Questionnaire on Exceptions and Limitations to Patent Rights

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

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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 the *Federal Law on Patents for Inventions (*SR 232.14, LBI) defines the terms of patentability, which are the same for all areas of technology that are the subject of a patent application, in so far as the law does not expressly exclude them from patentability:

"Patents for inventions are granted for new inventions that can be used industrially."

Paragraph 2 states: "that which is obvious from prior art (art. 7, para. 2) shall not constitute a patentable invention."

"Not belonging to a sphere of technology and therefore unable to benefit from the protection accorded by patents shall be systems directed only at the human mind, that focus solely on human behavior and that lead without direct intervention and through the forces of nature to a given result" (Order of the Federal Tribunal 95 I 579). The Message of March 24, 1967, p.67, provides a non-exhaustive list of what cannot be considered an invention: discoveries, mathematical methods, plans and methods for intellectual activities (Order of the Federal Tribunal 95 I 579), rules and methods concerning commercial activities, the rules of games, lottery systems and aesthetic creations.

(a) Article 1*a* of LBI: “1. The human body as such, at all stages of its formation and development, including the embryo, is not patentable.

2. Elements of the human body in their natural environment shall not be patentable. An element of the human body shall, however, be patentable as an invention if it is produced by means of a technical process, a beneficial technical effect shall be indicated and the further requirements of Article 1 fulfilled; Article 2 is reserved.”

(b) Article 1*b* of LBI: “A naturally occurring sequence or partial sequence of a gene shall not be patentable as such.

2. Sequences that are derived from a naturally occurring sequence or partial sequence of a gene may, however, be patented as an invention if they are produced by a technical process, their function is specifically described, and the further requirements of Article 1 are fulfilled; Article 2 is reserved.”

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]

Article 2 of LBI: “1. Inventions whose exploitation is contrary to public order or morality, in particular to human dignity or the integrity of living organisms, shall be excluded from patentability. In particular, no patent shall be granted for:

a. processes for cloning human beings and the clones obtained thereby;

b. processes for forming hybrid organisms by using human gametes, human totipotent cells or human embryonic stem cells and the entities obtained thereby;

c. processes of parthenogenesis using human germ cells and the parthenotes produced thereby;

d. processes for modifying the genetic reproductive identity of human beings and the germinative cells obtained thereby;

e. unmodified human embryonic stem cells and stem cell lines;

f. the use of human embryos for non-medical purposes;

g. processes for modifying the genetic identity of animals that are likely to cause suffering to the animals without being justified by reason of overriding interests that are worthy of protection, as well as the animals resulting from such processes.

2. Also excluded from patentability shall be:

a. surgical, therapeutic and diagnostic procedures practiced on the human body or the bodies of animals;
b. plant and animal varieties and essentially biological processes for the production of plants and animals; subject to the reservation of paragraph 1, however, microbiological or other technical processes and the products obtained thereby, as well as inventions that concern plants or animals, provided that their application is not technically confined to a single plant or animal variety, are patentable.

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

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?

Article 8 of LBI: "1. The patent shall confer on its owner the right to prohibit others from using the invention for professional purposes.
2. Use shall include, in particular, manufacturing, storing, offering, placing on the market, importing, exporting and carrying in transit, and possession for any of these purposes.
3. Carrying in transit may only be prohibited if the patentee is permitted to prohibit importation into the country of destination."

Concerning the patent for a manufacturing process, Article 8*a* of LBI stipulates that,
"1 If the invention relates to a manufacturing process, the protection conferred by the patent shall also extend to the products directly obtained by that process.
2 If the products directly obtained are biological material, the protection conferred by the patent shall also extend to products obtained by propagating the biological material and which demonstrate the same characteristics. Article 9*a*, paragraph 3, is reserved."

Concerning patents for genetic information, Article 8*b* of LBI stipulates that:
"If the invention relates to a product that consists of or contains genetic information, the protection conferred by the patent shall extend to any material in which the product is incorporated and in which the genetic information is contained and performs its function. Articles 1*a*, paragraph 1, and 9*a*, paragraph 3, are reserved."

Concerning patents for nucleotide sequences, Article 8*c* of LBI stipulates that:
"The protection conferred by a claim on a nucleotide sequence that is derived from a naturally occurring sequence or partial sequence of a gene shall be limited to the nucleotide sequence segments that perform the function specifically described in the patent."

All these exceptions should be interpreted on the basis of LBI, Article 8.

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 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.[2]

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

[2] For example, 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).

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 9, paragraph 1, of LBI provides that: “The scope of protection conferred by the patent shall not extend to: a. acts undertaken in the private sector 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:

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

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(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):

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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:

YES, no amendments to the law are foreseen.

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 [3]

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

Article 9, paragraph 1, of LBI stipulates that: "The scope of protection conferred by the patent shall not extend to… b. acts undertaken for experimental and research purposes in order to obtain knowledge on the subject of the invention, including its possible uses; in particular all scientific research concerning the subject of the invention shall be permitted."

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

In view of the fact that freedom of research in general, and in the field of biotechnology in particular, has great significance for the technological progress that patent law aims to promote, experimental use privilege [is regulated] in law (FF 2006, 66).

According to the current Swiss climate of opinion, acts that are undertaken to determine feasibility or suitability and those for the further technical development of a disclosed invention should be permitted. These acts may be undertaken for experimental purposes and therefore do not require the permission of the patentee.

The experimental use privilege secures, not only applied research, but basic research as well, and guarantees the inherent goal of the patent system to promote research and technological development (FF 2006, 66).

(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:

Swiss legislation establishes no distinction concerning the nature of the organization conducting the experimentation or research.

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

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

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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:

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

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

X Research and/or experimentation must be conducted on **the subject of** the patented invention
☐ 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):

Article 9, paragraph 1, of LBI stipulates that only acts undertaken for experimental and research purposes *on the subject of the invention* are excluded from the protection conferred by the patent.

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

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

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

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

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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:

No amendments to the law are foreseen.

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):

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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:

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(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:

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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 35, paragraph 1, of LBI: “A patent has no effect against anyone who, in good faith, prior to the date of filing of the patent application or the priority date, was using the invention for professional purposes in Switzerland or had been making special preparations for that purpose.”

Article 48 of LBI: “1. A patent has no effect against anyone who, in good faith and during the periods indicated hereafter, used the invention for professional purposes in Switzerland or had made special preparations for that purpose:
a. between the last day of the period provided for payment of an annuity and the day on which a request for further proceedings (art. 46*a*) or a request for restoration (art. 47) was submitted;
b. between the last day of the priority period (art. 17, para. 1) and the day on which the patent application was filed.

2. The right thereby acquired by a third party shall be regulated by Article 35, paragraph 2.

3. Anyone who claims a right based on paragraph 1(a) shall pay fair compensation to the patentee from the date on which the patent is reinstated.

4. In case of dispute, the court shall decide on the existence and scope of the rights claimed by a third party and set the amount of the compensation provided in paragraph 3.”

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:

This exception is aimed at limiting the consequences of the first to file system by protecting the investments made by the inventor of an unpatented invention that he has been keeping confidential since a date prior to the filing by a third party of an application concerning the same invention.

(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):

Article 35, paragraph 2, of LBI provides that a prior user, "shall be able to use the invention only for the needs of his business."

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

The payment of such remuneration is not provided for.

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

X Yes (a prior user may only assign his prior user's right, not license it)
☐ 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:

The second part of Article 35, paragraph 2, of LBI provides that the prior user's rights, "may only be transferred, inter vivos or by succession, with the business."

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
X 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):

The prior user must be acting in good faith.

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:

No amendments to the law are 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):

Article 35, paragraph 3, of LBI: “The protection conferred by the patent shall not extend to vehicles that are only temporarily present in Switzerland, nor to devices fitted to such vehicles.”

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:

Article 35, paragraph 3, of LBI corresponds to Article 5*ter* of the Paris Convention for the Protection of Industrial Property.

(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
X 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):

Article 35, paragraph 3, of LBI uses the term “temporarily” but this term is defined neither in legislation nor by case law.

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):

Article 5*ter* of the Paris Convention for the Protection of Industrial Property limits the exception to the use on board vessels of devices forming the subject of the patent in the body of the vessel, as well as the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles.

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 9, paragraph 1: “The scope of protection conferred by the patent shall not extend to… c. acts necessary to obtain marketing approval for a pharmaceutical product in Switzerland or in countries with comparable regulation for pharmaceutical products.”

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:

This exception enables medicine industries to start the procedure to obtain federally mandated marketing approval for a pharmaceutical product before patent protection expires.

(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 marketing approval applicant.

55. The exception covers the regulatory approval of:

☐ any products
X certain products. Please describe which products: medicine

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: The exception applies to, *inter alia*, experiments and clinical trials in which a pharmaceutical product containing a protected active ingredient is tested to obtain the data required for marketing approval. (FF 2006, 68).

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

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

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

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Section VIII: Exhaustion of patent rights

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

X National
X Regional (European Economic Area)
X International
☐ Uncertain, please explain.……

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

On December 19, 2008, the Federal Assembly of Switzerland adopted a unilateral, regional exhaustion regime (i.e. without agreeing to any reciprocity) with the Member States of the European Economic Area (EEA).

Regarding goods whose prices are set by the State in Switzerland or abroad, notably medicines, the Federal Assembly decided that their importation would continue to be subject to the agreement of the patentee.

Article 9*a* of LBI: "1. When patented goods are placed on the market in Switzerland or the European Economic Area by the patentee or with his agreement, they may be imported and used or resold in Switzerland for professional purposes.

2. When a device allowing the use of a patented process is placed on the market in Switzerland or the European Economic Area by the patentee or with his agreement, the first purchaser or any subsequent purchaser of the device shall be authorized to use the process.

3. When patented biological material is placed on the market in Switzerland or the European Economic Area by the patentee or with his agreement, it may be imported and propagated in Switzerland as many times as required for the intended use. The material thus obtained must not be used for further propagation. Article 35*a* is reserved.

4. When patented goods are placed on the market outside the European Economic Area by the patentee or with his agreement and, due to the functional characteristics of the goods, the protection accorded by the patent is of secondary importance, the goods may be imported for professional purposes. The protection accorded by the patent is assumed to be of secondary importance if the patentee does not convincingly demonstrate the contrary.

5. Notwithstanding paragraphs 1 and 4, when the price of the patented goods is set by the State in Switzerland or the country of commercialization, the goods may only be placed on the market in Switzerland with the agreement of the patentee."

Article 27*b* of the Law on Agriculture (RS 910.1) remains unchanged: international exhaustion shall remain applicable to the means of production and to agricultural capital equipment.

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:

The aim of the exception is to abolish the monopoly on the import of patented products for goods sold in the European Economic Area.

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

The national exhaustion doctrine concerning patent law was established in 1999 by an Order of the Federal Tribunal (ATF 126 III 129). In accordance with this Order, the patentee can assert his rights before the court to prevent products protected by his patent, which he has commercialized abroad, from being imported into Switzerland against his will. Since that time, the national exhaustion regime has been the subject of animated debate.

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
X No
X Uncertain

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

Article 9*a*, paragraph 5, of LBI provides that the patentee can apply import restrictions if the price of a patented good is set by the State.

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):

Dependent inventions
Article 36, LBI: “1. If an invention that is the subject of a patent cannot be used without violating a prior patent, the owner of the most recent patent shall be entitled to the grant of a non-exclusive

license in so far as required for the use of his invention, if that invention should present significant technical progress of considerable economic interest, compared with the invention that is the subject of the first patent.

2. The license to use the invention subject to the first patent may only be transferred in conjunction with the second patent.

3. The owner of the first patent may link the granting of the license to the condition that the owner of the second patent should in turn grant the first patent owner a license for using his invention."

Insufficient working by the license holder:
Article 37 of LBI: "1. Following a period of three years from the award of the patent, and at the earliest four years after filing, anyone with a demonstrated interest may request that the court should grant a non-exclusive license for using the invention if the patentee has not sufficiently worked the invention domestically by the time the claim is filed and cannot justify this omittance. Importing is considered working of the patent in Switzerland.

3. At the request of the applicant, the court may award a license as soon as the claim is filed, subject to judgment of the merits, if, in addition to the conditions set out in paragraph 1, the applicant convincingly demonstrates his interest in making immediate use of the invention and he offers the defendant sufficient guarantees; the defendant must be heard beforehand."

Claim that the patent has lapsed:
Article 38 of LBI: "1. If the granting of licenses is not sufficient to meet the needs of the Swiss market, anyone with a demonstrated interest may, following a period of two years from the grant of the first license awarded in accordance with Article 37, paragraph 1, request that the court should declare that the patent has lapsed.

2. When the legislation of the country of which the patentee is a national, or in which he is established, accepts, after a period of three years have passed since the award of the patent, the claim of lapse of the patent due to non-working of the invention in the country, this claim shall be admitted in lieu and place of the claim to grant a license in accordance with the conditions stated in Article 37 on the grant of a license."

Article 39 of LBI: "The Federal Council may declare that Articles 37 and 38 do not apply with regard to nationals of countries that confer reciprocity."

Compulsory license in the public interest:
Article 40 of LBI: "Where the public interest requires, a person with whom the patentee refused to conclude a license without sufficient reason may apply to the court for the grant of a license to use the patented invention."

Expropriation of the patent:
Article 32: "1. Where the public interest requires, the Federal Council may order the total or partial expropriation of the patent.

2. The person whose property has been expropriated shall be entitled to full and proper compensation, set in cases of dispute by the Federal Tribunal; the provisions of Chapter II of the Federal Law on Expropriation of June 20, 1930, shall be similarly applicable."

Compulsory licenses in the sphere of semi-conductor technology:
Article 40*a* of LBI: "In the case of an invention in the sphere of semi-conductor technology, a non-exclusive license may only be granted to remedy a practice held to be anti-competitive in judicial or administrative proceedings."

Instruments of research:

Article 40*b* of LBI: “Any person who intends to use a patented biotechnological invention as an instrument of or accessory to research shall be entitled to a non-exclusive license.”

Compulsory licenses for diagnostics:
Article 40*c* of LBI: “In the case of an invention relating to a human diagnostic product or process, a non-exclusive license shall be granted to remedy a practice held to be anti-competitive in judicial or administrative proceedings.”

General provisions on Articles 36 to 40*d*:
Article 40*e* of LBI: “1. The licenses provided for in Articles 36 to 40*d* shall be granted only if efforts by the applicant to obtain a contractual license on appropriate market terms have, within a reasonable period, been unsuccessful; in the case of a license in accordance with Article 40*d*, a period of 30 working days shall be regarded as reasonable. Such efforts shall not be required in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

2. The scope and duration of the license shall be limited to the purposes for which it has been granted.

3. The license may only be transferred with that part of the enterprise which uses it. This shall also apply to subsidiary licenses.

4. The license shall primarily be granted for supplying the domestic market. Article 40*d* shall be reserved.

5. The patentee shall be entitled to appropriate remuneration. In assessing the remuneration, the circumstances of the individual case and the economic value of the license shall be taken into account. In the case of a license in accordance with Article 40*d*, the remuneration shall be determined by taking into account the economic value of the license in the importing country, its level of development, and the urgency in public health and humanitarian terms. The Federal Council shall specify the method of calculation.

6. The courts shall decide on the granting and cancellation of licenses, their scope and duration, as well as the remuneration payable. In particular, they shall cancel a license on request if the circumstances that led to its being granted no longer apply and it is not expected that they will arise again, subject to the appropriate protection of the lawful interests of the licensee. Where a license is granted in accordance with Article 40*d*, legal remedies shall have no suspensive effect.”

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

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

X Non-working or insufficient working of the patented invention; Note: Article 37 of LBI only applies if the patentee is unable to give grounds for his inaction.
X Refusal to grant licenses on reasonable terms; Note: In accordance with Article 40 of LBI it must be in the public interest.
X Anti-competitive practices and/or unfair competition; Note: only Articles 40*a* and 40*c* of LBI provide for a compulsory license based on competition law.
X Public health; Note: Article 40 of LBI provides that it must be in the public interest. Public health is in the public interest.

X National security; Note: Article 40 of LBI provides that it must be in the public interest. National security is in the public interest.
X National emergency and/or extreme urgency; Note: Article 40 of LBI provides that it must be in the public interest. National emergency and extreme urgency are in the public interest. In a national emergency or circumstances of extreme urgency the applicant is not required to undertake efforts to obtain a contractual license on appropriate market terms.
X Dependent patents (Art. 36, LBI)
☐ Other, please specify: ……

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

Articles 36 to 40 of LBI indicate the legislator's fear that a patentee might abuse the monopoly position provided by Article 8 of LBI to the detriment of the interests of the whole community.

(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):

The law makes no reference to specific definitions. Articles 38, paragraph 1, and 40*e*, paragraph 4, of LBI, which provide that the license is granted primarily to supply the domestic market, assist in interpreting these terms. The standard for "sufficient working" is an analysis of the needs of the domestic market.

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):

Article 37, paragraph 1, second sentence of LBI provides that importing shall be considered working of the patent in Switzerland.

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?

Article 37, paragraph 1, provides a time period of three years after the award of the patent, and at the earliest four years after filing.

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?

X Yes
☐ No

If yes, what are “legitimate reasons”?

No legal definition.

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

No legal definition.

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):

In Swiss patent law, two provisions envisage the possibility of granting compulsory licenses to combat anti-competitive practices (Arts. 40*a* and 40*c*, LBI).

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:

The following conditions must be met for a compulsory license to be granted (art. 36 and art. 40*e*, para. 1, LBI):
1. Dependent invention: the subject of a patent cannot be used without violating a prior patent.
2. The applicant has undertaken efforts to obtain, within a reasonable period of time, a contractual license with appropriate market conditions.
3. The invention represents technical progress of considerable economic interest, compared with the subject of the first patent.

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:

Article 40*e*, paragraph 5, of LBI provides that when assessing remuneration, the circumstances of the individual case and the economic value of the license shall be taken into account.

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:

There are two cases in which the Federal Tribunal has granted a compulsory license in accordance with Article 36 of LBI (dependent invention). In the first case (ATF 29 II 564), the invention consisted of a school desk that allowed the user to work while standing or sitting and could be adapted to any height. In the second case (ATF 42 II 269), the invention was a ‘rectifier’ or ‘convertor’ which could transform alternating current into direct current. According to the information available, no cases have been recorded in other technological areas.

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:

It is very rare in Switzerland for recourse to be sought to compulsory license mechanisms. The existing legislation seems adequate.

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):

This exception does not exist in Swiss patent law.

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

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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?

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(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:

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

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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 35*a* of LBI: "1. Farmers who have acquired plant propagated material placed on the market by the patentee or with his consent, may propagate the product harvested from such material on their own farms.

2. Farmers who have acquired animals or animal reproductive material placed on the market by the patentee or with his consent, may propagate the animals raised from those animals or that material on their own farms.

3. Farmers must obtain the consent of the patentee in order to transfer to a third party, for the purposes of reproduction, the product of crops, animals or the reproductive animal material concerned.

4. All agreements restricting or invalidating the farmers' privilege with regard to food and animal feed shall be void."

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:

The exception permits farmers to continue to use plant seeds or their own animals for livestock farming, even if the gene sequences are protected by patent.

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

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

On the basis of Article 35*b* of LBI, the Federal Council defined the plant species to which the farmer's privilege applies (annex 1 to the Order of June 25, 2008, on the protection of plant varieties (SR 232.161)).

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 9, paragraph 1: "The scope of protection conferred by the patent shall not extend to… e. the use of biological material for the purposes of the production or the discovery and development of a plant variety.

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:

The breeders' privilege accorded by the Law on the Protection of Plant Varieties and the related issue of patent protection should be mentioned in connection with the experimental use privilege. The breeder's privilege is a significant restriction on the Law on the Protection of Plant Varieties

which makes possible not only the breeding and development of new plant varieties but also, at the present time, their commercialization without the permission of the legitimate owner of the original plant variety (FF 2006, 69).

(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:

There are two further exceptions and limitations in Swiss patent law:
(a) the compulsory license for users acting in good faith once the courts have ordered the transfer of the patent (Art. 29, LBI).
(b) the compulsory license for the manufacture of medicine destined for a developing country (Art. 40*d*, LBI).

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):

(a) Article 29 of LBI: "1. When the patent application has been filed by a person who had no entitlement to the grant of the patent in accordance with Article 3, the legal claimant may request that the patent application should be transferred or, if the patent has already been granted, request that it should be transferred or commence proceedings to have it declared invalid.

3. If the courts order a transfer, the licenses or other rights granted in the interim to third parties shall lapse; such parties shall, however, be entitled to the grant of a non-exclusive license if they

have already, in good faith, used the invention for professional purposes in Switzerland, or if they have made specific preparations for that purpose.

4. All requests for damages are reserved.

5. Article 40*e* similarly applies."

(b) Article 40*d*, LBI: "Anyone may apply to the courts to be granted a non-exclusive license for the manufacture of pharmaceutical products protected by patents and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector, and which requires these products to combat public health problems, in particular those related to HIV/AIDS, tuberculosis, malaria and other epidemics (beneficiary country).

2. Countries that have declared to the World Trade Organization (WTO) that they wholly or partly waive their claim to a license in accordance with paragraph 1 shall be excluded from being beneficiary countries, in accordance with the terms of their declarations. All other countries that fulfill the requirements of paragraph 1 may be beneficiary countries.

3. The license in accordance with paragraph 1 shall be limited to the production of the pharmaceutical products in the quantity that meets the requirements of the beneficiary country; the total quantity must be exported to the beneficiary country.

4. The owner of the license, in accordance with paragraph 1, as well as any manufacturer that produces products under license, must ensure that they are clearly identified as products that have been produced under a license in accordance with paragraph 1, and that the products are distinguished from patented products by their special packaging and/or coloring or shaping, provided that this does not have a significant impact on the price of the products in the beneficiary country.

5. The Federal Council shall regulate the requirements for granting licenses in accordance with paragraph 1. In particular, it shall stipulate the information or notifications that the courts responsible must possess in order to decide on the granting of the license and the measures in accordance with paragraph 4."

Article 40e of LBI and Article 111 to 111*c* of the Order on Patents for Inventions (OBI) apply.

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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:

b.) It is a measure to improve public health in least developed countries and countries that have little or no manufacturing capacity in the pharmaceutical sector. This compulsory license is based on the decision adopted on August 30, 2003, by the General Council of WTO (documents WT/L/540 of September 1, 2003, and JOB(03)/177 of August 30, 2003) which henceforth permits WTO members with sufficient manufacturing capacity to issue compulsory licenses to manufacture generic versions of patented pharmaceutical products for export to least developed member countries and member countries that have little or no manufacturing capacity in this sector.

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

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

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

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

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

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[End of Questionnaire]