



Australian Government

IP Australia

Exemptions to Patent Infringement

Toward a Stronger and More Efficient IP Rights System

**IP Australia
Consultation Paper
March 2009**





Introduction

This paper is the one of several papers setting out proposals directed at improving the fit and function of the Australian patent system as a vehicle to support innovation.¹

The object of this paper is to encourage discussion on the proposed changes and their likely impacts on Australian business and innovation.

IP Australia invites any interested parties to make a written submission, and in particular seeks responses to the questions posed in the paper. Comments will be welcome from anyone interested in the operation of the patent system in Australia and its interaction with patent systems in jurisdictions of Australian business interest, but especially from those who have been, are, or expect to be users of the Australian patent system and/or those of other jurisdictions.

IP Australia will consider submissions and then make recommendations to Government on the way forward.

The closing date for submissions is 8 May 2009.

Written submissions should be sent to:

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Please note that, unless requested otherwise, written comments submitted to IP Australia will be made publicly available.

A request made under the *Freedom of Information Act 1982* for access to a submission marked confidential will be determined in accordance with that Act.

¹ See also IP Australia consultation paper 'Getting the Balance Right' available at www.ipaustralia.gov.au



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1. Background

1. In recent years there has been a greater awareness and use of patent rights both in Australia and around the world. This has been driven by factors such as a growing appreciation of the importance of intellectual property rights in the successful commercialisation of technology, the realisation that successful innovation is a primary driver of economic growth, and pressure on public research organisations to commercialise their research and development. However, concerns have also been expressed that such growth in the number of patent applications and grant of patent rights may in fact be stifling research and development as a consequence of greater uncertainty among researchers and businesses as to where they have freedom to operate.

2. An experimental use exemption is one means of providing researchers and businesses with greater certainty as to where they have freedom to operate. However, the *Patents Act 1990* does not contain a specific research or experimental use exception and IP Australia is not aware of any legal cases in Australia where experimental use was argued as a defence against infringement litigation. As a consequence it is unclear whether an experimental use exemption exists in Australia, and if it does, the extent to which it applies. Experiences in other countries where there are no statutory experimental use provisions indicate that courts have struggled to ascertain the scope of the experimental use defence or have applied restrictive tests that are potentially detrimental to research.

3. It has been suggested that lack of certainty about an experimental use exemption deters research in areas that are the subject of existing patents. This may not only inhibit Australian research, it may also encourage business and researchers to move their research and development offshore to jurisdictions with more favourable experimental use exemptions. This could potentially result in a loss of research investment and employment opportunities in Australia.

4. In light of such concerns, reports by the Australian Law Reform Commission (ALRC) and the Australian Advisory Council on Intellectual Property (ACIP) have both recommended that the Patents Act be amended to include an explicit experimental use exemption. IP Australia subsequently undertook public consultation on the ACIP report and on the differences between the ACIP and ALRC recommendations in 2006.



5. A further issue involves use of the patented invention for the purpose of obtaining regulatory approval of a product during the term of the patent, such that the product may be used once the patent has ceased. Under Australian Law, such experimental use is only allowed on pharmaceutical patents. The absence of similar provisions for other types of regulated inventions in effect gives those patent owners a further period of market exclusivity (or a *de facto* extension of term of the patent) as it may take some time before an alternative manufacturer can gain regulatory approval and market a competing product. Favourable provisions in other countries arguably provide foreign manufacturers with a competitive advantage over local industry as they are better placed to quickly enter the market once a patent has expired.

6. The present paper sets out a proposal for a statutory exemption covering certain experimental activities.

2. Objectives

7. The objective of the proposals set out in this paper is to implement a statutory exemption that provides for certain experimental activities to be carried out without such activities constituting an infringement of a patent. In particular, the proposed changes are intended to:

- Provide researchers and business with greater certainty as to whether or not their activities will infringe existing patent rights.
- Assist researchers and business to more effectively use the patent system to commercialise their research and development.
- Ensure that existing patent rights do not impede research and development.
- Ensure that the IP system provides adequate incentive for innovation in Australia.
- Align exemptions from infringement for experiments aimed at obtaining regulatory approval across all types of regulated inventions.

3. Proposed Changes

8. IP Australia considers that the following underlying principles should underpin any statutory exemption:

- While it may be desirable to align Australian practice with overseas jurisdictions, there is no international ‘best-practice’ experimental use exemption. Accordingly while some guidance may be taken from overseas practice, the focus of the statutory exemption should be on meeting the interests of Australians stakeholders.
- The statutory exemption will need to be consistent with the Trade-Related Intellectual Property Rights agreement (TRIPS) to the extent that it will not unreasonably conflict with a normal exploitation of the patent.



- The statutory exemption should not derogate from any study or experimentation that may otherwise be permitted under the Patents Act. The statutory exemption should augment any exemption already available and not replace it.
- The statutory exemption should be drafted in such a manner that it can be readily understood by the relevant stakeholders, for example researchers.
- The statutory exemption should provide a reasonable amount of certainty as to the activities that are, or are not, subject to an exemption.

9. To this end, IP Australia proposes amendment of Part 1 of Chapter 11 of the Patents Act to include a statutory exemption that covers research, experimentation aimed at determining freedom to operate and experimental activities to obtain the information required for regulatory approval of a patented invention. Please note that the wording used to describe the exemptions is intended to be indicative of the broad intent of the changes rather than representing the specific wording that will ultimately be used in legislation.

Proposed Change

A person may, without infringing a patent, do any act *on* a patented invention which is solely for the purpose of:

- determining how the invention works
- seeking an improvement to the invention
- testing the validity of a patent
- determining the scope of the patent claims
- determining whether an act or product infringes a patent

or

- obtaining the information required for regulatory approval under Australian law or the law of any other country that regulates the manufacture, construction, use or sale of the patented invention.

The statutory exemption will not apply where the invention is used in, but is not the subject of, an experiment.

10. The proposal exempts experimental use such as: research to supplement existing knowledge of an invention; research to test a hypothesis about an invention; and research to determine hitherto unknown and useful properties of an invention. IP Australia considers that this is consistent with one of the key purposes of the patent system, namely that innovation is encouraged and technology advances. This meets the policy aim of helping researchers and businesses operate with increased certainty as to whether or not their activities constitute infringement of existing patent rights, and helps ensure that patents do not inhibit research and development in Australia. IP Australia notes that the exemption is limited only to research use of the invention and does not extend to commercial exploitation of the patented invention. This ensures that the exemption does not act as a disincentive to primary innovators pursuing patent protection.



11. A key issue in this regard concerns the experimental use of ‘research tools’. These inventions are used in upstream research discovery, and include genes, proteins, libraries (such as cDNA or genomic libraries), processes or procedures. Submissions suggested that in the case of research tools it may be difficult to distinguish whether an experimental use exemption applies to them since, for example, some research tools are at the same time the subject and the instrument of research. However, IP Australia considers that research tools are analogous to any other invention that is used in research and the established principles of patent law and infringement apply equally.

12. Thus, the use of a tool in research can generally be distinguished from research on the tool itself, and an exemption would only apply to the latter situation. For example, use of a known PCR technique in research into a new gene would not be exempted from infringement. However, research on the PCR technique to improve the way it works would most likely fall within a research exemption. This appears to be consistent with the approach of other jurisdictions. For example, in the UK a distinction has been drawn in a recent consultation paper that research tools which are used in, but are not the subject of, an experiment, do not fall within the exemption.²

13. On that basis, IP Australia considers a separate exemption relating only to research tools is unnecessary.

14. The proposed exemption may also be applicable to situations where a party is involved in infringement proceedings and seeks to test the validity of the patent or prove non-infringement through experimentation. Similarly the proposed exemption will assist parties in assessing their ‘freedom to operate’ in a field of research by exempting experiments relating to testing the validity of claims, determining the scope of claims or determining whether their product or process falls within the scope of an existing patent.

15. For example, a party might seek to ensure that the commercial production, marketing or use of a new product does not infringe any existing patent rights. This is particularly relevant where the usefulness of an invention can only be fully determined by experimentation, or where a particular style of claim precludes the ready determination of its scope and an alternative means of determination, such as experimentation, is required. For example, experimentation will generally be required to determine whether a product falls within the scope of a claim which characterises the invention using a functional definition such as biological activity. In the event that the party finds that their product potentially infringes a patent they may obtain advice on the validity of that patent and, if necessary, seek a licence, attempt to work around the patent, or decide to cease research and development in that area.

16. IP Australia considers that an exemption of this nature will meet the policy aim of assisting researchers and businesses to more effectively use the patent system to commercialise their research and development.

17. The proposed exemption also allows parties to undertake experimentation at any time during the term of a patent for the purpose of obtaining regulatory approval of the patented product or process. At present such activities are allowed only on pharmaceutical patents under 119A of the Act, and for purposes connected with obtaining inclusion in the Australian Register of Therapeutic Goods. In contrast, the proposed exemption is not intended to be restricted to any particular technology or regulatory process. This would make it applicable to existing regulated inventions such as agricultural chemicals and the like, or any future emerging industries that may be subject to

² UK Intellectual Property Office, ‘The Patent Research Exception: A Consultation’ 2008



regulation. However, the exemption would not extend to commercial purposes, such as the stockpiling of products for sale once the patent has expired.

18. IP Australia considers this is consistent with the aim that patents do not impede research and development in Australia while ensuring that the system provides adequate incentive for innovation in Australia. This would also align exemption provisions for all regulated inventions with those provided for pharmaceutical products in Australia. IP Australia expects that the proposed exemption would replace existing section 119A.

4. Questions for consideration

Please consider the questions below in relation to each of the proposals.

1. Do you agree in principle with IP Australia's proposal?
Please provide reasons and support for your answers.
2. Do you think that IP Australia's formulations are the best solutions?
Please provide reasons and support for your answers.