Medicines Australia

Senate Standing Committees on Economics
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**Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019**

Medicines Australia welcomes the opportunity to respond to the Senate Economics Legislation Committee Inquiry into the *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019* (the Bill).

Medicines Australia is the peak industry body representing the innovative research-based medicines industry in Australia. Our members are innovative companies that research, develop, manufacture and supply new medicines, therapies and vaccines to the Australian market. They are proud of the contribution they make to the health and well-being of everyday Australians, as well as to the local economy including when working with small and medium sized enterprises (SMEs). These SMEs support the work of our companies and sometimes even drive the innovations subsequently used and relied upon by our members. Our industry provides high value jobs for Australians, generates up to $4 billion in exports and invests over $1 billion in research and development every year.[1] This high level of investment has many important benefits, including enhancing the health and welfare of Australians and reducing healthcare costs. It has been estimated that for every $1 invested in Australian pharmaceutical research and development, the average return on health benefits is $2.17.[2]

The innovative medicines industry has developed some ground-breaking discoveries. These emerging innovative medicines and therapies (such as CAR-T and precision medicine) are helping to fight previously untreatable diseases and are providing patients with better survival rates and improved quality of life. More are under development, and Medicines Australia and our members would like to see this occur in Australia.

Medicines investment is high-risk with approximately only 12% of drugs that enter clinical trials reaching approval for use by patients.[3] Therefore, the research-based innovative pharmaceutical industry, like all research-based technology industries, relies on a robust intellectual property system to encourage investment and research and development in new medicines.

Indeed, research has shown that there is a positive relationship between the strength of an intellectual property system and levels of innovation, business investment, highly skilled jobs and economic growth[3].

Unfortunately, some of the amendments proposed in this Bill introduce legal uncertainty and undermine patent protection. In turn, this can make the commercial viability of developing and marketing medicines in Australia even riskier. This is significant as Australia's innovation ranking has fallen from 20th in 2018 to 22nd in 2019 on the World Intellectual Property Organization's (WIPO) Global Innovation Index.[4] Consequently, there is clearly a need for Australia to develop and maintain a strong and stable intellectual property environment to ensure we do not lose out on biomedical development opportunities.

Medicines Australia has previously provided submissions on the issues raised in this Bill and our comments remain relevant to, and should be considered as part of, this inquiry.[5] Our submissions clearly outlined the significance of a strong, effective and stable intellectual property system in fostering pharmaceutical innovation, investment, productivity and competitiveness. We outlined the importance of:

- retaining innovation patents
- if introduced, an unambiguous objects clause that is consistent with international obligations

- the granting of compulsory licenses only in exceptional circumstances and only when in accordance with international rules
- the application of Crown use provisions only where consistent with Australia's obligations under international treaties

These recommendations would maintain and strengthen an environment that supports intellectual property and encourage ongoing investment in research and development into medicines and biotherapeutics. A strong and stable intellectual property system in Australia is crucial for the thousands of Australian scientists, research organisations, universities and local biotechnology companies who rely on this system for investment and innovation in medicines for the benefit of all Australians.

*The Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019* will add to business uncertainty and signal that Australia is less interested in growing its economy through expansion of medical and biotherapeutic research and development – in effect that Australia will be a medicine taker first, and a medicine maker second.

Medicines Australia urges the Senate Economics Legislation Committee to reconsider the proposed amendments to Australia's Patents Act (as detailed in the Appendix) and to ensure that the Bill supports innovation, provides certainty to investors and is consistent with Australia's international obligations.

Please see the Appendix below for our detailed response to this Inquiry. Medicines Australia is available for further discussion if required. Any queries should be directed to Peter Komocki, Manager of Industry and Regulatory Policy on pkomocki@medaus.com.au.

Yours sincerely

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## APPENDIX

**Introduction of an 'Objects' clause to the *Patents Act 1990***

Medicines Australia maintains its position that introducing an objects clause is unnecessary and unhelpful to innovation.[6] The clause, like the Productivity Commission's recommendation that preceded it, lacks clarity and could create uncertainty and unpredictability to patent applications and protections. For example, the phrases 'promotes economic well being' and 'balances over time the interests of producers, owners and users of technology and the public.' Not only are these elements highly subjective, the long term economic impact and utility of a patent may not become fully apparent until years into the development and production processes, or even later after that.

Should the objects clause be retained, the wording of any such clause should provide clarity and not include words that can create confusion and scope for dispute, which may have the potential to bring down or undermine a valid patent.

This is relevant in the inclusion of the term 'technological' in the proposed objects clause. In the context of an object clause, the definition of 'technological' is unclear and arguments could arise claiming that certain therapies are not of a 'technological' nature. Given the ever-evolving nature of innovation, it is preferable to keep the language broad so as to accommodate, not restrict, future product, processes or service innovations.

The issue associated with qualifying inventions with words such as 'technological' has recently arisen in the United States where the Senate Judiciary Committee Subcommittee on Intellectual Property is currently looking at amendments proposed to 35 U.S.C. § 101. In the first meeting of this Committee the former Chief Judge of the Court of Appeals for the Federal Circuit, Paul Michel, described the word 'technology' as a 'weasel word', cautioning against its use in defining patentable subject matter in the United States.[7]

Australia's own Federal Court has commented on this issue and warned against introducing requirements that could restrict the application of the patent system. In relation to whether a patentable process must result in the application of science and technology the court stated "We think that to erect a requirement that an alleged invention be within the area of science and technology would be to risk the very kind of rigidity which the High Court warned against."[8]

As such, Medicines Australia opposes the proposed use of the word 'technological' in an objects clause given the uncertainty that surrounds it, ongoing international discussions and the risk of narrowing the scope of what types of innovations can be protected under Australia's patent system.

**Amendments to Schedule 6 and their interaction with Section 40(3A) of the Patents Act 1990**

Medicines Australia is strongly opposed to the proposed amendments set out in Schedule 6 of the Bill (e.g. of paragraphs 59(c), 98(a), 101G(3)(a), 101M(b), 102(2)(b) and 138(3)(f)). These amendments add subsection 40(3A) of the Patents Act 1990 as grounds for opposing, re-examining or revoking a patent. This is an unnecessary and inappropriate introduction of additional avenues to challenge and revoke patents that have already been accepted.

Subsection 40(3A) provides that descriptions, drawings, graphics or photographs can only be used in a patent application if absolutely necessary to define the invention. Our understanding is that this subsection was originally introduced for the sole purpose of making omnibus claims unacceptable. The amendment proposed in this Bill increases the scope subsection 40(3A) beyond its initial purpose.

This amendment could cause uncertainty for patent applications and ongoing patent protection for Medicines Australia's members. Some patent applications for pharmaceuticals use graphics to assist with

representing their innovation, such as a chemical compound, as this can be the most succinct and accurate way of relaying complex information. The alternative can mean relying on a chemical name which can be long, unclear and not provide a reliable 'picture' of the context in which it is innovative. There appears to be no clear rationale as to why this additional avenue for revocation, re-examination and opposition is being introduced when a patent claim must already be clear and succinct.

The consequences for Medicines Australia's members, and patent applicants writ large, is that patent protections become less certain and related commercial operations take on additional unnecessary risk due to a new avenue for their patent to be challenged. It also signals that the Australian Government is more concerned with weakening patent protection than it is with encouraging and commercialising innovation.

**Phasing out the innovation patent system**

Medicines Australia recommends that the Innovation Patent system be retained. We note that as recently as January 2018 the Australian Government identified the strengths and opportunities of Innovation Patents as being "a relatively quick and inexpensive way to obtain IP protection for a new medical device or pharmaceutical substance, method or process." [9]

It is critical that pharmaceutical innovations remain eligible for standard and innovation patents. There is a strong and enduring rationale for ensuring no changes are implemented that would, in any way, undermine the ability to access innovation patents to defend intellectual property.

Innovation can occur incrementally. Therefore, the innovation patent system is valuable as it allows a lower threshold for intellectual property protection whereby SMEs, in particular, benefit from their inventions and continue to develop novel products.

The innovation patent has played an important first step to patent protection for small business. Without it, the standard patent protection of 25 years is unnecessarily long and the examination process, which must be carried out early in the term, is lengthy and expensive relative to the incremental nature of the advances the innovation system was designed to protect. In our view the standard patent system is unsuitable for such advances and will not be utilised in the numbers required to protect SMEs' incremental innovations. Medicines Australia maintains (as in our previous submissions) that the Government should refine the innovation patent system to improve its effectiveness, rather than abolish it entirely.

**Crown use of patented technology and design**

Medicines Australia strongly recommends that the Bill make clear that the new provisions only apply in cases where the Crown use is consistent with Australia's obligations under international treaties including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The Bill proposes to add a Section 160A to the Patents Act that would expand the understanding of 'Crown purposes' from not only services of the Commonwealth or a State, but also to services that the Commonwealth, State and/or Territory Governments have the primary responsibility for providing or funding. This expanded definition would take account of all providers of similar services and would appear to potentially broaden Crown use beyond limited and exceptional circumstances. In doing so, the Bill could erode the rights of patent holders and thereby discourage investment in research and development in Australia.

**Compulsory licensing of patents**

Medicines Australia contends that the Bill proposes changes to compulsory licensing, including Crown use, that are unnecessary and add uncertainty, weaken patent protection, discourage investment and limit the potential benefits of innovation for Australians. Compulsory licensing is rarely the best policy option to promote access to medicines and as with Crown Use, should be used only very sparingly as they override and interfere with the private property law rights of the patentee.

Compulsory licenses should only be granted in accordance with international rules (including the Australia – U.S. Free Trade Agreement (AUSFTA)), and only in exceptional circumstances and after all other options have been explored. The proposal to replace the 'reasonable requirements of the public' test with a 'public interest' test may broaden the circumstances under which the courts grant compulsory licenses well beyond exceptional circumstances.

In respect of AUSFTA, Article 17.9.7 provides that the subject matter of a patent cannot be used without the authorisation of the patent holder except in a limited number of circumstances. Medicines Australia contends that the proposed Bill goes beyond the scope of what is envisaged under AUSFTA. Specifically, the proposed amendment to Section 133(3) of the Patents Act would permit compulsory licensing on grounds that are not related to a judicially or administratively determined remedy for anticompetitive behavior, a national emergency or other circumstance of extreme urgency.

Changes that would encourage or make it easier for third parties to acquire innovative technologies without authorisation could have significant unintended consequences. They could also unnecessarily undermine the usefulness and effectiveness of the Australian patent system by weakening patent protections, reducing investment in research and development and creating uncertainty in the long-term enforceability of patent rights.

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