

31 August 2018

Dr Frances Roden
Acting Director General, IP Australia
Ground Floor, Discovery House
47 Bowes Street
Phillip ACT 2606

Via email: consultation@ipaaustralia.gov.au

Dear Dr. Roden,

Thank you for the opportunity to make a submission to the consultation on the Intellectual Property Laws Amendment Bill 2018.

Medicines Australia (MA) represents the research-based medicines industry in Australia. Our members bring new medicines, vaccines and health services to the Australian market. Our industry generates around \$3 billion in exports and invests over \$1 billion in research and development (R&D) every year. This high level of investment has many important benefits for the country, including enhancing the physical health and welfare of Australians and helping to reduce health costs. It has been estimated that a dollar invested in Australian pharmaceutical R&D will return an average health benefit of \$2.17.¹ To achieve this, our industry is highly reliant on a stable and predictable policy and intellectual property (IP) environment in Australia.

MA's overarching message regarding intellectual property is simple:

A strong, effective and stable intellectual property system is critical to fostering pharmaceutical innovation, investment, productivity and competitiveness. In this way, it is a cornerstone of increased access to life-changing and life-saving medicines for Australian patients.

As such, MA supports efforts to strengthen Australia's IP arrangements to be consistent with international best practice. However, we are concerned that frequent and unnecessary changes to fundamental aspects of the IP system in Australia can lead to business uncertainty and can detract from Australia's attractiveness as an investment and innovation destination.

¹ Access Economics 2008. Exceptional Returns: The Value of Investing in Health R&D in Australia II



Medicines
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MA is available for further discussion if required. Any queries should be directed to Mr Andrew Bowskill, Manager, Policy and Research, abowskill@medaus.com.au, ph: (02) 61228513

Yours sincerely

Elizabeth de Somer
CEO, Medicines Australia

Appendix

Schedule 1, Part 1 – Inventive step

MA remains concerned that frequent, and unnecessary changes to fundamental aspects of the IP system in Australia can lead to business uncertainty and detract from Australia's attractiveness as an investment destination.

In 2016 the Productivity Commission (PC), in justifying further raising the threshold beyond what was already done through the Raising the Bar Act noted that the inventive step threshold adopted by the European Patent Office (EPO) is more effective at filtering out low value patents than the thresholds used by other patent offices in other large markets for technology. As such it recommended that Australia adopt the EPO approach. However, this recommendation predates the Raising the Bar Amendments. In addition, the current (i.e. post Raising the Bar) test for inventive step in Australia does not appear to be significantly inconsistent with Europe, and further, there is no evidence that it leads to different outcomes. Indeed, the PC in 2016 acknowledged that the Raising the Bar reforms were "clearly significant" and had been effective in narrowing the grant rate differential between IP Australia and the EPO.²

It is now proposed by IP Australia that the EPO approach is not adopted fully. However, the concern expressed in Consultation Question 1 highlights the difficulty of achieving full alignment with the EPO, as parts of Australia's Patents Act differ from EPO law, and this demonstrates the further potential for uncertainty which could result in unintended harmful consequences.

MA is also concerned that the proposed amendments would move Australia's standard above and beyond EPO's standard in a manner that could discourage innovation.

Other issues

Our sister organisations, EFPIA and PhRMA have highlighted concerns around the way in which the EPO problem and solution approach is being implemented. As they point out, Australia's current threshold is already in line with EPO's standard and changing the law only introduces uncertainty which may weaken Australia's patent system. Should this amendment proceed, MA would welcome a consultation process for any amendments to the Patent Manual of Practice and Procedure to ensure that any amendments are implemented in an effective manner.

² Productivity Commission 2016, Intellectual Property Arrangements, Inquiry Report No. 78, Canberra.

Schedule 1, Part 2 – Object of the Act

MA maintains its previously stated position that introducing an objects clause is unnecessary and unhelpful to innovation.³ In the event of the introduction of an objects clause, the wording of any such clause will need further careful consideration so as not to be overly prescriptive in relation to patentable subject matter, thereby unintendedly creating confusion and scope for dispute, which could prove to be a barrier for investment.

The use of 'technological' in this instance appears unnecessary in order to convey the concept of innovation, as the TRIPS Agreement states that patents shall be available 'in all fields of technology' and therefore it can be implied that all innovation will be of a technological nature. In addition, given the ever-evolving nature of innovation, it is preferable to keep the language broad so as to accommodate future innovations.

The use of the term 'economic wellbeing' in the proposed objects clause is an addition to the proposal that was made by the Productivity Commission and accepted by the Government in its initial response. MA is concerned that the addition of the term 'economic' wellbeing to the proposed object clause may have an unintended impact on the administration of the patent system. To the extent that wellbeing is considered to be a vague term, the addition of 'economic' merely adds to the ambiguity to the proposed objects clause.

The concept and use of 'economic wellbeing' raises questions including:

- How is 'economic wellbeing' to be measured?
- Does 'economic wellbeing' refer to direct or indirect effects, and must the effects be tangible?
- Which sector of the public must benefit and who decides what constitutes 'economic wellbeing'?
- What kinds of decisions will require consideration of 'economic wellbeing'? Does this mean that only patent applications with a foreseeable economic benefit should be encouraged? (which is a problematic concept when many patents do not obtain their full economic potential until closer to the end of their terms).

In addition, as stated in the Explanatory Memorandum the purpose of the objects clause is to articulate the underlying purpose of the patents system in Australia. The benefits of the patent system are achieved through incentivising innovation and the dissemination of technology, resulting in, among other things, better access to technology and new innovations. This improved access will clearly only be achieved through encouraging investment in research and technology. MA notes the text of the proposed objects clause makes no direct reference to the purpose of the patent system being to encourage the 'investment in research and technology'. As such, the definition previously proposed by MA

³ Medicines Australia, 2017. Submission to IP Australia's consultation on various IP policy matters

provides greater clarity and achieves the Government's desired policy objective, as well as being consistent with international obligations. The proposed definition is as follows:

- *To create a patent system that promotes innovation and the transfer and dissemination of technology by encouraging investment in research and technology and by providing an appropriate balance between the interests of inventors and patent owners and the interests of society as a whole.*⁴

Schedule 4 - Compulsory Licenses

Compulsory licenses should only be granted in accordance with international rules; and, as IP Australia agrees, only in exceptional circumstances and after all other options have been explored. MA believes that Australia's current laws are sufficient for the purposes of compulsory licensing and no amendments are needed.

Australia's international obligations require that compulsory licensing be limited to circumstances involving "anti-competitive practices" or, "in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency."⁵ IP Australia's proposal to replace the "reasonable requirements of the public" test with a "public interest" test would inappropriately expand compulsory licensing based on the broad factors enumerated in proposed subsection 133(3)(e). These amendments go beyond the limited circumstances permitted under Australia's international obligations and impose unnecessary regulatory burden.

MA agrees that the patentee has the right "...to obtain a return on investment commensurate with the regulatory and commercial risks involved in developing the invention" as described in paragraph 133(5)(b)(iii). However, guidance may be required on how the return is calculated to ensure Australia meets its international obligations that the compensation received by the patentee is adequate and reasonable.

Changes that would encourage or make it easier for third parties to acquire innovative technologies without authorization could have significant unintended consequences, and 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.

Regarding the appropriateness of the amendment that would allow a cross licence to be revoked under subsection 133(6), MA concedes that this is a stretch of interpretation and unlikely to occur. However, even if it were accepted, any cross-licences should be drafted to

⁴ Medicines Australia, 2017. Submission to IP Australia's consultation on various IP policy matters

⁵ U.S.-AUS FTA Article 17.9.7; see also TRIPS Article 31(b).

ensure the licence comes to an end if the compulsory licence is ever cancelled by the court, and it should set out the consequences for each party if that occurs.

Crown use of Patents

Medicines Australia strongly recommends that the legislation should 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).

As noted by our sister organisations, EFPIA and PhRMA, MA agrees that the proposed Crown use amendments would expand Crown beyond the limited circumstances that justify imposition of a patent licence and should be reconsidered.

Specifications and Section 40(3A) of the Patents Act 1990

Section 40(3A) states that claims must not rely on references to descriptions or drawings “unless absolutely necessary to define the invention.” MA is highly concerned that allowing a patent to be challenged on whether a claim’s reference to a figure was “absolutely necessary” after the Commissioner has already determined whether specifications comply with this prohibition would introduce unintended inefficiencies into the patent system.

Innovation Patents and the Australian Innovative Medicines Industry

Medicines Australia recommends that the Innovation Patent system be retained.

The Advisory Council on Intellectual Property (ACIP), in its 2014 final report stated, ‘The objective of the innovation patent system is to stimulate innovation in Australian Small to Medium Enterprises (SMEs)’. This is currently achieved by providing Australian businesses with intellectual property rights for their lower level inventions to prevent competitors from copying them. Innovation patents are also intended to reduce the compliance burden on users of the patent system by providing easier, cheaper and more rapid rights for inventions.⁶ The ACIP made a number of recommendations in their report that proposed changing and strengthening the IP system rather than completely abolishing innovation patents. MA continues to support those recommendations and recommends that they warrant further consideration.

Although the economic analysis conducted by IP Australia recommends ceasing offering innovation patents as they were not found to be effective, there are limitations acknowledged in this analysis that warrant further study before taking irreversible action by ceasing an important incentive for innovation and investment in intellectual property.

⁶ Advisory Council on Intellectual Property. 2014. Review of the Innovation Patent System Final Report. http://www.acip.gov.au/pdfs/ACIP_Final_Report_-_Review_of_the_Innovation_Patent_System.pdf

It is critical that pharmaceutical inventions and 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 their intellectual property. Patents allow companies to invest in R&D, with the expectation that they will have a fair opportunity to recoup this investment before others, whom did not bear the initial risk, are permitted to profit from new and improved products.