17 November 2017

IP Australia
Ground Floor
Discovery House
47 Bowes Street
Phillip ACT 2606

Via email: consultation@ipaustralia.gov.au

To whom it may concern,

Thank you for the opportunity to make a submission to the public consultation regarding the following IP policy matters:

- Amending the inventive step requirements for Australian patents
- Introduce an objects clause into the *Patents Act 1990*
- Amending the provisions for Crown use of patents and designs
- Amending the provisions for compulsory licensing of patents.

Medicines Australia represents the research-based medicines industry in Australia, which brings 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 every year. To achieve this, our industry is highly reliant on a stable and predictable policy and intellectual property environment in Australia.

Medicines Australia's submission at Attachment 1 does not respond in detail to each of the options for reform outlined in the four respective policy papers. Instead, we provide a principles-based response to each policy matter. Our overarching message 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.*

We urge IP Australia, in implementing the Government's response to the Productivity Commission's 2016 report, to recognise and account for this important tenet.

Again, we thank you for the opportunity to make a submission to this consultation. Medicines Australia is available at any time to discuss this submission. Any queries should be directed to Ms Elizabeth de Somer, Director, Policy & Research, edesomer@medaus.com.au ph. 02 6122 8519.

Yours sincerely,

Milton Catelin
Chief Executive

(i) Introduce an objects clause into the *Patents Act 1990*

There is no evidence from their judgments that Australian Courts are importing objectives for the Patents Act which are inconsistent with the public interest. Medicines Australia submits that amendments should only be made to established and important statutory regimes (which have been interpreted over many years by the Courts) if there is a clear and compelling need or benefit for so doing. In the case of an objects clause – no compelling case has been made for the problem that would be solved by the inclusion of an objects clause. There is no evidence that the "benefits" of an objects clause set out by the Productivity Commission are not already being achieved under the existing Act without an objects clause.

However, if the Australian Government wishes to proceed with the establishment of an objects clause, Medicines Australia's position is that neither Option A nor Option B as presented in IP Australia's consultation paper is appropriate. Each option centres on 'enhancing the wellbeing' of society or 'Australians' without further explanation. The wellbeing of the Australian society is enhanced by a number of factors. We note patents are not assessed, either historically or currently, by reference to the invention's contribution to the wellbeing of society nor do we think that it is possible or realistic for a patent examiner to be in a position to make such an assessment at the time of application. Medicines Australia therefore remains concerned that the introduction of an objects clause that references the objective of an overall enhancement of the "wellbeing of society" has the potential to create unnecessary legal and business uncertainty. At present, the courts do not hear evidence about, or investigate, whether a particular patent creates 'wellbeing' (or indeed any other subjective outcome) for Australians, nor do we think that it is appropriate to require the judiciary to do so. In this context, it is difficult to see how such a clause would be interpreted and applied by both patent examiners and the judiciary.

Further, any objects clause should also refer explicitly to the interests of the patentee and should recognise the need to afford equal treatment to foreign nationals and promote comity with international intellectual property laws. For this reason, Medicines Australia cautions against including language that specifically references Australian interests, so that any amendment does not risk jeopardising foreign investment and the distribution of foreign-developed technology in Australia.

If an objects clause is to be introduced despite the above, it must be drafted consistently with the purpose of the Patents Act as ascertained by reference to Australia's international obligations, the intent of the original drafters of the legislation and the expectations of all stakeholders. For example, Article 7 of the TRIPS Agreement states that the objective of that Agreement is as follows:

> *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.*

The objective of the TRIPS Agreement is clearly expressed. It makes clear that the purpose of intellectual property rights is to contribute to the promotion of innovation, and that innovation itself contributes to social and economic welfare. This is closer to Option B in the consultation paper, except that it removes the reference to the "wellbeing of society" and thus removes any ambiguity or risk of introducing uncertainty into the fundamental objectives of the Patents Act.

The Explanatory Memorandum to the Raising the Bar Bill described the objectives of the Bill as follows:

> *The objective of the intellectual property (IP) rights system is to support innovation by encouraging investment in research and technology in Australia and by helping Australian businesses benefit from their good ideas. The purpose of this Bill is to make improvements to IP rights legislation to better meet these objectives.*

Again, the Explanatory Memorandum makes the purpose of the Patents Act clear – to encourage and support innovation. This core purpose must be the central tenet of any proposed objects clause.

Finally, the consultation paper refers to the purpose clause introduced into the *New Zealand Patents Act 2013*. The drafting of this clause again puts the promotion of innovation and economic growth at the heart of the purpose of the legislation, consistent with the objectives of TRIPS.

Medicines Australia maintains its view that the introduction of an objects clause is unnecessary, and unhelpful to innovation. However, should such a clause be proceeded with, Medicines Australia would like to be consulted further to ensure that such objects clause espouses the broad tenet below:

> *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.*

(ii) Amending the inventive step requirements for Australian patents

Unnecessary legislative churn

Medicines Australia queries the rationale for seeking to amend the inventive step requirements for Australian patents. An insufficient period has elapsed since the implementation of the Raising the Bar Act to assess whether those amendments to inventive step have achieved their desired policy objectives. It is undesirable to make frequent changes to fundamental aspects of the intellectual property system in Australia – this leads to business uncertainty and can detract from Australia's attraction as an investment and innovation destination.

Lack of evidence for reform

Medicines Australia does not agree that a strong case has been made for further raising the threshold of the inventive step requirements for Australian patents.

First, and most importantly, the evidence cited by the Productivity Commission in support of its recommendation *predates* the Raising the Bar amendments. 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.

A strong case for amending the inventive step would include providing contemporary, real world examples of patents which have been granted under the existing regime which would not be granted under the proposed new regime – and which, as a consequence of their grant, are impacting detrimentally on competition or innovation in Australia. No such case has been made out, and no clear benefits have been articulated to offset the risk of unintended consequences, uncertainty and cost which the proposed amendments would entail.

Second, it appears that one of the primary contentions supporting the Productivity Commission's recommendation to amend the inventive step is the alleged practice of so-called "evergreening" in the pharmaceutical industry[1]. No specific cases are relied upon to support the contention that this practice occurs in relation to pharmaceutical patents. "Evergreening" discounts important improvements to medicines and loses sight of the fact that improvements to a medicine will not extend the patent life of the existing medicine, and in fact, any firm can produce and market the original medicine once the patent exclusivity expires (assuming they meet the requisite regulatory requirements). As Medicines Australia has stated in its previous submissions on this issue, under the current law, it is simply not possible for a second patent to be granted over an existing invention. When a patent on the original invention expires, imitators are free to exploit the original invention. Subsequent patent applications for the grant of a patent must, by definition, be for different inventions which may build on the prior original invention, but will be progressively narrower in scope and only granted over the new part of the invention.

Third, the recommendation to amend the inventive step test also appears to be derived from the premise that when an invention is for an incremental advance over the prior art in relation to pharmaceutical patents, only those incremental advances that result in an improvement in patient safety outcomes should justify the grant of a patent. The Productivity Commission report suggests that where an incremental advance relates, for example, to an improved process of production, that invention is somehow less worthy of patent protection. However, it is not and had not been, the role or purpose of the patent system to make an assessment as to what types of inventions are worthy of patent protection based on their ultimate benefit to the patient or consumer. The free market will determine the value of the patent to the end user by the demand that exists for the resulting product. The purpose of the patent system is to encourage investment in innovation. In order to qualify for patent protection, the patent system must dispassionately assess whether an invention: (a) meets the criteria of inventiveness and novelty under the Act; and (b) is useful/capable of industrial application. The type of invention, or the ultimate benefit of that invention for the consumer, is not relevant. Further, it is inaccurate to describe a process improvement invention, for example, as evergreening. A patent granted over a process improvement would simply provide the manufacturer with a competitive advantage over other manufacturers in relation to the production of a particular product. For the reasons provided above, it would not be possible for that new patent to extend the monopoly over any patent which may have existed in relation to the underlying product, the subject of the process improvement. That type of practice is simply not possible under the patent system.

When determining the appropriate test for an inventive step under Australian law, it is important to remember that the test must be a flexible one as recognised by the Australian courts. In *Aktiebolaget Hässle v Alphapharm Pty Ltd* [2002] HCA 59, the majority of the High Court of Australia (applying Aickin J's reasoning in *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 280 – 281) specifically noted that in that case, the invention lay not in perceiving "the true nature of the problem" to which "straightforward experiments" then would provide the solution; but rather that the invention was in the interaction between the integers of the compound, to answer the known problem. This highlights the complexity of innovation itself and the risks that arise when attempting to furnish a threshold for inventiveness when the nature of future inventions themselves are, as yet, unknown and the pace and extent of discovery, enhanced by technological advances such as Artificial Intelligence (AI)I, is unprecedented.

[1] pp. 20 and 319

A scintilla of invention

Medicines Australia considers that a focus on scintilla of invention and the proposed associated amendments will not have any practical impact on 21st century patentability in Australia.

The Productivity Commission has not articulated how the concept of "a scintilla of invention" is incorporated into modern Patent Law nor how making references to it in an Explanatory Memorandum would have any impact on the patentability (or otherwise) of an invention in the 21st century. The concept arose in cases from the mists of history when an invention was required merely to be "a manner of new manufacture". The modern statute delineates between eligible subject matter, novelty and inventive step. The modern statutory test for inventive step is clearly set out – and it does not refer to a "scintilla of invention".

(iii) Amending the provisions for Crown use of patents and designs

As the Productivity Commission acknowledges, "Crown use has rarely been used in Australia, with only two cases – both concerning patents – contested before the courts." Medicines Australia does not see this as a pressing issue for legislative amendment.

Should Government decide however to pursue legislative amendments in this area, 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. Such a provision already exists in relation to the compulsory licensing provisions at section *136 of the Patents Act*. It could also be included in relation to the Crown use provisions.

(iv) Amending the provisions for compulsory licensing of patents

IP Australia acknowledges that, "A compulsory licence has never been granted in Australia. There have been three cases where an application has been made." As with Crown use – this is not a pressing issue for legislative amendment.

In relation to both Crown Use and Compulsory Licensing – these are powers that should be used very sparingly as they override and interfere with the private property law rights of the patentee. Compulsory licensing is rarely the best policy option to promote access to medicines. While limiting their use to address a national health emergency can be appropriate when other access schemes have failed, regular use of compulsory licenses—for example, to support industrial policy objectives aimed at favoring domestic industries or as a routine cost containment measure when national resources and financial reserves are adequate and other alternatives are available, should not be pursued.

(v) Miscellaneous

Medicines Australia notes *recommendation 10.1* of the Productivity Commission's report regarding the extension of term for pharmaceutical patents. We would like to reiterate our strong opposition to this recommendation, which fails to acknowledge the unique Australian R&D and marketing regime and which, if implemented, would severely compromise the existing balance between the incentive to innovate and delivering affordable new innovative medicines to Australian patients. The Australian Government has stated that it will not proceed with the recommendation in the form proposed and that it will consult with industry directly on ways to improve the patent term extension system. Considering the Australian Government's response, Medicines Australia believes that any proposed amendments to the patent extension term are well beyond the scope of this review and does not intend to comment further at this time.