

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **Bosnia and Herzegovina**
Office: **Institute for intellectual property of Bosnia and Herzegovina**

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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.

PATENT LAW (Official Gazette of Bosnia and Herzegovina No 53/10)

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 article 6 of the Patent Law:"The following, in particular, shall not be regarded as inventions

a) discoveries, scientific theories and mathematical methods, b) aesthetic creations, c) schemes, rules and methods for performing mental Acts, playing games or doing business, d) computer programmes, e) presentation of information defined by the content of such information itself."

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

According to article 7 of the Patent Law: "A patent shall not be granted for: a) inventions concerning animal breeds and plant varieties and essentially biological processes for the production plants or animals, with the exception of inventions which concern non-biological and microbiological processes and products resulting from such processes, whereby, a microbiological process shall imply any process which involves or which is performed upon microbiological material or which results in microbiological material. b) the human body, various stages of its formation and development or the simple discovery of one of its elements, including the sequence or partial sequence of a gene, c) inventions concerning diagnostic or surgical methods or methods of treatment which are practiced directly on the human or animal body, with the exception of the products, in particular substances and compositions used in such methods. Inventions shall not be regarded as patentable where their commercial exploitation would be contrary to public order or morality, but not merely because such exploitation is prohibited by law or other regulation. The following in particular shall be regarded as inventions contrary to public order or morality a) processes for cloning human beings, b) processes for modifying the germ line genetic identity of human beings, c) use of human embryos for industrial or commercial purposes and 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, as well as animals resulting from such processes."

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

According to article 3 of the Patent Law a economic rights of a patent holder shall include the exclusive right of economic exploitation of an invention and the right of disposal of it in accordance with the provisions of this Law.

Further, article 66 of the Patent Law determines the exclusive rights acquired by a patent, and article 67 of the Patent Law determines the exclusive rights acquired by a granted patent related to inventions in the field of biotechnology.

Article 66, paragraph (1) of the Patent Law:

(1) Any other person not having a patent holder's consent is prohibited from:

- a) making, offering for sale, selling, using, exporting or importing and storing for such purposes a product carried out according to a protected invention;**
- b) using a process which is the subject matter of a protected invention or offering the use thereof;**
- c) offering for sale, selling, using, exporting or importing and storing for such purposes a product obtained directly from a process which is the subject matter of a protected invention**

Article 66, paragraph (2) of the Patent Law: "Any other person not having a patent holder's consent is also prohibited from offering and supplying a product (substance, composition, a part of the apparatus) constituting an essential element of a protected invention to persons who are not entitled to exploit such an invention if the offerer or supplier knows or must have known from the circumstances of the case that such an invention is intended for putting into function the protected invention of another person."

Article 67, paragraph (1) of the Patent Law: "If a patent protected biological material possessing specific characteristics arising from such an invention is protected by patent, the exclusive rights referred to in paragraphs (1) and (2) of Article 66 of this Law shall also extend to any biological material derived from such a biological material by propagation or multiplication in the identical or divergent form with identical characteristics."

Article 67, paragraph (2) of the Patent Law: “If a patent protected process allowing for the production of a biological material possessing specific characteristics resulting from the invention is protected by a patent, the exclusive rights referred to in paragraphs (1) and (2) of Article 66 of this Law shall relate also to the biological material directly obtained by that process, as well as to any biological material derived from such a biological material by propagation or multiplication in the identical or divergent form with identical characteristics.”

Article 67, paragraph (3) of the Patent Law: “If a product containing or consisting of genetic information is protected by a patent, the exclusive rights referred to in paragraphs (1) and (2) of Article 66 of this Law shall also extend to the entire material in which such product is embedded and in which genetic information is contained and performs its function, with the exception of the human body, various stages of its formation and development or a simple discovery of one of its elements, including the sequence or partial sequence of a gene.”

With regard to the exclusive rights of the patent applicant, the Patent Law accords an exclusive right to the patent applicant if the patent application is published.

Article 69, paragraph (1) of the Patent Law determines the exclusive rights conferred by a patent application, in particular: “By the publication of a patent application in accordance with Article 37 of this Law, the patent applicant shall acquire provisional rights on the basis of which he may claim damages from any third party who has exploited the invention in the period between the date of publication of the patent application and the date of publication of the mention of the grant of the patent, contrary to Articles 66 and 67 of this Law, which could be prohibited after the patent grant.”

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;**
- Laws for obtaining regulatory approval from authorities;**
- Exhaustion of patent rights;**
- Compulsory licensing and/or government use;**
- Exceptions and limitations related to farmers’ and/or breeders’ use of patented inventions.³**

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

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

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

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

Section II: Private and/or non-commercial use

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

According to article 73, point (a) of the Patent Law the patent owner's exclusive right of exploitation of the invention shall not apply to Laws in which the invention is exploited for private and non-commercial purposes.

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

None

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

-

(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 definition

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):

None

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

Yes

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

None

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 article 73, point (b) of the Patent Law: “The patent owner’s exclusive right of exploitation of the invention shall not apply to acts performed for research and development purposes, and for experiments relating to the subject matter of the protected invention, including the acts necessary for obtaining registration or marketing authorization for the product which is a medicine intended for humans or animals or a medicinal product.

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

None

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

-

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

-

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:

No

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):

None

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:

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

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):

According to article 73, point (b) of the Patent Law: “The patent owner’s exclusive right of exploitation of the invention shall not apply to acts performed for research and development purposes, and for experiments relating to the subject matter of the protected invention, including the acts necessary for obtaining registration or marketing authorization for the product which is a medicine intended for humans or animals or a medicinal product.

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

x 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):

No distinction

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:

Yes

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 article 73, point (c) of the Patent Law the patent owner's exclusive right of exploitation of the invention shall not apply to direct or individual preparation of a medicine in a pharmacy on the basis of an individual medical prescription and procedures relating to 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:

None

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

-

(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:

Pharmacists are entitled to use the exception, when making the preparation in a Pharmacy on the basis of a medical prescription.

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

Yes

No

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

-

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

None

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:

Yes

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

None

Section V: Prior use

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

Article 74 of the Patent Law

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

None

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

-

(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):

According to article 74, point (a) of the Patent Law: "A patent shall have no effect against a person who had, prior to the filing date or prior to the date of the granted priority of a patent application, exploited or manufactured in good faith and within his economic activities a product according to the protected invention or had made real and serious preparations for such an exploitation of the invention in Bosnia and Herzegovina."

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

No

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 prior user's right may be transferred or inherited only together with the working process and production plant in which the exploitation of the invention has been prepared or started.

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:

A patent shall have no effect against a person who had, prior to the filing date or prior to the date of the granted priority of a patent application, exploited or manufactured in good faith and within his economic activities a product according to the protected invention or had made real and serious preparations for such an exploitation of the invention in Bosnia and Herzegovina. (Article 74, point (1) of the Patent Law)

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:

Yes

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):

“The use of products made according to a protected invention in the construction or equipment of a vessel, aircraft or land vehicle belonging to any of the Member States of the Paris Union or WTO shall not be considered a patent infringement where such transport means is temporarily or accidentally in the territory of Bosnia and Herzegovina, provided that the built-in product serves exclusively for the purposes of the said means of transport”. (Article 77 of the Patent Law)

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

None

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

-

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

-

45. The exception applies in relation to:

- Vessels**
- Aircrafts**
- Land Vehicles**
- Spacecraft**

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

The applicable law applies the terms "temporarily" and "accidentally" but does not define them.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, devices used exclusively for the purposes of the listed transport means

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):

None

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:

Yes

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: Laws for obtaining regulatory approval from authorities

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

According to article 73 (b) of the Patent Law: “The patent holder’s exclusive right shall not apply to acts performed for research and development purposes, and for experiments relating to the subject matter of the protected invention, including the acts necessary for obtaining registration or marketing authorization for the product which is a medicine intended for humans or animals or a medicinal product,

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

None

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

-

(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:

Any person

55. The exception covers the regulatory approval of:

any products

certain products. Please describe which products: **Human or a veterinary drug or a medical product**

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

Making

Using

Selling

Offering for sale

Import

Export

Other. Please specify: **acts done for the purposes of research and development and for experiments necessary for obtaining registration or authorization for putting on the market a product being a human or a veterinary drug or a medical product**

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):

None

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:

Yes

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

None

Section VIII: Exhaustion of patent rights

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

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

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

Article 76 of the Patent Law-"The placing on the market within the territory of Bosnia and Herzegovina of a product made according to a protected invention or a product directly obtained by a process which is the subject matter of an invention by the patent holder or with his explicit consent shall exhaust for the territory of Bosnia and Herzegovina the exclusive rights conferred by the patent in respect of such a product."

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

None

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

-

(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:

None

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):

Articles 79 and 80 of the Patent Law

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

None

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

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

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

-

(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):

Article 79 (1) of the Patent Law: "If the right holder refuses to assign the right to the economic exploitation of a protected invention in Bosnia and Herzegovina or imposes unreasonable conditions for such an assignment without having made effective and serious preparations for the exploitation thereof in Bosnia and Herzegovina, the Court of Bosnia and Herzegovina may grant a compulsory license at the request of an interested party. In such a case, the right holder shall be informed of the grant of the compulsory license within a shortest possible time limit."

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):

The applicable law does not specify whether the importation of a patented product constitute “working” of the patent.

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?

A request for the grant of a compulsory license can be filed after the expiration of a period of four years as of the filing date of a patent application, or after the expiration of three years as of the date on which the patent was granted.

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

- Yes**
- No

If yes, what are "legitimate reasons"?

The applicable law does not define the "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):

No

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):

-

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:

-

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:

The patent holder shall be entitled to remuneration taking into account the economic value of a license and the need for correcting uncompetitive practices.

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:

Article 80 (1) of the Patent Law: "The Council of Ministers of Bosnia and Herzegovina (hereinafter referred to as the Council of Ministers) may grant a compulsory license if the exploitation of the invention protected by a patent is necessary due to national emergencies for the purpose of:

a) State security,

b) protection of public interest in the field of health and nutrition,

c) protection and improvement of human environment,

d) special interest in a particular branch of economy or where it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive."

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

Data relating to this issue is not available

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:

Yes

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

None

Government use

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

Articles 79 and 80 of the Patent Law

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

None

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:

The Council of Ministers of Bosnia and Herzegovina (hereinafter referred to as the Council of Ministers) may grant a compulsory license if the exploitation of the invention protected by a patent is necessary due to national emergencies for the purpose of:

- a) State security,**
- b) protection of public interest in the field of health and nutrition,**

- c) protection and improvement of human environment,
- d) special interest in a particular branch of economy or where it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive.

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

Data relating to this issue is not available

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:

Yes

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

None

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

Farmers' use of patented inventions

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

Article 75, paragraph (3) of the Patent Law

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

None

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

-

(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):

Article 75, point (2) of the Patent Law: "By way of derogation from the provision of Article 67 of this Law, by means of the sale or another form of commercialization of breeding stock or another animal reproductive material to a farmer by the patent holder or with his consent, the farmer acquires the authorization to use the protected livestock for agricultural purposes, including at the same time the availability of the animal or another animal reproductive material for the purpose of

carrying out his own farming activities, but not the sale within the framework or for the purpose of commercial reproduction activity."

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:

Yes

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:

None

Breeders' use of patented inventions

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

Article 75, paragraph (2) of the Patent Law

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

None

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

-

(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):

Article 75, paragraph (3) of the Patent Law: "By way of derogation from the provision of Article 67 of this Law, by means of the sale or another form of commercialization of the plant propagating material to a farmer by the patent holder or with his consent, for farming purposes, the farmer acquires the authorization to use the products of his harvest for the propagation or multiplication on his farm."

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:

Yes

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:

None

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:

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[End of Questionnaire]