



IP Australia's Public Consultation Papers

August 2017

**Further Submissions by AIPPI Australia
(IP Australia Papers 2 and 4)**

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1 BACKGROUND

We write in response to additional aspects of the public consultation document dated August 2017. In this submission, AIPPI Australia comments on:

- Paper 2: Introduce an objects clause into the *Patent Act 1990* (**Paper 2**);
- Paper 4: Amending the provisions for compulsory licensing of patents (**Paper 4**).

2 ABOUT AIPPI

AIPPI is the world's leading international organisation dedicated to the development and improvement of intellectual property, formed 120 years ago. It is a politically neutral, non-profit organisation, with its headquarters in Switzerland, having more than 9000 members in more than 100 countries. The members of AIPPI are actively interested in the intellectual property protection on a national or international level. They include lawyers, patent attorneys, trade mark attorneys, judges, academics, scientists and engineers.

The objective of AIPPI is to improve and promote the protection of intellectual property on an international and national basis. AIPPI pursues this objective by working for the development, expansion and improvement of international and regional treaties and agreements and by reviewing national laws relating to intellectual property. AIPPI operates by conducting studies of existing national laws and proposing measures to achieve harmonisation of these laws on an international basis. These measures are embodied in resolutions approved by the Executive Committee, after consultation and debate within our membership.

3 PAPER 2: INTRODUCE AN OBJECTS CLAUSE INTO THE PATENTS ACT 1990

IP Australia has presented two options for an objects clause in the *Patents Act 1990* (Cth) (**Patents Act**). The questions for consultation are:

- OC1 *Do you have a preference for one of the options proposed for the objects clause?*
- *If so, please explain the reasons for your preference.*
 - *If you disagree with the wording of these options, please explain which elements you disagree with and why.*

This is in the context that the Productivity Commission (**PC**) recommended in its final report that the Australian Government should incorporate an objects clause into the Patents Act, and the Government supported the PC's recommendation on the basis that a statement of objectives in the Patents Act:

... would provide a clear statement of legislative intent for the guidance of the court in the interpretation of the Act.¹

In summary, AIPPI Australia does not favour either option proposed for the objects clause and explains its reasons in section 3.3 below.

3.1 Background

AIPPI Australia made submissions in relation to the PC draft report addressing, amongst others, draft recommendation 6.2 concerning the incorporation of an objects clause into the Patents Act.

¹ Paper 2, page 24.

AIPPI Australia did not support that draft recommendation on the basis of considerable concern with the proposal of an objects clause in the Patents Act *per se*.

AIPPI Australia remains opposed to an objects clause, and maintains the view that an objects clause is parochial and out of step with global international efforts towards substantive patent law harmonisation. In this regard, AIPPI Australia has surveyed the position in the patents regimes of some of Australia's major trading partners and other developed countries², none of which have an objects clause, save for Japan. AIPPI Australia comments further in relation to Japan in section 3.4 below.

AIPPI Australia also acknowledges that section 3 of the New Zealand Patents Act 2013 is a purposes provision (**NZ Purposes Provision**) and also comments on the NZ Purposes Provision in section 3.4 below.

3.2 IPC Submission

AIPPI Australia largely endorses the Submission by the International Property Committee of the Law Council of Australia's Business Law Section dated 17 November 2017 (**IPC Submission**) in relation to Paper 2, and makes further reference to the IPC Submission in this respect in sections 3.3 and 3.4 below. In particular, AIPPI Australia endorses the IPC Submission that an objects clause is both unnecessary and undesirable.³

3.3 Paper 2 options for an objects clause

Paper 2 presents two options for the wording of an objects clause. AIPPI Australia comments below subject to its fundamental opposition to an objects clause.

AIPPI Australia agrees with the IPC Submission that Option B overcomes the potential issues previously raised with respect to Australia's international obligations under Article 3.1 of TRIPS and Article 17.1(6) of AUSFTA to accord treatment to nationals of other relevant states no less favourable than that accorded to Australian nationals⁴. However, AIPPI Australia considers that potential issues with Australia's international obligations persist even with Option B in that neither option is in keeping with the very limited exceptions to patentable subject matter found in Articles 27.2 and 27.3 of TRIPS. This concern is heightened if an objects clause is to be used 'in underpinning decisions on whether to grant a patent'⁵ and potentially erodes the key obligation under Article 27.1 of TRIPS that:

*... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.*⁶

² AIPPI Australia has surveyed the position in the United States of America, Canada, the United Kingdom, Germany, the Netherlands and Japan.

³ IPC Submission, paragraph 11.

⁴ IPC Submission, paragraphs 15-16.

⁵ Paper 2, page 23, citing in footnote 43, Productivity Commission 2016, Intellectual Property Arrangements, Inquiry Report No. 78, Canberra, pages 217-218.

⁶ Article 27.1 is subject to the provisions of Article 27.2 and 27.3. Article 27.2 provides:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, ...

'Ordre public' or 'morality' sets a high standard for exclusion.

Article 27.3 allows for the possibility of specific and limited exceptions, being:

Similarly, Articles 17.9 and 17.9.2 of the Australia-US Free Trade Agreement provide that, in general, patents will be available for all inventions, subject to the flexibilities provided in Articles 27.2 and 27.3(a) of TRIPS.

AIPPI Australia is also opposed to those aspects of the wording of both Options A and B cited, and for the reasons expressed, in the IPC Submission at paragraphs 17 – 19.

AIPPI Australia agrees with paragraph 18 of the IPC Submission that:

It will be particularly difficult for the Commissioner of Patents to determine whether a particular invention is likely to enhance the wellbeing of society/Australians at the time of deciding whether or not to grant a patent, when the invention may not have even yet been commercialised.

AIPPI Australia is further concerned that such determination can be no more than the individual opinion of a particular examiner. To the extent such concern can be addressed at all, the Commissioner of Patents would need to receive evidence on which an examiner could base such determination. This raises the difficult question as to what evidence would be appropriate to support such determination, and how such evidence may be obtained. Introducing such evidentiary step into the examination process will greatly enhance the complexity and cost of patent prosecution, both from the perspective of the party seeking the grant of the patent, and any party opposing such grant. This is entirely inconsistent with the overarching principle of efficiency which the PC wished to implement.

Yet another complicating factor is that the presence of an objects clause in the Patents Act may lead to the adoption of practices of trying to include drafting in patent specifications considered by the prosecuting patent attorney to satisfy the objects clause. To the extent that such drafting attempts to provide reasons, this not only increases the complexity of the examiner's role, but the evidence a patentee, or any party opposing the grant of the patent, would need to provide to address any specific statements as to the fact of or how the objects clause is satisfied. If such a practice develops, it also opens up the possibility of later allegations of fraud, false suggestion or misrepresentation under section 138(b) of the Patents Act – a notoriously fact specific and burdensome evidentiary allegation for the party seeking to revoke the patent, and for the patentee in seeking to defend its patent.

More generally, on the basis that an objects clause is said to 'assist[s] the courts in interpreting the legislation'⁷, the evidentiary issues identified above will be magnified in the context of the rules of evidence applicable in any litigation concerning the validity of a patent. This will also greatly increase the complexity and expense of patent litigation.

Additionally, any judgment as to the 'social value' of the invention in question at a point in time (possibly many years later) after the grant of patent may be quite different. The effluxion of time may introduce changing standards and expectations of different stakeholders, while the risk of a court applying a different interpretation upon the same, or possibly quite different, evidence remains constant. This promotes further uncertainty and complexity which serves neither the interests of 'producers, owners, users of technology' nor 'the public'.

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

(b) plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Australia has chosen not to avail itself of the exception in Article 27(a). Australia has chosen to avail itself of aspects of Article 27.3(b): see sections 18(2), (3) and (4) of the Patents Act.

⁷ Paper 2, page 21.

3.4 Alternative wording for an objects clause

Subject to its overarching objection to an objects clause, if an objects clause is to be introduced into the Patents Act, AIPPI Australia would prefer wording similar to the wording of the Patent Act of Japan, the objects clause in Article 1 of which provides:

The purpose of this Act is, through promoting the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry.

AIPPI Australia considers this avoids the difficulties identified in paragraph 18 of the IPC Submission, that is, a judgment as to the 'social value' of the invention being introduced by the 'wellbeing' notion in both Options A and B.

However, AIPPI Australia also recognises the efforts to harmonise Australian and New Zealand patent law, and therefore reluctantly concludes that wording substantially similar to the wording proposed in the IPC Submission (based on the NZ Purposes Provision and further referred to as the **Alternative Wording**) is preferred, for the reasons stated in the IPC Submission.⁸ The Alternative Wording proposed at paragraph 25 of the IPC Submission is:

The purposes of the legislation are to –

- (a) provide an efficient and effective patent system that –*
 - (i) promotes innovation and economic growth while providing an appropriate balance between the interests of inventors and patent owners and the interests of society as a whole; and*
 - (ii) [complies with Australia's international obligations; and]*
- (b) ensure that a patent is granted for invention only in appropriate circumstances by –*
 - (i) establishing appropriate criteria for the granting of a patent; and*
 - (ii) providing for procedures that allow the validity of a patent to be tested; and*
- (c) provide greater certainty for patent owners and the users of patented inventions that patents will be valid after they are granted; and*
- (d) [address Aboriginal and Torres Strait Islander concerns relating to the granting of patents for inventions derived from indigenous plants and animals or from Aboriginal and Torres Strait Islander traditional knowledge; and]*
- (e) ensure that Australia's patent legislation takes account of developments in the patent systems of other countries; and*
- (f) regulate the provision of patent attorney services by giving effect to the joint regime with New Zealand.*

AIPPI Australia notes that the IPC Submission endorses the inclusion of sub-paragraphs (a)(ii) and (d) in the Alternative Wording. In relation to sub-paragraph (a)(ii) of the Alternative Wording, AIPPI Australia maintains its reservations in relation to Australia's compliance with its TRIPS obligations as set out in section 3.3 above.

⁸ IPC Submission, paragraphs 20-25.

Sub-paragraph (d) of the Alternative Wording replicates sub-paragraph (d) of the NZ Purposes Provision which references 'Maori' rather than 'Aboriginal and Torres Strait Islander'. AIPPI Australia understands that the inclusion of sub-paragraph (d) of the NZ Purposes Provision is in relation to the creation of a Maori Advisory Committee within the New Zealand Patent Office. There is no corresponding body in Australia.

AIPPI Australia is not aware of any particular concerns expressed by Aboriginal and Torres Strait Islander people relating to the subject matter of sub-paragraph (d) of the Alternative Wording. AIPPI Australia has no objections to the inclusion of that sub-paragraph but notes it may be unnecessary in the absence of any particular concerns having been raised by the relevant stakeholder group. Indeed, if Aboriginal and Torres Strait Islander people were to reject any need for such 'special treatment', AIPPI Australia would support removing sub-paragraph (d) from the Alternative Wording.

4 PAPER 4: AMENDING THE PROVISIONS FOR COMPULSORY LICENSING OF PATENTS

IP Australia has presented three options for reform of the compulsory licensing regime in Chapter 12, Part 2 of the Patents Act, being the general compulsory licensing regime⁹.

The questions for this consultation are:

CL1.1 Which approach to compulsory licensing of patents do you favour and why?

CL1.2 What pros and cons have we not considered, including unintended or unforeseen consequences?

CL1.3 What other options are there?

CL1.4 Are there any particular aspects of compulsory licensing which should be a focus of public education and awareness efforts?

This is in the context of a number of reviews relating to the compulsory licensing provisions, and the PC identifying three issues as set out in Paper 4¹⁰:

- Issue One: overlap with the Competition and Consumer Act 2010
- Issue Two: uncertainty within the reasonable requirements of the public test
- Issue Three: compulsory licence orders and international obligations

The Productivity Commission *Compulsory Licensing of Patents* Inquiry Report No 61, 2013 (**Compulsory Licensing Report**) made a number of recommendations in relation to the compulsory licensing provisions. Paper 4 sets out these recommendations in general terms and as summarised below.

Recommendation 6.1	Remove the competition test from the Patents Act and add it to the <i>Competition and Consumer Act 2010</i> (Cth)
Recommendation 6.2	Replace the reasonable requirements of the public test with a general public interest test
Recommendation 6.3	Repeal section 136 of the Patents Act which prevents the court from making an order for a compulsory licence that is inconsistent with an international treaty

⁹ Neither Paper 4 nor this submission addresses the regime in Part 3 of Chapter 12 of the Patents Act which relates to compulsory licences for the manufacture and export of patented pharmaceutical inventions to eligible importing countries.

¹⁰ Paper 4, pages 38-40.

Recommendation 10.1	Provide a plain English guide on compulsory licensing, jointly developed by IP Australia and the Australian Competition and Consumer Commission
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The three options presented in Paper 4 are:

- Option 1: Public education and awareness
- Option 2: Implement the PC's recommendations in full
- Option 3: Implement a refinement of Recommendation 6.2 only

AIPPI Australia's response is set out in sections 4.3 to 4.6 below.

4.1 Background

At an international level, AIPPI has consistently maintained a position via various Resolutions that any compulsory licence should only be granted in exceptional circumstances¹¹. Relevantly for the purposes of this submission, one such circumstance is that the protected invention is not exploited in the relevant country.

4.2 IPC Submission

AIPPI Australia largely endorses the IPC Submission in relation to Paper 4, and makes further reference to the IPC Submission in its response to Questions CL.1 to CL1.4 in sections 4.3 to 4.6 respectively below.

4.3 Response to Question CL1.1 – AIPPI Australia's preferred approach

Option 1: Public education and awareness

AIPPI Australia does not consider that there is any evidence of a lack of awareness of the existing provisions that creates any disadvantage for, or imbalance between, any relevant stakeholders. However, AIPPI Australia generally supports public education and awareness about Australia's intellectual property laws, so endorses paragraph 43 of the IPC Submission that there is merit in a public education campaign being conducted by IP Australia to ensure that there is general awareness of the availability of compulsory licences, the means by which such licences are sought, and the factors which are relevant to their grant.

Options 2 & 3: Implement the PC's recommendations in full or in part

AIPPI Australia endorses the IPC Submission in paragraph 44 that there is no deficiency in the current law that needs to be remedied by legislative change as proposed in Options 2 and 3, and the remaining observations and submissions in the IPC Submission set out in paragraphs 45 to 55.

In relation to the 'problems' the PC has identified with the current test of 'reasonable requirements of the public'¹², AIPPI Australia has the following additional observations to those set out in paragraph 52 of the IPC Submission.

There have only been 3 cases under the current and previous compulsory licensing provisions in Australia, namely:

¹¹ Eg, Resolution on Q202 – "The impact of public health issues on exclusive patent rights" (Boston, 2008), Resolution on Q97 – "Dependent patents and their exploitation" (Barcelona, 1990), Resolution on Q67 – "Revision of the Paris Convention" (Montreux, 1977).

¹² Compulsory Licensing Report, pages 147-149.

- *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp* (1969) 119 CLR 572 (***Fastening Supplies***);
- *Wissen Pty Ltd v Kenneth Mervyn Lown* (1987) 9 IPR 124 (***Wissen***); and
- *Amrad Operations Pty Ltd v Genelabs Technologies Inc* [1999] FCA 633 (***Amrad v Genelabs***).

In *Fastening Supplies*, Menzies J, sitting as a single judge in the High Court of Australia had no difficulty identifying the purpose of the then compulsory licensing provisions, being:

- to foster the 'Australian manufacturing industry to make the patented article or to use the patented process'; and
- ensure 'that the Australian demand for the patented article or articles made in accordance with the patented process should be reasonably met whether from local production or from imports'.

Nor did he have any difficulty determining that the reasonable requirements of the public had been met, applying an appropriately broad interpretation of 'Australian manufacturing industry' and 'Australian demand' as set out above. Similarly, in *Wissen*, the Examiner of Patents had no difficulty determining that the reasonable requirements of the public had been met on the available evidence.

In *Amrad v Genelabs*, the Federal Court granted leave for the applicant, Amrad, to serve an application for the grant of a compulsory licence concerning patented diagnostic assay kits on the respondent, Genelabs, in the US. While it was not for the Federal Court to decide whether an order for a compulsory licence would be made in the US, the court commented in *obiter* to the effect that the applicant had established a prima facie case for the grant of a compulsory licence¹³. This was on the basis that the reasonable requirements of the public had not been met.

This case gives comfort that an Australian court would, in appropriate circumstances be prepared to grant a compulsory licence. In commenting that Amrad was not required to show that the patentee had given no satisfactory reason for failing to exploit the patent, the court impliedly endorsed the patentee bearing the onus of showing that it has a satisfactory reason for failing to exploit the patent¹⁴. AIPPI Australia considers this strikes an appropriate balance between the interests of the patentee and the public.

4.4 AIPPI Australia's response to Questions CL1.2: Pros and cons

AIPPI endorses the observations and submissions in the IPC Submission at paragraph 56 to 65. In particular, AIPPI Australia shares the concern that the introduction of a 'public interest' test (Recommendation 6.2) will create significant uncertainty. Under cover of its objection to a 'public interest' test, should such test be introduced, AIPPI would also see the need (at a minimum) for:

- meaningful guidance as to what is meant by 'public interest' in the context of the compulsory licensing regime, and how the court should balance the 'public interest' and the interest of the patentee; and
- an appropriate qualifier, such as the proposed 'substantial' public interest qualifier proposed in the Compulsory Licensing Report¹⁵.

¹³ *Amrad v Genelabs*, [15].

¹⁴ Applying *Re Hatschek's Patents, ex parte Zerenner* [1909] 2 Ch 68 at 82.

¹⁵ IPC Submissions, paragraphs 61 to 22.

AIPPI Australia would also be particularly concerned if Recommendation 6.3 (repeal of section 136 of the Patents Act) was adopted, not only for the reasons stated in paragraph 64 of the IPC Submission, but because such repeal would also be parochial and out of step with global international efforts towards substantive patent law harmonisation¹⁶. Further, AIPPI Australia considers such repeal would be damaging to Australia's international reputation due to its potential to be perceived as a desire to avoid, or even flout, Australia's international treaty obligations.

4.5 AIPPI Australia's response to Question CL1.3: other options

AIPPI endorses paragraph 67 of the IPC Submission. Similarly, AIPPI Australia does not accept there is any lack of clarity of purpose and uncertainty of language in the current regime, but agrees that a list of non-exhaustive examples, or additional factors, might be included in section 135 of the Patents Act to provide further guidance as to the meaning and scope of the 'reasonable requirements of the public' test.

4.6 AIPPI Australia's response to Question CL1.4: public education and awareness

AIPPI Australia endorses the suggestion at paragraph 68 of the IPC Submission for a general guide to Australia's compulsory licensing regime that could address the availability of compulsory patent licences, how such licences are sought, and the factors which are relevant to their grant.

¹⁶ See also section 3.1 of these submissions.