Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Hungary

Office: Hungarian Intellectual Property Office

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Section I: General

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

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

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

Article 1 of Act XXXIII of 1995 on the protection of inventions by patents (hereinafter referred to as "PA") provides for the criteria of patentability. In accordance with Paragraph (1) of Article 1, patents shall be granted for any inventions in any field of technology that are new, involve an inventive step and are susceptible of industrial 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.¹

Pursuant to Paragraph (2) of Article 1 of PA the following in particular shall not be regarded as patentable inventions

(a) discoveries, scientific theories and mathematical methods,

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

- (b) aesthetic creations,
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers,
- (d) presentations of information.
- (3) Patentability of the subject matters referred above shall be excluded only to the extent to which a patent application or the patent relates to such subject matter as such.

In accordance with Paragraph (2) of Article 6 of PA no patent protection may be granted for an invention if the exploitation thereof within the framework of economic activity would be contrary to public policy or morality; such exploitation may not be regarded as contrary to public policy merely because it is prohibited by law or regulation. On the basis of this the following, in particular, shall not be granted patent protection:

- (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;
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal; and
- (e) animals resulting from processes referred to in subparagraph (d).

Pursuant to Paragraph (4) of Article 6 of PA plant varieties and animal breeds, as well as essentially biological processes for the production of plants or animals shall not be patentable. A process for the production of plants or animals is essentially biological if it consists entirely of crossing, selection or other natural phenomena. (Plant varieties may be granted plant variety protection under the provisions of Chapter XIII of PA.)

The above provisions are without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such process. Microbiological process means any process involving or performed upon or resulting in microbiological material.

Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety or animal breed.

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be granted patent protection. This provision however does not apply to products, in particular substances (compounds) and compositions, for use in such methods.

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?

In accordance with Article 19 of PA the holder of the patent (patentee) has the exclusive right to exploit the invention. On the basis of this exclusive right, the patentee shall be entitled to prevent any person not having his consent (a) from making, using, putting on the market or offering for sale a product which is the subject matter of the invention, or stocking or importing the product for such purposes; (b) from using a process which is the subject matter of the invention or, where such other person knows, or it is obvious from the circumstances, that the process cannot be used without the consent of the patentee, from offering the process for use; (c) from making, using, putting on the market, offering for sale or stocking or importing for such purposes a product obtained directly by a process which is the subject matter of the invention.

Pursuant to Article 18 of PA patent protection begins with the publication of the patent application with retroactively effect from the date of the application. The protection resulting from the publication is provisional and becomes definitive when the patent is granted.

- 3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):
 - ξ Private and/or non-commercial use;
 - ξ Experimental use and/or scientific research;
 - ξ Preparation of medicines;²
 - ξ Prior use;
 - Use of articles on foreign vessels, aircrafts and land vehicles;
 - Acts for obtaining regulatory approval from authorities;
 - ξ Exhaustion of patent rights;
 - ξ Compulsory licensing and/or government use; Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.^{3 4}

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):

In accordance with Paragraph (6) (a) of Article 19 of PA the exclusive right of exploitation shall not extend to acts done privately or not involved in an economic/business activity.

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

The exception is not provided through case law.

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

The private use does not prejudice the normal exploitation of the patented invention. The basic function of the patent system, i.e. the provision of an incentive to innovate is not endangered by the private use.

For example, extemporaneous preparation of prescribed medicines in pharmacies.

Nevertheless, this limitation exists in the Hungarian law in respect of the exclusive right of the holder of plant variety right

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).

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

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

The PA itself does not define the above concepts. A definition of "economic/busienss activity" can be found in Act CXXVII of 2007 on Value Added Tax (VAT Act) which can be taken as a basis in the course of the interpretation of the above provisions. In accordance with Paragraph (1) of Article 6 of VAT Act economic/business activity means the performance of an activity in a professional manner either permanently or on a regular basis, if it aims at, or results in, achieving any value, and it is delivered in an independent way.

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):

There are no other criteria.

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:

The applicable legal framework is considered adequate; no amendments are foreseen.

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

None.

Section III: Experimental use and/or scientific research 5

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

In accordance with Paragraph (6) b) of Article 19 of the PA the patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting 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:

The exception is not provided through case law.

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

The first objective is to provide for the possibility of performing further important research activities, as this is important for the society. It is also important to enable the generic entry into

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

the market in due time, since this can provide patients with quality medicines at reasonable price, and decrease the costs related to the financing of medicines covered by the health scheme of the state.

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

The original wording of this provision was the following: The patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of medicines. This provision has been amended by Act XLVIII of 2001 in order to provide for a technology neutral terminology in conformity with Article 27 (1) of the TRIPS-Agreement. The amendment entered into force on 1.1.2002.

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

No.

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

The applicable law does not define the above concepts.

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

- ξ other, please specify: The exception includes any experimental purposes, in particular tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention.
- 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")

ξ Both of the above

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

In accordance with Paragraph (6) b) of Article 19, the experimentation must be conducted "relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention."

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

A non-commercial purpose A commercial purpose Both of the above

- ξ 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):

The applicable law does not make any distinction between "commercial" and "non-commercial" purpose.

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):

There are no other criteria.

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:

The applicable legal framework is considered adequate, there are no amendments foreseen.

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

None.

Section IV: Preparation of medicines

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

In accordance with Paragraph (6) c) of Article 19 of the PA, the exclusive right of exploitation does not extend to preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription, or acts concerning the medicine so prepared.

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

The exception is not provided through case law.

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

The policy objective is to provide patients with low cost quality medicines and to decrease the spending of the state health scheme. The use of the exception concerns minimal quantities, so this use is not prejudicial to the normal exploitation of the patent.

(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:

Those pharmacists, who are entitled to prepare medicines in a pharmacy in accordance with the relevant legal provisions.

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

Yes

٤ No

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

However, the legal provision states that medicines should be prepared on the basis of individual demand which indirectly determines the amount of the medicines prepared.

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

The medicines should be prescribed by a doctor and prepared for individual cases.

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:

The applicable legal framework is considered adequate, there are no amendments foreseen.

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

None.

Section V: Prior use

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

In accordance with Paragraph (1)-(3) of Article 21 of the PA a right of prior use belongs to any person who, in good faith, before the date of priority, in the territory of Hungary and within the framework of his economic activities, had begun to make or use the subject matter of the invention or had made serious preparations for that purpose. A prior user is considered a bona fide user until it is proved that the prior use was based on the inventive activity that led to the patented product. Patent protection does not have effect against a prior user in respect of the making, using of the patented invention, or any preparation related thereto, to the extent that these activities were performed at the priority date.

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

The exception is not provided through case law.

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

Protection of investments that were performed in bona fide.

(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):

Pursuant to Paragraph (3) of Article 21 of the PA, the patent protection does not have effect against a prior user in relation to the extent of making, using or any preparation existing at the priority date. Te applicable law does not provide for any other limitations.

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

No.

- 36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?
 - ξ 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?
 - $\begin{array}{cc} \xi & Yes \\ & No \end{array}$

If yes, please explain what those conditions are:

In accordance with Paragraph (3) of Article 21 of the PA, the right of prior use may only be transferred together with the entitled business entity or with that part of the business entity in which such making, using or preparation has taken place.

- 38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?
 - ξ Yes No

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

Pursuant to Paragraph (4) of Article 21 of the PA, a **right of continued use** belongs to any person who, in the period between a declaration of lapse of patent protection and restoration thereof, in the territory of Hungary and within the framework of their economic activities, has started to make or use the subject matter of the invention or has made serious preparations for that purpose.

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):

The subject matter of the invention should be used in the territory of the country and within the framework of the continued user's economic activities (Paragraph (4) of Article 21 of the PA)

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:

The applicable legal framework is considered adequate, there are no amendments foreseen.

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):

In accordance with Paragraph (5) of Article 21 of the PA – subject to reciprocity –, patent protection does not have effect with respect to means of communication and transport which are in transit in the territory of Hungary or to foreign goods which are not intended to be put on the market in the country.

The President of the Hungarian Intellectual Property gives a ruling on matters of reciprocity.

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

The exception is not provided through case law.

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

This exception is connected to the territoriality of patent rights. Those goods in transit that are not intended to be put on the market in Hungary do not enter the territory of Hungary. Valid patent rights are enforceable in the territory of Hungary.

(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:
 - ξ Vessels
 - ξ Aircrafts
 - ξ Land Vehicles
 - ξ Spacecraft

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

The applicable law applies the terms: "in transit" and "are not intended to be put on the market in the country".

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):

No.

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):

See answers to question no. 42 and 46.

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:

The applicable legal framework is considered adequate, there are no amendments foreseen.

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

None.

Section VII: Acts for obtaining regulatory approval from authorities

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

Pursuant to Paragraph (6) b) of Article 19 of the PA, the patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention.

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

The exception is not provided through case law.

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

See in point 13.

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

The original wording of this provision was the following: The patentee's exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of

medicines. This provision has been amended by Act XLVIII of 2001 in order to bring it into conformity with Article 27(1) of the TRIPS-Agreement and provide for technology neutral regulation. The amendment entered into force on 1.1.2002.

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

No restriction is foreseen.

- 55. The exception covers the regulatory approval of:
 - ξ any products certain products. Please describe which products:
- 56. Please indicate which acts are allowed in relation to the patented invention under the exception?
 - ξ Making
 - ξ Using

Selling

Offering for sale

Import

Export

Other. Please specify: any activities related research

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):

There are no other criteria.

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:

The applicable legal framework is considered adequate, there are no amendments foreseen.

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

None.

Section VIII: Exhaustion of patent rights

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

National

ξ Regional

International

Uncertain, please explain.....

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

Pursuant to Article 20 of PA the exclusive right of exploitation conferred by patent protection shall not extend to acts concerning a product put on the market in the territory of the **European**

Economic Area by the patentee or with his express consent, except where the patentee has legitimate interests in opposing the further marketing of the product.

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

The exception is not provided through case law.

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

The adopted exhausting regime reflects that Hungary is member state of the European Union.

- (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
 - ξ Yes No Uncertain

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

can override the exhaustion doctrine adopted in the country?

The patentee is entitled to oppose the further marketing of the product if he has legitimate interests in it.

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

Yes.

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

None.

Section IX: Compulsory licenses and/or government use

Compulsory licenses

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

In accordance with Article 31 of the PA, if within four years from the date of filing of the patent application or within three years from the grant of the patent, whichever period expires later, the patentee has not exploited the invention in the territory of the country to satisfy the domestic demand or if he has not undertaken serious preparations or has not granted a license for such purpose, a compulsory license shall be granted to the applicant for the license, unless the patentee justifies the lack of exploitation.

Pursuant to Paragraph (1) of Article 32 of the PA, if the patented invention cannot be exploited without infringing another patent (hereinafter referred to as "the dominant patent"), a compulsory license shall be granted, on request and to the extent necessary for the exploitation of the dominant patent, to the holder of the dependent patent, provided that the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the dominant patent.

Paragraph (1) of Article 33/A of the PA rules that the Hungarian Intellectual Property Office shall grant a compulsory license for the exploitation of an invention in the cases and on the terms laid down in Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2007 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (hereinafter referred to as "Regulation 816/2006/EC").

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

The exception is not provided through case law.

- 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
 - ξ Public health

National security
National emergency and/or extreme urgency

- ξ Dependent patents
 Other, please specify:
- 68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

The objective is to enable the exploitation of any useful patented inventions that are important for the development of the economy and the well-being of the society.

(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):

If within four years from the date of filing of the patent application or within three years from the grant of the patent, whichever period expires last, the patentee has not exploited the invention in the territory of the country to satisfy the domestic demand or if he has not undertaken serious preparations or has not granted a license for such purpose, a compulsory license shall be granted to the applicant for the license, unless the patentee justifies the lack of exploitation. (Article 31 of the PA)

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 importation per se does not constitute "working" of the patent, however, a legitimate import can mean that the patented invention is exploited in the territory of the country in order to satisfy the domestic demand.

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?

 ξ Yes No

If yes, what is the time period?

Four years from the date of filing of the patent application or three years from the grant of the patent, whichever period expires last.

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?

ξ Yes No

If yes, what are "legitimate reasons"?

The legitimate reasons are not listed by the applicable law. Legitimate reasons are taken into account in accordance with the circumstances of the given case.

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):

There is no definition in the applicable law. "Reasonable terms and conditions" and "reasonable period of time" are defined on a case by case basis.

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:

If the patented invention cannot be exploited without infringing another patent (hereinafter referred to as "the dominant patent"), a compulsory license shall be granted, on request and to the extent necessary for the exploitation of the dominant patent, to the holder of the dependent patent, provided that the invention claimed in the dependent patent involves an important

technical advance of considerable economic significance in relation to the invention claimed in the dominant patent. (Paragraph (1) of Article 32 of PA)

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:

Yes. In accordance with Paragraph (3) of Article 33 PA the patentee shall receive adequate compensation for the compulsory license, which shall be fixed, failing agreement between the parties, by the court. The compensation shall take into adequate account the economic value of the compulsory license. In particular, it shall be commensurate with the royalty the holder of the compulsory license would have paid on the basis of an exploitation contract concluded with the patentee, taking into account the licensing conditions in the technical field of the invention.

- 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:

No compulsory licenses have been issued so far.

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:

The applicable legal framework is considered adequate, there are no amendments foreseen.

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

None.

Government use

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

No such exception is provided for in the Hungarian law.

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

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

Non-working or insufficient working of the patented invention Refusal to grant licenses on reasonable terms Anti-competitive practices and/or unfair competition Public health National security

	National emergency and/or extreme urgency Dependent patents Other, please specify:	
84.	(a) What are the public policy objectives for providing government use in your country?	
	-	
	(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:	
	-	
85.	If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:	
	-	
86.	Please indicate how many times and in which technological areas government use has been issued in your country:	
	-	
87.	Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:	
	-	
88.	Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:	
	-	
Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions ⁶		
Farme	rs' use of patented inventions	
89.	If the exception is contained in statutory law, please provide the relevant provision(s):	
90.	If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):	

⁶ In the Hungarian law, exceptions and limitations related to farmers'/breeders' use exists in respect of the exclusive right of the holder of plant variety right

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:
Breed	lers' use of patented inventions
95.	If the exception is contained in statutory law, please provide the relevant provision(s):
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	on XI: Other Exceptions and Limitations		
101.	Please list any other exceptions and limitations that your applicable patent law provides:		
	No other exceptions and limitations are applicable in the Hungarian patent law.		
102.	In relation to each exception and limitation, please indicate:		
	(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):		

	(II) 	the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:
	(iii)	the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):
	In a	addition, in relation to each exception and limitation, please explain: 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.		er mechanisms for the limitation of patent rights external to the patent system exist in country (for example, competition law), please list and explain such mechanisms:

[End of Questionnaire]