AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

AusBiotech response to Senate Inquiry on 'Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019'

To: Senate Standing Committees on Economics
PO Box 6100
Parliament House
Canberra ACT 2600
economics.sen@aph.gov.au

15 August 2019

From: AusBiotech Ltd
ABN 87 006 509 726
Suite 1, Level 3, 15 Queen Street
Melbourne, VIC, 3000
[redacted]
Website: www.ausbiotech.org

Introduction

AusBiotech provides this submission in response to the Senate Inquiry into 'Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019'.

AusBiotech has a keen interest in the Australian patent system because it supports (or undermines) innovation, and has made multiple submissions to previous, related consultations. Without the system, products can be readily copied and the substantial costs accrued in developing life science products (especially relative to other industries) cannot be recuperated. It is the cornerstone on which life sciences companies are created, and the fundamental means through which revenue is generated. The challenge for the life sciences industry is that IP is also highly-portable. Decisions on where to locate the management, manufacture, registration and sale of life sciences-based products is therefore highly-dependent on the business and public policy environment, inclusive of IP arrangements.

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 biotechnology sectors; working on behalf of members for more than 30 years to provide representation to promote the global growth of Australian biotechnology.

With representation in each Australian state, AusBiotech members are diverse in size, approach and structure, ranging from SMEs to national and international businesses. This response has been led by AusBiotech's Intellectual Property Expert Panel, which provides expert advice on intellectual property issues in relation to medical devices and diagnostics, pharmaceuticals and therapeutics.

Background

AusBiotech has made multiple submissions to previous related consultations. In April 2016, AusBiotech responded to the Productivity Commission's (PC) *Draft Report Intellectual Property Arrangements* and in February 2017, AusBiotech provided a submission to the Federal Government in response to the PC's resulting report. In November 2017, AusBiotech also responded to consultations on amending inventive step requirements for Australian patents (Paper 1 in August 2017) and introducing an objects clause into the Patents Act 1990 (Paper 2 in August 2017). Most recently, AusBiotech response to the consulatation 'Intellectual Property Laws Amendment Bill (Productivity Commission Response Part 2 and Other Measures) Bill 2018' in August 2018.

Current consultation

We have focused our response to issues of most relevance to our members.

Schedule 1, Part 1 – Object of the Act

AusBiotech has concerns regarding the reference to "technological" innovation and whether the use of this term restricts or narrows the definition. The ICT industry has arguably appropriated the word 'technology' and the definition could change over time.

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

Schedule 4 – Compulsory licenses

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**.*

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*…"

Overall, 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 confusion, and provide patentees and licensees with greater certainty.

As to the specific factors:

(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 cannibalise 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*.

(iii) In contrast to the broad public interest rights in factor (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. For example, 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 cannibalise 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.

Suggested abolition of innovation patents

AusBiotech finds it disappointing that the Bill proposes to take steps that will lead to abolition of the Innovation Patent system. AusBiotech has always held the view that while there were issues with the Innovation Patent system, abolition of the system was an extreme and incorrect response to those issues. Rather, AusBiotech has supported the conduct of an enquiry into alternatives that might improve the Innovation Patent system in three key areas: raising the innovation threshold; requiring examination prior to grant; and setting an examination deadline.

Any such review should properly explore with stakeholders the merits or otherwise of any proposed changes. In particular, the review could consider whether:

- with appropriate modification, the Innovation Patent system can meet the needs of Australian innovators – particularly, but not limited to, those of small and medium enterprises;
- the threshold for an innovative step of an Innovation Patent should be raised;
- unexamined Innovation Patent applications should remain pending until an examination has been completed and the application accepted;
- all Innovation Patents should be examined within a defined period; and
- Australia should retain a second-tier or lower-innovation-threshold patent system.

Conclusion

AusBiotech has concerns about the objects clause 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*…"

AusBiotech also 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.

AusBiotech considers innovation patents worthwhile, and has supported the conduct of an Inquiry into alternatives that might improve the Innovation Patent system in three key areas: raising the innovation threshold; requiring examination prior to grant; and setting an examination deadline.