AusBiotech response to

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Introduction


AusBiotech has a keen interest in the Australian patent system to the extent that it 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 by the members of its Intellectual Property Advisory Panel.

Background


Current consultation

Schedule 1, Part 1 – Inventive step

Question 1: For item 2, the amendment to subparagraph 7(2) (definition of inventive step) uses the terminology ‘in comparison with’ the prior art base instead of the previously proposed ‘having regard to’ the prior art base. This change was made for consistency with the rest of the Act, but differs from the wording used in the European Patent Convention. Are there any unforeseen consequences of using this wording?

AusBiotech Response

Consistent with its response in November 2017, AusBiotech is of the view that amending the definition of inventive step is not required. Nevertheless, if such changes to the Patents Act 1990 are pursued, AusBiotech has no real issue with the proposed change of language in
Item 2, subparagraph 7(2) (definition of the inventive step), other than to note that the accompanying materials should make it clear that the ‘comparison’ is not an element-by-element comparison of components of the relevant claim with individual prior art documents where those individual components have been identified but, rather, the comparison to be made is between the prior art and the claimed invention, as a whole.

**Schedule 1, Part 2 – Object of the Act**

*Question 2: For item 8, does the term ‘technological innovation’ restrict or narrow the concept of ‘innovation’ to suit certain industries only? Which industries? What subject matter that is currently patentable would not be considered ‘technological’? Note that the TRIPS Agreement refers to ‘technological innovation’ (Article 7) and states that patents shall be available ‘in all fields of technology’ (Article 27).*

**AusBiotech Response**

Given the ICT industry has appropriated the word ‘technology’ and that the definition of technology could change over time, AusBiotech has concerns regarding the reference to “technological” innovation and whether the use of this term restricts or narrows the definition.

AusBiotech suggests that removing the word “technological” from Item 8 would be more appropriate, on the basis that “innovation” includes transfer and dissemination of technology in any industry.

**Schedule 4 – Compulsory licenses**

*Question 3: For item 5, amendments to paragraph 133(5)(b), are the factors listed relevant to the dependent patent licence?*

**AusBiotech Response**

The factors listed in paragraph 133(5)(b) are:

(i) the *economic value of the licence*; and
(ii) 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); and
(iii) the right of the *patentee to obtain a return on investment commensurate with the regulatory and commercial risks involved in developing the invention*; and
(iv) the *public interest in the efficient exploitation of the invention*.

Firstly, AusBiotech considers that the chapeau to paragraph 133(5)(b) (“Such amount as is determined to be just and reasonable, having regard to:”), and the enumeration of specific factors, limits the full range of considerations that should be considered when determining the amount of remuneration to be paid to the patentee. AusBiotech suggests that the chapeau could be amended to state, “Such amount as is determined to be just and reasonable, having regard to all relevant facts and circumstances including...”
Secondly, AusBiotech considers that factors (i), (iii) and (iv) are vague and/or unclear, and do little to reduce ambiguity of what the Federal Court must have regard to when determining the amount of remuneration to be paid to the patentee. AusBiotech suggests that further consideration should be given to these factors to reduce any vagueness and/or unclearness, and provide patentees and licensees with greater certainty.

As to the specific factors in particular:

(i) It is unclear how the “economic value” of the licence is to be assessed, and whether economic value to all parties is considered of equal weight: The economic value of a licence to an original patent may have significantly more value to the owner of a dependent patent, than to others. Without it, the dependent patentee has little of any economic value as it is blocked from exploiting its patent. Conversely, the economic cost to the holder of the original patent may be significant if it impairs its ability to freely and exclusively exploit the original patent. A follow-on product based on a dependent patent will cannibalize sales of the original product, and significantly impact the licensor. There is also an economic value to the public of permitting the dependent patent to be exploited, despite the original patent, and allowing competition to reduce prices.

(ii) AusBiotech agrees that it is desirable to discourage contraventions of Part IV of the Competition and Consumer Act 2010, and such consideration should not fail to consider the provisions of s 51(3).

(iii) In contrast to the broad public interest rights in (iv), this factor (iii) seems too narrowly defined. For example, it is important to consider that ROI is not simply a matter of providing a return in relation to “developing the invention” at issue. To illustrate the point: pharmaceutical product pricing must not only cover the development costs of the patented product, but also the development cost of the innovators many failures that may be in a completely different technology. Additionally, the marketing of the dependent invention may cannibalize sales of the original product, which is not a risk involved in “developing the invention”.

It is unclear in a dependent patent situation, which patentee’s rights to obtain an ROI are to be considered. Is it the right of the original or dependent patentee? How are their rights weighted (if at all)? A dependent inventor may face much less risk, because the original patentee has taken much of the regulatory and commercial risk off the table.

(iv) The public interest in the “efficient” exploitation, seems to be an argument for lowest cost and widest distribution, and it is unclear how this fits with general principles of patent law, including the provision of monopoly rights in exchange for disclosure. Those rights should be balanced, and not outweighed by the presence of a dependent invention, as described in the Objects clause.
**Question 4:** For item 7 – this amendment would allow a cross licence to be revoked under subsection 133(6). Is this appropriate?

**AusBiotech Response**

Yes, it seems anomalous and inequitable to allow the compulsory licence for an original invention to be revoked but not a cross licence under paragraph 133(3B) to be revoked. Allowing a court to revoke a cross licence if the circumstances justifying its grant have ceased to exist is appropriate in all the circumstances.

**Question 5:** For item 11, the application provisions, are there any unforeseen consequences which we have not considered?

**AusBiotech Response**

Making the changes applicable prospectively seems appropriate, on the basis these are primarily clarifications, and not reductions, in patentee rights.

**Conclusion**

AusBiotech remains of the view that amending the definition of inventive step is not required. However, if such changes are pursued, AusBiotech has no real issue with the proposed change of language, other than to note that the accompanying materials should make it clear that the ‘comparison’ is not an element-by-element comparison of components of the relevant claim.

In terms of the objects clause, AusBiotech has concerns regarding the reference to “technological” innovation and the capacity to restrict or narrow the definition or that the definition could change over time – and suggests removing it.

In reference to compulsory licensing, AusBiotech considers that the chapeau to paragraph 133(5)(b) and the enumeration of specific factors limits the full range of considerations that should be considered when determining the amount of remuneration. AusBiotech suggests that the chapeau could be amended to state, “Such amount as is determined to be just and reasonable, having regard to all relevant facts and circumstances including...”

Secondly, AusBiotech considers that factors (i), (iii) and (iv) are vague and/or unclear, and do little to reduce ambiguity of what the Federal Court must have regard to when determining the amount of remuneration to be paid to the patentee. AusBiotech suggests that further consideration be given to these factors to provide patentees and licensees with greater certainty.

It appears to be anomalous and inequitable to allow the compulsory licence for an original invention to be revoked but not a cross licence under paragraph 133(3B) and making the changes applicable prospectively seems appropriate, on the basis these are primarily clarifications, and not reductions, in patentee rights.