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**Generic Medicines Industry Association**

**SUBMISSION PAPER**

# **Public Response to the Pharmaceutical Patents Review**

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## Table of Contents

<b>1</b>	<b>OVERVIEW</b>	<b>4</b>
1.1	Executive Summary	4
1.2	GMiA	4
1.3	Background – strategies used to inappropriately delay the supply of generic medicines in Australia	5
1.4	GMiA applauds the IP Australia initiative in the PPR	9
<b>2</b>	<b>FRAMEWORK FOR THE REVIEW</b>	<b>10</b>
2.1	The problem of ‘evergreening’	10
2.2	Delays to the supply of generic medicines matter	10
2.3	IP provisions of international treaties matter	11
2.4	Relative market size matters	12
<b>3</b>	<b>PHARMACEUTICAL EXTENSIONS OF TERM</b>	<b>14</b>
3.1	Question 1: Extensions of Term	14
3.2	Question 2: Length of the extension of term	19
<b>4</b>	<b>PATENT STANDARDS</b>	<b>22</b>
4.1	Question 3: thresholds for patent grant	22
<b>5</b>	<b>JUDICIAL ISSUES</b>	<b>27</b>
5.1	Question 4: challenges to patents - opposition and re-examination	27
5.2	Question 5: interlocutory relief	32
5.3	Question 6: contributory infringement	35
5.4	Question 7: limitations period for patent infringement	38
5.5	Judicial issues – Other: Reducing the cost and complexity of patent litigation, and incentivising patent revocation in Australia	39

<b>6</b>	<b>FOLLOW-ON PATENTING</b>	<b>41</b>
6.1	Question 8 patent thickets	41
<b>7</b>	<b>THERAPEUTIC GOODS ADMINISTRATION RELATED ISSUES</b>	<b>49</b>
7.1	Question 9: data exclusivity	49
7.2	Question 10 - patent certificates	51
7.3	Question 11: Copyright of Product Information	55
<b>8</b>	<b>CONCLUSIONS</b>	<b>57</b>

# 1 Overview

## 1.1 Executive Summary

GMiA Members believe that the system for pharmaceutical patents in Australia is **not** effectively balancing the objectives of “securing timely access to competitively priced pharmaceuticals, fostering innovation and supporting employment in research and industry”<sup>1</sup>.

GMiA Members are not anti-patent, and are themselves regular users of the Australian patent system. However, GMiA Members are very concerned about regular misuses of patent and regulatory systems; legal developments which are inconsistent with legislative intent; and unintended consequences of health policies; which together result in unfortunate, inappropriate barriers to generic market entry in Australia.

The effect is that the supply of generic medicines in Australia is being inappropriately delayed, together with the resulting (very significant) cost savings to the government and the public.

## 1.2 GMiA

This submission has been prepared by the members of the Generic Medicines Industry (**GMiA**) in response to the Pharmaceutical Patents Review – Background and Suggested Issues Paper released on 21 November 2012 (the **PPR White Paper**) by the independent panel appointed by the Parliamentary Secretary for Innovation to review pharmaceutical patents (the **Panel**).

GMiA is the national association representing companies that manufacture, supply and export generic medicines. The generic 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 exports of over \$300 million.

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<sup>1</sup>The stated aim of the Pharmaceutical Patents Review is to evaluate the effectiveness of this balance - see page 42 (Appendix A) of the Background and Selected Issues Paper <http://pharmapatentsreview.govspace.gov.au/issues-paper/>

The generic medicines sector is currently delivering savings of a minimum \$1.9 billion over 2011-2015. These savings are in addition to savings to the PBS (Government contribution) of an estimated minimum \$1.4 billion over 2005-2009 that have been driven by the generic medicines industry sector.

Generic medicines deliver exactly the same health benefit to all Australians as the original brand and they must meet the same strict Australian standards, including the same manufacturing requirements, as branded medicines.

Australians deserve access to affordable, high quality medicines regardless of their socioeconomic background or whether they live in metropolitan or rural areas.

A national survey of more than 1,000 respondents reveals that Australians are very positive about generic medicines with 89% of Australians rating generic prescription medicines as ‘*a product I know and trust*’. Most people will trust their doctor (84%) and their pharmacist (86%) to help direct them regarding which medicine to purchase.

### **1.3 Background – strategies used to inappropriately delay the supply of generic medicines in Australia**

The Hon Mark Dreyfus QC MP, Parliamentary Secretary for Industry and Innovation, announced on 15 October 2012 that the Government will task an independent panel to evaluate 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*”. This presents a unique and important opportunity for Government to investigate the level of inappropriate delays to the supply of generic medicines in Australia (including inappropriate “evergreening” strategies used by industry players) and the associated cost to the Government and to redress that imbalance.

The problem of inappropriate delays to the supply of generic medicines is an international issue involving pharmaceutical companies operating globally.

On 8 July 2009 the European Commission adopted the Final Report on its Competition Inquiry into the Pharmaceutical Sector<sup>2</sup>(the “**2009 EU Commission Report**”). The inquiry was instigated to “*examine the reasons for observed delays in the entry of generic medicines to the market and the apparent decline in innovation as measured by the number of new medicines coming to market*”.<sup>3</sup>The EU Commission studied the pharmaceutical industries in EU, including the regulatory and commercial contexts, health policy considerations, and the economic considerations surrounding generic market entry.

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<sup>2</sup>[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)

<sup>3</sup>Id, Executive Summary, page 3

The 2009 EU Commission Report findings include concerns about company practices which result in delayed generic market entry (our emphasis):

*“The sector enquiry confirms that generic entry does not always take place as early as it potentially could under the current relevant legal framework. It shows that **company practices are amongst the causes** and suggests that a variety of other conditions might play also an important role. The sector inquiry also confirms a decline of novel medicines reaching the market and points to certain **company practices** that might, amongst other factors, contribute to this phenomenon...”<sup>4</sup>*

Further:

*“Originator companies use a variety of instruments to extend the commercial life of their medicines. The results of the sector inquiry suggest that the behaviour of companies contributes to the generic delay”<sup>5</sup>.*

The 2009 EU Commission Report called out the following as examples of such behaviour, used alone or in combination with each other<sup>6</sup>:

- patent thickets: “filing numerous patent applications for the same medicine (forming so called “patent clusters” or “patent thickets”) is common practice”<sup>7</sup>
- litigation as a strategy to delay, unrelated to prospects of success: “litigation can also be an efficient means of creating obstacles for generic companies... In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.”<sup>8</sup> And further, “... In contrast to the primary patents invoked in the pre-litigation phase, originator companies mainly invoked secondary patents during litigation.”<sup>9</sup>
- Other practices: sponsors intervening in pricing and reimbursement processes claiming that generics are less safe or effective, challenging the appropriateness of data exclusivity rules, commencing administrative proceedings to delay generic market entry, using marketing strategies which bring into question the quality of generics per se (even after generic authorisation by regulatory bodies), or interventions at supply sources for active pharmaceutical ingredients.<sup>10</sup>

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<sup>4</sup>Id, page 27

<sup>5</sup>Id, page 10

<sup>6</sup>Id, page 15

<sup>7</sup>Ibid

<sup>8</sup>id, page 11

<sup>9</sup>Ibid

<sup>10</sup>Id, page 13 - 14

- Life cycle strategies, involving moving the market from one form of a medicine to another form of the medicine just prior to anticipated generic market entry. <sup>11</sup>
- Defensive patent strategies: patenting strategies mainly focusing on excluding competition without pursuing innovative efforts.<sup>12</sup>

The behaviours identified in the 2009 EU Commission Report are not unique to Europe. They exemplify behaviours and strategies used by global pharmaceutical companies in national markets globally to “evergreen” their market monopoly for a medicine. Relevantly, they exemplify the strategies used by pharmaceutical companies to delay the launch of generic medicines in Australia. Australian specific legal considerations multiply the delay of generic medicine launches in Australia. Relevantly, such legal considerations (which are discussed in further detail in this submission) include:

- inappropriate grants of extensions of term (**EOT**) to a very broad range of pharmaceutical patents, contra to legislative intent;
- later expiring EOTs in Australia (as compared to EOTs on counterpart patents overseas) due to the Sponsor deprioritising the Australian market as compared to overseas markets (therefore maximising the potential length of the extension).
- lack of qualitative key performance indicators for Examiners at the APO;
- transitional provisions delaying the implementation of Raising the Bar Bill initiatives which target bringing certain aspects of Australian patent law back into line with overseas jurisprudence;
- the (internationally unique) very high likelihood that an interlocutory injunction will be awarded to prevent generic market entry if the generic has not removed all potential patent barriers to market entry, including those with marginal relevance and/or validity;
- the (internationally unique) pro-patentee position on contributory infringement in Australia;
- the unnecessarily long limitations period for the commencement of patent infringement proceedings, resulting in risks of massive potential damages liabilities, the scale of which will be much greater than the profit the generic supplier makes in Australia on sales of the medicine;

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<sup>11</sup>Id, page 14. “The findings of the inquiry suggest that for 40% of the medicines in the sample selected for in depth investigation, which had lost exclusivity between 2000 and 2007, originator companies launched second generation or follow-on medicines. Nearly 60% of the patent related litigation cases between originator and generic companies examined in the context of the inquiry concern medicines that moved from first to second generation products.”

<sup>12</sup>Id, pages 16, 19

- the supplier of a generic medicine carries the burden (at risk of criminal liability) of providing patent certificates as a pre-condition to regulatory approval, in the absence of (a) a simple means to search the patent register, and (b) any obligation on the Sponsor to identify relevant patents.

A further concerning practice GMiA Members have observed in Australia is that of Sponsors requesting PBS delisting of a product just prior to the date of anticipated generic market entry, in conjunction with seeking PBS listing of a revised, patented product (for example a new formulation of the first product).

As noted earlier, GMiA supports the grant and enforcement of valid patents. However these behaviours serve to delay generic entry well beyond expiry of valid patents, usually the API patent. GMiA conducted an analysis of the timing of generic pharmaceuticals launching into the Australian market with respect to the expiry of the API patent. The objective of this analysis was to consider the volume of molecules and potential financial implications in terms of foregone savings where there is a delayed generic medicine launch, or no launch at all, compared to the savings that may have occurred through Statutory Price Reductions on the Pharmaceutical Benefits Scheme had the generic medicine launched at API patent expiry. The analysis showed that the quantum of potential foregone savings is substantial. The analysis discussed further in section 2.2 below.

The launch of cost effective, high quality generic medicines in Australia is being inappropriately delayed as a result of the behaviours mentioned above. The size of the Australian market (relatively small), and unfortunate patent law jurisprudence cause even further inappropriate delays to the supply of generic medicines.

Members of GMiA welcome the Australian Government's review of Australian patent law in the broader context of health economics, regulatory nuances, and pharmaceutical company practices. GMiA Members have been long concerned that such factors have resulted in a very imbalanced pro-patentee position in Australia, resulting in the unnecessary and inappropriate delays to the supply of affordable, high quality generic medicines.

A solid understanding of the strategies used by pharmaceutical companies to delay generic medicine supply in Australia, Australian market realities (such as the size of the market), and legal nuances (such as the commonality of injunctions on launch of generic medicines) are critical to ensure legal reform supports the ongoing viability of generic medicines in Australia; in particular as the Australian government considers international agreements relating to pharmaceutical regulation and patents such as the Trans Pacific Partnership Agreement (**TPP**).

GMiA addresses each of these issues in this response to the PPR White Paper.

## **1.4 GMiA applauds the IP Australia initiative in the PPR**

Pharmaceutical patents play an important role in encouraging the innovation of new pharmaceutical 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.

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

For ease of reference, this submission roughly follows the order of issues outlined in the PPR White Paper.

## 2 Framework for the review

### 2.1 The problem of ‘evergreening’

Patents are effective tools for promoting innovation in the pharmaceutical sector, by providing a monopoly period during which originator companies can recoup their R&D investments. However, due to a diminishing number of newly registered products and contracting product pipelines, originator companies may be tempted to unjustly prolong the patent monopoly of existing products. The result is known as the ‘evergreening’ of a basic patent with the help of follow-on patents to keep generic competitors off the market beyond expiry of the patent to the active pharmaceutical ingredient. These follow-on patents often do not deliver improved health benefits, are often weak or trivial and, upon careful examination, it is clear that they should never have been granted.

The GMiA submission recommends sensible reform to address existing loopholes and remove the ability of originator companies to adopt ‘evergreening’ strategies. GMiA advocates for redressing the existing imbalance where there is a clear commercial benefit to the originator company to adopt such market tactics and limited consequences if these tactics are subsequently found to be invalid and / or inappropriate.

Government should not overpay for PBS medicines that are protected by questionable patents. Questionable patents are currently costing the Australian government hundreds of millions of dollars.

There is still tremendous potential for greater generic medicine uptake in Australia. **Measures must be taken by the Australian government to ensure that originator companies who choose to unjustly prolong the patent monopoly of existing products do not cause the Australian to overpay for medicines through the PBS.**

### 2.2 Delays to the supply of generic medicines matter

Delays to market entry of generic medicines matter. Timely market entry of generic medicines drive significant and important savings to the PBS.

GMiA carried out an analysis of the timing of generic pharmaceuticals launching into the Australian market with respect to the expiry of the API patent. The objective of this analysis was to consider the volume of molecules and potential financial implications in terms of foregone savings where there is a delayed generic medicine launch, or no launch at all, compared to the savings that may have occurred through Statutory Price Reductions on the Pharmaceutical Benefits Scheme had the generic medicine launched at API patent expiry, and to give an indication of how delays in generic launch generally can affect public health costs.

**This analysis showed, overall, for the 39 PBS-listed items where a generic launch was delayed after API patent expiry and before November 2012, the average days delay was 716 (median = 564 days). For molecules where no generic was launched following API patent expiry up to November 2012, the average days delay was 1,333 (median = 1,327 days, censored at 30 November 2012).**

The total annual value of this group of products is approximately \$300M. Based on the annual sales for these products, Statutory Price Reductions could have resulted in total potential savings of between \$37.8 M and \$48.4M for the 12 months to November 2012, depending on if a 12.5% or 16% reduction was applied. These figures do not include additional savings due to generic medicine entry, for example due to price disclosure reductions or the inherent downward pressure on prices in a competitive market.

In addition, for the 14 products in respect of which generic launch was delayed but which were not listed on the PBS, Statutory Price Reductions do not apply a mandated price reduction that results in immediate tangible savings. However, competitive market forces operate where there is no longer a monopolist supplier that result in lower prices for hospitals and pharmacies for these products. These potential savings too could have been forgone as a result of delay in generic launch beyond API patent expiry.

GMiA has also compared dossier submission dates in Australia and the US from January 2010 until November 2012. It considers the average time elapsed from dossier submission in the US until dossier submission in Australia, by reference to products in respect of which an application for an EOT was submitted in Australia. The timing of TGA approval, and therefore submission to the TGA, directly affects the duration of an EOT.

**These results show that on average sponsors submit dossiers to the TGA later than equivalent submissions to the FDA, the median delay being 297 days in 2012, 236 days in 2011 and 549 days in 2010.**

## **2.3 IP provisions of international treaties matter**

GMiA has previously expressed its concern regarding the recent trends to include specific (and mainly US pro-patentee) patent law provisions in international trade agreements.

The generic medicines industry relies on domestic policy makers to “get the balance right” (bearing in mind local market conditions) between patentee monopoly interests and public interest considerations.

Free trade agreements (FTAs) with patent provisions impact this balance. **GMiA strongly believes that FTAs must allow sufficient domestic policy space to support timely access to affordable health care. New overarching international IP obligations will wrongly upset this balance and will stymie local generic manufacture and timely access to affordable medicines.**

Recent (leaked) proposals regarding the TPP which are currently under negotiation have been of great concern to GMiA, and GMiA has expressed those concerns elsewhere.

GMiA is concerned that blanket adoption of US styled patent and pharmaceutical laws in the smaller economies of the negotiating countries will impede the ability of these nations to deliver affordable healthcare to their populations.

Extension of IP regimes will only further delay market entry of generic medicines, delaying the introduction of affordable medicines, and increasing the cost to the Government including costs of the health care system and the PBS. Remember: every time a generic medicine is dispensed, substantial savings are realised to the economy.

Australian generic medicine manufacturers will suffer if generic medicine penetration in FTA member countries is delayed by prolonged patent monopolies, protracted data exclusivity regimes, patent term adjustments, removal of pre-grant opposition and onerous patent linkage regimes are introduced.

## **2.4 Relative market size matters**

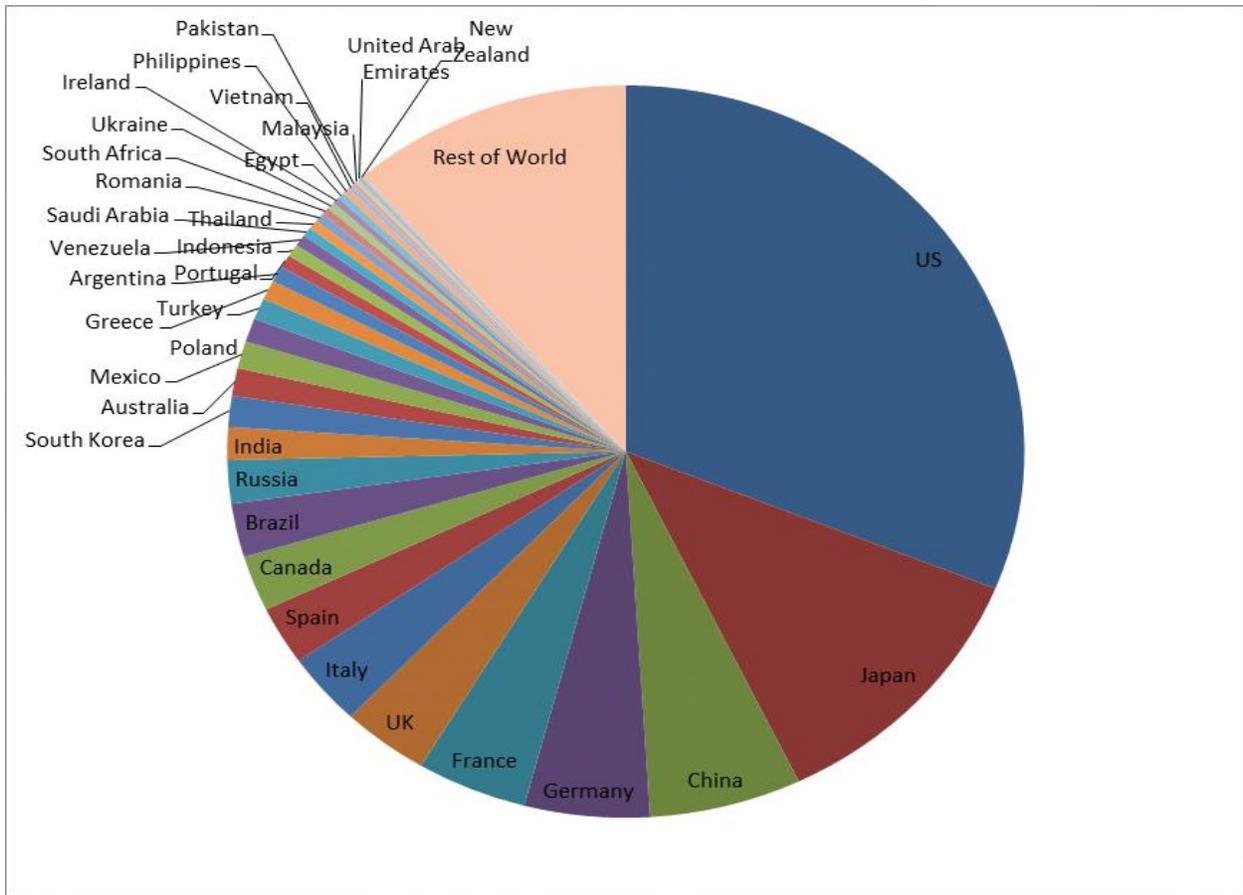
GMiA submits that in order to implement good policy, Australian policy makers will need a deep understanding of the similarities and differences in pharmaceutical law and practice in Australia as compared to the law and practice overseas.

Importantly, policy makers should appreciate that the pharmaceutical market in Australia is significantly smaller than that of Australia's major trading partners, mainly due to population sizes.

**Figure 1** below shows the share of global pharmaceutical sales by country at constant exchange rates for 2011. It is clear from **Figure 1** below, that the US and EU pharmaceutical markets dwarf the Australian market in relative pharmaceutical sales.

It is unsurprising then that product Sponsors de-prioritise filing applications for regulatory approval in Australia. It is incorrect to assume that what enables and supports optimal IP protection in the US will be good for other regions.

**Figure 1: Share of global pharmaceutical sales by country at constant exchange rates, 2011<sup>13</sup>**



As discussed in further detail below, pharmaceutical companies generally operate **globally**. Decisions regarding the pharmaceutical site of manufacture, regions for launch, and timing for seeking regulatory approval are strategically (not accidentally) made after thorough reviews of local patent laws and market considerations. In order to ensure that the Australian public are not disadvantaged relative to overseas markets, it is important to understand the global nuances, and correct for the peculiarities of the Australian market, including its relatively small size. GMiA strongly submits that a thorough understanding of the impact of the market size differentials is critical to the implementation of good health policy in Australia.

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<sup>13</sup>Source: "From vision to decision: Pharma 2020", PWC, 2012

## 3 Pharmaceutical extensions of term

### 3.1 Question 1: Extensions of Term

#### *Question 1: Is the breadth of pharmaceutical patents eligible for an extension of term appropriate?*

The current patent extension of term (**EOT**) regime was introduced in 1998. The clear legislative intent of these provisions was to provide ‘an effective patent life, or period after marketing approval is obtained during which companies are earning a return on their investment, more in line with that available to inventions in other fields of technology’. This is expressly acknowledged in the current Pharmaceutical Patents Review (page 4).

Explanatory Memoranda accompanying the 1998 amendments and in 2006 also made it clear that this regime was intended to relate to “new drugs”. Particularly, to provide an economic incentive for businesses to invest in the development of new chemical entities as active pharmaceutical ingredients (**APIs**) for potential therapeutic use. APIs are frequently more expensive and time-consuming to develop than other pharmaceutical inventions and marketing approval may take considerable time to be granted. This is explained in more detail below.

However, recent decisions of both the courts and the Commissioner of Patents have broadened the application of the EOT regime to cover formulation-type patents. GMiA submits no economic incentive for such inventions is justified and their eligibility for an EOT appears contrary to the stated legislative intent behind the EOT regime. EOTs for formulation-type patents have the effect of inappropriately delaying market entry of generic pharmaceuticals and therefore delaying public access to affordable medication.

#### ***Background: Extension of Pharmaceutical Patent Term Provisions***

Under section 70 of the Patents Act 1990 (Cth) (**Patents Act**) and related provisions, a patentee may apply for an EOT for a patent which discloses and claims a pharmaceutical substance per se,<sup>14</sup> provided goods containing or consisting of the substance are included in the Australian Register of Therapeutic Goods (**ARTG**) and at least five years have elapsed between patent filing and, in most cases, the date of first inclusion on the ARTG. The maximum duration of this extension is five years, and only one extension per patent is permitted.

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<sup>14</sup> The provisions also provide for term extensions on a similar basis for patents which disclose and claim pharmaceutical substances produced by a process that involves the use of recombinant DNA technology.

### ***Interpretation of ‘Pharmaceutical Substance’***

While there is no express wording in the Act, the legislative history of this wording evidences a clear intention of Parliament to enact provisions to restrict extensions to patents for APIs (being new APIs) and to exclude patents to pharmaceutical formulations as well as method, process and device-type patents.

In the Amended Explanatory Memorandum to the Intellectual Property Laws Amendment Bill 1997 (Schedule 1 – Extension of Pharmaceutical Patents) it is stated that a pharmaceutical substance is intended to be an API or a combination of such APIs:

*A ‘pharmaceutical substance’ is defined in Schedule 1 of the Patents Act 1990 and may comprise combinations of active ingredients or single active ingredients...*

*These claims to pharmaceutical substances per se would usually be restricted to new and inventive substances. Patents that claim pharmaceutical substances when produced by a particular process (product by process claims) will not be eligible unless that process involves the use of recombinant DNA technology. Claims which limit the use of a known substance to a particular environment, for example claims to pharmaceutical substances when used in a new and inventive method of treatment, are not considered to be claims to pharmaceutical substances per se.*

To the extent that a patent to a combination of APIs was envisaged to qualify for an EOT, the intention was that those APIs would be new.

Likewise, the Explanatory Memorandum to the Intellectual Property Laws Amendment Bill 2006 explained that:

*there are broadly four types of pharmaceutical patent: those on the active pharmaceutical ingredient (API); the formulation of the medication; the process for making the API; and methods of use of the medication. Only patents which claim a pharmaceutical substance (i.e. API) are currently eligible for patent extension in Australia...*

That legislative intent to only extend API patents is unsurprising once it is appreciated that the patent term extension is designed to bring the *effective* patent term for pharmaceutical products into line with the *effective* patent term for other technologies. For sound policy reasons unique to the supply of medicines, pharmaceutical suppliers (sponsors) must meet certain regulatory hurdles in order to supply their pharmaceutical products in Australia. The Australian government, in providing patent term extensions, recognises that requiring a sponsor to meet those industry specific regulatory standards, will result in delays to product launches in Australia. The patent term extension is designed to compensate the patentee for that industry specific delay.

This regulatory delay is primarily due to the evidence required to establish that an API is safe and effective for human use as a new medicine. The vast majority of information to be provided to the TGA to establish safety and efficacy of a medicine relates to the safety and efficacy of the actual new API (as

distinct from the formulation, process or other product features). Formulation details and indications/uses are often settled relatively late in the development process. Indeed, it is easier to meet these regulatory hurdles for a reformulated version of a known API (e.g. an oral version of a known IV medicine, or an extended release version of a known active) than for the first medicine including an API. This makes sense as the regulatory body, the public and industry are (by then) comfortable with the impacts of the use (in particular safety) of that API in medicines in Australia.

It follows that an EOT should not reward a pharmaceutical patent holder with an extended term for any patent other than an API patent. By definition the API would need to be novel and not obvious for an API patent to be granted in the first place. In particular, EOTs should not be granted for patents for formulations of a known API(s), for re-formulations, processes of manufacture of that known API or therapeutic uses of that known API(s).

The development of subsequent formulations for treatment of other conditions start later in the development cycle for those other conditions as safety has already been established over dosing studies (i.e. toxicology studies) in the original API Phase I trials. Therefore, subsequent formulations for other conditions do not encounter the developmental delays one experiences if starting to develop a new API for market.

The rationale for granting an extension of an API patent, namely an extension for delay (i.e. starting from initial preclinical and carrying out clinical trials) are not present for formulation-type patents, methods, processes or device-type patents, all of which have later filing dates. Their exclusion would be consistent with the apparent legislative intent explained above.

The courts have held, consistent with the above, that a 'pharmaceutical substance per se' within section 70(2)(a) of the Patents Act is a pharmaceutical substance that 'by or in itself'; 'intrinsically' or 'essentially' is in substance disclosed and claimed in the Patent.<sup>15</sup> Section 70(2)(a) 'is only to make extension rights available when the claim is for a pharmaceutical substance as such, as opposed to a substance forming part of a method or process'.<sup>16</sup>

However, these provisions have not been applied logically to different patent types since these findings have been made. Patents to substances as part of a delivery system such as a container with a nozzle or a transdermal patch have been found to be a pharmaceutical substance per se.<sup>17</sup>

The wording of the Patent Act provisions has been interpreted by the Commissioner of Patents and the Federal Court to allow EOTs for formulation-type patents, including, for example:

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<sup>15</sup>*Boehringer Inhelheim International GmbH v Commissioner of Patents* (2001) 112 FCR 595; *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424, 427.

<sup>16</sup>*Boehringer Inhelheim International GmbH v Commissioner of Patents* (2001) 112 FCR 595; *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424, 428, 429, 430.

<sup>17</sup>*Boehringer Inhelheim International GmbH v Commissioner of Patents* (2001) 112 FCR 595; *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424.

- a drug-permeable steroidal drug delivery system;<sup>18</sup>
- a bi-layered tablet;<sup>19</sup> and
- a drug solution comprising the drug salt dissolved in a solvent, the pH of which has been adjusted with an acid.<sup>20</sup>

The Patent Office appears to have formed the view that formulation-type claims are eligible for term extensions. This is because a particularly broad view has been taken by that office as to the meaning of the words ‘pharmaceutical substance’; namely, ‘any mixture or combination of substances that is formed by a union of parts...a tablet formed by the combination of union of two layers falls within the meaning of compound’.<sup>21</sup>

This is clearly inconsistent with the basic legislative intent of the provisions, namely to provide ‘an effective patent life, or period after marketing approval is obtained during which companies are earning a return on their investment, more in line with that available to inventions in other fields of technology’.

Such expansive application of the EOT legislation rewards patentees of non-APIs unfairly and causes the Australian government to incur significant unwarranted extra expense.

GMiA refers to Figure 3 of the PPR White Paper entitled “Types of pharmaceutical patents granted extensions of term”. GMiA conducted its own analysis of the patent types for which all EOTs have been granted on or after 1 January 1999. The results are represented graphically in **Figure 2** below. The relative distribution of patent types identified is similar to that set out in Figure 3 of the PPR White Paper. Importantly, GMiA’s analysis accords with that in the PPR White Paper, each of which demonstrate that a very significant proportion of extensions of term have been granted in respect of non-API patents.

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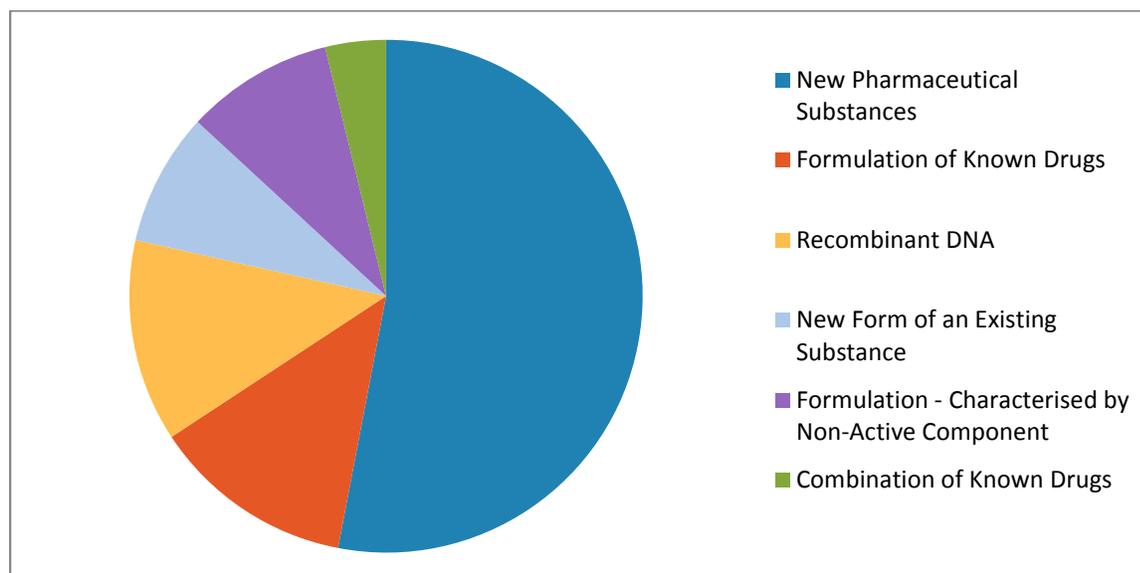
<sup>18</sup>*NV Organon* (2009) AIPC 92-345.

<sup>19</sup>*Sanofi-Aventis* [2007] APO 35.

<sup>20</sup>*Pharmacia Italia SpA v Mayne Pharma Pty Ltd* (2006) 69 IPR 1.

<sup>21</sup>*Sanofi-Aventis* [2007] APO 35 at [36] (Deputy Commissioner Jenkins); *NV Organon* (2009) AIPC 92-345 at [21] (Deputy Commissioner Spann) and *Re Application by LTS Lohmann Therapie-Systeme GmbH & Co KG* (2002) 57 IPR 104 (Deputy Commissioner Herald).

**Figure 2: Types of pharmaceutical extensions of term granted since 1 January 1999**



GMiA has determined that products approved by the TGA in respect of approximately 75 APIs are the subject of multiple patents for which EOTs have been granted. A significant proportion of these patents are non-API patents with an EOT.

***The impact on generic launch of EOTs granted for non-API patents.***

To the extent that a generic product is delayed by such an EOT, the financial impact may be substantial. The GMiA analysis set out in section 2.2, gives an indicative quantification of the financial implications in terms of foregone savings to the government where generic medicine launches are delayed, in that case beyond API patent expiry. Where a generic medicine launch is delayed until expiry of an EOT granted in respect of a *non-API* patent, in comparison to expiry of the original unextended patent term or an earlier launch constraint, the financial impact may be similarly high. As well as the deferral of any Statutory Price Reductions on the Pharmaceutical Benefits Scheme, the government and the public will miss out on other potential savings which naturally flow from the presence of generics, for example due to price disclosure reductions or the inherent downward pressure on prices in a competitive market.

GMiA submits that legislative change giving effect to the original intention of the EOT legislation would remove a barrier to generic market entry by preventing inappropriate extension of the patentee's monopoly and corresponding delay to public access to affordable medication. It would also save the Australian Federal government significant cost.

## 3.2 Question 2: Length of the extension of term

*Question 2: Is the length of the extension of term provided for appropriate?*

### ***Australian manufacture of medicines must be supported***

Australian manufacture of medicines has been suffering in Australia. As the PPR White Paper correctly outlines, Australia is a net importer of medicines. The manufacture of medicines in Australia (in particular generic medicines) is suffering. GMiA requests Government to support local medicines manufacturers by putting them on an equal footing with their overseas competitors by the following reform initiatives:

- Ensuring that EOTs are not inappropriately extended in circumstances where a Sponsor chooses to enter overseas markets but delays its Australian application for regulatory approval; and
- Ensuring that Manufacture for Export (MFE) is expressly exempted from infringement during the patent term extension.

GMiA proposes further changes aimed at supporting Australian manufacture of medicines are also addressed in other parts of this document<sup>22</sup>.

### ***Australian EOTs – why do they expire later than elsewhere?***

At page 8 of the Pharmaceutical Patents Review document there is a presumption that Australian Patents expire later than in other jurisdictions as a result of the differing methods for calculating the extension or differences taken to obtain regulatory approval.

An additional factor which will influence the extension of term and not acknowledged in the Review is the fact that sponsors of branded medicines often seek regulatory approval later in Australia which of course maximises the extension. Given the relatively small size of the Australian market, it is common for pharmaceutical companies to defer seeking regulatory approval in Australia until after approval in larger more attractive markets. If a medicine fails to obtain regulatory approval in the USA or Europe then an originator is unlikely to seek approval in Australia. This has the effect of creating default eligibility for the longest patent term extension, because later filing results in later approval, and therefore a longer EOT.

In an attempt to further understand and test the relative positions of Australia and USA in respect of regulatory delay in approval and timing of respective regulatory applications, GMiA has commissioned research into a comparison of timing of Australian and US dossier submission for products containing new APIs.

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<sup>22</sup>See for example, section 4.1 of this document

The GMiA carried out a further analysis of dossier submission dates in Australia and the US from January 2010 until November 2012. It considers the average time elapsed from dossier submission in the US until dossier submission in Australia, by reference to products in respect of which an application for an EOT was submitted in Australia. The timing of TGA approval, and therefore submission to the TGA, directly affects the duration of an EOT.

These results show that on average sponsors do submit dossiers to the TGA later than equivalent submissions to the FDA, the median delay being 297 days in 2012, 236 days in 2011 and 549 days in 2010.

***Support AU manufacturers by confirming that Manufacture for Export (MFE) during an EOT is allowed in Australia***

The PPR White Paper includes the following summary at page 52. IP Australia refers to TRIPS Article 30 and AUSFTA Article 17.9.6 and comments:

*“The AUSFTA and TRIPS also place restrictions on manufacturers of generic pharmaceuticals wishing to export pharmaceuticals. If an extension of term has been granted for the pharmaceutical in Australia, and that extension has not expired, it is an infringement to manufacture the pharmaceutical without the patent owner’s consent for export to a country where patent protection for the pharmaceuticals has expired or never existed.”*

With respect, GMiA members strongly disagree with this statement, which is not a correct summary of Australia’s international obligations.

GMiA has provided material to Government explaining why manufacture for export (**MFE**) during a patent term extension is clearly compliant with all of Australia’s treaty obligations. In particular, GMiA has brought to Government’s attention legal advice from US Attorneys specialising in international law, confirming that:

- There is no clear objection to MFE under the AUSFTA.
- AUSFTA requires Australia to provide patent term extensions, but allows Australia freedom on how to implement those extensions.
- The Australian Ambassador to the US has advised that once Australia has committed to the proposal, Australia will begin working with the US Department of Trade as well as relevant US officials.
- Israel has amended its patent term extension provisions to eliminate any de facto barrier to trade caused by these provisions. Not only has this substantially contributed to a thriving pharmaceutical industry in Israel, but the US has not taken any positive action against Israel in relation to these provisions.
- The introduction of any of the options for MFE will not impact the global sales or market entry date anywhere in the world, as companies can already manufacture from a number of

countries including Israel, Canada, South Africa, India, China, Brazil, Mexico, Turkey and New Zealand to meet the earliest market entry date anywhere in the world. The proposed measure will only allow Australian based manufacturers to compete fairly with manufacturers based in those countries. As a consequence, there is no commercial downside for patent owners caused by the introduction of these measures.

Further, GMiA has suggested that there are multiple TRIPS and AUSFTA compliant potential ways of implementing MFE, the preferred approach is to amend section 78 of the Patents Act 1990 to make manufacture for export an express exemption to infringement during the patent term extension.

Unless MFE is confirmed for Australia, the consequences for local medicine manufacturers are very significant. Global launches of the medicine will be delayed for the Australian manufacturer, depriving them of the “first (or early) mover advantage” all around the world. Australian manufacturers simply will not be able to compete with overseas manufacturers for early launch regions globally.

The consequences of not-introducing MFE into Australia are very significant. These have been explained in detail by GMiA previously.

GMiA is very concerned that IP Australia has misinterpreted Australia’s international obligations, and in doing so, has deprived Australian medicine manufacturers of the opportunity to make products for global supply. **GMiA requests the panel to reconsider issues regarding MFE in Australia. GMiA requests the MFE be introduced into Australia to protect the local manufacture of medicines.**

The PPR white paper correctly points out that Australia is a net importer of pharmaceutical products. This will not change unless the Australian Government introduces reforms to support local manufacture. Allowing MFE is a simple, effective, TRIPS/AUSFTA compliant, means to do so.

## 4 Patent standards

### 4.1 Question 3: thresholds for patent grant

*Question 3: Are the recent amendments to increase the thresholds for the grant of an Australia patent appropriate in the context of pharmaceuticals? If not, why not and what further changes are necessary?*

#### ***Raising the Bar Bill - previous GMiA submissions***

GMiA made a submission to IP Australia in April 2011 regarding the (as it was then) Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 ("**Raising the Bar Bill**")<sup>23</sup>.

In general, GMiA suggested that the changes introduced under the Raising the Bar Bill went a significant way toward achieving the right balance between granting strong patents, stimulating research, the interests of patentees, and the interests of society, and strongly supported the vast majority of the amendments proposed by the Bill.

However, it must be understood that the current balance of laws is not in the public's best interest. Patents that have been invalidated in other jurisdictions continue to deliver the owners of these patents rents in Australia, resulting in higher prices to the Australian public. Local researchers are disadvantaged given the broader reach of Australian patents. Granting of weak patents restricts innovation, competition and diffusion of knowledge and unnecessarily increases the cost to the public.

GMiA had also suggested further amendments to the Raising the Bar Bill, which were not accepted by the Government. GMiA believes that such further changes would start to correct the remaining imbalance.

#### ***GMiA does not support a "technology specific" patent threshold correction***

There are issues unique to the pharmaceutical industry which must be specifically addressed in Australian patent law. For example, issues relating to pharmaceutical extensions of term addressed in response to Questions 1 and 2 above are, appropriately, industry specific.

GMiA considers that issues relating to appropriate thresholds for the grant of a patent are not industry specific, and should be addressed holistically bearing in mind the implications for Australian industries.

Australian patent law, has for a long time, been out of step with the law in Australia's major trading partners. Even on similar legislative wording, the effect has been that patents the counterparts of which are either not granted, or granted and then revoked overseas, remain in force in Australia. GMiA has a number of suggestions in this document to further correct this Australian imbalance.

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<sup>23</sup>See GMiA submission of 4 April 2011

GMiA applauds the amendments introduced to s7(2) and s7(3) of the Patents Act 1990 (**the Act**) under the Raising the Bar Bill. However, GMiA believes that those amendments did not go far enough to correct the imbalance, as outlined here.

***GMiA suggests further threshold amendments are required***

***Inventive Step***

GMiA has previously submitted that it believes that IP Australia should legislate to formally raise the legal standard for establishing inventive step.<sup>24</sup> GMiA maintains its opinion that the changes to the guidelines for inventive step in the Examiner’s Manual will not clearly and permanently remedy the situation. This is because IP Australia is still bound by the current High Court authority which only requires a “scintilla” of invention<sup>25</sup> notwithstanding that the *Atkiebolaget Hassle v Alphapharm Pty Ltd*<sup>26</sup> (“**Alphapharm test**”) prescribes a narrower test which requires the pre-existence of a problem needing to be solved.

GMiA acknowledges that IP Australia has implemented a more rigorous examination of patent applications on the question of obviousness in recent years. However, if the standard for inventive step is not raised in the legislation, there remains a possibility that the test will be subject to future trends in the Patents Office and changes in examination practice. Moreover, given the High Court’s stated low threshold for inventive step, there will inevitably be appeals from decisions of the Commissioner of Patents (“**the Commissioner**”). This poses a real risk that the courts may overturn IP Australia’s current stricter approach to testing obviousness as a purported exercise of the Alphapharm test.

GMiA remains concerned that either (i) the “scintilla” authority, or (ii) an undue strict interpretation of the Alphapharm test, may ultimately undermine IP Australia’s efforts at raising the bar on inventiveness.

GMiA urges IP Australia to legislate on this issue as set out in our previous submissions to IP Australia.<sup>27</sup>

***Raising the Bar amendments should apply to all pending applications***

As the Issues Paper correctly identifies, the effects of many of the amendments introduced by the Raising the Bar Bill will not be seen for many years. The issue here is that amendments aimed at raising the patentability standards in Australia apply only to complete applications made on or after 16 April 2013, or applications made before 16 April 2013 where an examination report has not yet been requested.

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<sup>24</sup> See GMiA’s submission to the consultation papers entitled “Towards a Stronger and More Efficient IP Rights System” February 2010. See also GMiA’s submission to IP Australia on the Raising the Bar Bill in April 2011.

<sup>25</sup> *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2007) 235 CLR 173.

<sup>26</sup> (2002) 212 CLR 411.

<sup>27</sup> See GMiA’s submission to the consultation paper entitled “Getting the Balance Right”, May 2009.

This disappointing delay to the effective implementation of the new provisions deprives the Australian community of timely access to many inventions. It will also result in patent applications being granted after the introduction of the new legislation which do not meet the standards required by the new legislation.

GMiA is particularly concerned that the amendments to s 7(2) and s 7(3) do not apply to all pending standard patent applications, but only to (a) complete applications filed after 16 April 2013, and (b) pending applications where no examination request has been filed prior to 16 April 2013. For pending applications, it is at the absolute discretion of the patentee as to whether they want the “old” law, or the “new” law to apply.

GMiA has previously commented on the issues arising from this implementation “time lag”<sup>28</sup>, and recommended a number of ways statutory reform could be implemented with immediate effect. The Raising the Bar Bill amendments were aimed at bringing Australia’s standards for patentability into line with other jurisdictions and thereby prevent weak patents being issued with the associated costs to society. By failing to implement these amendments with immediate effect, Australia has delayed any such alignment by a number of years and forgone an opportunity to create certainty in the application of the law and for the public. As a result, patents with weak validity will continue to be granted under out-of-date laws which fail to acknowledge how information currently becomes part of the prior art base. GMiA notes this with disappointment.

#### **Further suggested amendments supporting Australian manufacture**

GMiA refers to the background comments above describing the impediments to the local manufacture of medicines where medicines (in particular generic medicines) are intended for global supply<sup>29</sup>. GMiA explained there why Australian manufacturers are disadvantaged in relation to the EOT regime, and suggested a number of amendments to address this.

GMiA wishes to bring to the Panel’s attention one further such impediment with serious deleterious consequences for Australian manufacturers.

Regulatory bodies globally require validation of the commercial scale process to ensure there is appropriate level of comfort regarding the manufacturing process for medicines. In order to provide data for process validation purposes, manufacturers usually will run multiple commercial scale batches for the manufacture of the product. Running multiple commercial scale validation batches is very costly and time consuming and uses up expensive API.

US patent law contains a statutory “safe harbour” for products or activities that would otherwise be infringing if they are solely for uses reasonably related to submission of required information to the

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<sup>28</sup> Ibid

<sup>29</sup> See section 3.2 of this document (in response to Question 3 of the PPR White Paper)

FDA. 35 U.S.C. § 271(e)(1) provides “It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . .”).

The US law further provides that if a product, including multiple process validation batches of a drug, is manufactured for the purpose of meeting the requirements of the FDA in relation to regulatory approval, not only does that activity fall within the safe harbour (so there is no infringement pre-patent expiry), sale of that product post-expiry cannot infringe the patent, which no longer has force and effect in the US.

US manufacturers may legally retain product produced by these batches, and sell them after expiry (or revocation) of the relevant patent. It is not an act of infringement to make such product (pre-patent expiry) or to keep it (pre-patent expiry) for purposes of supply post-patent expiry.

It is not clear that Australian suppliers have the benefit of such an exemption because of comments made by Government in the EM for the *Raising the Bar Bill*.

The EM for the *Raising the Bar Bill* included the following statement in relation to s119B (which the Bill amended):

*“The use of ‘solely’ ensures that a generic manufacturer may not use the exemption for purposes other than seeking regulatory approval. For example, they may not, in the process of seeking regulatory approval, stockpile the patented product for sale upon expiry of the patent, or manufacture the product for export to another country.”*

*The amendments are not intended to limit the type of regulatory approval for which the exemption may be used, save for the requirement that it must be imposed by law (in Australia or another jurisdiction). The provision is intended to account for changes in existing regulatory requirements. It is also intended to cover regulatory requirements that do not exist now, but may be imposed in the future as new regulatory regimes are created.”*

GMiA submission on the Raising the Bar Bill<sup>30</sup> included the following statement:

*“GMiA is of the opinion that the following paragraph should be deleted from the Explanatory Memorandum:*

*The use of ‘solely’ ensures that a generic manufacturer may not use the exemption for purposes other than seeking regulatory approval. For example, they may not, in the process*

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<sup>30</sup>4 April 2011

*of seeking regulatory approval, stockpile the patented product for sale upon expiry of the patent, or manufacture the product for export to another country.<sup>31</sup>*

*GMiA is concerned that the above statement would be taken to apply to s 119A as well as s 119B as the word 'solely' is also in s 119A. The above statement is broad enough to be considered applicable to both s 119A as well as s 119B. GMiA strongly believes that the above statement is not an accurate reflection of the law with respect to s 119A on many levels. For example, it would not apply to method of treatment patents."*

Unfortunately the GMiA recommendation was not accepted, and this incorrect summary was included in the EM for the Raising the Bar Bill.

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<sup>31</sup>Explanatory Memorandum, pg 42.

## 5 Judicial issues

### 5.1 Question 4: challenges to patents - opposition and re-examination

*Question 4: Do the systems for opposition and re-examination provide appropriate avenues for challenging the granting and validity of a pharmaceutical patent?*

#### *Summary*

GMiA recognises that recent reforms have made improvements to the scope of matters to be considered during examination and opposition, and applauds those reforms.

However, GMiA Members submit that whilst systems for opposition and re-examination provide avenues for challenging the grant and validity of a pharmaceutical patent, those avenues are failing to provide appropriate and workable alternative systems to patent litigation.

In particular:

- Re-examination findings are not subject to challenge or opposition, and the proceedings are ex parte so the public has little/no involvement in the examination process;
- Appeal on oppositions/re-examinations to Courts serve to delay public certainty regarding the scope of the patent, and also delay infringement/revocation suit on the broader s18 grounds;
- Patent Examiners are insufficiently resourced to provide thorough and robust analysis of patent applications;
- Key Performance Indicators for Patent Examiner performance require Patent Examiners to process patent applications in a timely fashion but do not sufficiently require robust examination to the point of ensuring the grant of strong, defensible patents.

The last 2 points in particular may undermine the public's trust of the APO, and in particular, may result in concerned persons preferring to have their validity concerns heard by the Courts, rather than relying on the APO to determine the matter.

The consequences are very significant. The cost of "bad patents" to generic medicines suppliers, to the public, and to the government are too significant to ignore.

GMiA recommends improving the quality of patents coming out of the APO process, rather than overhauling the patent system. GMiA respectfully submits that greater upfront quality control by the APO will minimise reliance on litigation. **GMiA acknowledges that additional "quality control" measures in the APO will require additional resources. Such additional resources will cost money, but**

**this will be significantly LESS costly for Government than health care costs to the government if the supply of generic medicines in Australia is inappropriately delayed by poor quality patents.**

**Recommendation 1:** GMiA recommends that greater resources be available to Patent Examiners, and that a more stringent review of the merits of the application be required at an early stage of Examination. This would result in better quality/defensible patents being granted by the APO.

**Recommendation 2:** GMiA requests IP Australia to ensure that there is a cultural lack of tolerance for the grant of weak patents at the APO. GMiA proposes that Patent Examiner Performance Indicators should include a qualitative assessment of the strength of the patents granted by Examiners.

### ***Patent challenge systems are not workable alternatives to litigation***

As noted by the Review Panel in the Background and Suggested Issues Paper (at page 20):

*"Efficient and effective mechanisms for challenging patents are an important element in maintaining a robust and appropriately balanced intellectual property system. Third-party challenge systems aim to provide a rapid, inexpensive **alternative** to litigation and additional mechanisms to ensure the validity of granted patents.*

***Certainty** regarding patent validity contributes to ensuring the patent system confers intellectual property rights as intended." (Our **emphasis** added.)*

If that statement provides guidance as to how the Panel would define the scope of "appropriate" in terms of Question 4, then the critical issues are:

- (1) are the systems a workable alternative to litigation?; and
- (2) do those systems provide certainty regarding patent validity?

In brief, it is clear that the non-judicial (Patent Office based) systems of examination (including third party notification), pre-grant opposition, and re-examination overall provide a relatively rapid and inexpensive means for challenging and determining the validity of a patent claim (and in "refining" or "editing" a patent application to provide a valid granted patent).

GMiA acknowledges that those systems have been strengthened by at least 3 aspects of the recent statutory changes made by the Intellectual Property Laws Amendments (Raising the Bar Act) 2012. These changes are: (1) increasing the standard of proof required during considerations of validity from "benefit of doubt" (to the patentee) to "balance of probabilities"; (2) expansion of the prior art base that

can be considered for analysis of inventive step and (3) expansion of the grounds of invalidity that can be considered at examination and re-examination. GMiA welcomes these changes<sup>32</sup>.

However, even in light of these changes, ***the systems do not provide the required certainty or a workable alternative to litigation*** – mainly because of the ready (and likely) possibility of appeal; with the *de novo* hearing of any or all of the issues that previously were considered by the APO. In reality, the only issues that are likely to be settled at this stage are those that are clearly untenable. All others will be subject to re-hearing in Court.

Each of the above procedures has benefits. However, opposition and re-examination are "reactive" procedures and seek to correct or add to matters that could (and GMiA Members say *should*) have been addressed by the Examiner.

Both opposition and re-examination are subject to appeal. Realistically, most pharmaceutical patent owners would exercise the right to appeal, even if the possibility of success were small. This substantially increases costs, delays the ultimate settlement of the matter and leads to public uncertainty regarding the scope of the monopoly.

It would be preferable to provide better support for the patent examination process to ensure that as much information as possible is provided to the Examiner at First Report stage. In addition, the Examiner should be allowed to dedicate sufficient time to consideration of the submissions made by the applicant in response to examination reports and in determining second and subsequent ("further") examination reports. Whilst it is true that there usually would be fewer tasks to perform during further examination, we believe that the issues at that stage would be more complex and important and would require more in-depth analysis and consideration. GMiA also requests IP Australia to introduce a scheme of Examiner collaboration and peer review for further reports.

With added support and consequent more stringent review of the merits of the applicant's submissions, the examination process would be more robust, leading to the grant of "better" patents.

If most (if not all) issues of potential invalidity could be removed during examination, there would be less need for the time-consuming, potentially costly and uncertain post acceptance/grant avenues of challenge.

GMiA has had difficulty obtaining full information on Patent Examiner's metrics. GMiA understands however that relatively recently Examiner's performance was measured by the number of "first report equivalents" that an Examiner completed in a given period. In that system, "further" reports were given a "performance value" of a fraction of a first report. That was meant to reflect the amount of time that an Examiner generally would spend on a further report but, as mentioned above, we would argue that

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<sup>32</sup>See for example GMiA submission to IP Australia in April 2011 regarding the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011.

the Examiners should be allowed more time in reviewing the applicants' responses and in preparing further reports. GMiA understands that current performance metrics do not place appropriate reliance on good quality examination. Rather, the focus of the metrics appears to be completing examination within a certain time period. GMiA Members believe that the Australian public is suffering as a result due to poor quality patents that are being granted in Australia compared to overseas.

Recently, IP Australia made a public announcement about its speedy examination time – discussed here <http://blog.patentology.com.au/2011/03/is-ip-australia-envy-of-patent-world.html>. With respect, GMiA submits that a quick result is not necessarily a good result; if that quick result is achieved at the expense of the "quality" of the granted patent. With the reform initiative that we propose, we hope that the patents that are granted are defensible and will stand when challenged on appeal.

GMiA Members routinely see patents granted in Australia which are very much broader in scope than counterpart patents granted elsewhere. This is unacceptable. GMiA would like to see a cultural lack of tolerance for the grant of weak patents at the APO. In order to ensure this occurs, GMiA suggests IP Australia build in relevant key performance indicators for Patent Examiners which reflect a qualitative assessment of the strength of patents granted in Australia, together with a comparison of the breadth of claims granted in Australia as compared to its major trading partners.

It is very important for IP Australia to understand the consequences for the generic medicines industries of poor patent quality in Australia. When a “bad” patent (i.e. one which on a robust assessment is not valid) is granted by the APO, the following occurs:

- a generic medicine supplier bears the burden of correcting the patent landscape by commencing re-examination or the Courts (usually the latter);
- that burden is significant given the costs (time, resources and legal) of patent litigation in Australia;
- where proceedings have not concluded prior to proposed generic launch date, interlocutory relief (by way of an injunction) is routinely sought, and routinely obtained on that “bad” patent.
- the Federal Court of Australia is influenced at the interlocutory stage by the mere fact that the APO has granted the patent, considering this to be relevant to a prima facie assessment of patent validity<sup>33</sup>.

Where appropriate rigour is not applied at the APO level, the public health consequences are very significant. The supply of generic medicines is wrongly delayed in Australia, and the cost to the PBS and the public is very significant.

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<sup>33</sup> See Yates J in *Novartis AG v Hospira Pty Ltd* [2012] FCA 1055 (28 September 2012 paragraphs 51, and 92 – 94).

As discussed above, additional “quality control” measures in the APO will require additional resources. Such additional resources will cost money, but this will be significantly LESS costly for Government than health care costs to the government if the supply of generic medicines in Australia is inappropriately delayed by poor quality patents.

## 5.2 Question 5: interlocutory relief

*Question 5: Do interlocutory injunctions, as the law is currently applied, provide appropriate relief in cases involving pharmaceuticals?*

### **Background: Interlocutory Injunctions**

GMiA has consistently maintained that the patent system is an important and essential means by which research and development is encouraged and rewarded. GMiA has also consistently maintained that the reward must be appropriate and not develop into a means to unfairly prevent sponsors of generic medicines introducing their products onto the Australian market.

Determining what is a proper reward is complex. As explored in question 1 relating to extensions of term for pharmaceutically related patents, once a patent is granted then it is possible for patents to be extended under certain circumstances.

It is unusual for generic medicine sponsors to endeavour to market a generic drug prior to the expiration of the API patent as normally such are new molecules and therefore likely to be novel. Accordingly, the following comments concern interlocutory relief granted for other pharmaceutical related patents (i.e. pharmaceutical formulations, methods, processes and device-type patents).

At present, it is only in exceptional circumstances (basically in strong non-infringement cases or where there is no live PBS issue) that an originator will not obtain an interlocutory injunction against a generic sponsor irrespective of the type of pharmaceutical patent asserted or its apparent invalidity. In fact, in the past 8 years there have been 22 proceedings concerning pharmaceuticals and medical devices, and in which interlocutory injunctions have been sought. Interlocutory injunctions have been granted in 18 of those cases and another granted by consent. Only one has been overturned on appeal. Therefore in only 4 cases has an interlocutory injunction been refused or revoked.

An added complication in pharmaceutical cases is that the generic Product Information leaflet (required to be provided for regulatory marketing approval) will be almost identical to that of the originator because the generic is asserting bioequivalent to a prescription drug. Hence any non-infringement case may be weak where the patent asserted is either a method of use and the originator pharmaceutical substance has only one approved use.<sup>34</sup>

Further, on the current authorities, a very strong obviousness case will never be a sufficient defence to avoid the grant of an interlocutory injunction. Inevitably, the originator will find a person skilled in the art able to assess the common general knowledge and/or prior publications differently to a generic sponsor's experts (at least at the interlocutory injunction stage, as the evidence whilst sworn is not

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<sup>34</sup>See GMiA response to PPR Question 6 in this document.

tested under cross examination). The court will not be in a position to test that competing evidence at that time.

Courts have also interpreted section 117 of the Patents Act as a wide provision which may capture generic conduct as an infringement which is otherwise non-infringing conduct by doctors. The interlocutory decision concerning this section in *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* is currently on appeal to the Full Federal Court.<sup>35</sup> Likewise, a special leave application to the High Court has been recently granted in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2)*<sup>36</sup> to review the operation and interpretation of that section. GMiA discusses this in detail in response to PPR Question 6 below.

In interlocutory injunction applications, the balance of convenience has fallen persistently against generic sponsors. As the generic medicine is a new entrant, it is always alleged by the originator that it will experience immediate adverse effects under the PBS pricing legislation (if applicable) if a generic medicine sponsor is permitted to launch.

So, disproportionate interlocutory relief is currently being granted against generic sponsors in patent litigation due to a combination of these factors.

GMiA Members believe the Australian legal framework should be changed to appropriately balance the protection of truly innovative medicines with processes which enable stakeholders to challenge patents of questionable validity and to avoid unmerited enforcement strategies. The stakeholders in such an outcome are not just the generic sponsors but the Australian government (for the Australian public) which suffers through delayed generic entry.

GMiA Members believe that the current damages undertaking given by an originator to the court in exchange for an interlocutory injunction does little to dissuade an originator from seeking an interlocutory injunction. The sanctions provided for under the Therapeutic Goods Act 1989 (Cth) (see section 26D) introduced in 2004 are still untested and present a low deterrent to originators seeking interlocutory injunctions.

Damages payable to a generic medicine sponsor are an inadequate disincentive and absent positive recovery action by the Australian government for its loss, there is no real deterrent to an originator seeking and relying upon an interlocutory injunction.

As is well known, the profitability per originator product sold (absent a generic product) is much higher than that attributable to a generic product once on the market. Consistently, upon generic product entry, the price of the originator product falls significantly but still competes, being evidenced by an otherwise high profitability. If a generic medicine sponsor is able to call upon an account of damages it

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<sup>35</sup>[2012] FCA 239.

<sup>36</sup>(2012) 290 ALR 1.

has endured as a result of the grant of an interlocutory injunction (i.e. upon a holding of invalidity at final trial or appeal), that account will never approximate the profits made by the originator during that same period. The difference basically represents the added expenditure by the Australian government under the PBS which is maintained at higher prices. Whilst the Australian government has raised the possibility of seeking damages under the damages undertaking (which includes third party damage), little has eventuated (though in the 2012 Federal Budget, a line item was included for expenses associated with seeking such damages). Consequently, to date that prospect has not appeared to deter originators seeking and securing interlocutory injunctions.

In light of these various factors, which are peculiar to pharmaceutical patent litigation, GMiA strongly recommends reform to redress this balance, and particularly to remove incentives to seek interlocutory injunctions regardless of patent strength. Reforms are required to avoid delays in generic market entry and thereby reduce the costs of pharmaceuticals to the government.

### 5.3 Question 6: contributory infringement

#### *Question 6: Is Australian Law on contributory infringement appropriate in relation to pharmaceuticals?*

##### ***Executive Summary***

GMiA members are very concerned about law regarding contributory infringement of patents in Australia.

The development of Australian law regarding contributory infringement has resulted in inappropriate potential liability for suppliers of generic medicines in Australia. The scope of that potential liability is inconsistent with both Australian legislative intent, and the position overseas (where it does not exist).

Such potential liability applies to both suppliers of generic medicines and suppliers of other therapeutic medicines in Australia.

A finding of contributory patent infringement in circumstances where the patented use has been “carved out” of the product label (and the generic supplier otherwise does not otherwise promote the product for that use) prevents the generic pharmaceutical manufacturer not only from supplying the drug for the patented indication but also from supplying it for any non-patented indication.

Such a result is clearly detrimental to the Australian public, the Government and to suppliers of medicines in Australia. The sale of generic products will be significantly delayed by inappropriate injunctions, and that delay will be for as long as the Sponsor can continue to “find” new uses for its product. By this mechanism, Sponsor’s will be motivated to continue to develop patent thickets (primarily focusing on use patents) thereby effectively prohibiting the development of generic medicines for legitimate non-infringing uses, and indefinitely delaying the supply of affordable medicines in Australia.

GMiA submits that suppliers of medicines (generic medicines and other therapeutic medicines) in Australia ought not be exposed to such potential risks. For the reasons set out below, GMiA requests the Government to amend s117 of the Patents Act to ensure that a “carve out” of an indication on the product label will be sufficient to ensure there is no contributory infringement of any related use patent (unless the medicine supplier otherwise represents that the product is suitable for such use).

### ***Use patents in Australia***

In Australia methods of medical treatment are presently patentable<sup>37</sup>. Consequently, patent claims in the form “The use of substance X for the treatment of condition Y” are frequently deployed by pharmaceutical patentees. Patents are also available to originators for new uses of known drugs<sup>38</sup>.

Assuming for present purposes that methods of medical treatment are properly patentable<sup>39</sup>, then GMiA recognises that inventors ought to be entitled to a reasonable scope of patent protection for the use of a pharmaceutical substance to treat new, non-obvious indications.

A balance needs to be struck so as to provide originators with a reasonable scope of patent protection for new, non obvious indications but without placing pharmaceutical manufacturers in the uncertain legal territory of being exposed to contributory patent infringement liability for marketing an off patent product for a non patented indication.

### ***What is contributory infringement?***

As outlined in the PPR White Paper, contributory infringement is a form of “indirect” infringement. In loose terms, a person is found to be *indirectly* infringing a patent where it does not directly engage in the infringing conduct, but either directs the party to infringe or (relevantly) contributes toward the infringing conduct. The potential liability for indirectly infringing a patent is the same as the potential liability for directly infringing it.

GMiA Members agree that where one person directs another party to infringe, there should be infringement.

It will generally be well understood what “directing” will mean, and GMiA does not wish to focus on this here.

GMiA Members are concerned about potential exposure where pharmaceutical companies have taken various steps to ensure that they are not actively “promoting or inducing” others to use their product in a certain way. When a medicine supplier takes steps to ensure that its product label does not include a patented use as an indication, and ensures that it does not otherwise recommend the use of the product in an infringing manner, GMiA Members strongly believe that there should be no *indirect* infringement.

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<sup>37</sup> Subject to the decision of the High Court of Australia in *Apotex v Sanofi Aventis* in which special leave to appeal on this issue was recently granted.

<sup>38</sup> Assuming the other standards of patentability such as novelty and inventive step are satisfied.

<sup>39</sup> Id, note 39

GMiA proposes the following worked **Example**:

- Active ingredient A was the subject of a compound patent now expired (**API Patent**).
- A first use patent (**U1 Patent**) (now expired) claimed the use of A in the treatment of medical condition U1.
- A product including A is approved by the TGA for U1 - U1 is “on label”.
- Subsequently, a second patent (**U2 Patent**) is granted for the use of A to treat condition U2. A is also subsequently approved by the TGA for U2 - U2 is “on label”.
- There are now 2 uses included by the Sponsor on its product label for A: U1, and U2.
- Whilst the patent for U2 is still in force (but after expiry of the API patent and the U1 Patent) a supplier of a generic medicine decides to develop Generic A for supply in Australia. It is apparent that the use of Generic A for U1 would be a legitimate, non-infringing use.

The supplier of Generic A may choose either of the following options for its regulatory approval:

- **Option 1:** Obtain approval for its Generic A for U1 and U2 by seeking TGA approval for both indications; or
- **Option 2:** Obtain approval for its Generic A for U1 by deleting U2 from the indication set in its product label. This is referred to in the industry as an indication “carve out”. The supplier of Generic A has “carved out” U2 from its product label.

GMiA strongly submits that the generic medicine supplier which adopts Option 2 should not be found to be infringing the U2 Patent unless it otherwise promotes Generic A for U2. The U2 indication “carve out” should be sufficient to circumvent the U2 Patent (in the absence of other relevant behaviour).

GMiA Members are very concerned that it is not clear that this is the law in Australia, and requests legislative clarification of s117 of the *Patents Act* accordingly.

## 5.4 Question 7: limitations period for patent infringement

*Question 7: Are the current timeframes in which infringement proceedings must commence appropriate for pharmaceutical patents?*

No. GMiA submits that the current limitations period leaves generic medicines companies exposed to a potentially very significant damages liability for an unnecessarily excessive period of time. Accordingly, GMiA requests the Government to reduce the limitations period in Australia for infringement of pharmaceutical patents to 1year from the act of infringement. GMiA believes that a 1year limitations period for pharmaceutical patent infringement would encourage swift resolution of patent infringement disputes and assist to contain the potential damages liability for an alleged infringer, without compromising the Patentee's ability to enforce its intellectual property.

## 5.5 Judicial issues – Other: Reducing the cost and complexity of patent litigation, and incentivising patent revocation in Australia

The granting of a patent provides the holder with exclusive monopoly rights. The granting of an Australian patent does not guarantee its validity. If the patent is subsequently found to be invalid, the patentee has obtained the economic benefit from the invalid patent. Noting that patents are not guaranteed validity under the Patents Act, the patentee has no legal or moral basis for retaining the benefit of the economic value provided by the invalid patent during the period in which it is improperly in force. The economic value of that benefit is unmerited and should be repaid to the government.

An analogy can be drawn with an entity that has under paid taxation. When it is discovered that the entity has under paid taxation, appropriately the entity is required to make payment of the unpaid taxation. The retention of the unpaid tax would undermine the integrity of the tax system.

**Moreover, the unjust enrichment of patentees encourages bad behaviour and the gaming of the patent system both of which have negative implications in regards to market behaviour and inefficiency.**

The limited resources of IP Australia and the relative expertise of patent applicants can undermine the robust examination of patent applications.

A significant burden is placed on generic medicine suppliers, who bear the burden of removing inappropriate patent barriers through the Courts. Patent litigation in Australia is relatively expensive. GMiA has identified the relative global pharmaceutical market size in Figure 1 in Chapter 2 of this document. It is very clear that the size of the Australian market is dwarfed by the size of the pharmaceutical markets in the US and Europe. This is mainly due to the relative population sizes of these regions.

Despite the fact that the US and EU markets are significantly larger than the Australian market, the costs of patent litigation in Australia approximate (a) half of the costs of similar patent litigation in the US, and (b) half of the total costs of similar patent litigation in multiple European regions (i.e. half the total costs involved in conducting litigation in several European regions at the same time). It is very clear that the patent litigation “investment” in Australia will not reap comparable commercial returns for suppliers of generic medicines as it does elsewhere.

The relative costs of patent litigation in Australia is exorbitant (estimated to be in excess of \$4-7 million per pharmaceutical patent case). The risks associated with pharmaceutical patent litigation are very significant, often requiring two if not three levels of judicial review (i.e., Federal, Full Federal and High Courts). The risks facing the generic litigant in Australia are greater than those overseas due to the

Australia-specific patent law challenges outlined here<sup>40</sup>, including in particular the high likelihood of an injunction being granted.

In this respect the cost and complexity of the litigation process itself acts as a structural barrier to timely generic launch in Australia.

***The odds are not in favour of suppliers of generic medicines in Australia.***

Whilst action has been taken in the recent Raising the Bar legislative changes to strengthen the examination and hopefully the ultimate validity of patents, for pharmaceutical patents those changes are unlikely to have any immediate effect or long term effect. The reality is that for at least the next 20-25 years, already-issued patents of weak validity will still be problematic to the generic pharmaceutical industry in Australia. The system is, and will be for the foreseeable future, reliant upon parties with a commercial interest to test the merits of such granted patents.

An invalid pharmaceutical patent (which has not been challenged successfully and revoked), detrimentally affects the Government's funds and the Australian economy generally. At present there is no incentive, other than market access (which will then be open to all comers), for generic sponsors to bring a pharmaceutical patent challenge. However, the benefit of the generic litigant's success flows directly to the government and to the Australian public. GMiA believes that if appropriate incentives were put in place, more proceedings would be commenced in Australia, and more invalid patents will be revoked.

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<sup>40</sup>See section 1.3 of this document

## 6 Follow-on patenting

### 6.1 Question 8 patent thickets

*Question 8: Are follow-on patents being used to inappropriately extend protection for pharmaceuticals? If so, how? And, if they are, is this sound policy and what changes, if any, are needed.*

GMiA Members remain very concerned about the inappropriate use of follow-on patents to extend protection for pharmaceuticals.

GMiA outlined in Section 1.3 of this document the multiple factors which result in the delayed supply of generic medicines in Australia. Drawing from the results of the 2009 EU Commission Report, GMiA outlined how behaviours and strategies used by global pharmaceutical companies inappropriately delay such supply. GMiA will not repeat that here, but refers the Panel to Section 1.3 of this document.

GMiA also explained in Section 1.3 why the delaying effect of such behaviours is multiplied in Australia due Australia-specific legal considerations, including inappropriate grants of extensions of term (discussed further in Section 3.1 here); poor patent quality in Australia (discussed further in section 5.1 in response to PPR Question 4); delayed implementation of the Raising the Bar Act initiatives (discussed further in Section 4.1 in response to PPR Question 3 here); internationally unique very high likelihood of interlocutory injunctions (discussed further in section 5.2 in response to PPR Question 5); internationally unique pro-patentee position on contributory infringement in Australia (discussed further in section 5.3 in response to PPR Question 6 here); unnecessarily long limitations periods for commencement of patent infringement suit (discussed further in section 5.4 in response to PPR Question 7 here) and the fact that the generic supplier carries the burden of patent certification in the absence of any simple means to identify relevant patents (discussed further in section 7.2 in response to PPR Question 10 here).

**The cumulative effect of all of these issues is that the Australian health/legal system is pro-patentee.**

GMiA members request the government to consider the use of “follow-on” patents in light of the multiple impediments to the supply of generic medicines in Australia outlined here.

#### ***Typical pharmaceutical patenting practice***

The typical patenting practice for a pharmaceutical company is to build a patent “portfolio” around its product. There are a number of reasons for this, but the main goal of the patentee is to maximize the market monopoly. A typical patent portfolio for a small molecule<sup>41</sup> medicine will contain the following:

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<sup>41</sup> Patent portfolios for large molecules (biologics) follow the same general themes

1. Patents to the **API**
2. Multiple patents to various **formulations** containing the API, one of which will be the commercial formulation
3. Multiple patents to various **methods of treatment** using the API, a subset of which will (initially or ultimately) be approved as an “indication” on the product label by the TGA
4. Multiple patents to various **combination uses** for the product, a subset of which may (initially or ultimately) be included as an approved “indication” on the product label for the commercial product
5. Multiple patents to **upstream processes** for making the product. These processes may or may not be used by the manufacturer. In some cases, the method used by the manufacturer is kept “secret” to ensure that manufacturers do not disclose their simplest/cheapest/cleanest process to their future competitors.
6. Multiple patents to **downstream processes** for making the product. Again, these processes may or may not be used by the manufacturer, and the preferred method may be kept “secret”.
7. Multiple patents to various **process intermediates**
8. Multiple patents to **various dosage regimes**, a subset of which will be the TGA-approved dosage regime(s).
9. Patents to the active **metabolites** of the API
10. Patents to the **impurity profiles** of the TGA-approved formulated product
11. Patents to the **physical features** of the API, process intermediates and/or the formulated product (e.g. particle size, enteric coating etc)
12. Patents to various **isomeric forms** of the API
13. Patents to various **crystalline forms** of the API, process intermediates and/or the formulated product
14. Patents to various **salt forms** of the API, process intermediates and/or the formulated product
15. Patents to various **container closure** systems, including the container closure system used by the product Sponsor in the TGA-approved product.

16. Patents to **devices and delivery systems supporting administration of the medicine** (e.g. machines, syringe systems, patches).
17. Patents to **analytical techniques** used to test the product at various stages of manufacture and/or development. A subset of these techniques may be included in various Pharmacopoeia (which set the standard for analytical data required by the TGA and its overseas counterparts for the assessment of pharmaceutical products)

In general, patent applications will be filed in the approximate order outlined above. For example, a patentee will first seek a patent for the API, and will subsequently file a patent application for formulations etc. Necessarily, the scope of the claims of the patent sought will narrow as the patent landscape begins to get crowded. Inevitably the patenting strategy will result in multiple patent families (often each with multiple patents) covering various overlapping aspects of the medicine. The goal of the patentee in doing so is:

- To continue to extend its market monopoly on the medicine for the full term of the last expiring patent or (failing that) to extend its market monopoly for as long as possible; and
- To patent broadly enough around the commercial product to prevent competitors “designing around” patents for the commercial product;
- consume resources of competitors (time, energy, cost) in identifying and analysing very significant numbers of patent applications.

The PPR White Paper has also rightly identified that patent applications will also be filed by parties other than the product sponsor, including research companies, generic medicine suppliers, and competitor manufacturing companies.

GMiA Members advise that a Freedom to Operate (**FTO**) analysis for a product in Australia will typically involve Members reviewing 100 - 500 potentially relevant patent families (each of which may have multiple patent applications, and/or patents). It is not uncommon for Members to review more than 500 potentially relevant patent families in a FTO analysis. It is not unheard of for Members to review more than 5,000 potentially relevant patent families in a FTO analysis.

The 2009 EU Commission Report<sup>42</sup>, summarises the position in Europe as follows:

*“The pharmaceutical sector is one of the main users of the patent system.... Patents concerning the active substances are also referred to by the industry as “primary patents” because they relate to the first patents for their medicines. Further patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations are referred to by the*

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<sup>42</sup> Discussed in Section 1.3 of this document

*industry as “secondary patents”. In general, blockbuster medicines’ patent portfolios show a steady rise in patent applications throughout the life cycle of a product, also after product launch. Occasionally they show an even steeper increase at the end of the protection period conferred by the first patent. In patent litigation cases originator companies often rely on patents that were not yet filed when their product in question was launched...*

*....Filing numerous patent applications for the same medicine (forming so called “patent clusters” or “patent thickets”) is common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines.*

*In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families which can lead to up to 1,300 patents and/or pending patent applications across the Member States.*

*When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their ability to enter the market. Statements in internal documents collected in the context of the sector enquiry point at the awareness by patent holders that some of their patents might not be strong.”<sup>43</sup>*

### **Follow-on patents are often the market entry barrier to the supply of generic medicines**

The PPR White Paper indicates (at page 25) that:

*“follow on patents do not prevent the original patent from expiring and generic versions of the original drug from entering the market.”*

GMiA members strongly disagree with this statement. Whilst it is correct that *follow on patents do not prevent the original patent from expiring*, it is certainly not correct that *follow on patents do not prevent generic versions of the original drug from entering the market*.

Using the categories outlined above, GMiA provides the following examples of where follow on patents have delayed the supply of generic medicines. Please refer to commentary in section 3 of this document relating to PPR Questions 2 and 3.

Recent high profile Australian Court cases also evidence the use of follow on or secondary patents to successfully delay market entry, as set out in **Table 3** below. This table adapts the patent categories GMiA outlined above:

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<sup>43</sup>Executive Summary of the *Pharmaceutical Sector Inquiry Report*, pages 9 -10  
[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)

**Table 3: Recent high profile Australian Court cases**

Patent Type	Product	Delay Type	Comment
1. API	Alendronic acid <sup>44</sup>	Injunction (matter subsequently discontinued)	
2. Formulation	Epirubicin <sup>45</sup>	Injunction	
	Venlafaxine <sup>46</sup>	Interlocutory injunction (subsequently overturned)	The time between the interlocutory injunction and final resolution of the dispute was 31 months (for Sigma), 28 months (for Alphapharm) and 24 months for Generic Health.
3. MOT	Leflunomide <sup>47</sup>	Injunction (appeal ongoing)	Note that the case was not determinative of whether a product indication “carve out” will be sufficient to avoid infringement. Please see GMiA submissions in response to Question 6 here.
	Zoledronic Acid <sup>48</sup>	Interlocutory injunction (matter ongoing)	
	Apriprazole <sup>49</sup>	Interlocutory injunction (matter ongoing)	
5/6. Process	Gemcitabine <sup>50</sup>	Injunction	Injunction was granted on the process patent (expiry in 2013) but not on the API patent (expiry in March 2009).
11. Physical features	Omeprazole <sup>51</sup>	Injunction	Patent to enteric coated tablet
12. Isomeric form	Clopidogrel <sup>52</sup>	Interlocutory injunction (matter ongoing)	Note that the interlocutory injunction in this case was granted in 2007, and the matter is still awaiting trial. This amounts

<sup>44</sup>*Merck & Co Inc v GenRx Pty Ltd (Merck v GenRx)* [2006] FCA 1407

<sup>45</sup>*Pharmacia Italia S.p.A v Interpharma Pty Ltd* [2005] FCA 1675

<sup>46</sup>*Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2009] FCA 595; *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2010) 88 IPR 633; *Alphapharm Pty Limited v Wyeth* [2009] FCA 945; *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2010] FCA 1211; *(Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2011] FCAFC 132; FCAFC 143, (No 3) [2011] FCAFC 165; *Generic Health Pty Ltd v Wyeth* NSD1124/2009

<sup>47</sup>*Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd* NSD1664/2008 (interlocutory decision not reported, but see *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)* [2011] FCA 846; [2011] FCA 1307)

<sup>48</sup>*Novartis AG v Hospira Pty Ltd* [2012] FCA 1055

<sup>49</sup>*Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd* [2012] FCA 239 (16 March 2012) (From Federal Court of Australia; 16 March 2012; *Generic Health Pty Ltd v Otsuka Pharmaceutical Co Ltd* [2012] FCA 412 (23 April 2012)

<sup>50</sup>*Interpharma Pty Ltd v Commissioner of Patents* [2008] FCA 1498

<sup>51</sup>*Aktiebolaget Hassle v Alphapharm Pty Limited* [2002] HCA 59

<sup>52</sup>*GenRx Pty Ltd v Sanofi-Aventis* [2007] FCA 1485

Patent Type	Product	Delay Type	Comment
			to a very significant delay to the supply of generic medicines if the generic supplier ultimately succeeds.
	Escitalopram <sup>53</sup>	Injunction	
13. Crystalline form			
14. Salt form			
15. Container closure			
16. Device/delivery systems	Smith & Nephew negative wound therapy device <sup>54</sup>	Injunction (which was subsequently overturned by the full federal Court)	Note that this case does not involve a generic medicine. Rather two proprietary companies. The launch of the Smith & Nephew wound healing device was inappropriately delayed by the grant of an injunction. The injunction was subsequently lifted, and the patent revoked)
	Medical Injector System <sup>55</sup>	Injunction	An interlocutory injunction was granted, and the proceedings settled with the alleged infringer accepting a final injunction (by consent)
17. Analytical tools			

These Australian high profile cases represent only the “tip of the iceberg” of the use of follow on or secondary patents successfully delaying the supply of generic medicines in Australia. GMiA Members regularly make commercial decisions regarding the supply of generic medicines. Where the risks involved in launching a generic medicine dwarfs the return on the necessary R&D investment, Members will generally not launch a generic medicine in Australia. Of course, one pertinent consideration for GMiA Members is how dense the “patent thicket” is for that product irrespective of the strength of the circumvention or invalidity position on those patents. This is primarily because the litigation costs and compounded risks (discussed elsewhere in this document) increase exponentially with each additional potentially relevant patent.

The Australian Federal Court’s comments in *Merck v Arrow*<sup>56</sup> are particularly pertinent to the issue of patent thickets in Australia. The patent in suit claimed methods of treatment and compositions that contained alendronate. In respect to the composition claims, Gyles J said in the Federal Court:

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<sup>53</sup>*H Lundbeck A/S v Alphapharm Pty Ltd* [2009] FCAFC 70; *H Lundbeck A/S v Alphapharm Pty Ltd (No 2)* [2009] FCAFC 118

<sup>54</sup>*Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* [2009] FCA 630

<sup>55</sup>*Medrad Inc v Alpine Medical Pty Ltd* [2009] FCA 949

<sup>56</sup>*Arrow Pharmaceuticals Limited v Merck & Co., Inc.* [2004] FCA 1282

*"It is tolerably plain on the face of the patent that the so-called composition claims lack subject matter. There is nothing that is claimed to be new or novel with any utility about the carrier, the active ingredient, or the quantity or the method by which the ingredients are 'composed'. Reference is only made to standard mixing and formulation techniques. In particular, there is no practical meaning or substance to the statement that the composition is 'adapted for oral administration as a unit dosage according to a continuous schedule having a periodicity of about once weekly'. It is not suggested that there is any problem with an oral composition of the type and size identified being used as a once weekly dose. There is nothing about the composition itself that 'adapts' it to once weekly dosing as compared with any other dosing. These are not composition claims as that concept would normally be understood, that is, claims to a new and unique compound. They are not combination claims whereby the whole is something different from the sum of the parts. When properly analysed the composition claims are devoid of practical content. They are not 'inventions' and are not a manner of manufacture".*

In regard to the method of treatment claims, Gyles J said:

*"... I would hold that each of the so-called method claims was one way of utilising alendronate and its known qualities for the known purpose of preventing or treating osteoporosis by a known method of oral administration. They are in the nature of directions for use. That does not constitute an invention or a manner of manufacture."<sup>57</sup>*

On the issue of patent thickets Gyles J said:

*"Once Merck obtained the base patent, it could control that field. As it controls use of the compound, it acquires the most widespread knowledge of the application of the compound. The patentee will thus have a virtual monopoly of the commercial development of it. In the present case, that led to the trihydrate salt patent, which had a life extending well beyond the life of the base patent in other jurisdictions. Certain of the claims of that patent would arguably include the method claims in issue here. The patentee has a practical monopoly of the opportunity of further refining the use of that invention. It would be a surprising result if using that monopoly and the information received from clinical trials of the compound would enable a further refinement of the necessary instructions for use of the compound to be itself patentable subject matter. This would extend the practical life of the patent by conferring a monopoly over the best method found in practice to put it into effect. There is something anomalous about a patent being obtained for all pharmaceutical uses of a chemical compound without disclosing any particular dosage regime for any particular use but with the patentee later claiming a new, stand-alone, patent for a particular dosage regime for a particular purpose that was contemplated at the time of the base patent, with no new properties of the compound having been discovered in an inventive fashion in the meantime."*

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<sup>57</sup> Id, page

The Full Federal Court agreed<sup>58</sup>:

*“The Patent specification discloses no new substance, no new characteristic of a known substance, no new use and no new method. There is, therefore, no manner of new manufacture.”*

GMiA respectfully submits that patent thickets are a very real problem in Australia, and their existence has radical implications for the supply of affordable medicines in Australia.

The Australian experience summarised above is consistent with the European experience, as highlighted in the 2009 EU Commission Report: *“in patent litigation cases originator companies often rely on patents that were not yet filed when their product in question was launched”*<sup>59</sup>. Where the patentee succeeds in obtaining an interlocutory injunction on the secondary patent (irrespective of whether they ultimately succeed), or a final injunction on such a secondary patent, the launch of the generic medicine is significantly delayed.

Marketing strategies are used in parallel to further delay the supply of generic medicines in Australia

The PPR White Paper rightly indicates that marketing strategies are also used in parallel to further delay the supply of generic medicines in Australia. GMiA has discussed those practices in section 1.3, and refers the Panel to that section. GMiA believes Section 1.3 of this document fairly summarises the relevant market practices in Australia. GMiA has made various recommendations in this document to address those practices, and will not repeat those recommendations here

**GMiA strongly believes that pharmaceutical practices (including patent practices) must be well understood in order to ensure best health policy is implemented for the Australian public. GMiA remains concerned that law and policy makers are not appropriately informed of the consequences of the decision on the suppliers of generic medicines in Australia.**

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<sup>58</sup>*Merck & Co Inc v Arrow Pharmaceuticals Limited* [2006] FCAFC 91

<sup>59</sup> *Id*

## 7 Therapeutic Goods Administration related issues

### 7.1 Question 9: data exclusivity

#### *Question 9: Is the law on data exclusivity appropriate?*

In brief: GMiA members support a 5 year data exclusivity period for all medicines, and suggests there is no sensible reason to extend data exclusivity for any product beyond 5 years.

**GMiA members believe that the law on data exclusivity in Australia is appropriate. In particular, GMiA members support a 5 year data exclusivity period for all medicines. There is no sensible reason to extend data exclusivity for any product beyond 5 years.**

Importantly, there is no international “norm” for data exclusivity. Many countries have no data exclusivity and most countries have five or six years data exclusivity. **In fact, most of the world’s population live with no more than six years or no data exclusivity at all.** Ten years or more data exclusivity is not the rule. Consequently, Australia’s current five years is a sensible middle ground and strikes an appropriate balance.

Critical to a proper discussion regarding the appropriateness of Australian data exclusivity regime is an understanding of the differing policy positions supporting data exclusivity, as compared to patents. Patents reward the patentee for innovation. For the potential prize of a 20-25 year patent monopoly (with extensions), a person is motivated to innovate. On the other hand, data exclusivity motivates a person to introduce a medicine into the Australian market. For the potential prize of five years data exclusivity a person is motivated to collate the clinical data necessary to support a new medicine application in Australia and to file an application for regulatory approval of that medicine with the TGA. Supporters of prolonged data exclusivity periods inappropriately confuse the purpose of data exclusivity with that of patents.

**Once these policy positions are clearly understood, it will become readily apparent that there is no good policy reason to extend the term of data exclusivity in Australia, or to provide a prolonged period of data exclusivity for biologics in Australia. To do so will inappropriately delay the supply of generic medicines in Australia.**

The social and economic impacts of extension of market monopolies weigh against extending data exclusivity periods in Australia. Such extension presents clear additional costs to the public by way of higher priced technology without providing any public benefit. An extension of market monopoly via extension of period of data exclusivity cannot be supported in the absence of a clear link to creation of public benefit, for example by clear evidence of increased investment in Australian research and development. There is no tenable link.

GMiA makes the following recommendations:

**Recommendation 3:** GMiA members support a 5 year data exclusivity period for all medicines, and suggests there is no sensible reason to extend data exclusivity for any product beyond 5 years. In general, GMiA members believe that the law on data exclusivity in Australia is appropriate. In particular, GMiA members support a 5 year data exclusivity period for all. There is no sensible reason to extend data exclusivity for any product beyond 5 years.

**Recommendation 4:** GMiA is also very concerned about the inclusion of data exclusivity provisions in international agreements such as TPP, and recommends caution when contemplating introducing changes to domestic law through international agreements. Relevantly, **GMiA strongly urges the Australian Government NOT TO AGREE** to any IP provisions in TPP or similar, which require changes to Australian domestic law, and in particular which will require extended data exclusivity regimes.

## 7.2 Question 10 - patent certificates

### *Question 10: Are the laws on patent certificates appropriate?*

GMiA submits that narrowing amendments are required to the Therapeutic Goods Act to realign the TGA patent certificate/notification system in Australia with Australia's international obligations under AUSFTA. In particular, as implemented:

1. Generic medicine suppliers unfairly bear the very significant burden (cost, time and risk) of determining which patents on the Australian Patent Register may be relevant to the medicine and require certification.
2. Generic medicine suppliers carry the risk of criminal penalties for errors on patent certifications.

The implementation of AUSFTA obligations in Australia has resulted in considerable burden to generic suppliers. GMiA submits that this burden could (and should) be carried easily by sponsors of therapeutic goods in Australia, by requiring sponsors to identify in the Patent Register each relevant patent for its product. GMiA further submits that the replacement of the current criminal penalties with civil penalties and the introduction of similar civil penalties for sponsors inappropriately identifying patents would assist to prevent abuse of the system.

#### ***The Australian certification/notification system***

Section 26B of the Therapeutic Goods Act 1989 (TGA) became effective on 1 January 2005. The section was introduced in order to satisfy Australia's obligations under the Free Trade Agreement with the US (**AUSFTA**). This obligation arose directly as a result of Article 17.10.4. The text of this Article is as follows (our emphasis):

*"4. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory:*

- (a) *that Party shall provide measures in its marketing approval process to prevent those other persons from:*
  - (i) *marketing a product, where that product is claimed in a patent; or*
  - (ii) *marketing a product for an approved use, where that approved use is claimed in a patent,*

*during the term of that patent, unless by consent or acquiescence of the patent owner;  
and*

- (b) if the Party permits a third person to request marketing approval to enter the market with:
  - (i) a product during the term of a patent identified as claiming the product; or*
  - (ii) product for an approved use, during the term of a patent identified as claiming that approved use,**

*the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.”*

Section 26B of the TGA addresses Article 17.10.4 of AUSTFA by requiring a generic medicines supplier to the Australian market to provide a patent certificate in certain circumstances.

Note:

- (a) The AUSFTA Article is quite specific in its obligations. That is, it only refers to patents where a product is claimed or patents where the use of a product is claimed. By contrast, section 26B is broader in its application as it refers to a “patent that has been granted in relation to the therapeutic goods”. Through the use of the language “in relation to”, the effect is to unfairly capture within its net patents such as those claiming processes for the manufacture of therapeutic goods.
- (b) The requirement to provide a certificate is invoked only if the generic medicines supplier is required to provide evidence or information to establish the safety or efficacy of the therapeutic goods it seeks to market and it is relying upon evidence or information submitted by another to the Therapeutic Goods Administration.
- (c) The penalty under the Crimes Act 1914 for a generic medicines supplier providing a certificate, which is false or misleading, is 1,000 penalty units (currently \$110,000).

It is therefore apparent that to comply with section 26B, a generic medicine supplier will generally have a search conducted for all Australian patents that have been granted in relation to the relevant therapeutic goods. This search is not a straightforward process as there is no requirement for a patentee to record the name of the therapeutic goods in relation to a patent record on the Australian Patent Register. That is, the name of the therapeutic goods does not appear on the Patents Register established under the Patents Act 1990. Rather a generic medicines supplier is required to undertake a review of the contents of each patent that has been identified in a full Patent Register search as potentially related to the relevant therapeutic goods. For example, on 16 January 2013, a search was

made of the Australian Patents Register in relation to the well known compound omeprazole. The search was conducted to identify all in force patents/applications which included a reference to omeprazole. This search revealed 900 patents/applications that satisfied the search criteria. To identify patents relevant to section 26B would require all 900 patents/applications to be reviewed. However, it would be expected that the vast majority of these patents/applications would not in fact be relevant to section 26B. However because a search of the Australian Patents Register may only be made in relation to a key word appearing anywhere in a patent document, many irrelevant patent documents for section 26B purposes are captured. It is therefore apparent that the review of so many search results is incredibly onerous. According to MIMS November/December 2012, 20 products containing omeprazole were available on the Australian market. Furthermore, to the best of our knowledge, there are no patent disputes on foot in relation to omeprazole.

For all practical purposes in giving a certificate under section 26B, the Patents Register may be regarded as materially deficient in the information it provides.

### ***Submission***

It is evident that the present section 26B certificate regime is not well balanced as and between the rights of a therapeutic goods patent holder and those of a generic medicine supplier. In particular, the net of patents captured by section 26B is overly broad as compared with the AUSFTA obligation. That is, the certificate process is strongly and unfairly biased in favour of therapeutic goods patentees. Moreover there is no ready means by which relevant therapeutic goods patents may be identified. Again, this situation unfairly favours a therapeutic goods patentee.

**Recommendation 5:** GMiA seeks a rebalancing of the rights as and between generic medicines suppliers and therapeutic goods patentees in relation to patent certificates.

Section 26B (2) provides a criminal penalty for any person who provides a certificate which is false or misleading. It is submitted that such a criminal penalty is unreasonable having regard to the fact that any hurt caused as a result of providing a certificate which is false or misleading is largely pecuniary. Therefore, paragraph 26B (2) ought to be amended to refer to a “Civil Penalty” rather than a “Penalty”.

**Recommendation 6:** GMiA recommends that criminal penalties in relation to patent certificates ought to be civil penalties (for both patentee and alleged infringer). GMiA recommends that s26 be amended accordingly.

It is further submitted that to provide the necessary balance, a similar provision should be made in the Patents Act 1990 in regards to a therapeutic goods sponsor. In particular, the same civil penalty should be imposed on any sponsor causing a false or misleading entry to be made in the Patents Register in relation to therapeutic goods. To not provide such a penalty is manifestly unjust in the sense that such an entry may well cause real business harm to a generic medicines supplier, the public and the Australian Government.

For section 26B purposes, the recordal of therapeutic goods on the Patent Register only becomes effective on patent grant. However, it would seem appropriate to permit the filing of a request to record therapeutic goods at any time in the term of a patent.

Irrespective of when a request to record was made, examination for compliance would be required. Essentially examination would be undertaken to establish that the therapeutic goods fell within the scope of at least one claim and the name complied with INN requirements.

It is noted that in certain cases, a number of therapeutic goods may be recorded against a patent. In this proposal there would be no restriction on such numbers provided that there are no adverse consequences in relation to the conduct of an efficient search of the Patents Register.

Should a third party believe that the recordal of therapeutic goods was in error, then existing Opposition, Re-examination and proposed Rectification of the Register procedures would be available to such third parties to challenge such a recordal.

Section 26B (3) states *“For the purposes of this section, a patent is taken to have been granted in relation to therapeutic goods if marketing the goods without the authority of the patentee would constitute an infringement of the patent”*.

It is therefore evident that section 26B (3) potentially has a very wide application in the sense that it covers patents where any aspect of the therapeutic goods is the subject of such patents. For example, patents to processes for the manufacture of pharmaceutical substances are relevant to section 26B (3). Importantly, in this regard, section 26B has a much wider application than required under Article 17.10.4 of AUSFTA.

### 7.3 Question 11: Copyright of Product Information

#### *Question 11: Are the laws on copyright of product information appropriate?*

The timely availability of generic medicines is an essential feature of the government's pharmaceutical brand substitution policy.

*“Any barriers that have the effect of preventing or delaying market entry of new brands of medicines will have significant financial implications for both government and consumers”<sup>60</sup>*

The *Therapeutic Goods Legislation Amendment (Copyright) Act 2011* (Cth) (**Amendment Act**) commenced on 28 May 2011. The Amendment Act inserted section 44BA into the Copyright Act, the effect of which was to exempt certain acts in relation to approved product information under the *Therapeutic Goods Act 1989* (Cth) (**TG Act**) from constituting an infringement of copyright under the Copyright Act.

Under the TG Act, all therapeutic goods (which includes most therapeutic devices<sup>61</sup>) are required to be approved for inclusion in the Register before they can be lawfully marketed and supplied in Australia.<sup>62</sup> The application process and administration of the Register is undertaken by the TGA. As part of the application process for obtaining registration, an applicant must submit, and have approved by the Secretary to the Department of Health and Ageing a “product information” document (**PI Document**).

The PI Document contains technical information about the therapeutic good such as the characteristics of the active ingredient, its indications and contraindications, a description of clinical trials that support the indications, precautions, possible adverse reactions, dosages and storage, and other information relating to the therapeutic good's safe and effective use.

As acknowledged in the EM and second reading speech for the Amendment Act, where the sponsor of a generic medicine applies for registration on the Register, it has been the long-standing practice of the TGA to approve text of the PI Document that is essentially the same as that currently approved for the “original” medicine.<sup>63</sup> It was also acknowledged that the practice is important for the safe and effective use of the medicine as it ensures that doctors, pharmacists and other health professionals receive the same information about a medicine regardless of the brand, thus avoiding any perception that differences in the text of the PI Documents reflect what are in fact non-existent clinical and/or pharmacological differences.

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<sup>60</sup> Hansard, House of Representatives, Second Reading (Ms King - Parliamentary Secretary for Health and Ageing and Parliamentary Secretary for Infrastructure and Transport), *Therapeutic Goods Legislation*

<sup>61</sup> See definition of ‘therapeutic device’ under section 3 of the *Therapeutic Goods Act 1989* (Cth).

<sup>62</sup> Section 19B(4), *Therapeutic Goods Act 1989* (Cth).

<sup>63</sup> Explanatory Memorandum, *Therapeutic Goods Legislation Amendment (Copyright) Bill 2011*; Hansard, House of Representatives, Second Reading (Ms King - Parliamentary Secretary for Health and Ageing and Parliamentary Secretary for Infrastructure and Transport), *Therapeutic Goods Legislation Amendment (Copyright) Bill 2011*, 24 February 2011.

Parliament's clear intention behind introducing the Amendment Act was to preserve the current process by which sponsors can obtain approval to include a generic medicine or device on the Register, without compromising the TGA's ability to ensure that consumers and prescribers of medicines have access to accurate and consistent information.

## **8 Conclusions**

GMiA thanks the Panel for the opportunity to address the PPR White Paper, which addresses critical questions for the pharmaceutical industry in Australia.

GMiA would welcome the opportunity to meet with the Panel to discuss this Submission. GMiA and GMiA Members would welcome the opportunity to be involved with the public hearings in February 2012.