Submission by the American Chamber of Commerce in Australia
to
IP Australia

Regarding the Australian Government’s Pharmaceutical Patents Review
Dear Mr Harris,

Thank you for the opportunity to participate in the Australian Government’s Pharmaceutical Patents Review.

The American Chamber of Commerce in Australia (“AmCham” or “The Chamber”) is a national organisation with over 1,700 member companies. Our members include many of the largest companies in Australia, involved in a diverse range of activities in the manufacturing, resources, technology and services sectors. Among other things, AmCham aims to distil and represent the business views of its members to government in Washington DC and Canberra.

Intellectual property is at the centre of the activities of many of the Chamber’s members, and in the context of the Government’s Pharmaceutical Patents review, the Chamber would seek to ensure that:
- There is no weakening of Australia’s currently strong Intellectual Property regime; and that
- Consideration should be given to improving the regime in the interests of investment attraction.

**AmCham Intellectual Property Policy**

“For 50 years, the Chamber has been, and continues to be actively committed to the promotion of a trade and investment environment that facilitates and does not impede commerce and the flow of capital. A critical aspect of this goal is ensuring that governments maintain and enforce intellectual property laws which both leverage and protect intangible assets of companies and business owners.

The Chamber strongly endorses the principle of strong protection of intellectual property consistent with Australia’s, the United States’ and other countries international obligations. The Chamber stands behind its members in the rightful pursuit of intellectual property rights, and the commercial benefits to which they are associated and entitled.

Where appropriate, the Chamber engages in constructive and informed dialogue amongst its members and with government officials and departments, both in Australia and the U.S., to promote the understanding and protection of proprietary ownership rights, including patents, designs, trademarks, trade secrets and confidential business information.
The Chamber and its members seek where possible, to enhance the current laws and mechanisms that drive more effective means of protecting and enforcing intellectual property rights globally.

The Chamber recognises that many companies have invested heavily in Intellectual Property through patents, copyrights and trademarks. These IP based assets represent important business assets, and are of considerable significance as part of shareholder value.”

The importance of Intellectual Property

The patent system provides an incentive for commercial operators to incur the cost and risk of research and to disclose information that might otherwise be kept secret. It does this by providing a time-limited exclusive right to commercialise a product which is novel (in the sense that it was not known prior to the invention), useful (in that it has commercial applicability), and inventive (in the sense that it was not obvious at the time it was invented). If the alleged innovation is neither new nor inventive, no patent should be granted; and if it is granted, it can be challenged.

To ensure there is a return on high-risk investment, new medicines are protected by patents. Without this intellectual property protection there would be no return on investment, and no re-investment in research, which leads to the discovery of new and innovative medicines such as new cures and treatments for cancers. Research by the Tufts Center for the Study of Drug Development (“Average Cost to Develop a New Biotechnology Product is $1.2 Billion” (Nov. 9, 2006), available at http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69) finds that it costs around $US 1 billion to develop a new medicine and takes some 12 years. Only 10% of potential drug candidates reach the human trial phase. Only a small portion of that 10% actually reach the market and only two out of marketed drugs ever produce revenues that match or exceed R&D costs.

Patents play an important role in underpinning innovation and economic growth. As the Parliamentary Secretary outlined when introducing the latest amendments to IP legislation, “Australian innovation is critical to the resilience of the economy through changing times. Innovation makes our economy more competitive, but the extent of innovation necessary to keep our economy competitive cannot happen on its own. In addition to requiring support and investment, innovation requires a strong intellectual property system. A strong IP system underpins investment in innovation. A strong IP system provides investors an opportunity to recoup the investments necessary to bring their ideas to the marketplace. The IP system also gives the public and innovators the tools necessary for further innovation through published information about new technology.” (Second reading speech, 19 March 2012, 3409). The Chamber fully supported the recent passage of the Raising the Bar Bill.

Outcomes sought from this Review

Given the importance of IP, the Chamber would not support any weakening of Australia’s current IP regime (for example, by winding back patent extension provisions; by changing the system of interlocutory injunctions etc) as this will detract from Australia’s investment attractiveness.

In fact, this review offers the opportunity to propose improvements to the IP regime, which would further strengthen Australia’s competitive position. The Chamber supports the
improvements proposed by the key pharmaceutical industry association, Medicines Australia (MA), many of whose members are also members of AmCham.

The key recommendation for improvement advanced by Medicines Australia is improved data exclusivity. The MA submission outlines the rationale for why improvements are needed.

Data exclusivity protects the information gathered by the innovator to demonstrate the safety and effectiveness of the product and is intended to encourage companies to embark on the lengthy, complicated, and risky development programme required for TGA approval. Without an adequate period of data exclusivity, other companies would be allowed to piggyback on the innovator’s pre-clinical and clinical data “for free” as the basis for approval of their copy product as soon as the innovative drug was approved. Together, patents and data exclusivity provide a limited period of protection for the innovator to attempt to recover the cost of product discovery and development. Without this opportunity, investment in medicines would be significantly diminished. The Chamber agrees with Medicines Australia that it is important to bring Australia’s data exclusivity regime up to the standards of other OECD countries, and – given AmCham’s constituency - the Chamber would like to see the Australian system aligned with the US system.

The Chamber would also support improvements to the patent certification process to ensure that originator companies receive notice from the TGA that a generic is entering the market.

Thank you for considering our submission. If you require any further information, please do not hesitate to contact the undersigned.

Yours faithfully,

Charles Blunt
National Director
American Chamber of Commerce in Australia
Suite 9, Ground Level | 88 Cumberland Street
Sydney NSW 2000 | Australia
T: +61 2 8031 9000 | F: +61 2 9251 5220
Email: ceo@amcham.com.au

Patrick Fazzone
Chairman, AmCham Trade &
Government Committee
Level 12 | 1 Bligh Street
Sydney NSW 2000 | Australia
T: +61 2 9262 6700
Email: PFazzone@bltplaw.com