



Australian Government

IP Australia

Patentable Subject Matter

*Consultation on an
objects clause and an
exclusion from
patentability*

July 2013

PATENTS

TRADE MARKS

DESIGNS

PLANT BREEDER'S RIGHTS

1. Introduction

This paper discusses proposed amendments to the *Patents Act 1990* (the Patents Act) to introduce an Objects Clause and an exclusion from patentability for an invention the commercial exploitation of which would be wholly offensive to a reasonable and informed member of the public.

The purpose of this paper is to encourage discussion and seek views on the proposed amendments.

IP Australia invites interested parties to make written submissions **by 27 September 2013** and in particular seeks responses to the questions posed in the paper. Comments are welcome from anyone interested in the operation or impact of the patent system in Australia.

IP Australia will consider the submissions, and undertake further consultation – including public exposure of the legislation drafting instructions.

Submissions should be sent to consultation@ipaaustralia.gov.au.

For accessibility reasons, please submit responses via email in a Word or RTF format. An additional PDF version may also be submitted.

The contact officer is Terry Moore, who may be contacted on (02) 6283 2632.

Please note that, unless requested otherwise, written comments submitted to IP Australia may be made publicly available or disclosed to another Commonwealth agency.

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.

IP Australia complies with the *Privacy Act 1988* when collecting, using and disclosing personal information. IP Australia's Privacy Policy can be viewed at www.ipaustralia.gov.au.

This paper is also available at:

www.ipaustralia.gov.au/about-us/ip-legislation-changes

Submissions should be received no later than 27 September 2013.

2. Background

In recent years there has been considerable debate about the extent to which the patent system should balance economic and social concerns, particularly with respect to the types of inventions that can be patented. Much of this debate has centred on the patenting of isolated gene sequences and the impact of this on access to affordable healthcare.

Reflecting these concerns, over the past 11 years there have been three reviews inquiring into the issue of patentable subject matter, particularly as it relates to the patenting of isolated gene sequences. The reviews were:

- The Australian Law Reform Commission (ALRC) 2004 'Genes and Ingenuity' Report
- The Senate Community Affairs Committee (SCAC) 2010 'Gene Patents' Report
- The Advisory Council on Intellectual Property (ACIP) 2010 'Patentable Subject Matter' Report.

The recommendations made by these reviews were considered by the Government in its November 2011 response to the Gene Patents Report.

A number of the recommendations have now been implemented, including:

- changes to raise patent standards, implemented by the *IP Laws Amendment (Raising the Bar) Act 2012* (Raising the Bar Act)
- establishment of a Patent Audit Committee, announced by the Parliamentary Secretary for Climate Change, Industry and Innovation, Hon. Yvette D'Ath MP on 30 May 2013
- introduction of a broad exemption from patent infringement for research activities, implemented by the Raising the Bar Act.

A further recommendation to clarify the Crown use provisions in the Patents Act is included in the amendments proposed in the IP Laws Amendment Bill 2013. The Bill was passed by the House of Representatives on 25 June 2013 and introduced into the Senate on 28 June 2013.

ACIP made a number of recommendations which the Government accepted but not yet implemented. This paper seeks to deal with two of the ACIP recommendations:

- introduce an Objects Clause
- introduce an exclusion from patentability for an invention the commercial exploitation of which would be wholly offensive to a reasonable and informed member of the public

Consultation on the remaining accepted ACIP recommendations will take place at a later date.

3. Proposals

3.1 Objects Clause

The purpose of an Objects Clause is to set out the underlying purpose of a piece of legislation. The Office of Parliamentary Counsel, which is responsible for drafting Australian Government legislation, states that:

Some objects provisions give a general understanding of the purpose of the legislation... Other objects provisions set out the general aim or principles that help the reader to interpret the detailed provisions of the legislation.¹

An Objects Clause may also be used by the Courts and others, such as patent examiners, in interpreting legislation where there is ambiguity or uncertainty.

In their Patentable Subject Matter report, ACIP explained that an Objects Clause (also referred to as a Statement of Objectives) 'would clarify the interaction between the patent system and competition policy'.² ACIP referred to the World Trade Organization Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) description of the objectives of the intellectual property system which states:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.³

ACIP provided a simplified alternative to the TRIPS definition, recommending that the Objects Clause

....should describe the purpose of the legislation as being to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technology, and Australian society as a whole.⁴

The Government accepted ACIP's recommendation in its response to the Gene Patents Report.⁵ ACIP's recommended wording is proposed as **Option 1** for the wording of the Objects Clause.

An important feature of both the ACIP and TRIPS descriptions is their technology neutrality. This reflects the rationale that the same requirements should apply to all technologies and that the system should have sufficient flexibility to deal with current and future issues as they arise.

¹ Office of Parliamentary Counsel, *Working with the Office of Parliamentary Counsel: A Guide for Clients* (3rd ed, 2008), [125].

² Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 3, paragraph 2.

³ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 7, 'Objectives'.

⁴ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 5, 'Recommendation 2'.

⁵ Australian Government Response to the Senate Committee Gene Patents Report (2011) page 13

The patent system has both economic and social welfare goals. This is reflected in the TRIPS Objectives and to a lesser extent in the proposed ACIP Objects Clause.

The economic goals of the patent system are to promote economic growth, trade and investment by encouraging innovation and the dissemination of knowledge and technology. The patent system encourages innovation by giving patentees a period of market exclusivity in which to recoup their development costs through commercialisation of their inventions. In exchange, patentees are required to disclose the details of their inventions to the public.

The patent system contributes to social welfare by providing Australians with access to new technologies and developments that otherwise would not have occurred and that improve our quality of life (for example new pharmaceuticals and medical technologies and improvements to safety and waste management technologies).

However, the patent system will only meet its economic goals if the positive effects of the patent system in stimulating investment in innovation and providing society with access to new technology are balanced against the potential negative effects of patents restricting access to follow-on innovation and increasing costs, and so restricting supply of new patented technologies.

One concern with the specific wording proposed by ACIP is that it is silent with respect to the interests of patent applicants. Patent applicants are an important element of the system and it is important that the combined interests of both patent owners and applicants are accounted for and balanced with the interests of society and users of technology. ACIP's wording also does not focus on the way in which the patent system promotes the national interest, as stated in TRIPS and as widely acknowledged in Government policy, which is by promoting innovation and the dissemination of technology.

An alternate wording that addresses these two issues without moving away from ACIP's approach is provided below.

the purpose of the patent system is to provide an environment that enhances the well-being of Australians by promoting innovation and the dissemination of technology and by balancing the competing interests of patent applicants and patent owners, the users of technology, and Australian society as a whole.

This wording is proposed as **Option 2** for the Objects clause.

3.2 Patentability Exclusion

Introducing an Objects Clause into the Patents Act will provide general guidance as to the intent and purpose of the patent system. However, it will not necessarily prevent the grant of patents to inventions the commercial exploitation of which society finds offensive. For this reason, both ACIP and the ALRC recommended the introduction of an explicit exclusion from patentability for inventions where society would have a moral objection to commercialisation of the invention.

As signatory to TRIPS, Australia is obliged to provide patent protection for inventions in all technologies where the invention satisfies relevant standards. However, TRIPS allows for some exclusions in certain circumstances. One such circumstance is to

protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.

Members may exclude from patentability inventions...the commercial exploitation of which is necessary to protect *ordre public* or morality.⁶

Similar patentability exclusions on non-economic grounds exist in the European Union (*via* the European Patent Convention), Japan and New Zealand.⁷ The patentability exclusion in the above countries excludes subject matter that is either 'contrary to public order or morality' (EPC), 'contravene public order, morality or public health' (Japan) or 'contrary to morality' (New Zealand).

The Patents Act currently has two specific exclusions - the first excludes the patenting of human beings and biological processes for their generation; and the second exclusion, only applicable to innovation patents, excludes the patenting of plants, animals and biological processes for their generation.

Subsection 18(2) of the Patents Act states that:

Human beings, and the biological processes for their generation, are not patentable inventions.⁸

This amendment was introduced into the *Patents Act 1990* to address ethical concerns about the patenting of human life forms. It is consistent with the view that the Government should not be granting rights in respect of a technology that society as a whole considers offensive or inappropriate for commercialisation.

Subsection 18(3) of the Patents Act states that:

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.⁹

This amendment was introduced at the time the Innovation Patent was introduced in 2001. Innovation patents were introduced to provide a shorter term of protection for lower level innovations that might not qualify for grant of a standard patent. The exclusion was to prevent the innovation patent interfering with Plant Breeder's Rights and in the absence of a clear need for protection for lower level animal inventions.

Paragraph 50(1)(a) of the Patents Act also allows the Commissioner to refuse to accept or grant a patent for an invention the use of which is contrary to law.

The paragraph states that:

(1) The Commissioner may refuse to accept a request and specification relating to a standard patent, or to grant a standard patent:
(a) for an invention the use of which would be contrary to law.¹⁰

⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 27(2), 'Patentable Subject Matter'.

⁷ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter: Issues Paper* (2008), Section 10, 'Overseas Law and Practice', pages 57-61.

⁸ *Patents Act 1990*, Section 18(2).

⁹ *Patents Act 1990*, Section 18(3).

This provision only applies where there is no lawful use for the invention. It does not address circumstances where there may be a lawful use for the invention but where society objects to commercialisation of the invention.

ACIP also noted that the exclusions in s 50, specifically the provisions relating to 'contrary to law', may not be compliant with TRIPS which states that a country cannot exclude an invention 'merely because the exploitation is prohibited by their law'.¹¹ Similar provisions in the New Zealand patents act have been removed as it was considered to be inconsistent with Article 27 of TRIPS.¹²

ACIP recommended retaining s 18(2) and s 18(3) but replacing s 50 with a patentability exclusion in view of the above. ACIP argued against specific exclusions, stating:

This mechanism lacks flexibility, because changes to technology or to Australian society's values would require that the list of specific exclusions be updated.....This mechanism could also work against the objectives of the patents system, because wholly pre-empting an area of technology from being patented would remove an incentive for any future innovation in that area, whether or not it is undesirable.¹³The ACIP report recommended the following exclusion:¹⁴

... exclusion for an invention the commercial exploitation which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.

In formulating the patentability exclusion, ACIP recommended that patent legislation should only address ethical issues associated with the commercialisation of the invention. ACIP believed that the ethical issues associated with the invention itself would be better addressed through other areas of law.

As with their recommendation for the Objects Clause, ACIP chose to translate TRIPS language into contemporary language: replacing the term '*ordre public*', which is not commonly used in Australia, with the more familiar term, 'wholly offensive'. It is important to ensure that any language that is adopted is applied in a manner consistent with Australia's international trade obligations, including with TRIPS.

To ensure the patentability exclusion test can be applied in a consistent, predictable and neutral manner, ACIP recommended the hypothetical addressee for the test should be an "ordinary reasonable and fully informed member of the Australian public".

¹⁰ *Patents Act 1990*, Section 50(1)(a).

¹¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 27, 'Patentable Subject Matter'.

¹² Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 63, paragraph 5; and Section 4.1.4, 'Commissioner's discretion to refuse patents', pages 61-62.

¹³ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 14, paragraph 2.

¹⁴ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 17, paragraph 1.

3.3 Implementing the Patentability Exclusion

Patent examiners will be expected to apply the patentability exclusion during examination of patent applications. However, as noted in the ACIP report, the consideration of ethical issues is not a routine exercise for patent examiners. Patent examiners may also not be equipped to consider whether the commercialisation of an invention would be offensive to the Australian public.

To address this problem ACIP recommended that the Patents Act be amended to provide the Commissioner with an explicit power to seek advice. This increases transparency and clarifies the Commissioner's powers to seek assistance when applying the patentability exclusion. ACIP recommended:

that the Commissioner be given the power to seek non-binding advice, and have the discretion to decide the most appropriate way to do this.¹⁵

4. Questions

1. Do you have a preference for either of the two options proposed for the Objects Clause?
 - If so, please explain the reasons for your preference.
 - If you disagree with the wording of both of these options, please explain which elements you disagree with and why.
2. Do you agree with the wording proposed by ACIP for the patentability exclusion?
 - If you disagree with the wording, please explain which elements you disagree with and why.
3. Do you agree with amending the Patents Act to explicitly provide the Commissioner of Patents with powers to seek advice on ethical matters?
 - If you disagree please explain why.

¹⁵ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 19, final paragraph

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