

6 October 2009

Jacqueline Carroll
Secretariat
Advisory Council on Intellectual Property
PO Box 200
WODEN ACT 2606

Dear Ms Carroll,

Re: Post-Grant Patent Enforcement Strategies – Interim Report

Thank you for this opportunity to comment on the ACIP's Interim Report on Post-Grant Patent Enforcement Strategies.

Medicines Australia supports the ACIP's interim recommendations:

- that IP Australia establish a consolidated resource to provide in-depth information on patent enforcement in Australia and overseas;
- that the Australian Government amend the *Patents Act 1990* to ensure that:
 - the Commissioner of Patents receives information about the existence and the outcome of relevant court proceedings; and
 - IP Australia makes any such information available to the public, either through or in association with its on-line searchable databases of patent information;
- that IP Australia continue to encourage and assist countries in the region to improve their patent enforcement systems;
- that IP Australia expand its advocacy program to other countries in the region in which Australian companies do business; and
- that the Australia Government introduce legislation to empower Customs to seize goods at the border when a patent holder has forewarned it of a shipment of un-authorized copies of patented products.

However, Medicines Australia does not support the establishment of a Validity and Infringement Opinion Service to be administered by IP Australia, as recommended in the Interim Report.

Firstly, IP Australia's opinion on validity is already implied in the grant of a patent. Opponents are free to utilise existing mechanisms to challenge any such opinion, for example, by requesting re-examination under section 97 of the *Patents Act 1990*.

Secondly, Medicines Australia does not believe that IP Australia should assess or determine infringement. Infringement proceedings typically involve consideration of complex evidence, including expert testimony, in accordance with the rules of evidence. Only courts, or a court-prescribed body, are qualified to oversee this process.

Moreover, preparing evidence in an infringement suit is costly and resource-intensive. Neither patent holders nor opponents should be expected to undertake such activities as part of a process where the outcomes will be non-binding and may be different from a final determination.

Thirdly, Medicines Australia does not believe that the proposed Service, in its recommended form, sufficiently protects patent holders from frivolous opposition. In fact, by forcing patent holders to respond to unrestricted public submissions, IP Australia would place an enormous cost and time burden on patent holders, materially undermining their ability to continue to innovate (and/or benefit from their inventions).

In short, Medicines Australia believes that a Validity and Infringement Opinion Service would impose additional costs and administrative burdens, without obvious gains for the large majority of relevant stakeholders.

Medicines Australia also does not support the establishment of a Patents Tribunal, as recommended in the Interim Report.

We believe that this Tribunal, which would administer a non-binding determinative alternative dispute resolution process, would also create additional steps in patent enforcement without significantly reducing the overall burden of patent enforcement in Australia.

The Interim Report argues that “there would be a portion of cases in which the Tribunal’s determination would be accepted by the parties.” (emphasis added) However, the Report implies that, based on similar overseas experience, only a fraction of determinations would be accepted by involved parties. This means that, with or without a Tribunal, most disputes will still be taken to court for resolution.

This would be especially concerning if, as the Report recommends, Australian courts were “required” to take into account the Tribunal’s determinations when awarding damages and/or costs or if Australian courts were “encouraged” to refuse to award costs in favour of a successful plaintiff where the court concludes that parties should have agreed to the Tribunal’s initial determination.

Medicines Australia believes that not only would this invest the Tribunal with de-facto judicial powers – the constitutionality of which is questionable at best – it would also require patent holders (and their opponents) to undertake significant additional activities that may have little to no bearing on a final determination.

Medicines Australia would strongly oppose the imposition of such requirements on Australian courts, even if a Patents Tribunal were set up.

Obviously, the process of patent dispute resolution in Australia needs to be streamlined. However, we believe that a more appropriate method of doing so is to reform case management processes in existing courts.

The Federal Court of Australia issued *Practice Note IP 1: Proceedings Under the Patents Act 1990 (Cth)* in September 2009. Its aim is to “accelerate the identification of issues and generally to improve the facilitation of the (litigation) process.”

The *Practice Note* does not address all of the relevant issues raised in the Interim Report. But this is an important first step in the process of streamlining patent dispute resolution in Australia.

Medicines Australia believes that this and similar actions are more likely to reduce the actual burden of patent enforcement in Australia. Their impact should be reviewed before additional measures, such as a Patents Tribunal, are implemented.

Finally, it is disappointing that the ACIP's Interim Report does not address the issues of "patent linkage"¹ and of unfair and inequitable penalties that may be imposed on pharmaceutical patent holders for attempting to enforce their patent rights.

Pharmaceutical patent holders in Australia do not receive formal notification of a third party's intention to seek marketing approval for a pharmaceutical product that may infringe a valid and enforceable patent until after the (potentially) infringing product has received marketing approval in Australia.

If the patent holder wishes to take action against an infringer, the patent holder must meet certification requirements under section 26 of the *Therapeutic Goods Act 1989* before commencing court proceedings. The patent holder is liable to pay the Commonwealth a pecuniary penalty of up to \$10 million if the presiding court finds the certification to be false or misleading in a material particular or an undertaking given in the certificate has been breached. Also, in circumstances where the patent holder has obtained an interlocutory injunction to restrain a person from infringing a patent, the patent holder may also be liable for potential damages or costs if a false or misleading certificate has been given (or an undertaking in a certificate breached).

The corresponding penalty for potential infringers is up to \$550,000 or up to only 5.5 percent of a patent holder's potential liability.

Medicines Australia considers that this situation significantly weakens an otherwise robust intellectual property regime in Australia. We strongly encourage the ACIP to review our initial submission to this review, which provides more details on this subject.

Thank you again for the opportunity to contribute to this review. Medicines Australia looks forward to ongoing dialogue with Government on all aspects of intellectual property policy in Australia.

If you have questions about views expressed in this letter, or you require further information, please do not hesitate to contact me at:

deborah.monk@medicinesaustralia.com.au or at **02 6122 8500**.

Yours sincerely,



Deborah Monk
Director, Innovation & Industry Policy

¹ By allowing patent holders to be notified of potential infringements, patent linkage promotes adequate and effective protection of intellectual property rights for the research-based pharmaceuticals industry.