

Questionnaire on Exceptions and Limitations to Patent Rights

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

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Section I: General

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

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

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

[From Section 18 Patentable Inventions, of the Patents Act 1990.](#)

- (1) [Subject to subsection \(2\), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:](#)
 - [\(a\) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and](#)
 - [\(b\) when compared with the prior art base as it existed before the priority date of that claim:](#)
 - [\(i\) is novel; and](#)
 - [\(ii\) involves an inventive step; and](#)
 - [\(c\) is useful; and](#)
 - [\(d\) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.](#)

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an innovative step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention

The requirement that a patentable invention be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies, imports a number of threshold and subject matter limitations from common law. The most significant case in this regard is the High Court decision in *National Research and Development Corporation v Commissioner of Patents* [1959] HCA 67; [1959] 102 CLR 252. That decision is understood to require that patentable subject matter be for "a mode or manner of achieving an end result which is an artificially created state of affairs of utility in the fields of economic endeavour" (CCOM Pty Ltd v Jiejing [1994] FCA 1168 at [128]).

Accordingly it is understood that a distinction lies between the fine and useful arts and that mere schemes, abstract ideas and mere intellectual information are not patentable.

The Advisory Council on Intellectual Property has recently concluded a study of patentable subject matter requirement in Australia, *Patentable Subject Matter* December 2010 (<http://www.acip.gov.au/library/ACIP%20PSM%20final%20report%204%20Feb%202011.pdf>)

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

From Section 18 Patentable Inventions, of the Patents Act 1990.

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

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

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

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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?

From Section 13 of the Patents Act 1990.

Section 13. Exclusive rights given by patent

- (1) Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.
- (2) The exclusive rights are personal property and are capable of assignment and of devolution by law.
- (3) A patent has effect throughout the patent area

From Section 57 of the Patents Act 1990

Section 57. Effect of publication of complete specification

- (1) After a complete specification relating to an application for a standard patent has become open to public inspection and until a patent is granted on the application, the applicant has the same rights as he or she would have had if a patent for the invention had been granted on the day when the specification became open to public inspection.
- (2) Subsection (1) does not give the applicant a right to start proceedings in respect of the doing of an act unless:
 - (a) a patent is granted on the application; and
 - (b) the act would, if done after the grant of the patent, have constituted an infringement of a claim of the specification.

From Schedule 1 – Definitions

Exploit, in relation to an invention, includes:

- (a) where the invention is a product-make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- (b) where the invention is a method or process-use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use;

It is clear however that the rights granted to a patentee are “negative” rights. That is, they prevent exploitation by others without authorisation of the patentee. They do not however amount to right to exploit and any such exploitation is subject to

any other law that may regulate activities in the field of the patented invention.
See *Grain Pool of WA v Commonwealth* [2000] HCA 14 [81]-[85].

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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

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.).

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

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

Section II: Private and/or non-commercial use

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

In Australia there is no statutory exclusion for private and/or non-commercial use.....
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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:

While not a matter yet determined by Australian Courts, it is considered that a non-commercial use defence may arise under common law - see the UK decision *Frearson v Loe* (18760 9 ChD 48. (Genes and Ingenuity, Chapter 13, Report 99, Australian Law Reform Commission, June 2004.)
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6. (a) What are the public policy objectives for providing the exception?

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

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

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

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

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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 research⁴

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

Currently in Australia there is no statutory provision clarifying researchers' freedom to conduct experiments.

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

The Australian courts have not tested any implicit exception for experimental research. It is however considered that a research exemption may exist under the non-commercial use defence referred to at question 5. Given this uncertainty a statutory research exemption is under consideration in Australia as discussed at question 21 below. .

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13. (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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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:

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

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

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:

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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):

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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):

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

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

The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 is currently (July 2011) being considered by Parliament. The Bill amends the Patents Act to draw a line between research and commercial activities. The amendments are designed to clarify that research and experimental activities relating to patented inventions are exempt from infringement, whereas commercial activities are not. The intent is to give broad and clear protection to research and experimental activities in order to maximise the potential for research in Australia.

The Bill includes the following amendment, please note however that these amendments have not been approved by the Australian Government at the time of writing.

After section 119A (see answer to question 51)

Insert:

- 119C Infringement exemptions: acts for experimental purposes
- (1) A person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention.
 - (2) For the purposes of this section, experimental purposes relating to the subject matter of the invention include, but are not limited to, the following:
 - (a) determining the properties of the invention;
 - (b) determining the scope of a claim relating to the invention;
 - (c) improving or modifying the invention;
 - (d) determining the validity of the patent or of a claim relating to the invention;
 - (e) determining whether the patent for the invention would be, or has been, infringed by the doing of an act.

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The Explanatory Memorandum to the Bill (http://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s837_ems_561ef790-9811-43d0-b14f-04c924723c94/upload_pdf/356916em.pdf) contains a discussion of the policy background and consideration relevant to the proposed provision.

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):

Section 119 (Patents Act 1990). Infringement exemptions: Prior use.

(1) A person may, without infringing a patent, do an act that exploits a product, method or process and would infringe the patent apart from this subsection, if immediately before the priority date of the relevant claim the person:

- (a) was exploiting the product, method or process in the patent area; or
- (b) had taken definite steps (contractually or otherwise) to exploit the product, method or process in the patent area.

(2) Subsection (1) does not apply if, before the priority date, the person:

- (a) had stopped (except temporarily) exploiting the product, method or process in the patent area; or
- (b) had abandoned (except temporarily) the steps to exploit the product, method or process in the patent area.

(3) Limit for product, method or process derived from patentee

Subsection (1) does not apply to a product, method or process the person derived from the patentee or the patentee's predecessor in title in the patented invention unless the person derived the product, method or process from information that was made publicly available:

- (a) by or with the consent of the patentee or the patentee's predecessor in title; and
- (b) through any publication or use of the invention in the prescribed circumstances mentioned in paragraph 24(1)(a).

(4) Exemption for successors in title

A person (the disposer) may dispose of the whole of the disposer's entitlement under subsection (1) to do an act without infringing a patent to another person (the recipient). If the disposer does so, this section applies in relation to the recipient as if the references in subsections (1), (2) and (3) to the person were references to:

- (a) the disposer; or
- (b) if the disposer's entitlement arose because of one or more previous applications of this subsection--the first person:
 - (i) who was entitled under subsection (1) (applying of its own force) to do an act without infringing the patent; and
 - (ii) to whom the disposer's entitlement is directly or indirectly

attributable.

(5) Definition

In this section:

exploit includes:

- (a) in relation to a product:
 - (i) make, hire, sell or otherwise dispose of the product; and
 - (ii) offer to make, hire, sell or otherwise dispose of the product; and
 - (iii) use or import the product; and
 - (iv) keep the product for the purpose of doing an act described in subparagraph (i), (ii) or (iii); and
- (b) in relation to a method or process:

- (i) use the method or process; and
- (ii) do an act described in subparagraph (a)(i), (ii), (iii) or (iv) with a product resulting from the use of the method or process.

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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:

The grant of a patent should not deprive a party from continuing to do what they were doing before the patent was granted. On the other hand an inventor should not be deprived of patent protection by the secret acts of third parties, of which they can have no knowledge. Section 119 attempts to provide a balance between the rights of the patentee and those of the third party. It is intended to safeguard the rights of third parties who have independently used an invention before the priority date of an application for a patent.

It should also be noted that Australia has a grace period for prior public disclosure of the invention by the inventor or successors in title. The prior use exception is also seen as an important balancing provision such that a person who relies on an unfettered disclosure remains free to exploit the invention despite the grant of a patent. Subsection 119(3) has the effect of applying the prior use exemption to public disclosures by the patentee or predecessor in title which would be covered by the grace period provisions.

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

This provision was amended by the Intellectual Property Laws Amendment Act 2006. The amendments clarified the existing legislation in three key areas: whether the prior use had to be in Australia; whether the provision was limited to commercial use; or whether the right is limited to the actual user of whether it can be assigned or licensed. The amendments ensured that the prior user right is limited to use in Australia, that the benefit of the right extends to assignees, but not licensees and that the use encompasses acts which would otherwise constitute an infringement of the patent, including commercial use.

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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):

The scope of 'use' is defined in section 119 by referring to the definition of 'exploit'. Exploit is defined for this section of the Act in section 119(5).

(5) Definition

In this section:

exploit includes:

(a) in relation to a product:

- (i) make, hire, sell or otherwise dispose of the product; and
- (ii) offer to make, hire, sell or otherwise dispose of the product; and
- (iii) use or import the product; and
- (iv) keep the product for the purpose of doing an act described in subparagraph (i), (ii) or (iii); and

(b) in relation to a method or process:

- (i) use the method or process; and
- (ii) do an act described in subparagraph (a)(i), (ii), (iii) or (iv) with a product resulting from the use of the method or process.

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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:

No. The exception to infringement is absolute and not dependant on the payment of reasonable remuneration.
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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 (section 119(4) allows the person to assign. However prior users cannot licence their rights)
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. However other provisions apply

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

Where an application or patent ceases to have effect in certain circumstances but is restored, for example through the granting of an extension of time, special provisions apply to allow a third party to apply to the Commissioner of Patents for a licence to continue to exploit the invention. The person must show that they took definite steps to avail themselves of or exploit the invention as a result of the ceasing of the application or patent. See for example subsection 223(9) and regulation 22.21. The terms of such a licence are determined by the Commissioner (22.21(5)) taking into account the circumstance but the licence is royalty free (See *HRC PROJECT DESIGN PTY LTD v. ORFORD PTY LTD* [1997] APO 12.)

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:

No amendments to this section of the Patents Act 1990 are currently being considered.

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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):

Section 118 (Patents Act 1990). Infringement exemptions: use in or on foreign vessels, aircraft or vehicles

The rights of a patentee are not infringed:

(a) by using the patented invention on board a foreign vessel, in the body of the vessel, or in the machinery, tackle, apparatus or other accessories of the vessel, if the vessel comes into the patent area only temporarily or accidentally and the invention is used exclusively for the needs of the vessel; or

(b) by using the patented invention in the construction or working of a foreign aircraft or foreign land vehicle, or in the accessories of the aircraft or vehicle, if the aircraft or vehicle comes into the patent area only temporarily or accidentally.

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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:

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

Paris Convention
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45. The exception applies in relation to:

- √ Vessels
- √ Aircrafts
- √ Land Vehicles
- √ Spacecraft

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

The terms temporarily and accidentally are included in section 118 of the Patents Act 1990. These terms are not defined within the Act.

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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 118(a) relating to foreign vessels includes the restriction “the invention is used exclusively for the needs of the vessel”

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

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

No amendments are planned to this section of the Patents Act 1990.

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

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Section VII: Acts for obtaining regulatory approval from authorities

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

Section 119A (Patents Act 1990). Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals

(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

(a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:

(i) are intended for therapeutic use; and

(ii) are not medical devices, or therapeutic devices, as defined in the Therapeutic Goods Act 1989; or

(b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

(2) Subsection (1) does not apply to the export from Australia of goods for purposes described in paragraph (1)(b) unless the term of the patent has been extended under Part 3 of Chapter 6 and the goods consist of or contain:

(a) a pharmaceutical substance per se that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification.

Note: Part 3 of Chapter 6 provides for the extension of the term of standard patents claiming pharmaceutical substances.

(3) In this section:

pharmaceutical patent means a patent claiming:

(a) a pharmaceutical substance; or

(b) a method, use or product relating to a pharmaceutical substance, including any of the following:

(i) a method for producing a raw material needed to produce the substance;

(ii) a product that is a raw material needed to produce the substance;

(iii) a product that is a pro-drug, metabolite or derivative of the substance.

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

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

This exception seeks to prevent patentees having a *de facto* extension of the patent term. Without the exception alternative manufacturers could not gain regulatory approval until the term has expired. These processes would take some time and amount to an extended period of exclusivity for the original patentee.

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

This type of exception was first introduced in 1998 (Intellectual Property Laws Amendment Act 1998) along with provisions for pharmaceutical extensions of term. The exceptions for regulatory approval were amended in 2006 (Intellectual Property Laws Amendment Act 2006) to introduce section 119A (see above, answer to question 51).

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

Under Section 119A of the Patents Act 1990 (see answer to question 51) there are no restrictions as to who may use the exception.

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55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products: ...[Pharmaceutical Patents](#) (see answer to question 51)

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

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

Other. Please specify: ...Any use for the purpose of obtaining regulatory approval as indicated above

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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 rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is *solely* for purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods or for obtaining similar regulatory approval under the law of a foreign jurisdiction.

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

The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 introduces an exemption for activities solely for the purpose of gaining regulatory approval to market or manufacture a patented technology. This expands the existing exemption for pharmaceutical inventions to all technologies.

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

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Section VIII: Exhaustion of patent rights

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

- National
- Regional
- International
- Uncertain, please explain.....

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

The issue is not specifically dealt with in Australia Patents Act, however the Act states that a patent holder has exclusive rights to exploit their invention in Australia. Exploit is specially defined in the Act, this definition includes importation.

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

The situation for exhaustion and parallel importation in Australia is that national, rather than international, exhaustion applies. However, there is little Australian case law on this issue.

Exhaustion and parallel importation seems to apply to patents, unless the patent owner has placed contractual restrictions to the contrary. This principle is part of the existing Australian law, subject to a qualification that importation of the patented article put into circulation outside Australia by the Australian patentee will be an infringement if, at the time of first putting the article into circulation, that patentee attached an express stipulation against bringing it into Australia.

The general legal principle that applies in Australia is that it is not an infringement of a patent for a purchaser to use or dispose of as the purchaser pleases, assuming the purchase was by way of an authorised sale of the product. In general the sale of the product is the trigger for exhaustion.

Australia is also bound by international obligations under Free Trade Agreements. For example the Australia – United States FTA (Article 17.9.4) states that “Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.”

.....

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

It is currently considered to provide an adequate balance between the interests of patentees and consumers.....
.....
.....

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

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

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that 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):

It is not clear and Australian courts have not considered the circumstances where a condition expressed as a notice on a product would be binding... ..
.....

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

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

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

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

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 133 (Patents Act 1990). Compulsory licences

(1) Subject to subsection (1A), a person may apply to the Federal Court, after the end of the prescribed period, for an order requiring the patentee to grant the applicant a licence to work the patented invention.

(1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.

(2) After hearing the application, the court may make the order if satisfied that:

(a) all the following conditions exist:

(i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;

(ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;

(iii) the patentee has given no satisfactory reason for failing to exploit the patent; or

(b) the patentee has contravened, or is contravening, Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.

(3) An order must direct that the licence:

..(a) is not to give the licensee, or a person authorised by the licensee, the exclusive right to work the patented invention; and

. (b) is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;

and may direct that the licence is to be granted on any other terms specified in the order.

(3A) [repealed]

(3B) If the patented invention cannot be worked by the applicant without his or her infringing another patent:

(a) the court is to make the order only if the court is further satisfied that the patented invention involves an important technical advance of considerable economic significance on the invention (other invention) to which the other patent relates; and

(b) the court must further order that the patentee of the other invention:

(i) must grant to the applicant a licence to work the other invention insofar as is necessary to work the patented invention; and

(ii) is to be granted, if he or she so requires, a cross-licence on reasonable terms to work the patented invention; and

(c) the court must direct that the licence granted by the patentee of the other invention may be assigned by the applicant:

- (i) only if he or she assigns the licence granted in respect of the patented invention; and
- (ii) only to the assignee of that licence.

(4) An order operates, without prejudice to any other method of enforcement, as if it were embodied in a deed granting a licence and executed by the patentee and all other necessary parties.

(5) The patentee is to be paid in respect of a licence granted to the applicant under an order:

- (a) such amount as is agreed between the patentee and the applicant; or
- (b) if paragraph (a) does not apply—such amount as is determined by the Federal Court to be just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act).

(6) The patentee or the Federal Court may revoke the licence if:

- (a) the patentee and the licensee are agreed, or the court on application made by either party finds, that the circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur; and
- (b) the legitimate interests of the licensee are not likely to be adversely affected by the revocation.

Section 134 (Patents Act 1990). Revocation of patents after grant of compulsory licence

(1) Where a compulsory licence relating to a patent is granted, an interested person may apply to the Federal Court, after the end of the prescribed period, for an order revoking the patent.

(2) After hearing the application, the court may make the order if satisfied that:

- (a) both:
 - (i) the reasonable requirements of the public with respect to the patented invention have not been satisfied; and
 - (ii) the patentee has given no satisfactory reason for failing to exploit the patent; or
- (b) the patentee is contravening Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.

Section 135 (Patents Act 1990). Reasonable requirements of the public

(1) For the purposes of sections 133 and 134, the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:

- (a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:

(i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or

(ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or

(iii) to carry on the patented process to a reasonable extent; or

(iv) to grant licences on reasonable terms; or

(b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or

(c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.

(2) If, where paragraph (1)(c) applies, the court is satisfied that the time that has elapsed since the patent was sealed has, because of the nature of the invention or some other cause, been insufficient to enable the invention to be worked in Australia on a commercial scale, the court may adjourn the hearing of the application for the period that the court thinks sufficient for that purpose.

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

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

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:

Compulsory licensing provisions are provided to ensure the balance between the granted monopoly and the public interest.

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

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):

As stated in the answer to question 65, one of the ground that must be met for the grant of a compulsory licence is that the patentee has given no satisfactory reason for failing to exploit the patent.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, the patentee enjoys exclusive rights to exploit their invention. The definition of ‘exploit’ given in the Patents Act 1990 includes importation.

However, this question relates to the principle of exhaustion addressed in question 60. In Australia a product purchased in another jurisdiction legally and with no conditions attached can be imported by the purchaser.

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? 3 years after sealing (as specified by Regulation 12.1(1)

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”? The reasons are not described in the Act and would be determined on a case-by-case basis.

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):

Section 133(2) deals with the conditions require for the court order the patentee to grant a licence (see answer to question 65).

The “reasonable period” of section 133(2)(a)(i) has not been the subject of judicial interpretation in Australia.

Section 133(5) deals with payment to the patentee (also see answer 65)...

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):

Section 133(2)(b) is relevant.

“After hearing the application, the court may make the order if satisfied that:

...

(b) the patentee has contravened, or is contravening, Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.”

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:

Section 133(3B) deals with the circumstances where the patented invention cannot be worked without infringing another patent. The conditions associated with the grant of a licence in such cases are given in section 133(3B)(a-c). See answer to question 65.

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 133(5)(b) provides such a general policy (see answer to question 65).

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:

IP Australia is not aware of any instances any compulsory licences being granted by the courts in Australia.

.....

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:

.....

.....

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

.....

.....

.....

Government use

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

Chapter 17 of the Patents Act 1990 relates to The Crown. Sections 163 – 172 are relevant to this question.

Section 163. Exploitation of inventions by Crown

- (1) Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement:
- (a) if the application is pending-of the nominated person's rights in the invention;
 - or
 - (b) if a patent has been granted for the invention-of the patent.
- (2) A person may be authorised for the purposes of subsection (1):
- (a) before or after any act for which the authorisation is given has been done; and
 - (b) before or after a patent has been granted for the invention; and
 - (c) even if the person is directly or indirectly authorised by the nominated person or patentee to exploit the invention.
- (3) Subject to section 168, an invention is taken for the purposes of this Part to be exploited for services of the Commonwealth or of a State if the exploitation of the invention is necessary for the proper provision of those services within Australia.

Section 164. Nominated person or patentee to be informed of exploitation

As soon as practicable after an invention has been exploited under subsection 163 (1), the relevant authority must inform the applicant and the nominated person, or the patentee, of the exploitation and give him or her any information about the exploitation that he or she from time to time reasonably requires, unless it appears to the relevant authority that it would be contrary to the public interest to do so.

Section 165. Remuneration and terms for exploitation

- (1) [repealed]
- (2) The terms for the exploitation of the invention (including terms concerning the remuneration payable to the nominated person or the patentee) are such terms as are agreed, or determined by a method agreed, between the relevant authority and the nominated person or the patentee or, in the absence of agreement, as are determined by a prescribed court on the application of either party.
- (3) For the purposes of subsection (2), the terms, or the method, may be agreed before, during or after the exploitation.
- (4) When fixing the terms, the court may take into account any compensation that a person interested in the invention or the patent has received, directly or indirectly, for the invention from the relevant authority.

Section 165A. Exploitation of invention to cease under court order

- (1) A prescribed court may, on the application of the nominated person or the patentee, declare that the exploitation of the invention by the Commonwealth or the State is not, or is no longer, necessary for the proper provision of services of the Commonwealth or of the State if the court is satisfied that, in all the circumstances of the case, it is fair and reasonable to make the declaration.
- (2) The court may further order that the Commonwealth or the State is to cease to exploit the invention:
 - (a) on and from the day specified in the order; and
 - (b) subject to any conditions specified in the order. In making the order, the court is to ensure that the legitimate interests of the Commonwealth or of the State are not adversely affected by the order.

Section 166. Previous agreements inoperative

- An agreement or licence (whether made or given before or after the commencement of this Act) fixing the terms on which a person other than the Commonwealth or a State may exploit an invention is inoperative with respect to the exploitation, after the commencement of this Act, of the invention under subsection 163 (1), unless the agreement or licence has been approved:
- (a) if the relevant authority is the Commonwealth-by the Minister; or
 - (b) if the relevant authority is a State-by the Attorney-General of the State.

Section 167. Sale of products

- (1) The right to exploit an invention under subsection 163 (1) includes the right to sell products made in exercise of that right.
- (2) Where under subsection 163 (1) the sale of products is not an infringement of:
 - (a) a patent; or
 - (b) a nominated person's rights in the products;the buyer, and any person claiming through the buyer, is entitled to deal with the products as if the relevant authority were the patentee or the nominated person.

Section 168. Supply of products by Commonwealth to foreign countries

- Where the Commonwealth has made an agreement with a foreign country to supply to that country products required for the defence of the country:
- (a) the use of a product or process by the Commonwealth, or by a person authorised in writing by the Commonwealth, for the supply of that product is to be taken, for the purposes of this Chapter, to be use of the product or process by the Commonwealth for the services of the Commonwealth; and
 - (b) the Commonwealth or the authorised person may sell those products to the country under the agreement; and
 - (c) the Commonwealth or the authorised person may sell to any person any of the products that are not required for the purpose for which they were made.

Section 169. Declarations that inventions have been exploited

- (1) Subject to subsection (4), a patentee who considers that the patented invention has been exploited under subsection 163 (1) may apply to a prescribed court for a declaration to that effect.
- (2) In proceedings under subsection (1):
 - (a) the alleged relevant authority is the defendant; and
 - (b) the alleged relevant authority may apply by way of counter-claim in the proceedings, for the revocation of the patent.
- (3) The provisions of this Act relating to the revocation of patents apply, with the necessary changes, to a counter-claim.
- (4) An application under subsection (1) in respect of an innovation patent cannot be made unless the patent has been certified.

Section 170. Sale of forfeited articles

Nothing in this Chapter affects the right of the Commonwealth or a State, or of a person deriving title directly or indirectly from the Commonwealth or a State, to sell or use an article forfeited under a law of the Commonwealth or the State.

Section 171. Acquisition of inventions or patents by Commonwealth

- (1) The Governor-General may direct that a patent, or an invention that is the subject of a patent application, be acquired by the Commonwealth.
- (2) When a direction is given, all rights in respect of the patent or the invention are, by force of this subsection, transferred to and vested in the Commonwealth.
- (3) Notice of the acquisition must be:
 - (a) given to the applicant and the nominated person, or the patentee; and
 - (b) published in the Official Journal and the Gazette unless, in the case of the acquisition of an invention that is the subject of an application for a patent, a prohibition order, or an order under section 152, is in force in respect of the application.
- (4) The Commonwealth must pay a compensable person such compensation as is agreed between the Commonwealth and the person or, in the absence of agreement, as is determined by a prescribed court on the application of either of them.

Section 172. Assignment of invention to Commonwealth

- (1) An inventor, or an inventor's successor in title, may assign the invention, and any patent granted or to be granted for the invention, to the Commonwealth.
- (2) The assignment and all covenants and agreements in the assignment are valid and effectual, even if valuable consideration has not been given for the assignment, and may be enforced by proceedings in the name of the Minister.....

.....

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

.....

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

- Non-working or insufficient working of the patented invention
 - Refusal to grant licenses on reasonable terms
 - Anti-competitive practices and/or unfair competition
 - Public health
 - National security
 - National emergency and/or extreme urgency
 - Dependent patents
 - Other, please specify: ...
- The grounds stated in section 163 of the Patents Act 1990 are "for the services of the Commonwealth or the State"
-

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

Historically, the two main justifications for use of the Crown use provisions have been:

- (i) the Crown should not be impeded by patents (which are, in effect, Crown grants) from acting in the public interest, particularly in relation to matters of national defence; and
- (ii) unlike private traders, the Crown, through its departments and authorities is ordinarily engaged in public services, rather than commercial activities, and therefore should be in a special position in regards to use of patented inventions.

.....

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

In 1903, Crown use and acquisition provisions were included in Australian patents legislation. Barwick CJ described the purpose of the Crown use provisions in the Patents Act 1952 (Cth) as being to 'ensure that the governments of the Commonwealth and of the States have the invention available to them for the benefit of the services of the respective governments at once, rather than at the end of the term of the letters patents'

In *Stack v Brisbane City Council* (1994) 131 ALR 333, the Federal Court considered the reasoning of the House of Lords in *Pfizer Corporation v Ministry of Health* [1965] AC 512 (Pfizer), in which it was held that the use of a patented drug (tetracycline) in National Health Service hospitals for patients was 'for the services of the Crown'. The House of Lords held that the phrase was not to be limited to the internal activities of Crown authorities, but that the services at issue could ultimately benefit individual members of the public. The House of Lords held, by majority, that an act was done 'for the services of the Crown' if it was done for the purpose of performing a duty or exercising a power which was imposed

upon or invested in the executive government by statute or by prerogative, including providing services to the general public.

The Advisory Council for Intellectual Property has considered Crown Use Provisions

(<http://www.acip.gov.au/library/Review%20of%20Crown%20Use%20Discussion.PDF> and

http://www.acip.gov.au/library/review_of_Crown_Use_provisions.pdf).

The Australian Law Reform Commission has also considered the issue in “ALRC Discussion Paper 68 Gene Patenting and Human Health”

(<http://www.austlii.edu.au/au/other/alrc/publications/dp/68/>)

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

N/A

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

If the Crown use provisions were invoked the case would be between the relevant instrumentality of the Crown and the patentee and would not involve any of the administrative bodies responsible. As such it is difficult to determine the frequency of use, though we expect this has been minimal.

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 to this section of the Patents Act are currently planned

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

The main difficulty that has been tested by the courts is in defining which bodies can be considered to fall within the scope of the Crown.

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):

.....
.....

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

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

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

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

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

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

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

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

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

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

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

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

Breeders' use of patented inventions

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

.....
.....

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

.....
.....

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

.....
.....

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

.....
.....

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

.....
.....

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

.....
.....

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

.....
.....

Section XI: Other Exceptions and Limitations

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

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

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

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

.....
.....

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

.....
.....

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

.....
.....

In 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?):

.....
.....

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

.....
.....

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:

.....
.....

[End of Questionnaire]