Questionnaire on Exceptions and Limitations to Patent Rights

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

Country:Slovak RepublicOffice:Industrial Property Office of the Slovak Republic

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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.

 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(1) of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (hereinafter referred to as "The Patent Act"; see <u>http://www.upv.sk/swift_data/source/pdf/legislation/pravo_01435.pdf</u>) patents are granted for **inventions from all fields of technology, which are new, involve an inventive activity and are industrially applicable**.

According to article 5(2) of The Patent Act patents are also granted for **biotechnological** *inventions* concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilized, including cases when invention relates to

- a) biological material which is isolated from its natural environment or is produced by means of a technical process, already occurred in a nature,
- b) a plant or an animal, if a technical feasibility of an invention is not limited to a particular plant or animal variety,
- c) a microbiological or other technical process or to a product obtained by such process,
- d) an element isolated from a human body or produced by other means of a technical process, including a sequence or partial sequence of a gene also in the case when the structure of such element is identical with a structure of a naturally existing element.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.¹

Patents are not granted for

- a) discoveries, scientific theories and mathematical methods,
- b) aesthetic creations,
- c) schemes, rules and methods for performing intellectual acts, games or business,
- d) programs for computers and
- e) presentations of information,

as these subject-matters or activities are **not regarded as inventions** (see Article 5(3) of The Patent Act). However, above listed subject-matters and activities are excluded from patentability only to the extent to which a patent application relates to such subject-matter or activity as such (see Article 5(4) of The Patent Act).

According to article 6(1) of The Patent Act patents are **not granted either in respect of**

- a) plant and animal varieties,
- b) essentially biological processes for creation plants or animals,
- c) methods of surgical or therapeutic treatment of human or animal body and diagnostic methods and methods of illness prevention practiced on human or animal body; this is not apply to products, in particular substances or compositions usable in any of abovementioned methods of treatment, diagnostics or illness prevention,
- d) inventions relating to human body in different stages of its formation or development or relating only to discovery of some elements of human body, including sequences or partial sequence of a gene,
- e) inventions commercial exploitation of which would be in contradiction with public order or good manners; the sole prohibition of exploitation of an invention by law shall not be considered to be in contradiction with public order or good manners. Article 6(2) of The Patent Act specifies that pursuant to article 6(1) patents are not granted in particular for
 - a) processes of cloning human beings,
 - b) processes of modifying germ line genetic identity of human beings,
 - c) utilization of human embryos for industrial or commercial purposes,
 - d) processes of modifying genetic identity of animals which are likely to cause suffering to animals without having substantial medical benefit for people or animals, neither on animals which are results of such processes.

Above listed inventions are **excluded from patentability**.

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 14(1) of The Patent Act **an owner of a patent shall have exclusive right** to exploit an invention, to grant consent for exploitation of an invention, to assign a patent to another person or to establish right of lien to a patent.

According to article 15(1) of The Patent Act without consent of a patent owner following shall be prohibited

- a) producing, exploitation, offering or placing on the market, or for this purpose storing or importing a product which is a subject-matter of a patent,
- b) exploitation of a production process which is a subject-matter of a patent (hereinafter

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

referred to as "protected process") or offering such protected process for exploitation to another person,

- c) producing, exploitation, offering or placing on the market, or for this purpose storing or importing a product directly obtained by a protected process,
- d) supplying or offering for delivery to a person not entitled to exploit an invention any means enabling him to carry out an invention, if a person infringing right has been informed or with regard to circumstances he should have been informed that these means are intended or suitable to carry out an invention; this shall not apply if these means are currently available on the market and a supplier did not instigate the person not entitled to perform acts in contradiction with points (a) to (c).

According to article 15(2) of The Patent Act **exclusive rights pursuant to article 15(1) shall also belong to an applicant**, starting from the day of publication of an application in the Official Journal of the Industrial Property Office of the Slovak Republic, provided that a patent has been granted for an invention, which is a subject-matter of an application. However, claiming of these rights vis-à-vis third parties shall be possible only as from the day on which effects of a patent begin.

- 3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):
 - X Private and/or non-commercial use;
 - X Experimental use and/or scientific research;
 - X Preparation of medicines;²
 - X Prior use;
 - X Use of articles on foreign vessels, aircrafts and land vehicles;
 - X Acts for obtaining regulatory approval from authorities;
 - X Exhaustion of patent rights;
 - X Compulsory licensing and/or government use;
 - X Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³

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

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):

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

For example, in some countries where patent rights extend to propagated or multiplicated 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).

According to article 18(1)(e) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in activity conducted **privately** and **for non-commercial purposes**.

- 5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
- 6. (a) What are the public policy objectives for providing the exception?

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

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

According to article 3(h) of The Patent Act "**commercial exploitation**" of a patent or an invention shall mean any activity related to a patent as a subject-matter of right or in relation to an invention as a subject-matter of a patent, performed by an owner or any other authorized person with a purpose of making profit.

The applicable law does not define the term "non-commercial" either the term "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):
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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:
- 10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

Section III: Experimental use and/or scientific research ⁴

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

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

According to article 18(1)(e) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in activity conducted **for experimental purposes** which shall also be studies and tests necessary for registration proceedings pursuant to a special regulation (Act No 140/1998 Coll. on Medicines and Medical Devices).

- 12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
- 13. (a) What are the public policy objectives for providing the exception?
 - (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:
- 14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

The applicable law does not make any 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 applicable law does not define the term "experimental use" either the term "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:

- 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):

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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):
 - -
- 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):

According to article 18(1)(e) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in **individual preparation of a medicine in a pharmacy according to a medical prescription** or in **activity related to a medicine prepared in this way**.

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

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

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

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

The applicable law does not specify who is entitled to use the exception.

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

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

Section V: Prior use

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

According to article 17(1) of The Patent Act right of a patent owner shall not be exercised vis-àvis a person who before priority right has exploited an invention **in a good faith** or has made appropriate arrangements directly aiming at exploitation of an invention independently from an inventor or a patent owner (hereinafter referred to as "prior user") within the territory of the Slovak Republic. In case of doubts action of a prior user shall be considered acting in a good faith unless proved otherwise.

- 32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
- 33. (a) What are the public policy objectives for providing the exception? Please explain:

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

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

The applicable law does not define the scope of "use" either provides for any quantitative or qualitative limitations on the application of the "use" by prior user.

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?
 - X Yes

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- No
- 37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?
 - X Yes
 - No

If yes, please explain what those conditions are:

According to article 17(2) of The Patent Act assignment or transfer of right of a prior user for exploitation of an invention is possible exclusively as a part of assignment or transfer of ownership of a company or its part, within which an invention is being utilized.

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

No

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

According to article 52(1) of The Patent Act if a party to proceedings before the Office that, in spite of all due care required by the circumstances having been taken, was unable to observe a time limit for performing an act where the direct consequence of non-observance of this time limit is the termination of the procedure or the loss of any other right, it is entitled to request the Office for **re-establishment of rights.** If the Office grants the request, the legal effects of the decision issued as a consequence of non-observance of the time limit shall lapse or shall not arise (see article 52(7) of The Patent Act).

However, third party that has exploited an invention, which was a subject-matter of an application or a patent, or has made provable preparations directly aiming at utilization of such invention within the territory of the Slovak Republic in a good faith from validity of a decision issued as a consequence of non-observance of the time limit until the lapse of legal effects of this decision, shall be entitled to **exploit an invention within his business activity without an obligation for remuneration for exploitation of an invention** (see article 52(8) of The Patent Act). Assignment or transfer of right of an entitled user shall be possible exclusively as a part of assignment or transfer of a company or its part, within which an invention is being used (see article 52(9) of The Patent Act).

- 39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
- 40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
- 41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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

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

According to article 18(1)(a) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited on boards of vessels of other states which are contracting parties to Paris Convention on Protection of Industrial Property or parties to the World Trade Organization (hereinafter referred to as "Union countries") to which the Slovak Republic is a contracting party, in a body of a vessel, machinery, tackle, gear and other accessories, if these vessels temporarily or accidentally enter the territory of the Slovak Republic provided an invention is used exclusively for needs of a vessel.

According to article 18(1)(b) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in construction or operation of aircrafts or land vehicles of the Union countries, or in their components or other accessories when they temporarily or accidentally enter

the territory of the Slovak Republic.

- 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:

(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:
 - 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 applies term "temporarily" as well as term "accidentally" but does not define them.

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

According to article 18(1)(a) of The Patent Act the patented product must be used **exclusively** for needs of a vessel.

- 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:

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

Section VII: Acts for obtaining regulatory approval from authorities

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

According to article 18(1)(f) of The Patent Act rights of a patent owner shall not be infringed if an invention is exploited in activity conducted for experimental purposes which shall also be **studies and tests necessary for registration proceedings pursuant to a special regulation** (Act No 140/1998 Coll. on Medicines and Medical Devices)

- 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:

(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:

The applicable law does not specify who is entitled to use the exception.

- 55. The exception covers the regulatory approval of:
 - any products
 - X certain products. Please describe which products: medicines
- 56. Please indicate which acts are allowed in relation to the patented invention under the exception?
 - Making
 - □ Using
 - Selling
 - Offering for sale
 - □ Import
 - Export
 - X Other. Please specify: conduct studies and tests necessary for registration of a

medicine prescribed by Act No 140/1998 Coll. on Medicines and Medical Devices

- 57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
- 58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
- 59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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

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

According to article 16 of The Patent Act a patent owner shall not be entitled to prohibit third parties to dispose of a product which is a subject-matter of a patent after this product has been placed on the market **in the member state of the European Union** or **in the state which is a contracting party to the Agreement on the European Economic Area** by a patent owner or with his explicit consent. This shall not apply if there are reasons for extension of rights to a patent for such treatment.

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

- 61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:
 - (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:
- 62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- Yes
- No
- X 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:
- 64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

Section IX: Compulsory licenses and/or government use

Compulsory licenses

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

According to article 27(1) of The Patent Act on request the court shall be entitled to grant a compulsory license to any person who can prove the capability to exploit an invention, which is a subject-matter of a granted patent, within the territory of the Slovak Republic, provided that

- a) 4 years have expired since filing of an application or 3 years have expired from granting a patent, where the time limit, which expires later, shall apply,
- b) person requesting granting of a compulsory license has offered before filing a request to a patent owner a proper conclusion of a license agreement, whilst this offer was not accepted by a patent owner within three months from its filing, and
- c) invention has not been exploited within the territory of the Slovak Republic without an appropriate reason by a patent owner, or it has been exploited insufficiently, while a subject-matter of a patented invention as a product has not been supplied to the market of the Slovak Republic in a sufficient quantity. Non-existence of an appropriate reason shall be presupposed, unless proved otherwise.

According to article 27(2) of The Patent Act compulsory license may be granted only as a nonexclusive license, whilst its duration and scope shall be limited to purpose for which it has been granted provided that domestic market needs shall be satisfied preferentially.

According to article 27(3) of The Patent Act if a subject-matter of a patent is a **technology of semiconductor products**, compulsory license may be granted only for public non-commercial exploitation or in order to prevent a patent owner from further action, which pursuant to a decision of a competent body can be considered as an action abusing or restricting economic competition or in case of serious public interest menace.

According to article 27(4) of The Patent Act notwithstanding article 27(1)(a) and article 27(1)(b) compulsory license may be granted **in case of serious public interest menace**.

According to article 27(5) of The Patent Act notwithstanding presuppositions pursuant to article 27(1) and conditions pursuant to article 27(2), a court shall be entitled to grant a compulsory nonexclusive license for utilization of a **biotechnological invention** on request, if a cultivator shall not be able to exploit or acquire right to a plant variety without infringing earlier right to a patent, if the plaintiff proves that

a) before filing a request he has offered to a patent owner a proper conclusion of a license

agreement, whilst this offer was not been accepted by a patent owner within three months from its filing, and

b) plant variety represents an important technical progress of a considerable economic importance comparable with an invention which is a subject-matter of a request for granting a compulsory license.

According to article 27(6) of The Patent Act in case of granting a compulsory license pursuant to article 27(5), a patent owner shall have right for granting a **cross compulsory license** for utilization of a plant variety pursuant to a special regulation (Act No 132/1989 Coll. on Protection of Rights to New Plant and Animal Variety as amended).

According to article 27(7) of The Patent Act if a patent owner has been granted a **compulsory** *license for utilization of a plant variety* pursuant to a special regulation (article 10 of the Act No 132/1989 Coll. on Protection of Rights to New Plant and Animal Variety as amended), an owner of a cultivator certificate shall have right for granting a cross compulsory license for utilization of a biotechnological invention.

According to article 27(8) of The Patent Act **assignment or transfer of right of a compulsory license holder** shall be possible exclusively as a part of an assignment or transfer of a company or of its part, within which an invention is being used on a basis of a compulsory license.

According to article 28(2) of The Patent Act in case of substantial change of circumstances, which led to granting a compulsory license, the court shall be entitled on a request of one of parties to license relation to **cancel a decision on granting a compulsory license**, provided that re-occurrence of reasons for granting a compulsory license is improbable or compulsory license rights have not been used during one year.

- 66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
- 67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):
 - X Non-working or insufficient working of the patented invention
 - X Refusal to grant licenses on reasonable terms
 - □ Anti-competitive practices and/or unfair competition
 - Public health
 - □ National security
 - □ National emergency and/or extreme urgency
 - Dependent patents
 - X Other, please specify: serious public interest menace
- 68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

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

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

The applicable law does not define the term "non-working" either the term "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):

The applicable law does not specify whether the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent.

- 71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?
 - X Yes
 - □ No

If yes, what is the time period?

Four years have expired since filing of an application or three years have expired from granting a patent, where the time limit, which expires later, shall apply (see article 27(1)(a) of The Patent Act).

- 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
 - X 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):

The applicable law does not define the term "reasonable terms and conditions". The term "reasonable period of time" means three months from the request for the license (see article 27(1)(b) of The Patent Act).

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

- 75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:
- 76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

According to article 28(1) of The Patent Act right of a patent owner to adequate compensation shall remain unaffected by granting a compulsory license; article 26(3) of The Patent Act shall apply mutatis mutandis to purposes of determining compensation for exploitation of an invention, which is a subject-matter of a compulsory license.

According to article 26(3) of The Patent Act if no agreement on compensation for granted license has been concluded among parties to license agreement, notwithstanding negotiations relating thereto, amount of an adequate compensation as well as terms of payment shall be determined by a court on proposal of one of parties to license agreement taking into consideration **importance of an invention** and **usual license prices in particular field**. In case of a substantial change of circumstances decisive for determining an adequate compensation, the court shall be entitled on proposal of one of parties to license agreement to change amount of a compensation or terms of payment originally negotiated or settled by a court, if no agreement has been concluded among parties, notwithstanding negotiations relating thereto.

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

Data relating to the number of compulsory licenses issued in the Slovak Republic is not available.

- 79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
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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:
- 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:
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- 85. If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:
- 86. Please indicate how many times and in which technological areas government use has been issued in your country:
- 87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
- 88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

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

Farmers' use of patented inventions

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

According to article 16(3) of The Patent Act acquisition of protected plant reproduction material by a farmer within the scope of a commercial relation with a patent owner or with his consent implies right of a farmer **to utilize a product of his work for reproduction** of this product **in his farm**. Provisions of a special regulation (Article 14 of the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights) shall apply mutatis mutandis for determination of a scope of right of a farmer and condition of claiming such right.

- 90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):
- 91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

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

- 92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):
- 93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
- 94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

Breeders' use of patented inventions

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

According to article 16(4) of The Patent Act acquisition of protected animal reproduction material by a breeder within the scope of a commercial relation with a patent owner or with his consent implies for right of a breeder to use a protected livestock for agricultural purposes including using of an animal reproductive material for his agricultural activity with exception of sale of animal reproduction material form performing agricultural activities of a breeder with exception of a sale of an animal reproduction material in relation with business or for the purpose of business in the form of a subsequent reproduction 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):

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

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

- 98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):
- 99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
- 100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

Section XI: Other Exceptions and Limitations

- 101. Please list any other exceptions and limitations that your applicable patent law provides:
- 102. In relation to each exception and limitation, please indicate:
 - (i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):
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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:
- (iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

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

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- (i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):
- (ii) if there have been any challenges encountered in the practical implementation of the exception in your country:
- 103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

[End of Questionnaire]