AusBiotech response to ‘Paper 1: Amending inventive step requirements for Australian patents (August 2017)’

To: IP Australia
PO Box 200
WODEN ACT 2606
Email: consultation@ipaustralia.gov.au

17 November 2017

From: AusBiotech Ltd
ABN 87 006 509 726
Level 4, 627 Chapel St
South Yarra VIC 3141
Telephone: +61 3 9828 1400
Website: www.ausbiotech.org
Introduction

AusBiotech provides this submission in response to IP Australia’s consultation on ‘Paper 1: Amending inventive step requirements for Australian patents (August 2017)’.

AusBiotech has a keen interest in the Australian patent system to the extent that is supports (or undermines) innovation, and its ability to provide appropriate incentives for companies to develop and bring new technologies to patients.

AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial biotechnology sectors; working on behalf of members for more than 30 years to provide representation to promote the global growth of Australian biotechnology.

Please find following AusBiotech’s comments, based on feedback from its membership and developed the members of its Intellectual Property Advisory Panel.

Background

The Productivity Commission (PC) in releasing its Report on Intellectual Property Arrangements (20 December 2016) considered (in Finding 7.1) that “...there is a strong case, however, for further raising the threshold” of the inventive step, despite the 2013 ‘Raising the Bar’ legislation “having moved the inventive step and other elements of patent law in the right direction.”

The PC considered that the threshold level of inventive step to be too low and that the “Australian patent system could be more effective at encouraging socially valuable innovations.”

The PC suggested that the threshold for inventive step used by the European Patent Office (EPO) “was more effective at ‘filtering out low-value patents than patent offices in other large markets for technology’” and Recommendation 7.2 of the PC’s report stated:

<table>
<thead>
<tr>
<th>The Australian Government should amend ss. 7(2) and 7(3) of the Patents Act 1990 (Cth) such that an invention is taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art. The Explanatory Memorandum should state:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• a ‘scintilla’ of invention, or a scenario where the skilled person would not ‘directly be led as a matter of course’, are insufficient thresholds for meeting the inventive step</td>
</tr>
<tr>
<td>• the ‘obvious to try’ test applied in Europe would in some instances be a suitable test.</td>
</tr>
</tbody>
</table>

| IP Australia should update the Australian Patent Office Manual of Practice and Procedure such that it will consider the technical features of an invention for the purpose of the inventive step and novelty tests. |

In its response, the Federal Government said that it is desirable for the “Australian threshold for inventive step to be consistent with international best practice and that the Raising the Bar Act reforms had this as a stated policy goal,” noting that “while that Act broadened the scope of the prior art base to be used in assessing inventive step, the fundamental threshold test for inventive step established by Australian courts remained unchanged.” The Government said, therefore, that it
“intends to build on the Raising the Bar Act, and take this opportunity to align the threshold of inventive step in Australia with the threshold of inventive step used by the EPO.”

In February 2017, AusBiotech’s submission to the Federal Government in response to the Productivity Commission’s Report said it was surprised by the PC’s recommendation to amend the definition of an inventive step in Australia to bring it into line with the definition used in Europe, as the ‘Raising the Bar’ legislation was specifically enacted in 2013 to align with Europe.

The cause of the surprise was two-fold: firstly the legislation was considered sound; and the recommendation of the PC was made such a short time after the legislation had been enacted that it was too soon to assess its impact.

AusBiotech also noted concern about the PC’s several references to the principle that, in Australia, all that is required is a "scintilla" of invention, and suggested that a scintilla is too low. The concern was that the principle has been misunderstood, as once the inventive step bar is set, an invention is either inventive or it is not.

Current consultation:

IP Australia notes it has not yet formed a view on the preferred option for implementing the PC’s recommendation and lists four options for amending Australia’s inventive step threshold:

- Option IS-1: Implement the PC recommendation verbatim
- Option IS-2: Implement Option IS-1 with clarification of prior art base and interpretation
- Option IS-3: Implement Option IS-2 with amendments to Section 45 to codify that the Commissioner must determine if an invention is a solution to a technical problem
- Option IS-4: Enshrine the EPO problem-and-solution approach in the Patents Act

Three options are presented in relation to technical features:

- Option TF-1: Assessment by examiner through modified claim requirements
- Option TF-2: Assessment by examiner through inventive step requirements
- Option TF-3: Assessment by examiner through a separate document requirement

And three distinct options are presented in relation to transitional arrangements for the amended inventive step requirements:

- Option TA-1: Changes affect all patent applications without a first examination report
- Option TA-2: Changes affect all patents applications without an examination request
- Option TA-3: Changes affect all newly filed patent applications

Consultation questions:

P1 Which options under Parts 1, 2 and 3 do you prefer and why?

AusBiotech would strongly prefer that the current arrangement be given time to settle and that no change be made at this time. Continuing tinkering with Australia’s IP system is unsettling to business
and unnecessary. AusBiotech does not consider there is such a problem with the current arrangements that compels the government to consider and propose changes to the legislation at this time. Further time would allow a greater period for the current arrangements to bed down. A decision as to any change can then be made following a reasonable period of the current arrangements.

However, if IP Australia feels compelled to change, please note the following remarks on the options noted in the consultation paper:

An issue of concern for AusBiotech with the PC report and the government’s response is that proposals and options are being considered in regard to inventive step threshold in isolation to other patentability requirements. While there is a view that Australia should adopt a European standard on inventive step, such a simple statement fails to reflect the reality that overall the Australian and European systems have different approaches to the notion of what constitutes patentable subject matter. Merely proposing changes to the inventive step threshold without consideration of the relationship between the various tests for patentable subject matter in Australia and in Europe, respectively, is ill-considered in AusBiotech’s view.

**Inventive step threshold**

Of the options, AusBiotech considers Option IS-2 to be the best of the options presented as it would cause the least disruption to the current approach.

**Technical features**

Overall all options presented under this heading put Australia at odds with the rest of the world, however option TF-2 is the preferred option as it would retain drafting of claims in line with most other jurisdictions. Implementation of Option TF-3 would represent an unreasonable imposition and proposes requirements unlike anywhere else in the world, while TF-1 places too much of a special onus on applicants, so taking Australia’s requirement with regard to drafting of claims out of step with the rest of the world.

**Transitional arrangements**

TA-3 is preferred as it is only fair for the new arrangements to apply to new applications filed after the imposition of any change. Implementation of TA-1 would result in new standards being applied many years after the filing of existing applications and would be clearly unfair, while adoption of Option TA-2 is exactly what was criticised in the implementation of the “Raising the Bar” legislation.

P2 What are other possible benefits and disadvantages of options under each part, including any unintended consequences?

As above. In addition, we note that the discussion paper (Page 6) raises the view with which AusBiotech fully agrees and subscribes: that the characterisation by the PC of the ‘scintilla’ of invention is false. AusBiotech has previously voiced concern that the principle has been misunderstood and should not be the basis for change. The paper says:

“A further risk is that the PC’s characterisation of the ‘scintilla’ of invention as a threshold standard for inventive step may be incorrect. The principle of ‘a scintilla of invention’ is
generally intended to convey that the test for obviousness is that either an inventive step is present or it is not, and not question of degree. As such, the inclusion of the PC’s text in the explanatory memorandum may not achieve what is intended by the PC.”

P3 Are there any other better options that have not been considered?

Yes, making no change at this time would be a better option. It would be vastly preferable to see the current arrangements given time to settle and be assessed before further change is considered. The ‘Raising the Bar’ legislation was and still is considered sound and the recommendation of the PC was made such a short time after the legislation had been enacted that it was too soon to assess its impact.

P4 Should Option IS-3 as proposed under Part 1 (inventive step) also include amendments to grounds to re-examine or to oppose grant of standard patent? Are there any other implications not considered?

IS-3 is not considered a sensible approach.

P5 Does your preferred option under Part 2 (technical features) depend on the option that is chosen for Part 1 (inventive step)? If so, please explain.

No. All options will disharmonise Australia with the rest of the world and will mean more training for examiners and place an unreasonable burden on Australian patent applicants.

P6 As noted above, for the purposes of novelty, the Commissioner already disregards features that do not materially affect the way the invention works.1 Do you foresee any problems with maintaining this approach?

No.

Conclusion

AusBiotech would like to see the current arrangements for the inventive step given time to settle and be assessed before further change is considered. The ‘Raising the Bar’ legislation was and still is considered sound and the recommendation of the PC was made such a short time after the legislation had been enacted that it was too soon to assess its impact – let alone make disruptive and premature change.

---

1 Patents Manual of Practice and Procedure 2.4.8.4
AusBiotech response to
‘Paper 2: Introducing an objects clause into the Patents Act 1990 (August 2017)’

To: IP Australia
   PO Box 200
   WODEN ACT 2606
   Email: consultation@ipaustralia.gov.au

17 November 2017

From: AusBiotech Ltd
   ABN 87 006 509 726
   Level 4, 627 Chapel St
   South Yarra VIC 3141
   Telephone: +61 3 9828 1400
   Website: www.ausbiotech.org
Introduction

AusBiotech provides this submission in response to IP Australia’s consultation on ‘Introducing an objects clause into the Patents Act 1990 (August 2017’.

AusBiotech has a keen interest in the Australian patent system to the extent that is supports (or undermines) innovation, and its ability to provide appropriate incentives for companies to develop and bring new technologies to patients.

AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial biotechnology sectors; working on behalf of members for more than 30 years to provide representation to promote the global growth of Australian biotechnology.

Please find following AusBiotech’s comments, based on feedback from its membership and developed the members of its Intellectual Property Advisory Panel.

Background

AusBiotech has actively contributed to previous consultations in this regard, including in 2010, when the then Advisory Council on Intellectual Property (ACIP) recommended the introduction of an objects clause in the Patents Act and its 2011 acceptance by the Australian Government. The basis was that a statement of objectives in the Patents Act would provide a clear statement of legislative intent for the guidance of the courts in the interpretation of the Act.

In July 2013, IP Australia released a consultation paper seeking interested parties’ views on the wording of the objects clause.

AusBiotech did not support either of the two options proposed and believes that no compelling rationale to moving away from the TRIPS language has been articulated.

AusBiotech had and has a preference that the wording to remain consistent with the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) wording:

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.

Biotechnology is a global industry and the extent to which already complex web of patent laws and provisions can be harmonised globally is substantially more helpful for technology developers to traverse.

Since then, and after consulting on IP issues during 2015 – 2016, the Productivity Commission (PC) recommended that the Australian Government should incorporate an objects clause into the Patents Act. In its report, the PC noted that it had refined the proposed objects clause to more closely reflect the TRIPS objectives, as follows:
...enhancing the wellbeing of Australians by promoting technological innovation and the transfer and dissemination of technology. In so doing, the patent system should balance over time the interests of producers, owners and users of technology.

The Commission identified two values to address with an objects clause: the idea that inventions be “socially valuable” to warrant being patent eligible, and that only “additional” IP should be eligible for a period of protection.

When the Government opened a consultation in response to the PC’s Report on Intellectual Property Arrangements (20 December 2016), AusBiotech made a submission, which said it is unclear how the objects clause would or could be applied.

This proposal has the potential to create substantial uncertainty and greater burden for patent examiners, who may be tasked with making decisions about a patent’s public interest, and applicants, who may be in the position of having to divulge commercially sensitive information to the Patent Office.

It may also lead to litigation to determine the parameters around what is “socially valuable”, adding cost time and not necessarily achieving a clear outcome.

Furthermore, the proposal that patents should not be granted for inventions that would have been made in the absence of patent protection, seems to misconceive the purpose of the patent system in encouraging and incentivising innovation. It is not claimed that patents are necessary for humans to be innovative; inventiveness is a natural human characteristic. But in a market economy, an invention will generally not benefit humankind unless and until it is turned into a product or process that can be commercially supplied. It is mostly this aspect of innovation – the creation of a saleable product or process out of an invention – that is incentivised by the patent system. It may be true to say that a person would have thought of an idea even in the absence of patent protection, but that in no way establishes that the idea would benefit humanity in the absence of a commercial incentive in the form of a temporary legal monopoly, allowing for the cost of necessary commercial development of the idea to be recouped.

Current consultation

The Government supported the PC’s recommendation in August 2017 and now proposes two options and questions for consultation:

Option A: The purpose of the legislation is to enhance the wellbeing of Australians by promoting technological innovation and the transfer and dissemination of technology. In so doing, the patent system should balance over time the interests of producers, owners and users of technology.

Option B: The purpose of this Act is to provide a patent system in Australia that enhances the wellbeing of society by promoting technological innovation and the transfer and dissemination of technology. In so doing, the patent system should balance over time the interests of producers, owners, users of technology, and the public.

Consultation questions and AusBiotech’s response:

• Do you have a preference for one of the options proposed for the objects clause?
The Industry is not keen on Option A nor Option B overall, and would prefer to see no objects clause or if one is considered necessary, an objects clause that is much more specific. The material difference is the well-being of ‘Australians’ (Option A) versus the well-being of ‘society’ (Option B). Both inclusions appear to divert attention from the object, which is to promote and protect investment in innovation. We also note the inclusion of the ‘public’ (Option B), which could largely be understood to be synonymous with ‘users of technology’.

- If so, please explain the reasons for your preference.

Despite preferring an alternative to Option A or B, if given the choice between only the two options - the well-being of Australians and the well-being of society – we would prefer option B because historically, there has been an argument that as Australia is a net importer of technology the country should have a weak patent system and essentially free-ride off the innovation of others in more innovative countries, by offering a lesser degree of patent protection.

It’s important to recognise that the Australian patent system protects the interests of innovators whether they are based in Australia, or overseas. Further, our patent system exists under multilateral treaty obligations that are designed to reduce the tendency for individual countries to simply favour their own interest in designing their patent systems.

However, it is acknowledged that this carries with it the risk that the ‘well-being of society’ may be interpreted as a means of providing free access to patented products, without taking the interests of innovators, and those who invest in innovation, sufficiently into account.

Both options talk about balancing of interests, pointing out that innovators and investors must be fairly rewarded if there are to be any new innovative products at all – and this is key.

On the inclusion of a reference to the ‘public’, the inclusion of a reference to the public interest may invite anti-patent advocacy, and so too may the reference to the ‘well-being of society’. While this can be argued both ways, the public does have an interest in incentivising future innovation. Therefore, while it might help to keep the focus on technology and innovation by using ‘users of technology’ rather than the ‘public’, a word with broader meaning in the objects clause may be more suitable.

- If you disagree with the wording of these options, please explain which elements you disagree with and why.

AusBiotech holds the view that the objects clause should be more specific. The purpose of a Patents Act is not to benefit society in some nebulous fashion, it is to benefit society by helping innovators, and people who invest in innovation, to be motivated to do so – and by that mechanism, to bring new products and services to the market that will benefit society. A sensible objects clause for a Patents Act could begin with acknowledging the historical purpose of patents and go on to talk about dissemination of knowledge and the balancing of interests.

Conclusion

AusBiotech represents Australian life sciences technology developers that are working in a global context to bring new products to market, which by their very nature have enormous potential to
benefit society as therapies, cures, vaccines and life enhancements via medicines and medical devices. These products require multi-million investments to be secured to enable their development and there is strong link between motivation to invest and a healthy patent system. While AusBiotech does not oppose an objects clause, it remains to be seen if workable wording can be found.