products, in particular substances or compositions, for use in any of these methods;*
 - 3. plant or animal varieties;*
 - 4. essentially biological processes for obtaining plants and animals.*
- (2) The use referred to in paragraph (1) shall not be deemed to be so contrary merely because it is prohibited by legislation.*

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 Law on Inventions, Utility model Registration (LPUMR), Art. 19. (1) The exclusive right in an invention shall comprise the right to use the invention, the right to prohibit other persons from using it without the consent of the owner of the patent and the right to dispose of the patent.

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

Art. 18. (1) *Provisional protection shall subsist for the period from the publication of a mention of the application up to the publication of a mention of the grant of a patent; the scope of such protection shall be defined by the claims as formulated in the application.*

(2) *The protection referred to in paragraph (1) shall have a retroactive effect as from the publication of the mention of the patent grant, in so far as the patent does not extend it.*

(3) *The applicant shall have the right to equitable remuneration to be paid by any person who without his authorization has performed any of the acts referred to in Article 19(3) during the period of provisional protection, provided that a patent is granted for the invention concerned.*

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

Private and/or non-commercial use;

Experimental use and/or scientific research;

Preparation of medicines;²

Prior use;

Use of articles on foreign vessels, aircrafts and land vehicles;

Acts for obtaining regulatory approval from authorities;

Exhaustion of patent rights;

Compulsory licensing and/or government use;

Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³

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

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

Section 2: Private and/or non-commercial use

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

The Law on Inventions, Utility model Registration (LPUMR), Art. 20, item 1,

The effect on patent shall not extend on use of the patented invention for non-commercial use with a view to private needs, where such use does not cause significant material prejudice to the owner of the patent

5.-10.

[Note from the Secretariat: response was not provided]

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).

Section 3: Experimental use and/or scientific research ⁴

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

The Law on Inventions, Utility model Registration (LPUMR), Art. 20, item 2, The effect on patent shall not extend on use of the invention for experimental or research and development purposes relating to the to the subject matter of the patented invention

12.-19.

[Note from the Secretariat: response was not provided]

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

The Law on Inventions, Utility model Registration (LPUMR), Art. 2, item 7 conduction of necessary researches and tests for the purpose of filing a marketing authorization request for a generic medical product to be used in the human medicine or a generic medical product to be used in the veterinary medicine, as well as any other act related to subsequent practical requirements in connection with the filing of the request.

21.-22.

[Note from the Secretariat: response was not provided]

Section 4: Preparation of medicines

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

The Law on Inventions, Utility model Registration (LPUMR), Art. 20, item 3, The effect on patent shall not extend on extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription

24.-26.

[Note from the Secretariat: response was not provided]

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

No

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

N/A

28.-30.

[Note from the Secretariat: response was not provided]

⁴ Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section 7 of the questionnaire.

Section 5: Prior use

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

*The Law on Inventions, Utility model Registration (LPUMR), Art. 21,
A person who, prior to the filing date of the patent application, has used the invention in good faith or has made the necessary preparations for its use may continue to use the invention after such date on condition that the volume remains the same*

32.-37.

[Note from the Secretariat: response was not provided]

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

Right of Subsequent Use: The Law on Inventions, Utility model Registration (LPUMR), Art. 22 A person who, after the lapse of a patent, has used the patented invention or has made the necessary preparations for such use may continue to use the invention in the same volume after renewal of the patent under Article 26(2).

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

The right of of subsequent use may be transferred only together with the enterprise or that part of the enterprise in which such rights have arisen and may be exercised, subject to there being no increase in the volume of such use outside the enterprise (Art.23)

39.-41.

[Note from the Secretariat: response was not provided]

Section 6: Use of articles on foreign vessels, aircrafts and land vehicles

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

*The Law on Inventions, Utility model Registration (LPUMR), Art. 20, item 6,
The effect on patent shall not extend to use of the patented invention on board any foreign land vehicle. Vessel or aircraft, which temporarily or accidentally enters the territory, waters or airspace of the country, provided that the patented invention is used exclusively for the needs of such means of transport*

43.-44.

[Note from the Secretariat: response was not provided]

45. The exception applies in relation to:

Vessels
Aircrafts
Vehicles

46.-50.

[Note from the Secretariat: response was not provided]

Section 7: Acts for obtaining regulatory approval from authorities

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

The Law on Inventions, Utility model Registration (LPUMR), Art. 20, item 7

Art. 20. The effect of a patent shall not extend to: conduction of necessary researches and tests for the purpose of filing a marketing authorization request for a generic medical product to be used in the human medicine or a generic medical product to be used in the veterinary medicine, as well as any other act related to subsequent practical requirements in connection with the filing of the request.

52.-59.

[Note from the Secretariat: response was not provided]

Section 8: Exhaustion of patent rights

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

Regional

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

Art. 20a. (1) (in force as from the date of accession of the Republic of Bulgaria to the European Union) The exclusive patent right in an invention shall not extend to acts relating to the product enjoying patent protection, where that product has been put on the market in the territory of the European Economic Area by the patent owner or with his consent.

(2) The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to biological material obtained through propagation or multiplication of biological material placed on the market by the patent owner or with his consent, where the multiplication or propagation is an indispensable result of the application for which the biological material is placed on the market, provided that the obtained material is not used later for further propagation or multiplication.

(3) The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to the sale or any other form of trading in plant propagation material performed by the patent owner or with his consent to an agricultural producer for agricultural purposes. The selling or any other form of trading comprises an authorization for the agricultural producer to use the product of his harvest for propagation or multiplication purposes in his farm.

(4) The procedure of applying paragraph (3) shall be specified in an ordinance of the Minister for Agriculture and Forestry.

(5) The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to the sale or any other form of trading in breeding stock or other animal reproduction material performed by the patent owner or with his consent to an agricultural producer, such sale comprising an authorization for the agricultural producer to use such stock or other animal reproduction material for the purposes of conducting his agricultural activity, but not to sell it within or for the purposes of commercial reproduction activity.

(6) The procedure of applying paragraph (5) shall be specified in an ordinance of the Minister for Agriculture and Forestry.

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

[Note from the Secretariat: response was not provided]

61.-64.

[Note from the Secretariat: response was not provided]

Section 9: Compulsory licenses and/or government use

Compulsory licenses

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

The Law on Inventions, Utility model Registration (LPUMR), Art. 32, Any person concerned, who has unsuccessfully tried to get a contractual license from the holder under fair conditions, may request the Patent Office to grant him a compulsory license to use the invention,

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

[Note from the Secretariat: response was not provided]

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

*Non-working or insufficient working of the patented invention
Public interest*

68.-70.

[Note from the Secretariat: response was not provided]

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

If yes, what is the time period?

Failure to use the invention for a period of four years from filing of the patent application or three years from the grant of a patent, the time limit which expires later being applicable;

72.-74.

[Note from the Secretariat: response was not provided]

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:

Art. 32 (4) A compulsory license may be granted to a holder, whose invention is the subject matter of a later patent and is included in the scope of another, earlier patent, if the owner of the earlier patent refuses to grant a license under fair conditions, where the subject matter of the later patent represents significant technical progress of great economic importance compared to the subject matter of the earlier patent. The owner of the earlier patent shall be entitled to a cross license under reasonable conditions for working the invention claimed in the later patent.

76.-79.

[Note from the Secretariat: response was not provided]

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.-88.

[Note from the Secretariat: response was not provided]

Section 10: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89.-91.

[Note from the Secretariat: response was not provided]

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

The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to the sale or any other form of trading in plant propagation material performed by the patent owner or with his consent to an agricultural producer for agricultural purposes. The selling or any other form of trading comprises an authorization for the agricultural producer to use the product of his harvest for propagation or multiplication purposes in his farm.

The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to the sale or any other form of trading in breeding stock or other animal reproduction material performed by the patent owner or with his consent to an agricultural producer, such sale comprising an authorization for the agricultural producer to use such stock or other animal reproduction material for the purposes of conducting his agricultural activity, but not to sell it within or for the purposes of commercial reproduction activity. (Art.20a (3) and (5))

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:

[Note from the Secretariat: response was not provided]

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):

Compulsory Cross-License

Art. 32a (1) Where a breeder cannot obtain or use the right in a plant variety without infringing an earlier patent, he may apply for a compulsory license for non-exclusive use of the invention enjoying patent protection, in so far as the license is required for using the plant variety for the purposes of its legal protection, subject to the payment of a respective remuneration. Where such a license is granted, the patent owner shall be entitled to a cross-license for using the protected plant variety under fair conditions. (2) Where the owner of a patent for a biotechnological invention cannot use it without infringing an earlier plant variety right, he may apply for a compulsory license for non-exclusive use of the protected plant variety, subject to the payment of a respective remuneration. Where such a license is granted, the

protected variety owner shall be entitled to get a cross-license for using the invention under fair conditions.

(3) The person applying for the grant of a compulsory license according to paragraphs (1) and (2) shall prove that:

- 1. he has tried unsuccessfully to get a contractual license from the patent or plant variety owner;*
- 2. the plant variety or the invention represents significant technical progress of great economic importance compared to the patented invention or the protected plant variety.*

96.-100.

[Note from the Secretariat: response was not provided]