



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA welcomes Productivity Commission Draft Report in Australia and supports immediate Australian patent reform

Friday June 3, 2016

The International Generic and Biosimilar Medicines Association (**IGBA**) represents companies that are actively engaged in the global manufacturing and trading systems for medicines. Our membership includes the EGA (Europe), the CGPA (Canada), the GPhA (USA), the JAPM (Jordan), the NAPM (South Africa), the TGPA (Taiwan) and the JGA (Japan). Associations from Australia (GBMA), Brazil (ProGenericos), Mexico (AMEGI) and Malaysia (MOPI) are Associate Members.

IGBA supports the timely and cost effective entry of generic and biosimilar medicines in markets worldwide in order to increase access and affordability of health care for patients.

IGBA aims to increase market penetration of generic and biosimilar medicines by dismantling inappropriate barriers to trade, encouraging regulatory harmonisation, reducing the costs related to administrative processes, and striking a fair balance between patent protection and public health needs. We strongly support a balanced approach to IP rights to ensure timely access to affordable medicines for patients around the world.

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

The IP system in Australia has been out of step with that of its key trading partners such as the US, EU, and Canada (**ROW**) for too long. As a direct result, inappropriate market entry barriers (which do not exist in ROW) operate in Australia to prevent the timely launch of affordable medicines, and cost the Australian Government and Australian public greatly.

The time for rebalancing Australia's patent system is now. The IGBA encourages the Australian Government to action the recommendations of the Productivity Commission in the Draft Report. Immediate law reform in Australia is needed to remove unnecessary, costly, and internationally misaligned market entry barriers to the launch of generic and biosimilar products in Australia.

Australia's patent system and law remains out of step with ROW, despite Raising the Bar.



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IGBA members have been long concerned about inappropriate barriers to market entry for affordable medicines in Australia. In particular, IGBA has previously expressed a very real concern regarding the following issues, raised by the Productivity Commission in the Draft Report:

- **The Australian "pro-patentee" approach in the Patent Office and in the Courts results in pharmaceutical patents standing in Australia that are revoked elsewhere**

IGBA agrees with the Productivity Commission that Australia's patent system grants protection too easily, allowing a proliferation of low-quality patents, frustrating the efforts of follow-on innovators, stymieing competition and raising costs to the community.

Patents are easier to obtain, and harder to revoke in Australia than in ROW. This is in part due to lower threshold for "inventive step" (obviousness) that exists in Australia.

Recent 2012 "Raising the Bar" amendments went part of the way to redress this issue, but further reform is needed to bring Australia into line with ROW.

IGBA strongly supports immediate reform aligning Australia's test for inventive contribution with that in Europe.

- **Patent term extensions (PTE) last longer in Australia than in ROW.**

As the Australian market is smaller than those overseas, often product Sponsors de-prioritise the Australian market in favour of more lucrative markets. As a result of this Australian market de-prioritisation (as correctly outlined in the Draft Report), the date of expiry of patent term extensions in Australia are routinely later than patent term extensions granted in ROW.

The current PTE system in Australia does not disincentivise the delayed entry of Sponsor medicines in Australia (in practice, the longer they wait to launch a product, the later their extension of term will expire), which, in turn, wrongly delays market entry for affordable generic and biosimilar medicines.

IGBA strongly supports the urgent implementation of a patent term extension regime under which patent term extensions are calculated by virtue of only any unreasonable delay by the Australian Therapeutic Goods Administration (TGA) (if any) in approving a medicine, and irrespective of any market driven behaviour by the product Sponsor.

- **Lower thresholds for patentability and higher thresholds for revocation result in greater (and more effective) patent thickets and "evergreening" behaviour**

IGBA members agree with the Productivity Commission that the pro-patentee stance to patents in the Courts and in the patent office has resulted in more complex and more effective "evergreening" behaviour and patent thickets. Patents for pharmaceutical products in Australia are regularly granted in Australia where they are not in ROW, and are routinely broader in Australia than counterpart patents granted in ROW. IGBA strongly supports the Productivity Commission recommendations addressing such misuses of the patent system in Australia.

- **High costs of patent litigation in Australia and small market size prevent generic/biosimilar companies taking steps to remove inappropriate patent barriers to launch**

The costs of pharma/biopharma patent litigation in Australia (say \$2-\$4M to first instance) is not dissimilar to that of Hatch-Waxman litigation in the US and is roughly equal to the costs of equivalent patent litigation in the UK. The impact is amplified considering the market size in Australia is significantly smaller than the US, or the UK.

As a result, the costs of removing inappropriate patent barriers to market entry in Australia (which are carried by generic/biosimilar sellers in Australia) are only justified for "blockbuster" medicines. The disproportionately high costs of patent litigation in Australia result in many weak and vulnerable patents remaining unchallenged, and the public is denied the benefit of access to affordable medicines as a result.

IGBA strongly supports the urgent implementation of fast tracked, lower cost Federal Court system for pharma/biopharma patent litigation in Australia, as contemplated by the Productivity Commission.



- **Lack of ability to Manufacture for Export (MFE) in Australia, combined with factors outlined above influence pharma/biopharma companies to manufacture outside Australia to ensure timely global market entry**

Given pharma/biopharma companies operate globally, there are many options for the region in which to place a manufacturing facility. Various factors are relevant to such a decision, including the ability to manufacture product locally for export to meet market formation.

Given the strength of patents in Australia, the longer patent term extensions, and the disproportionately high cost of clearing inappropriate barriers to market entry, Australia is often a very poor choice for the manufacture of generic and biosimilar medicines. As a result IGBA members routinely prioritise manufacturing facilities outside Australia.

IGBA strongly supports the urgent introduction of MFE in Australia, supporting the manufacture of generic and biosimilar medicines in Australia for export. Such an initiative is not inconsistent with any of Australia's international trading obligations, and is consistent with the position taken by some of its major trading partners (including Canada, Israel and recently Europe).

While the IGBA applauds Australia's progress in recent years through the Raising the Bar amendments and the Pharmaceutical Patents Review, IGBA believes Australia needs to take immediate steps to rebalance the patent system in Australia supporting timely access to affordable medicines in Australia.

About IGBA

The International Generic and Biosimilar Medicines Association (IGBA) was founded as IGPA (International Generic Pharmaceutical Alliance) in March 1997 to strengthen cooperation between associations representing manufacturers of generic medicines. Its membership includes the EGA (Europe), the CGPA (Canada), the GPhA (USA), the JAPM (Jordan), the NAPM (South Africa), the TGPA (Taiwan) and the JGA (Japan) while the associations from Australia (GBMA), Brazil (ProGenericos), Mexico (AMEGI) and Malaysia (MOPI) are Associate Members.

The IGBA is at the forefront of stimulating competitiveness and innovation in the pharmaceutical sector by providing high quality pro-competitive medicines to millions of patients around the world. Through its constituent member associations, the IGBA maintains constant dialogue with government authorities (including the European Commission for Europe) as well as with international institutions such as WTO, WIPO and WHO. More information: www.igbamedicines.com