

Questionnaire on Exceptions and Limitations to Patent Rights

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

Country: **New Zealand**
Office: Competition, Trade and Investment Branch, Ministry of Economic Development

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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 relevant legislation is the Patents Act 1953. To be patentable, an invention must be a “manner of manufacture”, and be “new”. There is no examination for obviousness, or utility, although obviousness and lack of utility are grounds for third parties to oppose the grant of a patent, or to apply for the revocation of a granted patent. Text of the act can be found at: <http://www.legislation.govt.nz/act/public/1953/0064/latest/DLM280031.html>

The term “manner of manufacture” has been interpreted by the New Zealand Courts to exclude such things as “products of nature”, mathematical operations, bare principals, mathematical algorithms, schemes or plans, and methods of medical treatment of humans.

An invention will be considered “new” if a description of the invention has not been published in New Zealand prior to the priority date of the relevant claims (a “local novelty” standard).

There is currently a Patents Bill before the New Zealand Parliament that will replace the Patents Act 1953. Under the provisions of this new Bill, to be patentable, an invention must be a “manner of manufacture”, new, involve an inventive step, be useful, and not be excluded subject matter. All

*of these criteria must be satisfied before a patent can be granted. Novelty and inventive step will be determined on the basis of matter that has been made available to the public, whether by written or oral description, or by use or in any other way, anywhere in the world prior to the priority date of the relevant claims. The text of the Bill can be found at:
<http://www.legislation.govt.nz/bill/government/2008/0235/latest/viewpdf.aspx>*

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

..... Under New Zealand's current legislation (the Patents Act 1953), there is only one statutory exclusion: grant of a patent may be refused if use of the invention would be contrary to morality. Very few patents have been refused under this provision, and there are no relevant judicial decisions.

The Patents Bill currently before Parliament includes explicit exclusions from patentability. These are:

*Inventions whose commercial exploitation would be contrary to public order or morality;
Human beings and biological processes for their generation;
Methods of treatment of human beings by surgery or therapy;
Methods of diagnosis practiced on human beings;
Computer programs;
Plant varieties.*

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?

Under the Patents Act 1953, a patent owner has the exclusive right to "make, use, exercise and vend the invention during the term of the patent, subject to the provisions of any statute or regulation currently in force. (See Patents Form A, Third Schedule, Patents Act 1953).

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;

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.

- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³

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

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

Section II: Private and/or non-commercial use

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

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

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

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

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

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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. 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).

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8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

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

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

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Section III: Experimental use and/or scientific research ⁴

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

New Zealand's current patent legislation, the Patents Act 1953, does not contain a statutory experimental use exception. The new Patents Bill, currently before the New Zealand Parliament does contain an experimental use exception.

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

Under the Patents Act 1953, questions of whether or not a particular use is experimental are determined through case law. The most relevant case-law would appear to be Smith Kline & French Laboratories Ltd vs Attorney General (1991) 4 TCLR 199. In this decision, the Judge stated:

"Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself, and does no more than further his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance in the actual

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

market place, then he infringes”.

It would appear from this decision that it is the ultimate objective of the research which determines whether or not the use of a patented invention for research or experimental purposes infringes a patent. “Non-commercial” research would not infringe, while “commercial” research would. It is not clear though, just where the boundary between “commercial” and “non-commercial” research lies.

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

Question not applicable as the experimental use exception is provided by caselaw.

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

Not applicable (see answers to question 13(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:

The relevant case law suggests that the nature of the organization involved is not relevant to whether a use is “experimental”, rather, it is the nature of the use (whether “non-commercial” or “commercial”) that determines whether a particular use is experimental. “Commercial” use, will generally not be considered to be experimental use, but the boundary between “commercial” and “non-commercial” use is unclear.

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

The relevant caselaw does not define these concepts.

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

Experimentation and/or research should aim to:

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

The relevant case law does not deal with these issues.

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):

While the relevant case law makes a distinction between a “commercial” purpose (which is not considered experimental use) and “non-commercial” (which may be considered as “experimental” use), there are no explicit definitions of these terms – the question of whether a particular use or purpose is “commercial” or “non-commercial” is likely to be considered on a case by case basis.

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):

No other criteria are currently applied.

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

The current legal framework relating to experimental use of patented inventions is not considered adequate as there is considerable uncertainty as to what does or does not constitute experimental use. The new Patents Bill that is currently before the New Zealand Parliament contains an explicit experimental use exception. The exception (clause 136 of the Bill) provides that it is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention. Clause 136 also contains a non-exhaustive list of acts which are considered to have an experimental purpose: determining how an invention works, determining the scope of an invention, determining the validity of the claims and seeking to make an improvement to the invention (for example determining new properties, or new uses of the invention).

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

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Section IV: Preparation of medicines

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

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

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

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

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

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

- Yes
- No

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

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

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

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

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Section V: Prior use

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

There is no prior use exception in New Zealand's patent legislation, however, secret use of an invention prior to the grant of a patent may be grounds for revocation of the patent. (s41(1)(l) of the Patents Act 1953. That is, while prior secret use is not a defence against infringement, the prior user can initiate proceedings to revoke the patent.

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

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

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

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

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

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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:

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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:

Where a lapsed patent has been restored, the restoration is subject to conditions protecting the interests of third parties who may have used or made preparations to use the the patented invention after the patent lapsed, but before restoration (s35(7) of the Patents Act 1953)

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):

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

The new Patents Bill, currently before Parliament will contain an explicit prior use provision (clause 138A of the Bill).

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

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

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

The exception is provided in section 79 of the Patents Act 1953.

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

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

The exception is provided for compliance with Article 5ter of the Paris Convention.

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

Not applicable.

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 applicable law refers to accidental or temporary entry of the foreign transportation means into New Zealand. These terms are not defined in the legislation, and there is no applicable case law.

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

Section 79 of the Patents Act 1953 provides that the patented product must be used on board the transportation means and for its actual needs only.

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):

Not applicable.

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:

No changes to this provision are being considered.

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

Not applicable.

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 for in section 68B of the Patents Act 1953.

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

... Case law does not provide for this type of exception in New Zealand. The New Zealand courts have indicated that any such exception must be provided for through amendment to the legislation.

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

The reason for providing the exception is to facilitate the entry of generic products onto the New Zealand market when a patent expires. It was also intended to ensure that New Zealand manufacturers of generic products could enter the export market promptly when the relevant New Zealand patent(s) expired.

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

The exception (known as the Regulatory Review Exception) was inserted into the Patents Act 1953 by the Patents Amendment Act 2002.

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

Any person may use the exception.

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:.....

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):

Not applicable.

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:

No amendments to the law are planned; the exception will be retained in the new Patents Bill.

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

Not applicable.

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:

The circumstances in which patent rights are exhausted will depend on the conditions under which the patent owner has decided to make the patented product available.

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

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

Exhaustion is determined by case law: Betts V Wilmott (1871) 6 Ch App 240. Whether the rights are exhausted or not is likely to depend on any conditions attached to the initial sale by the patentee.

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

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

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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):

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

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

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Section IX: Compulsory licenses and/or government use

Compulsory licenses

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

Section 46 of the Patents Act 1953 provides for compulsory licenses.

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

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

- 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:

To ensure that New Zealand businesses and consumers have reasonable access to patented products at reasonable prices.

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

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

Not applicable.

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):

Not applicable.

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?

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”?

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

There is no definition of these terms in the legislation, and there appear to be no legal decisions by the New Zealand courts defining these terms (although it is likely that decisions made under the UK Patents Act 1949 would be applied by the New Zealand courts if the need arose).

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):

Not applicable

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:

Not applicable

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:

.Section 46(6) of the Patents Act 1953 requires that licensee must pay “such remuneration to the patentee as may be agreed” between the licensee and the patentee. If they cannot agree, the Court will determine the remuneration.

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:

Not applicable

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

Very few compulsory licenses have been granted in New Zealand, and those that have been issued have related to pharmaceuticals.

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

The only amendments contemplated are those necessary to allow New Zealand to become an exporting member under the Protocol to amend the TRIPS Agreement implementing the Doha Declaration on the TRIPS Agreement and public health (see clauses 165A – 165D of the new Patents Bill).

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

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Government use

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

. Sections 55 – 58C of the Patents Act 1953 provide for Crown use of patented inventions without the authority of the patentee.

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

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

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security
- National emergency and/or extreme urgency
- Dependent patents
- Other, please specify: *While the applicable law refers to matters of national security or national emergency, it does not specifically exclude the other grounds.*

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

The prime public policy objectives relate to ensuring that the public has access to patented products, and it has not been possible to obtain the product from the patentee on reasonable terms and conditions.

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

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85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

The Patents Act 1953 defines national emergency by reference to the Civil Defence Emergency Management Act 2002 (see <http://www.legislation.govt.nz/act/public/2002/0033/latest/DLM149789.html>).

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

There have been no instances of the Crown use provisions being invoked.

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

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

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

Farmers’ use of patented inventions

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

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

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

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

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

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

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94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

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Breeders' use of patented inventions

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

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

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

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

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

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

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100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

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Section XI: Other Exceptions and Limitations

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

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102. In relation to each exception and limitation, please indicate:

- (i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

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- (ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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

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

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

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

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

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[End of Questionnaire]