



**Generic and Biosimilar
Medicines Association**

Unit 4, 20 Napier Close
Deakin ACT 2600

PO Box 87
Deakin West ACT 2600

gbma.com.au

3 June 2016

Intellectual Property Arrangements
Productivity Commission
GPO Box 1428
Canberra City ACT 2601
By email: intellectual.property@pc.gov.au

GBMA Response to the Productivity Commission Draft Report

The Generic and Biosimilar Medicines Association (**GBMA**) is the national association representing companies that predominantly manufacture and supply generic and biosimilar medicines to the Australian market, or for export. Our members include Alphapharm Pty Limited, Amneal Pharma Australia Pty Ltd, Apotex Pty Ltd, Arrow Pharmaceuticals Pty Ltd, Sandoz Pty Ltd., Southern Cross Pharma Pty Ltd, and Generic Health Pty Ltd with associate members including Commercial Eyes Pty Ltd, Generic Partners Pty Ltd, IMS Health and Sinapse Pty Ltd.

The generic and biosimilar medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public.

The Australian generic and biosimilars medicines industries rely on domestic policy makers to "get the balance right" between patentee monopoly interests and public interest considerations. A balanced pharmaceutical sector supports the timely and cost effective launch of generic and biosimilar medicines worldwide, thereby improving access and affordability of health care for patients.

The situation in Australia has been imbalanced for far too long, resulting in persistent and inappropriate market entry barriers to the launch and manufacture of generic and biosimilar medicines in Australia, which do not exist in our closest trading partners (including the US, EU, and Canada; our **Trading Partners**). The Australian public and the Australian Government have long suffered through delayed access to affordable medicines in Australia, and through lost opportunities to build and utilise world class generic/biosimilar manufacturing facilities in Australia for export.

GBMA Applauds Productivity Commission Draft Report

As stated in our 30 November 2015 submission to the Productivity Commission, GBMA strongly supports the removal of inappropriate market barriers preventing the entrance of generics and biosimilars into the Australian market to ensure ongoing and reliable access of affordable generic and biosimilar medicines, to cost effectively prevent, treat and cure illness or maintain health in Australia.

GBMA applauds the statements and recommendations of the Australian Productivity Commission in the recent 29 April 2016 Draft Report on Intellectual Property Arrangements (**the Draft Report**).

GBMA Members strongly concur with the Productivity Commission recommendations discussed below, and believe urgent patent reform is required to right the long standing and persistent imbalance between pharma/biopharma monopoly interests and public health needs in Australia.

Summary of GBMA Submissions

In particular, GBMA strongly supports urgent reform addressing the following comments and recommendations of the Productivity Commission in the Draft Report:

1. Inventive Step threshold must be increased further

The breadth of patent protection granted in Australia is internationally misaligned. Soft standards for "inventive step" in Australia have resulted in weak patents being granted (or in patents with broader claims being granted) in Australia as compared to our Trading Partners. Patents are being granted too easily in Australia, resulting in low-quality pharma/biopharma patents subsisting where no equivalent monopoly rights (or significantly narrowed rights only) are granted in our Trading Partners. While the 2012 *Raising the Bar* amendments went some way to correct this, further urgent reform is needed.

2. Strategic misuse of the patent system by pharma/biopharma patentees must be acknowledged, addressed and removed

Strategic misuse of the patent system in Australia is common for pharma/biopharma patentees. Pharma/biopharma ever-greening strategies and patent thickets are rife in Australia because patents are easy to obtain, inexpensive to maintain, the Australian Courts are pro-patentee, the Australian pharma/biopharma market is relatively small and patent litigation is relatively expensive.

GBMA supports the Productivity Commission recommendations to reduce patent thickets, including significantly increasing renewal fees to disincentivise misuse of the Australian patent system.

3. The innovation patent system has failed and should be abolished

GBMA supports the position of the Productivity Commission regarding the abolition of the innovation patent system. GBMA agrees that the removal of innovation patents altogether would simplify the patent system, reduce the volume of low value patents, and minimise the strategic misuse of the patent system.

Innovation patents are far too easy to obtain. GBMA agrees with the Commission that this has resulted in a multitude of low-value patents and that these weak patents may

be used strategically to create inappropriate barriers to market entry in Australia for generic and biosimilar medicines.

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 (**PBS**).

4. The Patent Term Extension (PTE) regime requires urgent reform

The PTE system in Australia fails to incentivise product Sponsors to promptly introduce new products to the Australian market, and in turn, wrongly delays market entry for generic and biosimilar medicines. GBMA strongly supports overhaul of the PTE regime in Australia, and agrees with the Productivity Commission that any PTE (if any) should be calculated by virtue of only unreasonable delays by the Therapeutic Goods Administration (**TGA**) in approving a medicine.

5. An affordable/fast tracked Federal Court system for patent litigation in Australia is urgently needed

Patent litigation costs in Australia are very significant compared to costs in our Trading Partners, and the size of the Australian pharma/biopharma market is small. In GBMA Members' experience, the costs of removing inappropriate patent barriers to market entry will be justified for only medicines of "blockbuster" status. The disproportionately high costs of patent litigation in Australia therefore result in many weak and vulnerable patents remaining unchallenged. In the absence of a low cost/fast tracked Federal Court system for patent litigation, the public (and the Australian budget) are denied the benefit of timely access to affordable medicines.

6. Manufacture for Export (MFE) can, and must, be implemented in Australia

The pharma/biopharma industries are global. Given Australian patents are broader than overseas counterparts, patents expire later, and it is more difficult and expensive to remove patent barriers, Australia is generally a poor choice for the manufacture of pharma/biopharma products, in particular for products where patents are likely to exist, such as generic and biologics medicines. Australia has become a net *importer* of pharma/biopharma products as a result. GBMA Members who once manufactured products in Australia have had no choice but to move their manufacture off-shore to meet earlier market formation dates overseas. GBMA strongly supports the urgent introduction of MFE in Australia, and believe neither domestic nor international laws or agreements provide any barriers to urgent implementation.

7. There is no reason to extend data exclusivity beyond 5 years in Australia for small molecule or biologics medicines

GBMA also strongly agrees that there is benefit in the eventual publication of such data, and that Australia should seek consensus with our Trading Partners facilitating greater domestic and international transparency relating to such data.

8. Trade Agreement negotiations must be transparent and should be informed by a bipartisan "base" Australian International Trade Policy

GBMA strongly supports the September 2015 International Generic and Biosimilar Medicines Association Trade Principles Paper¹ (ITP) previously provided to the Productivity Commission, and strongly recommends that the principles in the ITP inform such an Australian International Trade Policy.

Conclusion

GBMA provides further commentary in the attached **Confidential Appendix** which is "commercial-in-confidence", provided for the information of the Commission, and is not for publication.

GBMA strongly supports the recommendations proposed by the Productivity Commission to rebalance Australia's patent system. However, the recommendations are ineffective without implementing changes to the Australian IP system. While the GBMA applauds Australia's reforms in recent years through the 2012 *Raising the Bar* amendments and the recommendations of the Pharmaceutical Patents Review, urgent reform is needed to balance IP rights in the pharmaceutical sector and enable timely and cost effective entry of biosimilar medicines.

The Australian Government must consider the Draft Report as cause for immediate legislative reform of the IP system to remove unnecessary, costly, and internationally misaligned market entry barriers to the launch of generic and biosimilar products in Australia.

GBMA welcomes the opportunity to be involved in public hearings

GBMA welcomes the opportunity to assist the Productivity Commission by being involved in public hearings and has registered to attend the public hearing to be held in Canberra on 22 June.

Yours faithfully,

Belinda Wood

Chief Executive Officer

¹ http://www.igbamedicines.org/doc/09.24.15%20IGBATradePrinciples_ForWeb_FINAL.pdf

About GBMA

GBMA (formerly the Generic Medicines Industry Association, GMiA) is the national association representing companies that manufacture, supply and export generic and biosimilar medicines. GBMA represents all major generic medicine suppliers in Australia and more than 90% of all generic medicines dispensed in Australia. Members of GBMA ensure all Australians are offered the highest quality generic and biosimilar medicines whilst providing affordable health outcomes that benefit all Australians.

Members of GBMA take seriously their role in the responsible provision of affordable medicines in Australia as described in the National Medicines Policy. The generic and biosimilar medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public. The availability of generic medicines in this country helps to deliver:

- Timely access to affordable medicines;
- Substantial savings to the PBS;
- Thousands of highly skilled jobs; and
- Domestic manufacturing and annual exports of around \$300 million.