Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: Canada .....
Office: Industry Canada and Canadian Intellectual Property Office .....

Person to be contacted:

Name: .....
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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.

The legal standard to determine whether an invention is patentable can be found in the *Patent Act R.S.C., 1985, c. P-4* :

s. 2 "invention" - "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

s.2 "patent" - "patent" means letters patent for an invention;

.....

s. 28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

(*a*) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and

(*b*) information disclosed before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the information became available to the public in Canada or elsewhere .....
.....

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]

In Canada, exclusions to patentability include:
- Methods of Medical Treatment – Based on the Supreme Court of Canada decision in *Tennessee Eastman Co. et al. v. Commissioner of Patents*, [1974] S.C.R. 111, which concluded that a surgical procedure is not patentable.
- *Patent Act* s. 27 (1) (8) No patent shall be granted for any mere scientific principle or abstract theorem. .....
.....

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?

Patent Act s.42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction. .....
.....

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

- ☐ Private and/or non-commercial use;
- ☑ Experimental use and/or scientific research;
- ☐ Preparation of medicines;[2]
- ☑ Prior use;
- ☑ Use of articles on foreign vessels, aircrafts and land vehicles;
- ☑ Acts for obtaining regulatory approval from authorities;
- ☑ Exhaustion of patent rights;
- ☑ Compulsory licensing and/or government use;
- ☐ Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.[3]

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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 For example, extemporaneous preparation of prescribed medicines in pharmacies.

3 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).

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):

N/A.....

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

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:

N/A.....

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):

N/A.....

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):

N/A.....

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

This point has rarely been litigated in Canada. See for example:
Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp. (1971), 2 C.P.R. (2d) 193 (S.C.C.).
Cochlear Corp. v. Cosem Neurostim Ltée (1995), 64 C.P.R. (3d) 10 (F.C.T.D.)
Dableh v. Ontario Hydro (1996), 68 C.P.R. (3d) 129, at 145 (F.C.A.)
These cases taken together have been considered to demonstrate that there is a judicially recognized research exception but no case to date has clearly set out the scope of this exception. .....
.....

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

When inventors submit a patent application they agree to the disclosure of their invention. An experimental use exception permits other individuals to investigate that invention, making use of that disclosure. As such it is part of the balance of rights and obligations under the patent system. .....
.....

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

N/A.....

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, it is the activity which is distinguished. .....

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

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

- ☐ determine the validity of the claims
- ☐ seek an improvement to the patented invention
- ☐ invent around the patented invention
- ☐ other, please specify: ……

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

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

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

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):

N/A.....

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:

There are no current plans. .....
.....

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

Some commentators have expressed concerns that the lack of case law may lead to uncertainty in this area and have called for legislative change. However, we are unaware of any problems with the practical implementation of the exception. .....
.....

Section IV*: *Preparation of medicines

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

N/A.....

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):

Patent Act s. 56. (1) Every person who, before the claim date of a claim in a patent has purchased, constructed or acquired the subject matter defined by the claim, has the right to use and sell to others the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired without being liable to the patentee or the legal representatives of the patentee for so doing.
.....

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:

To achieve an appropriate balance of rights; protecting prior users.
.....

(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):

Under s. 56 the prior user "has the right to use and sell to others." "Use" is not legislatively defined within the *Patent Act.* .....
.....

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

No, it does not. .....
.....

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:

N/A.....

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:

The provision is silent on this point. .....
.....

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:

There are no amendments planned for this provision. .....
.....

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

No significant challenges have been identified .....
.....

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):

Patent Act s. 23. No patent shall extend to prevent the use of any invention in any ship, vessel, aircraft or land vehicle of any country entering Canada temporarily or accidentally, if the invention is employed exclusively for the needs of the ship, vessel, aircraft or land vehicle, and not so used for the manufacture of any goods to be sold within or exported from Canada.
.....

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:

The objectives include respecting the sovereign rights of nations over their own intellectual property laws and ensuring that movement of foreign ships, etc is not impeded by threat of patent infringement and respecting our international obligations under 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:

N/A .....

45. The exception applies in relation to:

- ☑ Vessels
- ☑ Aircrafts
- ☑ Land Vehicles
- ☐ Spacecraft

The provision also refers to ships.

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):

Both terms are used with the provision, but neither is defined within the *Patent Act.* Canadian legal principles suggest that the ordinary meaning of the words should be used. .....
.....

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):

The phrase used in the provision is “exclusively for the needs of the ship, vessel, aircraft or land vehicle.” .....
.....

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):

The use is further defined by specifying that it is “not so used for the manufacture of any goods to be sold within or exported from Canada”.....
.....

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:

There are no amendments planned for this provision. .....
.....

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

No significant challenges have been identified. .....
.....

Section VII: Acts for obtaining regulatory approval from authorities

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

Patent Act s. 55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any 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:

To ensure that regulatory requirements are not stifling competition.
.....

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

This provision has been the subject of a WTO challenge. An extensive discussion of Canada's public policy objectives may be found in that report (World Trade Organization Panel Report WT/DS114/R, March 17, 2000).....
.....

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

Any person. .....
.....

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:…… Constructing

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):

The overarching criterion is the purpose of the uses of the patent. They must be "soley for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product" .....
.....

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:

There are no foreseen amendments for this provision.....
.....

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

We are not aware of any significant challenges. .....
.....

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):

N/A.....

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

Eli Lilly and Co. v. Apotex Inc., [1998] 2 S.C.R. 129 says, "If the patentee sells the patented article that he made, he transfers the ownership of that article to the purchaser. This means that, henceforth, the patentee no longer has any right with respect to the article which now belongs to the purchaser who, as the new owner, has the exclusive right to possess, use, enjoy, destroy or alienate it."

Canada also has a doctrine of implied licence which indicates that when a patent holder sells the patented item (or item created due to a process patent) the buyer acquires a licence to use and sell the item and all subsequent buyers receive the same license. .....
.....

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

The patent holder has received compensation for the sale of the item on terms agreed to by the patent holder. .....
.....

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

E.G. Signalisation de Montreal Inc. v. Services de Béton Universels Ltée (1992), 46 C.P.R. (3d) 199, at 208 (F.C.A.), which states: .....

> It is settled law that the purchaser of a patented article from a patentee acquires, at the same time, the right to use the article and the right to sell it, together with the same "right of use," to another person. As long ago as 1871, this right was described as a "licence." .....
.....

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):

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

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

No legislative changes are being considered.....
.....

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

No significant challenges have been identified. .....
.....

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):

There are two separate types of compulsory licenses in Canada. The first is covered by *Patent Act* s.65-66 and the second by s. 21.01-21.2.

65. (1) The Attorney General of Canada or any person interested may, at any time after the expiration of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act.
(2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:

(a) and (b) [Repealed, 1993, c. 44, s. 196]
(c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;
(d) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;
(e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or
(f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

(3) and (4) [Repealed, 1993, c. 44, s. 196]
(5) For the purposes of this section, the expression “patented article” includes articles made by a patented process.

66. (1) On being satisfied that a case of abuse of the exclusive rights under a patent has been established, the Commissioner may exercise any of the following powers as he may deem expedient in the circumstances:

(a) he may order the grant to the applicant of a licence on such terms as the Commissioner may think expedient, including a term precluding the licensee from importing into Canada any goods the importation of which, if made by persons other than the patentee or persons claiming under him, would be an infringement of the patent, and in that case the patentee and all licensees for the time being shall be deemed to have mutually covenanted against that importation; […]
(c) if the Commissioner is satisfied that the exclusive rights have been abused in the circumstances specified in paragraph 65(2)(f), he may order the grant of licences to the applicant and to such of his customers, and containing such terms, as the Commissioner may think expedient; […]

(4) In settling the terms of a licence under paragraph (1)(a), the Commissioner shall be guided as far as possible by the following considerations:

(a) he shall endeavour to secure the widest possible use of the invention in Canada consistent with the patentee deriving a reasonable advantage from his patent rights;
(b) he shall endeavour to secure to the patentee the maximum advantage consistent with the invention being worked by the licensee at a reasonable profit in Canada; and
(c) he shall endeavour to secure equality of advantage among the several licensees, and for this purpose may, on due cause being shown, reduce the royalties or other payments accruing to the patentee under any licence previously granted.

21.01 The purpose of sections 21.02 to 21.2 is to give effect to Canada’s and Jean Chrétien’s pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

21.02 The definitions in this section apply in this section and in sections 21.03 to 21.19.
“authorization” *« autorisation »*
“authorization” means an authorization granted under subsection 21.04(1), and includes an authorization renewed under subsection 21.12(1).
“General Council” *« Conseil général »*
“General Council” means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.
“General Council Decision” *« décision du Conseil général »*
“General Council Decision” means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson’s statement of that date.
“patented product” *« produit breveté »*
“patented product” means a product the making, constructing, using or selling of which in Canada would infringe a patent in the absence of the consent of the patentee.
“pharmaceutical product” *« produit pharmaceutique »*
“pharmaceutical product” means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product.
“TRIPS Agreement” *« Accord sur les ADPIC »*
“TRIPS Agreement” means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.
“TRIPS Council” *« Conseil des ADPIC »*
“TRIPS Council” means the council referred to in the TRIPS Agreement.
“WTO” *« OMC »*

"WTO" means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

21.03 (1) The Governor in Council may, by order,
(*a*) on the recommendation of the Minister and the Minister of Health, amend Schedule 1
(i) by adding the name of any patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by adding one or more of the following in respect of the patented product, namely, a dosage form, a strength and a route of administration, and
(ii) by removing any entry listed in it;
(*b*) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 2 by adding the name of any country recognized by the United Nations as being a least-developed country that has,
(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, and
(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;
(*c*) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision; and
(*d*) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 4 by adding the name of
(i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, or
(ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance and that has provided the Government of Canada with a notice in writing through diplomatic channels
(A) stating that it is faced with a national emergency or other circumstances of extreme urgency,
(B) specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency,
(C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and
(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.
(2) The Governor in Council may not add to Schedule 3 the name of any WTO Member that has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, only if faced with a national emergency or other circumstances of extreme urgency.
(3) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend any of Schedules 2 to 4 to remove the name of any country or WTO Member if
(*a*) in the case of a country or WTO Member listed in Schedule 2, the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or, in the case of a country that is not a WTO Member, the country has permitted any product imported into that country under an authorization to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision;

(*b*) in the case of a WTO Member listed in Schedule 3, the WTO Member has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, only if faced with a national emergency or other circumstances of extreme urgency;
(*c*) in the case of a WTO Member listed in Schedule 4, the WTO Member has revoked any notification it has given to the TRIPS Council that it will import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision, only if faced with a national emergency or other circumstances of extreme urgency;
(*d*) in the case of a country listed in Schedule 4 that is not a WTO Member,
(i) the name of the country is no longer on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance,
(ii) the country no longer faces a national emergency or other circumstances of extreme urgency,
(iii) the country has permitted any product imported into that country under an authorization to be used for commercial purposes, or
(iv) the country has failed to adopt the measures referred to in Article 4 of the General Council Decision;
(*e*) in the case of any country or WTO Member listed in Schedule 3 or 4, the country or WTO Member has become recognized by the United Nations as a least-developed country; and
(*f*) in the case of any country or WTO Member listed in any of Schedules 2 to 4, the country has notified the Government of Canada, or the WTO Member has notified the TRIPS Council, that it will not import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision.

(4) An order under this section shall be made in a timely manner.

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.

(2) The application must be in the prescribed form and set out
(*a*) the name of the pharmaceutical product to be manufactured and sold for export under the authorization;
(*b*) prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization;
(*c*) the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;
(*d*) for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued in respect of that invention;
(*e*) the name of the country or WTO Member to which the pharmaceutical product is to be exported;
(*f*) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and
(*g*) any other information that may be prescribed.

(3) The Commissioner shall authorize the use of the patented invention only if
(*a*) the applicant has complied with the prescribed requirements, if any;
(*b*) the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements of the *Food and Drugs Act* and its regulations, including the requirements under those regulations relating to the marking, embossing, labelling and packaging that identify that version of the product as having been manufactured
(i) in Canada as permitted by the General Council Decision, and
(ii) in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by, or with the consent of, the patentee or patentees, as the case may be;
(*c*) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least thirty days before filing the application,

(i) sought from the patentee or, if there is more than one, from each of the patentees, by certified or registered mail, a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful, and

(ii) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(*a*) to (*g*); and

(*d*) the applicant also provides the Commissioner with

(i) if the application relates to a WTO Member listed in Schedule 2, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that WTO Member, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(ii) if the application relates to a country listed in Schedule 2 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the country, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that country, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iii) if the application relates to a WTO Member listed in Schedule 3, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iv) if the application relates to a WTO Member listed in Schedule 4, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member is faced with a national emergency or other circumstances of extreme urgency and that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product, or

(v) if the application relates to a country listed in Schedule 4 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the country, and stating that it is faced with a national emergency or other circumstances of extreme urgency, that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, that it agrees that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that country, or

(B) a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product.

21.05 (1) The authorization must be in the prescribed form and, subject to subsection (2), contain the prescribed information.

(2) The quantity of the product authorized to be manufactured by an authorization may not be more than the lesser of

(*a*) the maximum quantity set out in the application for the authorization, and

(*b*) the quantity set out in the notice referred to in any of subparagraphs 21.04(3)(*d*)(i) to (v), whichever is applicable.

21.06 (1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the country or WTO Member to which it is to be exported, the quantity that is authorized to be manufactured and sold for export and the distinguishing features of the product, and of its label and packaging, as required by regulations made under the *Food and Drugs Act*, as well as information identifying every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported.

(2) The holder must maintain the website during the entire period during which the authorization is valid.

(3) The Commissioner shall post and maintain on the website of the Canadian Intellectual Property Office a link to each website required to be maintained by the holder of an authorization under subsection (1).

(4) The Commissioner shall, within seven days of receipt, post on the website of the Canadian Intellectual Property Office each application for authorization filed under subsection 21.04(1).

21.07 Before each shipment of any quantity of a product manufactured under an authorization, the holder of the authorization must, within fifteen days before the product is exported, provide to each of the following a notice, by certified or registered mail, specifying the quantity to be exported, as well as every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported:

(*a*) the patentee or each of the patentees, as the case may be;

(*b*) the country or WTO Member named in the authorization; and

(*c*) the person or entity that purchased the product to which the authorization relates.

21.08 (1) Subject to subsections (3) and (4), on the occurrence of a prescribed event, the holder of an authorization is required to pay to the patentee or each patentee, as the case may be, a royalty determined in the prescribed manner.

(2) In making regulations for the purposes of subsection (1), the Governor in Council must consider the humanitarian and non-commercial reasons underlying the issuance of authorizations under subsection 21.04(1).
(3) The royalties payable under this section must be paid within the prescribed time.
(4) The Federal Court may, in relation to any authorization, make an order providing for the payment of a royalty that is greater than the royalty that would otherwise be required to be paid under subsection (1).
(5) An order may be made only on the application of the patentee, or one of the patentees, as the case may be, and on notice of the application being given by the applicant to the holder of the authorization.
(6) An order may provide for a royalty of a fixed amount or for a royalty to be determined as specified in the order, and the order may be subject to any terms that the Federal Court considers appropriate.
(7) The Federal Court may make an order only if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration for the use of the invention or inventions to which the authorization relates, taking into account

(*a*) the humanitarian and non-commercial reasons underlying the issuance of the authorization; and
(*b*) the economic value of the use of the invention or inventions to the country or WTO Member.

21.09 An authorization granted under subsection 21.04(1) is valid for a period of two years beginning on the day on which the authorization is granted.
21.1 The use of a patented invention under an authorization is non-exclusive.
21.11 An authorization is non-transferable, other than where the authorization is an asset of a corporation or enterprise and the part of the corporation or enterprise that enjoys the use of the authorization is sold, assigned or otherwise transferred.
21.12 (1) The Commissioner shall, on the application of the person to whom an authorization was granted and on the payment of the prescribed fee, renew the authorization if the person certifies under oath in the renewal application that the quantities of the pharmaceutical product authorized to be exported were not exported before the authorization ceases to be valid and that the person has complied with the terms of the authorization and the requirements of sections 21.06 to 21.08.
(2) An authorization may be renewed only once.
(3) The application for renewal must be made within the 30 days immediately before the authorization ceases to be valid.
(4) An authorization that is renewed is valid for a period of two years beginning on the day immediately following the day of the expiry of the period referred to in section 21.09 in respect of the authorization.
(5) Applications for renewal and renewed authorizations issued under subsection (1) must be in the prescribed form.
21.13 Subject to section 21.14, an authorization ceases to be valid on the earliest of

(*a*) the expiry of the period referred to in section 21.09 in respect of the authorization, or the expiry of the period referred to in subsection 21.12(4) if the authorization has been renewed, as the case may be,
(*b*) the day on which the Commissioner sends, by registered mail, to the holder of the authorization a copy of a notice sent by the Minister of Health notifying the Commissioner that the Minister of Health is of the opinion that the pharmaceutical product referred to in paragraph 21. 04(3)(*b*) has ceased to meet the requirements of the *Food and Drugs Act* and its regulations,
(*c*) the day on which the last of the pharmaceutical product authorized by the authorization to be exported is actually exported,
(*d*) thirty days after the day on which

(i) the name of the pharmaceutical product authorized to be exported by the authorization is removed from Schedule 1, or
(ii) the name of the country or WTO Member to which the pharmaceutical product was, or is to be, exported is removed from Schedule 2, 3 or 4, as the case may be, and not added to any other of those Schedules, and

(*e*) on any other day that is prescribed.

21.14 On the application of a patentee, and on notice given by the patentee to the person to whom an authorization was granted, the Federal Court may make an order, on any terms that it considers appropriate, terminating the authorization if the patentee establishes that

(*a*) the application for the authorization or any of the documents provided to the Commissioner in relation to the application contained any material information that is inaccurate;

(*b*) the holder of the authorization has failed to establish a website as required by section 21.06, has failed to disclose on that website the information required to be disclosed by that section or has failed to maintain the website as required by that section;
(*c*) the holder of the authorization has failed to provide a notice required to be given under section 21.07;
(*d*) the holder of the authorization has failed to pay, within the required time, any royalty required to be paid as a result of the authorization;
(*e*) the holder of the authorization has failed to comply with subsection 21.16(2);
(*f*) the product exported to the country or WTO Member, as the case may be, under the authorization has been, with the knowledge of the holder of the authorization, re-exported in a manner that is contrary to the General Council Decision;
(*g*) the product was exported, other than in the normal course of transit, to a country or WTO Member other than the country or WTO Member named in the authorization;
(*h*) the product was exported in a quantity greater than the quantity authorized to be manufactured; or
(*i*) if the product was exported to a country that is not a WTO Member, the country has permitted the product to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision.

21.15 The Commissioner shall, without delay, notify the patentee, or each of the patentees, as the case may be, in writing of any authorization granted in respect of the patentee's invention.

21.16 (1) Within fifteen days after the later of the day on which the authorization was granted and the day on which the agreement for the sale of the product to which the authorization relates was entered into, the holder of an authorization must provide by certified or registered mail, the Commissioner and the patentee, or each patentee, as the case may be, with

(*a*) a copy of the agreement it has reached with the person or entity referred to in paragraph 21.04(2)(*f*) for the supply of the product authorized to be manufactured and sold, which agreement must incorporate information that is in all material respects identical to the information referred to in paragraphs 21.04(2)(*a*), (*b*), (*e*) and (*f*); and
(*b*) a solemn or statutory declaration in the prescribed form setting out

(i) the total monetary value of the agreement as it relates to the product authorized to be manufactured and sold, expressed in Canadian currency, and
(ii) the number of units of the product to be sold under the terms of the agreement.

(2) The holder of an authorization may not export any product to which the authorization relates until after the holder has complied with subsection (1).

21.17 (1) If the average price of the product to be manufactured under an authorization is equal to or greater than 25 per cent of the average price in Canada of the equivalent product sold by or with the consent of the patentee, the patentee may, on notice given by the patentee to the person to whom an authorization was granted, apply to the Federal Court for an order under subsection (3) on the grounds that the essence of the agreement under which the product is to be sold is commercial in nature.
(2) In determining whether the agreement is commercial in nature, the Federal Court must take into account

(*a*) the need for the holder of the authorization to make a reasonable return sufficient to sustain a continued participation in humanitarian initiatives;
(*b*) the ordinary levels of profitability, in Canada, of commercial agreements involving pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision; and
(*c*) international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes.

(3) If the Federal Court determines that the agreement is commercial in nature, it may make an order, on any terms that it considers appropriate,

(*a*) terminating the authorization; or
(*b*) requiring the holder to pay, in addition to the royalty otherwise required to be paid, an amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent.

(4) If the Federal Court makes an order terminating the authorization, the Federal Court may also, if it considers it appropriate to do so, make an order, on any terms that it considers appropriate,

(*a*) requiring the holder to deliver to the patentee any of the product to which the authorization relates remaining in the holder's possession as though the holder had been determined to have been infringing a patent; or

(*b*) with the consent of the patentee, requiring the holder to export any of the product to which the authorization relates remaining in the holder's possession to the country or WTO Member named in the authorization.

(5) The Federal Court may not make an order under subsection (3) if, under the protection of a confidentiality order made by the Court, the holder of the authorization submits to a Court-supervised audit and that audit establishes that the average price of the product manufactured under the authorization does not exceed an amount equal to the direct supply cost of the product plus 15 per cent of that direct supply cost.

(6) The following definitions apply in this section.

"average price" *« prix moyen »*

"average price" means

(*a*) in relation to a product to be manufactured under an authorization, the total monetary value of the agreement under which the product is to be sold, expressed in Canadian currency, divided by the number of units of the product to be sold under the terms of the agreement; and

(*b*) in relation to an equivalent product sold by or with the consent of the patentee, the average of the prices in Canada of that product as those prices are reported in prescribed publications on the day on which the application for the authorization was filed.

"direct supply cost" *« coût direct de fourniture »*

"direct supply cost", in relation to a product to be manufactured under an authorization, means the cost of the materials and of the labour, and any other manufacturing costs, directly related to the production of the quantity of the product that is to be manufactured under the authorization.

"unit" *« unité »*

"unit", in relation to any product, means a single tablet, capsule or other individual dosage form of the product, and if applicable, in a particular strength.

21.18 (1) The Minister and the Minister of Health shall establish, within three years after the day this section comes into force, an advisory committee to advise them on the recommendations that they may make to the Governor in Council respecting the amendment of Schedule 1.

(2) The standing committee of each House of Parliament that normally considers matters related to industry shall assess all candidates for appointment to the advisory committee and make recommendations to the Minister and the Minister of Health on the eligibility and qualifications of those candidates.

21.19 The person designated by the Governor in Council for the purpose of this section must maintain a website on which is set out a copy of every notice referred to in subparagraphs 21.04(3)(*d*)(ii) and (v) that is provided to the Government of Canada through diplomatic channels by a country that is not a WTO Member. The copy must be added to the website as soon as possible after the notice has been provided to the Government of Canada.

21.2 (1) A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force.

(2) The Minister must cause a report of the results of the review to be laid before each House of Parliament on any of the first fifteen days on which that House is sitting after the report has been completed.

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: TRIPS Waiver (international public health)……

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

There are two separate objectives. The overall purpose of s. 65- s.66 is to ensure a balance of rights is maintained by preventing anticompetitive behaviour or other activities by patent holders that are not in the public interest.

The purpose of s. 21.02- s.21.2 is facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
.....

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

N/A.....

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):

N/A.....

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):

N/A.....

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? N/A .....

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):

These terms are not defined in the *Patent Act* and judicially are fact dependent.. .....
.....

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):

The *Patent Act* does not use the term "anticompetitive practices" *per se* but rather indicates specific behaviour which is unacceptable in s.65. Many of these are anticompetitive in nature.....
.....

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 *Patent Act* does not use the term "dependent patents" *per se* but rather in s. 65 indicates specific behaviour which can unreasonably affect the ability of the holders of dependent patents from working their invention. .....
.....

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:

Patent Act s. 66(4) contains the general policy regarding remuneration. Under s. 66 (4)(B) the Commissioner of Patents should ensure the maximum advantage for the patent while permitting the licensee a reasonable profit. The Commission must also ensure that all licensees are treated equally.
.....

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:

This information is unavailable. .....
.....
.....

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:

There is a private member's bill currently being considered by parliament to change s. 21.01-21.2.....

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

These compulsory licensing systems have been little used. .....
.....

Government use

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

19. (1) Subject to section 19.1, the Commissioner may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government.
(2) Subject to section 19.1, the use of the patented invention may be authorized for such purpose, for such period and on such other terms as the Commissioner considers expedient but the Commissioner shall settle those terms in accordance with the following principles:
(*a*) the scope and duration of the use shall be limited to the purpose for which the use is authorized;
(*b*) the use authorized shall be non-exclusive; and
(*c*) any use shall be authorized predominantly to supply the domestic market.
(3) The Commissioner shall notify the patentee of any use of the patented invention that is authorized under this section.
(4) Where the use of the patented invention is authorized, the authorized user shall pay to the patentee such amount as the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization.
(5) The Commissioner may, on application by the patentee and after giving all concerned parties an opportunity to be heard, terminate the authorization if the Commissioner is satisfied that the circumstances that led to the granting of the authorization have ceased to exist and are unlikely to recur, subject to such conditions as the Commissioner deems appropriate to protect the legitimate interests of the authorized user.
(6) An authorization granted under this section is not transferable.

19.1 (1) The Commissioner may not authorize the use of a patented invention under section 19 unless the applicant establishes that
(*a*) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention; and
(*b*) its efforts have not been successful within a reasonable period.
(2) Subsection (1) does not apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.
(3) The Commissioner may not, under section 19, authorize any use that is a prescribed use unless the proposed user complies with the prescribed conditions.
(4) The Commissioner may not, under section 19, authorize any use of semi-conductor technology other than a public non-commercial use.

19.2 Any decision made by the Commissioner under section 19 or 19.1 is subject to appeal to the Federal Court.
19.3 (1) The Governor in Council may make regulations for the purpose of implementing, in relation to patents, Article 1720 of the Agreement.

(2) In subsection (1), “Agreement” has the same meaning as in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*.
.....

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: Grounds are specified in s. 19.1. Note that it is not that the patentee has refused to grant a license but rather that reasonable governmental efforts have failed to secure a license. This requirement is waived in some circumstances, including a national emergency. .....

84. (a) What are the public policy objectives for providing government use in your country?

To enable the work of the government to proceed, while ensuring proper compensation to the patent holder. .....
.....

(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:

They are undefined and have not been used.....
.....

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

To date no government in Canada has made use of these provisions.....
.....

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:

No amendments are foreseen. .....
.....

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

As no government in Canada has chosen to use these provisions, no challenges in its use have been identified. .....
.....

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):

N/A.....

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:

N/A.....

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:

Specific reference is made to IP rights in a number of provisions of Canada's *Competition Act*. The circumstances in which the Competition Bureau may apply these provision to anti-competitive conduct involving IP or IP rights fall into two broad categories: those involving anti-competitive conduct that is something more than the mere exercise of the IP right, and those involving the mere exercise of the IP right and nothing else. The general provisions of the Competition Act address the former, while section 32 (special remedies) addresses the latter. The Bureau's approach is consistent with subsection 79(5), which acknowledges that the mere exercise of an IP right is not an anti-competitive act, while acknowledging the possibility that under the very rare circumstances set out in section 32 the mere exercise of an IP right might raise a competition issue.

For example, If an IP owner licenses, transfers or sells the IP to a firm or a group of firms that would have been actual or potential competitors without the arrangement, and if this arrangement creates, enhances or maintains market power, the Bureau may seek to challenge the arrangement under the appropriate section of the *Competition Act.*

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[End of Questionnaire]