

## **Questionnaire on Exceptions and Limitations to Patent Rights**

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

Country: Republic of Serbia  
Office: Intellectual Property Office

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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.

The Law on Patents provided exceptions and limitations:

Article 14 - Biological material obtained by multiplication or propagation of the material put on the market by the patent owner for that purpose, but not used for multiplication or propagation purposes without authorization.

Article 21 - Use for personal, non-commercial purposes; Acts related to research and development, including acts obtaining an authorization to market drugs and medicinal products; Preparation of prescribed drugs in pharmacies and placement of such drug on the market.

Article 22 - Use and disposal of product is placed on the market in Republic of Serbia by, or with the consent of, the patent owner.

Article 23 - Continued prior use by a person who, in good faith before the filing date (priority date), exploited the invention in Serbia and Montenegro, or made all necessary preparations for that purpose.

Article 24 - Certain uses concerning foreign ships, aircraft, hovercraft or vehicles which temporarily or accidentally enter national territory.

Article 26-29 Compulsory licenses

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.<sup>1</sup>

The Law on Patents provided exclusions from patentability:

Article 7 paragraph 4 items 1-5 Discoveries, scientific theories and mathematical methods; Aesthetic creations; Schemes, rules and methods for performing mental acts, playing games or doing business; Computer programs; Presentation of information.

Article 8 paragraph 1 - The human body, at any stage of its formation and development, and the simple discovery of one of its elements, including gene sequences of genes.

Article 9 paragraph 1 items 1-3 - Inventions contrary to public order or morality, in particular: processes for cloning humans; modifying the germ line genetic identity of humans; uses of human embryos for industrial or commercial purposes; and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit, and animals resulting from such processes;

Therapeutic, surgical and diagnostic methods for treating humans or animals;

Plant and animal varieties and essentially biological process for their production, other than: (a) biotechnological processes whose technical feasibility is not confined to a particular plant or animal variety (b) microbiological and other technical process and products.

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 Patents Article 14 provided which exclusive rights are granted with a patent -

The owner of a patent or petty patent shall have the exclusive right to:

- 1) use the protected invention in production;
- 2) place on the market products made by the protected invention;
- 3) dispose of the patent or petty patent.

In exercising his exclusive right to the commercial use of a protected invention, the owner of a patent or petty patent shall have the right to prevent any third party not having his consent from:

- 1) making, offering for sale, placing on the market or using the product made by means of the protected invention or from importing or storing the product for such purposes;
- 2) using the patented process;
- 3) offering the patented process for sale;
- 4) producing, offering for sale, placing on the market, using, importing or storing for such purposes a product directly obtained by the patented process;
- 5) offering for sale or supplying products that constitute essential elements of an invention to parties unauthorized to use such invention, if the offerer or supplier knows or has demonstrable grounds to know that such products are intended for the use of an invention owned by someone else.

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;<sup>2</sup>

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

<sup>2</sup> For example, extemporaneous preparation of prescribed medicines in pharmacies.

- 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.<sup>3</sup>

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

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

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

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

The Law on Patents Article 21 item 1:

The exclusive rights of a patent owner referred to in Articles 14 and 15 of this Law shall not apply to:

- 1) the use of an invention or the use of products made by means of the invention for personal, non-commercial purposes;

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

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

Bearing in mind that the patent is designed to be used by its holder for the economic benefits of exploiting in the commercial activities finding that it is used in the domain satisfying personal non-commercial goals of the individual are not of interest to the patent protection system, which is the reason for their exemption from the effects of patent.

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

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<sup>3</sup> 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).

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

The Law on Patents does not define the concepts “non-commercial”, “commercial” and/or “private”.

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):

The Law on Patents provides that the requirement for non-commercial and private use must be cumulatively met.

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

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

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

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

The Law on Patents Article 21 item 2:

The exclusive rights of a patent owner referred to in Articles 14 and 15 of this Law shall not apply to:

2) research and development activities relating to the subject matter of a protected invention, including activities that are necessary for obtaining an authorization from the competent authority for placing on the market a product which is a drug intended for use on humans or animals, or a medicinal product or plant protection products defined by the law regulating plant protection products ;

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

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

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

Meaning of patent protection is to encourage the technological development and innovations and not to inhibit it, so this exception provides that a patented invention can be used for research and development in order to obtain new inventions based on the patented invention.

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

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

The applicable law make no distinction concerning the nature of the organization conducting the 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):

The Law on Patents does not define the concepts "experimental use" and/or "scientific research"

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:

- X determine how the patented invention works
- X determine the scope of the patented invention
- X determine the validity of the claims
- X seek an improvement to the patented invention
- X invent around the patented invention

other, please specify: .....

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

Research and/or experimentation must be conducted on or relating to the patented invention ("research on")

Research and/or experimentation must be conducted with or using the patented invention ("research with")

- X Both of the above

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

The applicable law provided that research and development activities relating to the subject matter of a protected invention, including activities that are necessary for obtaining an authorisation from the competent state authority for placing on the market a

product which is a drug intended for use on humans or animals, or a medicinal product. Research activities are relating to the subject matter of a protected invention and the interpretation of this provision is to the point that is permissible "research on" and "research with" patented invention.

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):

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

The applicable law provided research and development activities relating to the subject matter of a protected invention, including activities that are necessary for obtaining an authorisation from the competent state authority for placing on the market a product which is a drug intended for use on humans or animals, or a medicinal product.

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

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

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**Section IV: Preparation of medicines**

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

The Law on Patents Article 21 item 3:

The exclusive rights of a right holder referred to in Articles 14 and 15 of this Law shall not apply to:

3) the direct, individual preparation of a drug in a pharmacy based on a single prescription, and to the placement of such drug on the market.

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

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

General etical and helth interest requires that the patent for the drug would not be an obstacle that the drug in individual cases, produce and put on the market. This exception does not apply for preparation dugs for stockpiling, but only applies to the case when the drug is aimed at making the execution of a specific medical orders for tretment a particular person in accordance with a prescription.

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

The subject mater of patent protection until 1995 in Patent legislation could be just the proces for obtaining a drug, product can be subject mater of a patent protection from 1995.

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

The Law on Patents does not define the persons authorized to prepare such drug but the interpretation is to the point that they can be doctors and pharmacis.

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

Yes  
 No

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

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

The applicable law does not provide other criteria to be applied in determining the scope of the exception.

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

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

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**Section V: Prior use**

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

Law on Patents Article 23:

A patent or petty patent shall have no effect against a person acting in good faith who has, before the date of priority, already started exploiting a protected invention in production in the territory of the Republic of Serbia, or has made all necessary preparations to initiate such use.

The person referred to in paragraph 1 of this Article shall be entitled to continue exploiting the invention exclusively for production purposes, in his own plant or in the plant of another person for his own needs.

The person referred to in paragraph 1 of this Article cannot assign his right to exploitation of the invention to another person, except together with the enterprise or part of the enterprise in which the preparation for use or the use of the invention has taken place.

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

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

It is possible that several persons who are independent of each other at the same time reach the same finding, but just one person file patent application and be obtain priority date of filling. A person who is in good faith and that began to use the invention before the date of priority, or has made all necessary preparatins to initiate such use may continue to use the subject invention, but only in his own plant or in the plant of another person for his own needs. This exception is provided for the reasons of fairness and economic security nessesary for investment and exploitation of the invention that was made before the filling the application.

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

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

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

The applicable law does not provide for a remuneration to be paid to the patentee for the exercise of the exception.

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 person who use the invention cannot assign his right to exploitation of the invention to another person, except together with the enterprise or part of the enterprise in which the preparation for use or the use of the invention has taken place.

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:

The Law on Patents provide this exception in Article 73 paragraph 11 which read as following:

Any person acting in good faith, who has, in the course of production, started exploiting an invention which is the subject matter of a published application, or has made all necessary preparations to initiate such exploitation within the period between the loss of rights and the publication of the notification on the reestablishment of rights, shall be entitled to continue exploiting the invention for production purposes only in his own production plant or in the plant of any other person for his own needs.

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

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

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

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

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

Law on Patents Article 24:

A patent or petty patent shall have no effect against a person who uses devices made on the basis of a protected invention where such devices constitute an element in the structure or equipment of a vessel, aircraft or land vehicle or which serve exclusively for the operation of such vessel, aircraft or land vehicle belonging to a Member State to the Paris Union or member of the World Trade Organization (hereinafter: WTO) when it enters the territory of Republic of Serbia temporarily or accidentally.

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

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

This exception is necessary from the standpoint of the international transport and transport equipment and is in public interest.

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

Patent Law in 1995 was introduced this provision

45. The exception applies in relation to:

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

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

The applicable law apply terms temporarily or accidentally and those terms are provided in Article 24 of The Law on Patents.

(Art. 24 - A patent or petty patent shall have no effect against a person who uses devices made on the basis of a protected invention where such devices constitute an element in the structure or equipment of a vessel, aircraft or land vehicle or which serve exclusively for the operation of such vessel, aircraft or land vehicle belonging to a Member State to the Paris Union or member of the World Trade Organization (hereinafter: WTO) when it enters the territory of Republic of Serbia temporarily or accidentally.)

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

The applicable law provide two following restrictions:

- 1) devices constitute an element in the structure or equipment of a vessel, aircraft or land vehicle,
- 2) serve exclusively for the operation of such vessel, aircraft or land vehicle.

(Art. 24 - A patent or petty patent shall have no effect against a person who uses devices made on the basis of a protected invention where such devices constitute an element in the structure or equipment of a vessel, aircraft or land vehicle or which serve exclusively for the operation of such vessel, aircraft or land vehicle belonging to a Member State to the Paris Union or member of the World Trade Organization (hereinafter: WTO) when it enters the territory of Republic of Serbia temporarily or accidentally.)

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

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

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

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**Section VII: Acts for obtaining regulatory approval from authorities**

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

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

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

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

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

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55. The exception covers the regulatory approval of:

any products  
certain products. Please describe which products: .....

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

- Making
- Using
- Selling
- Offering for sale
- Import
- Export
- Other. Please specify:.....

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

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

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

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**Section VIII: Exhaustion of patent rights**

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

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

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

The Law on Patents Article 22 read as follows:

If a protected product is placed on the market in the territory of the Republic of Serbia by the right holder or with his consent, the person coming into possession of such product may use and dispose of it freely.

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

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

Institute of exhaustion of rights concerns interest of society that legal transactions be clear and sure. And on the other hand by assuming that the patent holder determined conditions under wich a patented product placed on the marked considered that he earned enough economic benefits that patent gives him.

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

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62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- X Yes
- No
- Uncertain

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

The patent owner can prevent the importation of goods into the territory of the Republic of Serbia, if such goods are put into circulation of the other countries and without his consent.

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

Bearing in mind that international exhaustion can lead to impairment of the patent, legislator has decide to prescribe provisions of national exhaustion. The patent holder has exhausted his right on the territory of the Republic of Serbia and can prevent parallel imports of goods that were on the markets of other countries which are protected by patent on the territory of the Republic of Serbia.

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

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**Section IX: Compulsory licenses and/or government use**

*Compulsory licenses*

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

Law on Patents Article 26-28:

*Compulsory License*

Article 26

If the right holder refuses to license the right of commercial use of a protected invention to other persons or sets unreasonable conditions for such licensing, the government authority competent in the field in which the invention shall be employed may, at the request of an interested party after considering the merits of each individual case, grant a compulsory license, in the following cases:

- 1) if the right holder himself or a person authorized by him does not use the protected invention or uses it insufficiently in the Republic of Serbia;
- 2) if the commercial use of an invention that has been subsequently protected in the name of another person is not possible, without the use of the protected invention in whole or in part;
- 3) when it is necessary to remedy a practice determined after judicial or administrative process to be anti-competitive

The request for the grant of a compulsory license cannot be filed before the expiration of a period of four years from the date of filing of the patent application or before the expiration of a period of three years from the grant of the patent or petty patent, whichever period expires last.

Before making a request under the paragraph 1 of this Article the interested person shall be required to prove that he has made efforts to obtain authorization for the use of the protected invention from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

The interested person, referred to in paragraph 1, item 1) of this Article, may only be a person who proves that he has the appropriate technological capacity and production facilities for the commercial use of the protected invention.

The interested person referred to in paragraph 1, item 2) of this Article may only be the right holder of the second invention, under the following conditions:

- 1) that the second invention involves a technical advancement of special economic significance in relation to the first protected invention and that
- 2) the owner of the first invention is entitled, on reasonable terms, to a cross-license to use the second invention.

Authorization for the use of the earlier protected invention shall be non-assignable except with the assignment of the second patent.

A compulsory license cannot be granted if the patent owner provides legitimate reasons to justify non-exploitation or insufficiency of exploitation of the protected invention

Provisions of paragraphs 2. and 3. of this Article shall not apply to compulsory license granted when the public emergency endangers the survival of the state or its citizens or in cases of public non-commercial use.

Holder of patent shall be promptly informed on the procedure on granting compulsory license referred to in paragraph 8. of this Article.

In the case of semi-conductor technology, a compulsory license may be granted only in cases of public non-commercial use or when it is necessary to remedy a practice determined after judicial or administrative process to be anti-competitive.

#### *Remuneration to the Right Holder*

#### Article 27

The holder of a compulsory license shall be required to pay the right holder a mutually agreed remuneration. In the absence of an agreement on the amount and method of payment of such remuneration, the competent court shall decide, taking into account the merits of each individual case and the economic value of the compulsory license.

#### *Scope and Duration of Compulsory License*

Article 28

The scope and duration of a compulsory license shall be limited to the purpose for which it has been granted.

A compulsory license shall not be exclusive.

A compulsory license may be assigned only with the manufacturing plant that exploits the invention for which the license has been granted.

A compulsory license shall predominantly be granted for the supply of the domestic market.

A compulsory license may be terminated if and when circumstances that have led to its grant cease to exist and are unlikely to recur.

On reasoned request, the government authority competent in the field in which the invention shall be employed shall re-examine the further existence of circumstances referred to in paragraph 5 of this Article.

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

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

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

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

There are several reasons for granting a compulsory licence, but the main reason is that the holder can not capture the patent because the patent must be available to potential users. The patent Law provides the conditions under which potential user can issue a compulsory licence.

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

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69. If the applicable law provides for the grant of compulsory licenses on the ground of "non-working" or "insufficient working", please provide the definitions of those terms by citing legal provision(s) and/or decision(s):



Article 26 : If the right holder refuses to license the right of commercial use of a protected invention to other persons or sets unreasonable conditions for such licensing, the government authority competent in the field in which the invention shall be employed may, at the request of an interested party after considering the merits of each individual case, grant a compulsory license, in the following cases:

1) if the right holder himself or a person authorized by him does not use the protected invention or uses it insufficiently in the Republic of Serbia;

As seen from the provisions of Article 26 in each individual case insufficient use of patent will be valued and The Law on Patents does not provide definitions of the terms "non-working" or "insufficient working".

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

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

Yes  
 No

If yes, what is the time period?

An application for the grant of a compulsory licence cannot be filed before the expiry of a period of four years from the filing date of the patent application or three years from the date of the grant of a patent, whichever of the two time limits expires later.

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

Yes  
 No

If yes, what are "legitimate reasons"?

A compulsory licence shall not be granted if the patent owner provides valid reasons for non-use or for insufficient use of a protected invention.

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):

The Law on Patents does not prescribed definition of terms "reasonable terms and conditions" and within a "reasonable period of time"

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

The Law on Patents does not indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses.

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:

- 1) the second invention involves a technical advancement of special economic significance in relation to the invention protected by the first patent; and that
- 2) the owner of the first patent is entitled, on reasonable terms, to a cross-licence to use the second invention.

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 holder of a compulsory licence shall be required to pay the patent owner a mutually agreed remuneration. In the absence of an agreement on the amount and method of payment of such remuneration, the competent court shall decide, taking into account the merits of each individual case and the economic value of the compulsory licence.

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:

The Law on Patents defines “national emergency” or “circumstances of extreme urgency”, as the public emergency endangers the survival of the state or its citizens.

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

In The Republic of Serbia has never been requested compulsory licence for granted patent.

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

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

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*Government use*

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

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):

Article 25

By acquiring protected plant propagating material from the owner of a patent or with his consent, a farmer shall obtain authorization to use the product of said propagating material for further propagation or multiplication on his own farm, under conditions prescribed by the law on the protection of, plant breeders' rights. whereas products obtained thereby may not be used for commercial purposes.

By acquiring protected animal reproductive material or breeding stock from the owner of a patent or with his consent, a farmer shall obtain authorization for use protected livestock or for reproductive material for the purpose of his own agricultural activities, but not for sale within the framework or for the purpose of a commercial reproduction activity.

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

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.....

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

May not be used for commercial purposes.

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

In 2004 frst time this provision was prescribed in The Patent Law

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 25

By acquiring protected plant propagating material from the owner of a patent or with his consent, a farmer shall obtain authorization to use the product of said propagating material for further propagation or multiplication on his own farm, under conditions prescribed by the law on the protection of, plant breeders' rights. whereas products obtained thereby may not be used for commercial purposes.

By acquiring protected animal reproductive material or breeding stock from the owner of a patent or with his consent, a farmer shall obtain authorization for use protected livestock or for reproductive material for the purpose of his own agricultural activities, but not for sale within the framework or for the purpose of a 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:

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

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*Breeders' use of patented inventions*

95. If the exception is contained in statutory law, please provide the relevant provision(s):  
Article 29:

Where a plant breeder cannot obtain or exploit a protected plant breeders' rights without infringing a prior patent concerning a biotechnological invention, he may file the request for the grant of a compulsory license to the government authority competent for the Agriculture for the use of the invention protected by the patent.

The compulsory license referred to in paragraph 1 shall not be exclusive and such license shall be issued in the scope which is necessary for the exploitation plant breeders' rights.

If such a license is granted, the owner of the patent shall be entitled to a compulsory cross-license to use the protected plant breeders' rights on reasonable terms.

Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior protected plant breeders' rights, he may file the request for the grant of a compulsory license to the government authority competent for the Agriculture, that cannot be exclusive, for the use of the plant breeders' right, under the condition that he pays an appropriate remuneration. If such a license is granted, the holder of the plant breeders' right will be entitled to a compulsory cross-license to use the protected biotechnological invention on reasonable terms.

A requester for the compulsory license referred to in paragraphs 1 and 4 of this Article must prove that:

- 1) he has unsuccessfully made efforts to obtain a contractual license;
- 2) the plant variety or the biotechnological invention constitutes significant technical advance of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

The compulsory license referred to in paragraphs 1 and 4 of this Article may only be assigned with the manufacturing plant that exploits the invention for which the license has been granted.

For compulsory license referred to in paragraph 1 and 4 of this Article, the licensee shall pay appropriate compensation.

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

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

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

In 2004 frst time this provision was prescribed in The Patent Law

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

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

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

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**Section XI: Other Exceptions and Limitations**

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

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

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

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

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

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

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

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

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

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[End of Questionnaire]