

## Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: ALBANIA .....  
Office: GENERAL DIRECTORATE OF PATENTS AND TRADEMARKS .....

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### Section I: General

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

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

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

*According to Article 5 of our Law No 9947 date 07/07/2008 Patentable Inventions are:*

- *Patents shall be granted for inventions, in all fields of technology, provided that they are:*
  - a) *new;*
  - b) *involve an inventive step; and*
  - c) *are susceptible of industrial application.*

- *The subject-matter of an invention protected by a patent may be a product or a process.*

- *Biotechnological inventions shall also be patentable if they concern:*

- a) *biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;*
- b) *plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;*
- c) *microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety;*

*ç) an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.*

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>

*According to Article 6 of our Law No 9947 date 07/07/2008 Patents shall not be granted in respect of:*

*- Inventions the commercial exploitation of which would be contrary to public order, morality or public health and human life; such exploitation may be deemed to be so contrary even if it is not prohibited by law or regulation. On this basis, the following, in particular, shall be considered unpatentable:*

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

*- Plant or animal varieties or essentially biological processes for the production of plants or animals, without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process;*

*- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene*

*- Methods for treatment of the human body or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.*

*- Substances obtained through internal nuclear transformations for military purposes.*

*- The following in particular shall not be regarded as inventions within the meaning of paragraph 1 Article 6 of Law No 9947 date 07/07/2008:*

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

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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.

*- The above paragraph shall exclude patentability of the subject-matter or activities referred to therein only to the extent to which a patent application or a patent relates to such subject-matter or activities as such.*

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 36 of our Law No 9947 date 07/07/2008 the rights conferred by a patent are :*

- 1. When a patent is related to a product, the owner of the patent shall have the exclusive right to prohibit any third party from performing the following actions without his authorization: making, using, offering for sale, selling, stocking or importing for these purposes that product.*
- 2. When the patent is related to a process, the owner of the patent shall have the exclusive right to prohibit third parties from performing the following actions without his authorization:
  - a) to use the process that constitutes the subject of the patent;*
  - b) to use, offer for sale, sell, stock or import for these purposes at least the product obtained directly by that process.**
- 3. The owner of a patent has the right to assign and to transfer the patent to his successors in title, as well as to make license agreements on the patent.*

*Article 37 Prohibition of indirect use of the invention*

- 1. The owner of a patent shall have the right to impede third parties, other than those who have gained the right to use the invention for which the patent was granted, from supplying or offering to supply to a Person, other than one entitled to exploit the patented invention, means relating to an essential element of the invention, for putting it into effect therein, when the third party has knowledge, or when from the circumstances it becomes clear that those means are suitable and intended for putting that invention into effect.*
- 2. This provision shall not apply if these means are staple commercial products, except when the third party induces the Person supplied to commit acts prohibited by article 36.*

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;<sup>2</sup>
- Prior use;
- Use of articles on foreign vessels, aircrafts and land vehicles;
- Acts for obtaining regulatory approval from authorities;
- Exhaustion of patent rights;
- Compulsory licensing and/or government use;
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.<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):

*Article 38 (a) Limitation of the Effects of the Patent*

*The rights conferred by the patent shall not extend to:*

- a) Acts performed privately, not for 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?

*Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions*

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

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

<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):

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

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

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

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

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

*Article 38(b) Limitation of the Effects of the Patent*

*The rights conferred by the patent shall not extend to:*

*b) acts performed merely for experimental purposes relating to the subject matter of the invention;*

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.

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

*Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions*

(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:

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15. If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):

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16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- seek an improvement to the patented invention
- invent around the patented invention
- other, please specify: .....

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

- **Research and/or experimentation must be conducted on or relating to the patented invention ("research on")**  
Research and/or experimentation must be conducted with or using the patented invention ("research with")  
Both of the above

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

*Acts performed merely for experimental purposes relating to the subject matter of the invention (Article 38(b) ).....*  
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18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

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

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

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

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

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

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**Section IV: Preparation of medicines**

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

*Article 38 (c) Limitation of the Effects of the Patent*

*The rights conferred by the patent shall not extend to:*

*c) The extemporaneous individual preparation of a medicine in a pharmacy according to a medical prescription or with other processes that lead to its preparation.*

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:

*Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions*

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

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

*pharmacists .....*

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

- Yes
- No

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

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

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

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

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**Section V: Prior use**

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

*Article 43 Prior Users*

*1. The rights conferred by a patent shall have no effect on Persons who within the territory of the Republic of Albania, have used the invention or are in the process of serious and effective preparations for its use, before the filing date of the application, or, in cases when priority is claimed, before the priority date. These Persons shall have the right to continue use or preparations for use.*

*2. The right of prior use may be transferred, with the enterprise or company, or with that part of the enterprise or company where the use or the the preparations for use have been made.*

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

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

*Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions*

(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:

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

- Yes
- No

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

- Yes
- No

If yes, please explain what those conditions are:

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38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

- Yes
- No

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

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

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

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

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

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

*Article 38 Limitation of the Effects of the Patent*

*The rights conferred by the patent shall not extend to:*

*ç) the use on board **vessels** of other countries of the Paris Union of devices forming the subject of the patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter Albanian waters, provided that such devices are used there exclusively for the needs of the vessel;*

*d) the use of devices forming the subject of the patent in the construction or operation of **aircraft** or **spacecraft** or **land vehicles** of other countries of the Paris Union, or of accessories of such aircraft or land vehicles, when those aircraft or spacecraft or land vehicles temporarily enter Albania;*

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:

*Law 9947 date 07.08.2008 "On Industrial Property" is approximated with EPC 2000 and EU directives concerning inventions*

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

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45. The exception applies in relation to:

- 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 rights conferred by the patent shall not extend to the use on board vessels of other countries of the Paris Union of devices forming the subject of the patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels **temporarily or accidentally** enter Albanian waters, provided that such devices are used there exclusively for the needs of the vessel*

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):

*Patent Act explicitly stipulates that the subject matter of the patented invention is used **exclusively** for the needs of the vessel. Article 38(ç)*

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):

*Article 38 Limitation of the Effects of the Patent*

*The rights conferred by the patent shall not extend to:*

- a) acts performed privately, not for commercial purposes;*
- b) acts performed merely for experimental purposes relating to the subject matter of the invention;*
- c) the extemporaneous individual preparation of a medicine in a pharmacy according to a medical prescription or with other processes that lead to its preparation.*
- ç) the use on board vessels of other countries of the Paris Union of devices forming the subject of the patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter Albanian waters, provided that such devices are used there exclusively for the needs of the vessel;*
- d) the use of devices forming the subject of the patent in the construction or operation of aircraft or spacecraft or land vehicles of other countries of the Paris Union, or of accessories of such aircraft or land vehicles, when those aircraft or spacecraft or land vehicles temporarily enter Albania;*
- dh) biological material obtained from the propagation or multiplication of biological material placed in the market by the holder of the patent or with its consent, where multiplication or propagation necessarily results from the application for which the biological material was*

*marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.*

*e) the use by a farmer of the product of his crop for propagation or multiplication on his own holding, provided that the reproductive vegetable material was sold or otherwise commercialized by the holder of the patent or with his consent to the farmer, for agricultural purposes.*

*ë) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animals reproductive material was sold or otherwise commercialized to the farmer by the holder of the patent or with his consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his agricultural activity, but not the sale as part of or for the purpose of commercial reproductive activity.*

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

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

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

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

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55. The exception covers the regulatory approval of:

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

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

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

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

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

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

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**Section VIII: Exhaustion of patent rights**

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

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

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

*Article 39 Exhaustion of rights*

*The rights conferred by a patent shall not extend to acts committed in the Republic of Albania with regard to a product protected by the patent after the said product has been put on the market in the Republic of Albania by the patent's owner or with his consent.*

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:

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

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

- Yes
- No
- Uncertain

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

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

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

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

*Compulsory licenses*

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

*Article 50 Compulsory Licenses*

*1. On request, the court is entitled to grant a compulsory license to any Person who can demonstrate the capability to exploit the invention which is the subject-matter of the granted patent in the Republic of Albania when he meets all the requirements defined in the implementing regulation of this Law, provided that:*

- a) four years have expired from the filing of the application and three years have expired from the grant of the patent;*
- b) the patent owner has not exploited the patent on reasonable terms or has not made effective and serious preparations to do so, unless he provides legitimate reasons to justify his inaction.*

*c) the Person requesting the compulsory license has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions, and if such efforts have not been successful within a reasonable period of time.*

*2. On request, the court is entitled to grant a compulsory license in respect of a first patent to the owner of a subsequent patent who cannot use his patent without infringing the first patent, provided that the invention in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. In the case of a compulsory license in respect of a dependent patent, the owner of the first patent shall be entitled to use the subsequent patented invention on reasonable terms.*

*3. On request, the court is entitled to grant a compulsory license in respect of patents and supplementary protection certificates relating to the manufacture and sell of pharmaceutical products, when such products are intended for export to importing countries in need of such products in order to address public health problems, subject to the implementing regulation.*

*4. The type of use covered and the conditions to be met shall be specified by the court. The following conditions shall apply:*

*a) The scope and duration of the exploitation shall be limited to the purpose for which it was authorized;*

*b) The exploitation shall be non-exclusive;*

*c) The exploitation shall be non-assignable. In the case of a compulsory license in respect of a dependent patent, the exploitation authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.*

*ç) The amount of products manufactured under the license shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of products manufactured under other compulsory licenses granted elsewhere.*

*5. The exploitation shall be authorized, above all, to supply the market of the Republic of Albania, except in the case provided in paragraph 3 of this article.*

*6. A compulsory license shall be valid until the end of the time period designated by the court or until the end of the term of the patent. However, the court may, on reasoned request, decide to cancel the authorization, subject to adequate protection of the legitimate interests of the Persons so authorized, if and when the circumstances which led to it cease to exist and are unlikely to recur.*

*7. Compulsory licenses shall be registered in the patent register.*

*8. The owner of the patent shall be entitled to adequate compensation for a compulsory license, taking into account the economic value of the authorization. When the parties do not agree, the amount of this compensation shall be set by the court.*

*9. The holder of a compulsory license may renounce at it at any time. If the holder does not begin exploitation within one year from the final grant of the compulsory license, the owner of the patent may claim for the compulsory license to be modified or annulled.*

*10. The requirements of paragraphs 1(c) and 5 of this article shall not be applicable when such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account of in determining the amount of remuneration in such cases. The court shall have the authority to refuse termination of an authorization if the conditions that led to such authorization are likely to recur.*



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

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

- 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: .....

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

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

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

Yes  
No

If yes, what is the time period? .....

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

Yes  
No

If yes, what are "legitimate reasons"? .....

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

*Article 50 Compulsory Licenses*

*1. On request, the court is entitled to grant a compulsory license to any Person who can demonstrate the capability to exploit the invention which is the subject-matter of the granted patent in the Republic of Albania when he meets all the requirements defined in the implementing regulation of this Law, provided that:*

*a) **four years** have expired from the filing of the application and three years have expired from the grant of the patent;*

*b) the patent owner has not exploited the patent on reasonable terms or has not made effective and serious preparations to do so, unless he provides legitimate reasons to justify his inaction.*

*c) the Person requesting the compulsory license has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions, and if such efforts have not been successful within a reasonable period of time.*

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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):

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.....  
.....

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

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.....

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

.....  
.....  
.....

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:

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

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

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

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.....

*Government use*

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

*Article 51 Exploitation by the Government or Third Parties Authorized by the Government*

*1. When the interests of essential defense or national security require it, the Minister of Defense or the Minister of Health may, even without the approval of the owner of the patent or the applicant, by a notification in the GDPT Gazette, authorize a governmental agency or a specific Person to make, use or sell the invention for which the patent application was submitted, or the patent was granted, subject to payment of equitable remuneration to the owner of the patent or to the patent applicant. The owner of the patent or the patent applicant shall be notified as soon as possible.*

*2. An appeal to the court can be taken against the decision of the Minister of Defense or the Minister of Health.*

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?

*To protect health and security interests.....*  
.....  
.....

(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:

.....  
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.....

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:

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

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

*Farmers' use of patented inventions*

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

*Article 38 Limitation of the Effects of the Patent*

*The rights conferred by the patent shall not extend to:*

*e) the use by a farmer of the product of his crop for propagation or multiplication on his own holding, provided that the reproductive vegetable material was sold or otherwise commercialized by the holder of the patent or with his consent to the farmer, for agricultural purposes.*

*ë) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animals reproductive material was sold or otherwise commercialized to the farmer by the holder of the patent or with his consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his agricultural activity, but not the sale as part of or for the purpose of commercial reproductive 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:

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.....  
.....

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

.....  
.....  
.....

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

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

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

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.....  
.....

*Breeders' use of patented inventions*

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

*Article 38 Limitation of the Effects of the Patent*

*The rights conferred by the patent shall not extend to:*

*ë) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animals reproductive material was sold or otherwise commercialized to the farmer by the holder of the patent or with his consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his agricultural activity, but not the sale as part of or for the purpose of commercial reproductive activity. ....*

.....  
.....

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:

.....  
.....  
.....

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

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

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

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

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**Section XI: Other Exceptions and Limitations**

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

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.....

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

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

.....  
.....  
.....

- (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?):

.....  
.....  
.....

- (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]