

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **ISRAEL**

Office: **Israel Patent Office**

Person to be contacted:

Name: Ms. Noa Amit

Title: International Relations Officer

E-mail: NoaAmit@justice.gov.il

Telephone: +972-2-5651759.....

Facsimile: +972-2-6462555.....

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.

Patentable inventions are defined in Section 3 of the Israel Patent Law 5727-1967 (IPL): "An invention, whether a product or a process, in any field of technology, which is new and useful, can be used industrially, and involves an inventive step, is a patentable invention".

Explanations regarding interpretation of the terms used in Section 3 as to be implemented by the patent examiners at the ILPO can be found at the guidelines for examination, published at the ILPO's website.

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

Exclusions from patentability under Section 7 of IPL:

- (1) a method of therapeutic treatment on the human body;
- (2) new varieties of plants or animals, except microbiological organisms not derived from nature.

A discovery, a scientific theory, a mathematical formula, rules for playing games and mental acts are considered to be abstract ideas or non-technical processes, therefore under examination guidelines Appendix B, paragraph 7.3 they are not a patentable subject matter under Section 3 of IPL.

In addition, based on The Registrar's Decision at ex-parte proceeding in the matter of Patent Application No. 131733 in the name of Eli Tamir, business methods per-se, which are in the field of economics, are not considered to be in a field of technology, therefore they are not patentable subject matter.

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?

Rights of Patent holder and restrictions on exploitation of patent under Section 49 of the IPL:

"A patent holder is entitled to prevent any other person from exploiting the invention for which the patent has been granted without his permission or unlawfully, either in the manner defined in the claims or in a similar manner, in the light of what is defined by those claims, involves the essence of the invention which is the subject matter of the patent (hereafter: "infringement").

(b) The grant of a patent does not constitute permission to exploit any invention unlawfully or in a manner that constitutes laws rights exist under any enactment"

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

The term "exploiting the invention" is defined at Section 1 of the IPL as follows:

(1) in respect of an invention that is a product—any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the said acts;

(2) in respect of an invention that is a process—use of the process, and in respect of a product directly derived from the process—any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the said acts;

Moreover, Section 49 of IPL was interpreted by Israeli courts to include both the English "Doctrine of Variants" and the U.S. "Doctrine of Equivalents" (C.A. 345/87, Hughes Aircraft Company vs. The State of Israel; PD 44(4)045).

Regarding the publication of a patent application, according to Section 16 of IPL, the full patent's description is not published until the patent is allowed; therefore there are no exclusive rights that can be used by the applicant before the allowance of the patent application. Note that Section 16 of IPL is about to be amended and it is subject to final approval by the Israeli parliament. According to the amendment, a Patent application will be published 18 months after the filing date or the priority date (PCT application will be published 45 days after entering the national phase) and the patent applicant will be entitled to demand royalties according to Section 179(1)(1) starting from the first such publication date.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- Private and/or non-commercial use; Yes**
- Experimental use and/or scientific research; Yes**
- Preparation of medicines;² NO
- Prior use; Yes**
- Use of articles on foreign vessels, aircrafts and land vehicles; YES**
- Acts for obtaining regulatory approval from authorities; YES**
- Exhaustion of patent rights; YES**
- Compulsory licensing and/or government use; YES**
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³ NO

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

³ For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement.

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

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

Section II: Private and/or non-commercial use

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

The private or non-commercial use is not considered to be exploitation of patent rights (infringing) under definitions of Section 1 of the IPL:

“exploitation of an invention”—

(1) in respect of an invention that is a product—any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the said acts;

(2) in respect of an invention that is a process—use of the process, and in respect of a product directly derived from the process—any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the said acts;

but exclusive of any of the following:

(1) an act that is not on a commercial scale and is not commercial in character;

(2) an experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention;

(3) an act performed under the provisions of section 54A.

.....

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

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).

N/A

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

N/A.....

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

According to explanatory memorandum to the 4th patent law amendment bill, the non-commercial use means: private home use or use for pure scientific research. Nevertheless, these definitions have been subject to extensive academic writing in this field.

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

According to Tel Aviv District Court Decision (C.S. 1512/93(Tel Aviv), *The Welcome Foundation Limited vs. Teva Pharmaceutical Industries LTD, Takdin-DC, 94(2), 197*), the definition of the non-commercial use is an unprofitable private use, such as exploitation of the invention for a home purpose.

The matter of pure scientific research was discussed at the later Tel Aviv District Court Decision (C.S. 881/94(Tel Aviv) ,*Eli Lilly and Company vs. Teva Pharmaceutical Industries LTD, Takdin-DC, 1586(3)98*). The court's decision was that pure medical research for the discovery of medicinal properties of the material will not be considered a business even if it involves investment and experiments in a large scale. But if the material will be distributed for free (not to mention, if offered for sale) to potential clients of the patent holder, then such activity will be considered as a business activity. Similarly, if there will be business-oriented activities, such as development of process for commercial production or shipping samples to customers, it will go into the forbidden area. The pure research activity may later become a commercial activity, but it should be ensured, that the commercial nature did not exist from the beginning, but rather appeared after the expiration of patent's rights.

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):

N/A

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:

N/A

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

N/A

Section III: Experimental use and/or scientific research ⁴

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

An experimental use for improving the patented invention or for developing another invention is not considered to be exploitation of patent rights (infringing) under definitions of Section 1 of the IPL:

“exploitation of an invention”—

(1) in respect of an invention that is a product—any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the said acts;

(2) in respect of an invention that is a process—use of the process, and in respect of a product directly derived from the process—any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the said acts;

but exclusive of any of the following:

(1) an act that is not on a commercial scale and is not commercial in character;

(2) an experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention;

(3) an act performed under the provisions of section 54A.

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

N/A

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

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

As predicted in the explanations to the relevant amendment, this exception was introduced into the law (3rd amendment) together with the exception of obtaining regulatory approval from authorities and provisions for patent term extension. Those exceptions meant to create a balance between the interests of generic industries and the interest of innovative industries.

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

One of the purposes for providing the exception was to overcome the anomaly, which was created by the original definition of the term "exploitation of an invention", especially in the pharmaceutical industry. The original definition (before the 3rd amendment at 1998) prevented from starting performing research and development of patented product or performing any experimental action regarding the patented invention, including improving the invention or developing a new invention, as long as the patent was valid (M.C.P. 814/05(Jerusalem), Orbotech LTD vs. Kamtech LTD, (2006) Nevo).

Tel Aviv District Court discussed the meaning of the above exception (M.C.P. 19682/05, Transkaryotic Therapies INC vs. Genzyme Corporation, (2006) Nevo). It was ruled that the law permits experimental operations, which are using existing and protected procedures (or products) in order to improve the process or the product, or in order to develop another process or product. Plaintiff's arguments that the exception applies only to developing of the same invention were rejected.

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 (See previous explanation regarding M.C.P. 19682/05).

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):

N/A.....

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

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- [seek an improvement to the patented invention](#)
- invent around the patented invention
- other, please specify: [improvement of the patented invention or developing a new one.](#)

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

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

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

[N/A](#)

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

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

[The commercial intention of the experimentation and/or research is not relevant.](#)

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

[The distinction between commercial” and “non-commercial” purpose is not relevant for the experimental use exception. Furthermore, both purposes are allowed under this exception.](#)

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):

N/A

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:

N/A

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

N/A

Section IV: Preparation of medicines

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

In Israel, there is no statutory exclusion for preparation of medicament.

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

N/A.....

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

N/A.....

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

N/A.....

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

N/A.....

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):

N/A

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):

N/A.....

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:

N/A.....

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

N/A.....

Section V: Prior use

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

Prior user rights are defined in section 53 of IPL as follows:

"If, on the determining date, a person in Israel in good faith exploited the invention for which the patent is applied for, or if he in good faith made actual preparations for its exploitation, then he shall be entitled to exploit the invention himself and in the course of his business without consideration; for the purpose of this provision, the "determining date" is the date on which application for the patent was submitted in Israel or – if priority right under section 10 is claimed for that application – the date of submission of the previous application on which the claim for priority right is based".

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

N/A

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

N/A.....

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

N/A.....

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):

N/A.....

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

N/A.....

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

[Yes](#)

No

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

[Yes](#)

No

If yes, please explain what those conditions are:

According to provisions of the section 54 of IPL the prior use rights can be transferred only together with the business in which that invention was used (section 54: "The right under section 53 cannot be transferred, devolved or transmitted by inheritance, except together with the business in which that invention was used").

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

[Yes](#)

No

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

If renewal fees were not paid on time and thereupon the patent was lapsed, then a third party can use patented invention under the provisions of Section 63 of IPL: "If a person began to exploit in Israel an invention on which the patent lapsed after the lapse of the patent was published under Section 58, or if a person after that date made actual preparations for its exploitation, then he shall be entitled to continue to exploit the invention only for the requirements of his business, even after the patent is reinstated." The right of exploitation cannot be transferred according to Section 64 of IPL: "The right to exploit an invention under Section 63 cannot be transferred, devolved or transmitted by inheritance, except together with the business in which that invention was used".

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):

N/A.....

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 relevant sections of IPL are currently being considered.

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

N/A

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):

The exception provided by Section 181 of IPL:

"The following shall not be deemed infringements:

(1) the use of an invention patented in Israel in the body of a vessel registered in a Member State other than Israel, in its machinery, tackle, apparatus or other accessories, when the vessel is temporarily or incidentally in Israel territorial waters, on condition that the exploitation is exclusively for the needs of the vessel;

(2) the use of an invention patented in Israel in the construction or operation of an aircraft or land vehicle registered in a Member State other than Israel, or of the accessories of such an aircraft or land vehicle, when they are temporarily or incidentally in Israel."

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

N/A.....

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

N/A.....

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

N/A.....

45. The exception applies in relation to:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

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

The terms "temporarily" and "accidentally" are applied by provisions of the law:.....

"The following shall not be deemed infringements:

(1) the use of an invention patented in Israel in the body of a vessel registered in a Member State other than Israel, in its machinery, tackle, apparatus or other accessories, when the vessel is temporarily or incidentally in Israel territorial waters, on condition that the exploitation is exclusively for the needs of the vessel;

(2) the use of an invention patented in Israel in the construction or operation of an aircraft or land vehicle registered in a Member State other than Israel, or of the accessories of such an aircraft or land vehicle, when they are temporarily or incidentally in Israel."

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):

N/A

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):

N/A

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:

N/A

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

N/A

Section VII: Acts for obtaining regulatory approval from authorities

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

The exception is provided by Article 54A of IPL:

An experimental act, which is part of an effort to obtain a license to market the product after the patent has lapsed, does not constitute "exploitation of an invention", if the following two conditions are met:

(1) the effort to obtain a license is made in order to obtain a license in Israel or in a country, in which an experimental act on a patent protected invention for the purpose of obtaining a license is permitted before the patent lapses;

(2) any product produced under the terms of this section is not used – both while the patent is in effect or thereafter – for any purpose other than obtaining a license as aforesaid;

for purposes of this section, "license" – certification, permit or any other document required under Law in order to market the product"

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

N/A

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

See the below explanation at 53(b).

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

The 3rd amendment of IPL (1998) created a new regime in patent protection of medicines, in order to "balance the conflicting interests of the generic pharmaceutical industry on the one hand and those of the pharmaceutical industry which is engaged in research and development on the other hand" (the explanatory memorandum to the 3rd patent law amendment).

According to the Jerusalem District Court Decision (M.A. 223/09 (Jerusalem), H. Lundbeck A/S vs. Unifarm LTD, (2009) Nevo) the public interest in the activities of generic companies combines the significant contributions in promotion of exports from Israel and providing an employment for large numbers of workers, mostly academics, with the public benefits derived from a competition at the pharmaceutical market and the price reduction as a result of the competition.

Additional Court decision discusses the public policy objectives for providing of the above exception. According to Tel Aviv District Court Decision (M.C.P 19682/05 (Tel Aviv), Transkaryotic Therapies Inc. vs. Genzyme Corporation, (2009) Nevo), Article 54A is intended to encourage development and licensing of competing products (generic and not generic, drugs and not just drugs) and to prevent de facto extension of patent rights beyond the term prescribed by the law.

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

The exception can be used by any person or entity which is seeking to get a regulatory approval for a patented product in Israel or in a country which is permitted such activity by the law.

55. The exception covers the regulatory approval of:

any products

certain products. Please describe which products:

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

- Making
- Using
- Selling
- Offering for sale
- Import

Export

Other. Please specify: [any experimental act for obtaining a license to market the product, which may include making, using, import and export.](#)

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):

N/A

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:

N/A

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

N/A

Section VIII: Exhaustion of patent rights

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

National

Regional

International

[Uncertain, please explain.](#)

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

[There is no exception provided by statutory law.](#)

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

An adoption of International Exhaustion Doctrine was suggested by the High court of Justice (H.C.J. 5379/00, Bristol-Myers Squibb Company vs. The Minister of Health, PD 55 (4), 447), but the final decision was left for further consideration. Later on, the Exhaustion of Rights in patents, trademarks, industrial designs and copyrights was discussed at the Haifa District Court (C.S. 1089/05 (Haifa), Dyson Limited vs. Shalom LTD, (2007) Nevo) and the decision was that the doctrine of exhaustion in IP rights restricts and limits monopoly rights to control the use or further marketing of products after the first authorized sale.

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

N/A

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

N/A

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

- Yes
- No
- Uncertain

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

The above question was not discussed yet at any instance.

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

N/A

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

N/A

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):

The exception of compulsory licenses provided by Chapter 7, Article 1 of IPL (the article was changed in 1999, after Israel signed on TRIPS agreement) as follows:

116. In this Article –

"patented product" – a product for which, or for the production process of which a patent was granted;

"patent holder" includes the holder of an exclusive license under the patent.

Power to grant compulsory license

117. (a) If the Registrar is satisfied that a patent holder abuses his monopoly, then he may grant a license to exploit the invention that is the subject of the patent to a person who applied therefor in the prescribed manner and paid the prescribed fee.

(b) The Registrar shall not entertain an application under this section, unless it was submitted later than three years after the date on which the patent was granted or four years after the date on which the patent application was submitted, whichever is later.

Power to require notification concerning exploitation of patent

118. (a) At the end of the time said in section 117, the Registrar may demand that a patent holder notify him in writing, within sixty days of the date of the demand, whether he exploits the patented invention in Israel by way of production or of importation, and if so, what is the extent of the production or of the importation and the location of the production area.

(b) The Registrar shall demand the notification under this section if he was requested to do so by use of the prescribed form and if the prescribed fee was paid.

(c) If the patent holder does not respond to the demand within 60 days after the date of the demand or within an additional period prescribed by the Registrar, then that shall be deemed an admission on the part of the patent holder that he abuses the monopoly conferred on him by the patent for the invention, in respect of which the notice was sent.

Abuse of monopoly defined

119. The exercise of a monopoly conferred by a patent shall be deemed abusive, if one of the following circumstances exists in respect of the invention, the product or the process which is the subject of the patent, and if the patent holder did not provide a reasonable justification for its existence:

(1) all the demand for the product is not satisfied in Israel on reasonable terms;

(2) the conditions attached by the patent holder to the supply of the product or to the grant of a license for its production or use are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent.

Compulsory license to exploit earlier patent on which the fate of a later patent depends

121. (a) If a patented invention (hereafter: later invention) cannot be exploited without infringing an invention, for which the patent application date was earlier (hereafter: earlier invention), then the Registrar may, if so requested by the patent holder of the later invention, grant him a license to exploit the earlier invention to the extent necessary for the exploitation of the later invention, on condition that the later invention incorporates an important technological innovation over the earlier invention, which is of great economic importance.

(b) If the earlier and the later invention serve the same purpose, then a license under subsection (a) shall be granted on condition that the owner of the later invention grant a similar license to the owner of the earlier invention if he so requests.

(c) In the case of a patent application for which priority was claimed under section 10(a), the date of the previous application, within the meaning of section 10(a), shall be deemed the patent application date for purposes of this section.

(d) A license given to the owner of a later invention under the provisions of subsection (a) is not transferable, unless the rights to the later invention are transferred together with the license.

Factors to be taken into account in granting compulsory license

122. In dealing with an application for a license under section 117, the Registrar shall also take the following factors into account:

- (1) the applicant's ability to remedy the fault, because of which the license was applied for;
- (2) the public interest, which generally requires that inventions that can be exploited in Israel by way of production or by way of import should be so exploited to the greatest extent possible under existing circumstances and without delay;
- (3) the right to reasonable remuneration, taking the nature of the invention into account, for exploitation of the patented invention;
- (4) protection of the rights of any person who exploits in Israel, by way of production or by way of import, the invention to which the application for the license relates and of persons engaged in developing that invention;
- (5) the nature of the invention, the time elapsed since the patent was granted, and the steps taken by the patent holder or by his representative for the exploitation of the invention in Israel by way of production or by way of import.

Restriction of scope of compulsory license

123. A license under this Chapter shall be granted mainly for the requirements of the local market.

Effect of compulsory license

125. A compulsory license under this Chapter shall go into effect thirty days after the day of the Registrar's decision or on a later date prescribed by the Registrar; if an appeal was submitted against the decision, then the Court may delay its going into effect or it may attach conditions to its going into effect or to its delay.

Conditions of license

126. A license under this Chapter shall be a non-exclusive license, and the Registrar shall prescribe its conditions when he grants it, including the royalties or other consideration which the licensee shall pay to the patent holder, all as is reasonable and appropriate in the circumstances of the case and having taken the patent holder's legitimate interests into account, and the Registrar shall also prescribe –

- (1) circumstances under which the license shall be deemed void or shall be cancelled or its conditions shall be changed;
- (2) having taken into account, inter alia, the economic value of the license and the patent, the ways of determining the amount of the royalties or of the other consideration, when and how they shall be paid;
- (3) the ways of marking the product produced under the license.

Forced transfer of license

126A. A license granted under this Chapter is not transferable, unless the part of the business or of the good will connected to the use of the patent is transferred together with the license.

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

N/A

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

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

- National security

- National emergency and/or extreme urgency
- [Dependent patents](#)
- Other, please specify:

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

N/A

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

As it can be understood from the explanatory memorandum to the 4th patent law bill, the provisions of the law were amended as a result of signing the TRIPS agreement in purpose to apply TRIPS provisions regarding compulsory licenses into the national law.

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):

According to Section 117 of IPL:

117. (a) If the Registrar is satisfied that a patent holder abuses his monopoly, then he may grant a license to exploit the invention that is the subject of the patent to a person who applied therefor in the prescribed manner and paid the prescribed fee.

Wherein, abuse of monopoly defined by Section 119 of IPL as follows:

119. The exercise of a monopoly conferred by a patent shall be deemed abusive, if one of the following circumstances exists in respect of the invention, the product or the process which is the subject of the patent, and if the patent holder did not provide a reasonable justification for its existence:

(1) all the demand for the product is not satisfied in Israel on reasonable terms;

(2) the conditions attached by the patent holder to the supply of the product or to the grant of a license for its production or use are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent.

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 119 of IPL defines what is considered to be an abuse of monopoly, which can be regarded as a basis for granting compulsory license. According to explanatory memorandum

to the 4th patent law bill, Article 119 was changed to fit Article 27(1) of TRIPS, according to which patent exploitation by way of exportation will not be considered as abuse of monopoly.

Article 122 of IPL was changed also to fit Article 27 of TRIPS Agreement and it doesn't permit granting of compulsory license based on importation of a patented product (explanatory memorandum to the 4th patent law bill).

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

Yes

No

If yes, what is the time period?

According to Section 117(b) of IPL: "The Registrar shall not entertain an application under this section, unless it was submitted later than **three years** after the date on which the patent was granted or **four years** after the date on which the patent application was submitted, whichever is later"

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

Yes

No

If yes, what are "legitimate reasons"? N/A.....

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):

According to Section 119(2) of IPL: "the conditions attached by the patent holder to the supply of the product or to the grant of a license for its production or use are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent". There are no additional interpretations of those definitions other than those provided by the law.

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):

N/A

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:

According to provisions of Section 121 of IPL compulsory license can be granted for exploiting of earlier patent on which the fate of a later patent depends.

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:

N/A

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:

N/A

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

After the 4th amendment to the patent law was approved by the government, no compulsory licenses have been granted yet.

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:

N/A

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

N/A

Government use

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

According to Sections 104-106, Article 3 of IPL, the rights of the State to exploit the invention are defined as follows:

Right of State to exploit invention

104. The Minister may permit the exploitation of an invention by Government departments or by an enterprise or agency of the State, whether a patent for it has or has not already been granted or has or has not already been applied for, if he finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services.

Right of State to permit exploitation of invention

105. The Minister may, if he finds that that is necessary for the purposes enumerated in section 104, grant a permit under that section to a person who operates under contract with the State, in order to ensure or facilitate the implementation of that contract and for the requirements of the State only.

Notice of Grant of exploitation permit

106. When a permit has been granted under this Article, the Minister shall notify the owner of the invention or the patent holder and the holder of the exclusive license that the permit was granted and the scope of the permitted use, unless National security requires otherwise.

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

N/A

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?

N/A

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

N/A

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:

N/A

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

N/A

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:

N/A

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

N/A

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):

There are no special provisions regarding farmers or breeders use of patented inventions in Israeli Patent Law. As a rule, plant breeder's rights are considered by "Plant Breeders' Rights Act, 5733-1973", which is synchronized with the principals of the International Union for Protection of new Varieties of Plants (UPOV).

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

N/A

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

N/A

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

N/A

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):

N/A

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:

N/A

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:

N/A

Breeders' use of patented inventions

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

N/A

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

N/A

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

N/A

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

N/A

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):

N/A

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:

N/A

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:

N/A

Section XI: Other Exceptions and Limitations

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

Chapter 6 of IPL defines powers of state regarding inventions which can be required for national defense or which are related to nuclear energy.

CHAPTER SIX: POWERS OF THE STATE**Article One: Powers Required for National Defense****Restriction on Registrar's activities for national security**

94. (a) The Minister of Defense may, by order, if he deems it necessary so to do in the interests of National security, including the protection of defense secrets, and after consultation with the Minister of Justice –

(1) order the Registrar to refrain from performing any act which he is required or permitted to do under this Law on a certain application, or to postpone its performance;

(2) prohibit or restrict the publication or release of information concerning a particular application, or in connection with the information in it.

(b) A copy of the order of the Minister of Defense shall be delivered to the applicant.

Transmission of certain applications to Minister of Defense

95. The Minister of Defense may direct the Registrar to transmit to a person he designated therefor a copy of applications of a certain category, and the Registrar may transmit to the Minister of Defense applications the matter of which appears to him to be relevant to National security or which includes a defense secret, all in order to enable the Minister to weigh whether an order under section 94 should be made in their respect; the Minister of Defense shall decide on every said application not later than four months after it was transmitted, and as long as he has not decided or as long as the said period has not expired, whichever is shorter, the Registrar shall not perform any act in respect of the said applications, except to acknowledge their submission under section 14.

Contestation of order that restricts activities

96. (a) The applicant may contest an order under section 94 before a three member contestations committee appointed by the Minister of Justice, the members of which shall include a judge of the Supreme Court – the chairman of the committee – and a person recommended by the Minister of Defense.

(b) Notice of the appointment and address of the committee shall be published in Reshumot.

(c) Submitting the objection shall not stay implementation of the order.

(d) The contestations committee may confirm, change or cancel the order.

Right to further contestation

97. An applicant has the right to contest an order under section 94 as long as the order is in effect, and he may contest it again even after a decision was made on the contestation, if – in his opinion – the circumstances that existed at the time of the decision have changed; however, the committee may order the applicant to pay costs if, in its opinion, submitting a further contestation was not in place.

Restriction of right to submit patent applications abroad

98. An Israel national, a permanent resident of Israel or any other person who owes allegiance to the State shall not submit any application abroad for a patent for an invention the subject of which is weaponry or ammunition, or which is otherwise of military value, or for an invention with which section 95 deals, and he shall not – directly or indirectly – cause a said application to be submitted, unless one of the following applies:

- (1) he received written permission from the Minister of Defense in advance;
- (2) he submitted an application in respect of that invention in Israel and within six months after that application was submitted the Minister of Defense did not make an order on it under section 94, or he made such an order, but it is no longer in effect.

Article Two: Powers on Inventions that Relate to Nuclear Energy

Restriction on activities that relate to nuclear energy

99. (a) If the Minister finds that an invention for which a patent application was submitted is important for the development of the use of nuclear energy in Israel, or that the publication of an invention is liable to cause damage to nuclear research in Israel, then he may, by order after consultation with the Minister of Justice –

- (1) order the Registrar to refrain from performing any act which he is required or permitted to do under this Law on the application, or to postpone its performance;
- (2) prohibit or restrict the publication or release of information concerning the application, or in connection with the information in it.

(b) A copy of the order of the Minister of Defense shall be delivered to the applicant.

Transmission of certain applications

100. The Minister may direct the Registrar to transmit to a person he designated therefor a copy of applications of a certain category, and the Registrar may transmit to the Minister applications in respect of which the Registrar thinks an order under section 99 would be proper, all in order to enable the Minister to weigh whether a said order should be made; the Minister shall decide on every said application not later than four months after it was transmitted, and as long as he has not decided or as long as the said period has not expired, whichever is shorter, the Registrar shall not perform any act in respect of the said applications, except to acknowledge their submission under section 14.

Contestation of order that restricts activities

101. (a) The applicant may contest an order under section 99 before a three member contestations committee appointed by the Minister of Justice, the members of which shall include a judge of the Supreme Court – the chairman of the committee – and a person recommended by the Prime Minister.

(b) Notice of the appointment and address of the committee shall be published in Reshumot.

(c) Submitting the objection shall not stay implementation of the order.

(d) The contestations committee may confirm, change or cancel the order.

Right to further contestation

102. An applicant has the right to contest an order under section 99 as long as the order is in effect, and he may contest it again even after a decision was made on

the contestation, if – in his opinion – the circumstances that existed at the time of the decision have changed; however, the committee may order the applicant to pay costs if, in its opinion, submitting a further contestation was not in place.

Right of further contestation

102. The applicant has the right to contest an order under section 99 as long as the order is in effect, and he may contest it again after a decision was given on a contestation, if he believes that the conditions which existed at the time of the decision have changed; however, the committee may order the applicant to pay costs if, in its opinion, there was no occasion for making a further contestation.

Restriction of right to submit patent application abroad

103. An Israel national, a permanent resident of Israel or any other person who owes allegiance to the State shall not submit any application abroad for a patent for an invention with which section 100 deals, and he shall not – directly or indirectly – cause a said application to be submitted, unless one of the following applies:

(1) he received written permission from the Minister in advance;

(2) he submitted an application in respect of that invention in Israel and within six months after that application was submitted the Minister did not make an order on it under section 99, or he made such an order, but it is no longer in effect.

Having said the above, note that currently an amendment to the law has been tabled by the legislative and some of the above provisions may be amended in the coming months. Namely, the term of time of limitations that can be prescribed by the Minister of Defence.

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):

N/A.....

(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:

N/A.....

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

N/A.....

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?):

N/A.....

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

N/A.....

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:

N/A.....

[End of Questionnaire]