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Intellectual Property Arrangements
Productivity Commission
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A Submission to the Productivity Commission Inquiry into Australia's Intellectual Property Arrangements

The Generic and Biosimilar Medicines Association (GBMA) is the national association representing companies that manufacture, supply and export generic and biosimilar medicines. The generic and biosimilar medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public.

GBMA welcomes the opportunity to make this submission in response to the Productivity Commission inquiry into Australia's intellectual property arrangements. As GBMA is dedicated to making medicines affordable, this submission will focus on four topics, particularly relevant to pharmaceuticals.

1. An Imbalanced Pharmaceutical Intellectual Property System Delays Access to Affordable Medicines

Pharmaceutical patents play an important role in encouraging the innovation of new medicines and it is imperative that innovation is directed to the invention of products that improve health outcomes. Patents already provide exclusivity for up to 25 years and most medicines are protected by many different patents.

However, inappropriate extension of patents and the granting of inappropriate patents cost the national economy, and the public, dearly and should be guarded against. The patent system should not support trivial patents that extend market exclusivity to products that do not deliver an incremental health benefit.

GBMA members have been long concerned that Australia's intellectual property system delivers an imbalanced pro-patentee position, resulting in unnecessary and inappropriate delays to the supply of affordable, high quality generic and biosimilar medicines.

Granting of weak patents restricts innovation, competition and diffusion of knowledge and unnecessarily increases the cost to the public. It is imperative that the legal framework supports appropriate, timely and efficient market entry of follow-on generic and biosimilar medicines.

2. The Pharmaceutical Patents Review (PPR) Remains Highly Relevant

Announced in 2012, the PPR saw an Expert Panel consider whether the system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively priced pharmaceuticals, fostering innovation and supporting employment in research and industry.

In January 2013, the Generic Medicines Industry Association (as we were then known) made a comprehensive submission to the PPR. All of the issues highlighted in our 2013 PPR submission remain highly relevant and unresolved today. Therefore, a copy of our 2013 PPR submission is attached to this letter for the information of the Commission 'in-confidence' and is not for publication.

GBMA encourages the Commission to consider the Final Report of the PPR in the context of this current inquiry. Although commissioned under a previous government, the PPR comprised an in-depth review of pharmaceutical patents in Australia. It proposes a number of recommendations that GBMA believe if implemented, would balance pharmaceutical intellectual property in Australia, encourage innovation and prevent strategic gaming of the system by patent holders to delay market access for generic and biosimilar medicines.

A copy of the PPR Final Report is available at http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf.

3. The Innovation Patent System Should Be Abolished

As the threshold for granting innovation patents is low and an application is not subject to a stringent examination process, GBMA argues that innovation patents are easy to obtain. Considering some recent changes to increase the threshold for patentability, it follows that in future, easily obtainable innovation patents may be strategically used to create a barrier to market entry in Australia for generic and biosimilar medicines.

Therefore, GBMA is of the opinion that abolishing the innovation patent system will level the playing field and not delay generic and biosimilar medicine market entry and the follow-on savings these medicines provide to the Pharmaceutical Benefits Scheme.

The corrigendum to the Advisory Council on Intellectual Property (ACIP) Review of the Innovation Patent System Final Report dated May 2015 notes some additional information that has become available to suggest innovative activity is not being stimulated among Australian small to medium enterprises (SMEs) by the innovation patent system. GBMA agrees with the key finding of the IP Australia Economic Research Paper 05 that private gains from innovation patents are likely to be offset by the uncertainty in costs to consumers and producers, resulting in a net cost to society.

GBMA therefore supports the ACIP determination that the innovation patent system is not achieving its objective to stimulate innovation among SMEs. GBMA supports the ACIP recommendation to government to abolish the innovation patent system.

4. International Trade Agreements Must Not Delay Access to Affordable Medicines

GBMA strongly supports the negotiation of trade agreements aimed at fostering trade in generic and biosimilar medicines.

GBMA believes a number of principles should guide decision making for future negotiations on intellectual property rights. As a member of the International Generic and Biosimilar Medicines Association (IGBA), GBMA supports the IGBA Trade Principles Paper available at http://www.igbamedicines.org/doc/09.24.15%20IGBATradePrinciples_ForWeb_FINAL.pdf

Specifically, the Trade Principles Paper outlines that trade agreements should seek to:

- Ensure that the regulation of intellectual property rights in trade agreements does not lead to excessive IP standards that delay access to generic and biosimilar products; and
- Establish an appropriate framework of pro-competitive provisions to prevent intellectual property right abuse/misuse,

GBMA notes the commitment made by Trade Minister Robb in the Trans Pacific Partnership that no change will be made to the five year data exclusivity term for biological medicines. The fact is, the longer the term of data exclusivity granted by a country, the longer that country will be without generic versions of patent-expired medicines and the longer patients will have to wait for affordable access to the latest therapies.

Yours faithfully,

Belinda Wood
Chief Executive Officer