Generic Medicines Industry Association

SUBMISSION PAPER

Response to the DRAFT REPORT - Pharmaceutical Patents Review

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1 Overview

1.1 Executive Summary

GMiA Members welcome the release of the Pharmaceutical Patents Review Draft Report that addresses the very important terms of reference of, “securing timely access to competitively priced pharmaceuticals, fostering innovation and supporting employment in research and industry”¹.

GMiA notes that a number of the recommendations do not go far enough in redressing the imbalance in Australia’s pharmaceutical patents system and recommends the Panel reassess a number of recommendations in preparation of the Final Report. For reasons set out in this response, GMiA Members specifically request the Panel (listed in order of priority):

- Make more specific draft Recommendation 8.1 to reduce the current disincentives for generic medicine sponsors to challenge the validity of sub-standard pharmaceutical patents;
- Make more specific draft Recommendation 6.4 to amend section 117 to provide an unqualified and unambiguous legislative exemption for generic pharmaceutical companies to carve-out specific therapeutic indications;
- Amend draft Recommendation 6.1 so that formulation patents are not eligible for extensions of term; and
- Ensure that draft Recommendation 8.2 clearly states the purpose of the register it to enhance transparency of patents relating to therapeutic goods, and that any requirement for a generic to notify the originator of its application for regulatory approval prior to ARTG listing is not recommended.

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”.

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 barriers to generic market entry in Australia.

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

In response to the Draft Report, this submission will call out four specific recommendations and outline the rationale for reconsideration. These four issues are considered of high importance by members of GMiA. The paper will then address the remaining draft recommendations in turn, providing further clarity to inform the Panel in preparing its Final Report. Finally, this report highlights a number of issues made in the original GMiA submission (January 2013) that GMiA strongly encourages the panel to address.

¹The 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/
1.2 Introduction

GMiA commends the panel on a comprehensive and extensive draft report. It is critical that Australia consider the benefit and cost of patents from a national perspective, while being mindful of our international obligations. Indeed, the panel has taken exactly this approach.

It is clear that the granting of inappropriate patents and the inappropriate extension of patents cost the national economy, and the public, dearly and should be guarded against. The health and legal systems 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.

Delays to market entry of generic medicines matter. Timely market entry of generic medicines drive significant and important savings to the Pharmaceutical Benefits Scheme (PBS).

GMiA is not anti-patent, a point we have repeatedly stated. In fact, GMiA is an advocate for well-balanced intellectual property that appropriately rewards invention of innovative and health enhancing pharmaceuticals. However, GMiA reiterates that (i) the Australian patent examination process results in the grant of patents of highly questionable validity and, and (ii) the current legal and pharmaceutical regulatory infrastructure means that such patents can be very effective tools to delay generic market entry.

Patents provide the holder twenty years of market exclusivity. Holders of pharmaceutical patents can apply for a five year extension in many instances. After the active pharmaceutical ingredient (API) patent has expired, subsequently filed patents (follow-on patents) can be an effective barrier to generic medicine market entry, regardless of their quality. If those patents are not in fact novel and inventive they become a burden to society.

The purpose of the patent system is to reward innovation, not necessarily investment in clinical trials. There is no per se justification to patent protection because of time and effort for satisfying marketing approval. However the grant of patents, and extension of them for various formulations of an old and known active pharmaceutical ingredients extends the overall monopoly of the originator in the molecule.

The proposition linking time and effort to justify a new patent (albeit method and Swiss style claims) was recently considered in Apotex Pty Ltd v AstraZeneca AB (no.4)[21012 FCA 162] concerning the hypercholesterol lowering drug rosuvastatin (Crestor). In that case, Jagot J found both patents invalid on, interalia, inventive step. The fact that the trials were time consuming and expensive was not determinative.

The recently released McKeon Review: Strategic Review of Health and Medical Research states that “There is a need for the Australian Government to ensure the strength and stability of Australia’s IP
GMiA agrees with this statement and encourages the Panel of the PPR in its support of a stable, balanced IP system in Australia.

The McKeon Review focused on maximising Australia’s capacity to produce world class health and medical research across the research spectrum, from discovery through to translation. As such, this review encourages investment in programs to support early phase medical research and maintain a reputation for excellence. This review does not consider Australia’s complex IP system apart from stating that “over-patenting can be a perverse driver, hindering or preventing commercialisation”.

Recently, there has been some independent commentary that raises concerns that the price the government pays for some generic medicines are higher in Australian than other comparable countries. These concerns are unfounded as the market-based price disclosure policy ensures that the government benefits from the competitive generic medicines sector in Australia.

When the first generic medicine lists on the PBS, there is an immediate automatic statutory 16 per cent price reduction applied to both the generic medicine and the original brand. This price reduction delivers significant savings to the Commonwealth. The price of PBS medicines is further reduced repeatedly over time under the price disclosure policy - the market based pricing mechanism that delivers further additional significant savings.

The price disclosure policy recognises that there are two prices for generic medicines – the PBS list price and the market price. The price disclosure policy ensures that over time the PBS list price is set at the actual market price.

GMiA cautions against the PHARMAC system of tendering in New Zealand as recommended by independent (but unfortunately not fully informed) commentary. The Australian PBS has already been subject to significant reforms that are having a major impact on the generic medicines industry. It is critical that the current reforms to the PBS are allowed to play out before other systems – all with their own inherent problems – are contemplated for the Australian market.

The PBS has been subject to significant reforms. These reforms are still playing out and more importantly these reforms are driving significant savings to the PBS. GMiA counsels against further cost cutting to the PBS that would risk jeopardising the continuity of supply of medicines to Australian patients. Safeguarding Australians’ continuing, affordable access to high quality, necessary medicines is paramount. The PBS, arguably the world’s best pharmaceutical re-imbursement system, must not be jeopardised through inappropriate, ill-considered reform.

1.3 GMiA

This submission has been prepared by the members of the Generic Medicines Industry (GMiA) in response to the Draft Report of the Pharmaceutical Patents Review released on 3rd April 2013 (the PPR Draft Report) 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.

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.
2 GMiA response to specific draft recommendations

2.1 Recommendation 8.1

Draft recommendation 8.1:

As the party that ‘internalises’ the most benefits of a successful challenge to a patent for a product on the PBS, the Government should take a more active role in managing the cost of the PBS where a patent relating to a PBS-listed pharmaceutical is successfully challenged in the courts. This could involve ensuring that the Government recoups more of the cost to the PBS arising from delayed generic entry.

It should also include implementing measures to reduce disincentives for generic manufacturers to challenge patents by providing negotiated incentives for a party who successfully challenges a patent.

GMiA Members welcome draft recommendation 8.1 which advocates measures to ensure savings to the PBS and reduce disincentives for generic manufacturers to challenge patents. GMiA recommends inclusion of Recommendation 8.1 in the final report of the Pharmaceutical Patents Review with the adoption of specific suggestions endorsed by the Panel.

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.

GMiA Recommendation

GMiA recommends that Recommendation 8.1 is made more specific to address the existing absence of an incentive for generic medicine sponsors to challenge the validity of sub-standard pharmaceutical patents.

2.2 Recommendation 6.4

Recommendation 6.4:

Section 117 of the Patents Act should be amended to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement where reasonable steps have been taken to ensure that the product will only be used in a non-infringing manner. Policy should further impose a presumption that “reasonable steps” have been taken where the product has been labelled with indications which do not include any infringing indications.
GMiA Members welcome draft recommendation 6.4 however such an exemption will only be effective if it is clearly delineated. However, Recommendation 6.4 should be further detailed in the final report of the Pharmaceutical Patents Review to the effect that the exemption will apply if the patented use is excluded from the Indication section of the generic Product Information and Consumer Medicine Information documents.

GMiA Recommendation

GMiA recommends that Recommendation 6.4 is made more specific to amend section 117 to provide unqualified and unambiguous legislative exemption for generic pharmaceutical companies to carve-out specific therapeutic indications.

2.3 Recommendation 6.1

**Draft Recommendation 6.1:**

The Government should maintain the current approach that allows extensions for drugs and formulations but not for methods of use and manufacture, which will continue to provide an incentive for the development and supply of active pharmaceutical ingredients and new formulations, without adding to the existing cost of medicines in Australia.

GMiA reiterates its recommendation that the scope of patents eligible for an extension of term be limited to API patents and asserts that this is in the national interest. Specifically, GMiA calls for an amendment to the Patents Act so that formulation-type patents are excluded from eligibility for an extension of term.

GMiA submits that legislative change giving effect to the apparent original intention of the extension of term legislation would remove a barrier to generic market entry by preventing inappropriate extension of the patentee’s monopoly. This would also save the Australian government significant cost.

The Australian government, in providing patent term extensions, recognises that requiring a sponsor to meet 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.

GMiA explained in its original submission that the rationale for granting an extension of an API patent term, namely an extension for delay associated with preclinical and clinical trials, is not present for formulation-type patents - in the same way that it is not present for method, process or device-type patents. All of these have later filing dates. The exclusion of formulation-type patents from eligibility for extensions of term would be consistent with the apparent legislative intent of the extension of term provisions.
On page 94 of the Draft Report, there is discussion of whether formulation pharmaceutical patents should continue to benefit from an EOT. The review panel concludes, based upon Figure 6.2 in the Draft Report, that “Limiting extensions to patents on new active ingredients would therefore have little effect in reducing the overall cost of pharmaceuticals.” The Panel has interpreted these data as showing that formulation patents make up approximately 12% of extended patents. GMiA submits that the mere fact that the proportion of formulation pharmaceutical patents at present is low (on the Panel’s analysis) is not sufficient justification for a continued eligibility of such patents for extensions of term. Clearly the proportion of formulation patents may vary and significantly increase in future. Additionally, the GMiA’s submission dated 21st January 2013 at pages 17-18 revealed that the proportion may be in excess of twice that figure (28%). This latter figure is consistent with the percentages given in the November 2012, “Background and Suggested Issues Paper” where it was said on page 11 to be 28%.

GMiA submits that continuing to include formulation patents on the basis of clearly variable statistics is not a sound approach. Further, it appears that the review panel has dealt with formulation patents as a whole without considering the nuances of the different R&D efforts which are associated with the first approved formulation compared to second and subsequent formulations. The following comments try and explain those nuances.

Formulation patents may separately protect various ways of formulating the API, for example tablet formulations (oral), ointments (transdermal) and liquids (oral or parenteral). Under current Australian patent law (even under the Raising the Bar amendments) each formulation is patentable assuming it is novel and inventive. The same applies to new methods of use of the API. However, while the Panel accepts that use patents should not be eligible for an extension of term, formulation patents may potentially be extended under the legislation as currently applied. This is despite the fact that the R&D expenditure/clinical trial requirements for such later formulations and later uses are comparable, and that neither is comparable to the effort required to bring the API in its first formulation to market.

By way of background, animal studies and Phase 1 clinical trials (in healthy humans) establish the safety of an API over a “dose range”. Formulations for Phase 2 trials (testing efficacy in humans) are designed based upon a selection of dosages from the Phase 1 clinical trials. More extensive trials (Phase 3) follow. So in bringing the API (in its first formulation) to market, a huge amount of safety and efficacy data is amassed which is usable in bringing to market a second formulation for the same or new use. The safety of any modified dosage will be known (given the dose range safety trials and clinical results) and the efficacy testing in clinical trials will be more directed. When merely changing to a different presentation (for example from an immediate release tablet to a modified release tablet), little additional clinical investigation is needed. However, under the current EOT regime, a separate formulation patent may be secured and extended.

Accordingly, GMiA would agree that as indicated on page 93 of the report under Analysis 6.3, “considerable R&D” may be needed for formulations, but this is relatively less than for the API itself, and is only for those formulations the subject of the first approval. Later in page 96, the report indicates that the data do not support that new uses of a previously registered pharmaceutical are subject to the
same delay and risk as pharmaceuticals. It is submitted that as a minimum the same comment applies to subsequent formulations or presentations.

Finally, several submissions referred to the effective patent life of pharmaceutical products. Much of the discussion about effective patent life in the pharma space appears to assume that a 15 year effective patent life is ideal. However GMiA has identified no foundation for selecting this particular period, and notes that a 15 year period from ARTG listing until patent expiry is the maximum that can be obtained through the extension of term provisions in Part 3 of the Patents Act 1990, not a minimum, average or target. It is argued that a 15 year period would equate the pharma industry with other industries. However, Panel members have publicly acknowledged that there are no data to support this. Therefore any informed discussion of the appropriate duration of an effective patent life first requires further economic analysis.

**GMiA Recommendation**

GMiA recommends that the Panel reconsider recommendation 6.1, and that the final report of the Pharmaceutical Patents Review recommends excluding formulation-type patents from eligibility for extensions of term. GMiA recommends that the Government amend the Patents Act so that formulation-type patents are excluded from eligibility for an EOT under Part 3 of the Patents Act (as is currently the case for patents to a method or process). Such an amendment would alleviate some concerns surrounding inappropriate delay to generic market entry.

### 2.4 Recommendation 8.2

**Draft recommendation 8.2:**

A transparency register linking therapeutic goods registered with the TGA with related patents should be introduced.

GMiA supports Recommendation 8.2, subject to the clarification that the purpose of the register is solely to provide ‘greater transparency and easier discovery of patents relating to therapeutic goods’ (refer to the Draft Report page 163).

GMiA submitted in its original application that the burden of identifying relevant patents for the purposes of completing a certificate pursuant to s26B of the Therapeutic Goods Act 1989 could (and should) be carried easily by sponsors of therapeutic goods in Australia, by requiring sponsors to identify in a patent register each patent relevant to its product. To give effect to this recommendation it would be necessary to restrict an originator’s ability to commence infringement proceedings in respect of patents which are not included.
However the Panel stated at pages xii of the Draft Report that ‘If such a register was established, the Panel further suggests it could be appropriate for generic manufacturers to advise originators of their application for regulatory approval.’ **GMI A does not support such a suggestion.** The sole purpose of the register should be to increase transparency of patents relating to therapeutic goods, thus reflecting a basic premise of the patent system – the disclosure of the invention in return for a period of exclusivity.

It is neither necessary nor appropriate for such a register to give rise to any notification obligations.

GMI A strongly urges against the inclusion of this suggestion in the final report as it would:

i. be anti-competitive; and
ii. not have the Panel’s hoped for effect of reducing the incidence of interlocutory injunctions.

The suggestion, that it could be appropriate for generic manufacturers to advise originators of their application for regulatory approval, does not take into account the strategic way patent litigation is used in Australia to delay generic launch AND that originators have no incentive to resolve litigation early. The Panel’s suggestion implies adoption of features of the US Hatch-Waxman regime which is neither desirable nor appropriate for the Australian pharmaceutical industry.

In no other technology area is it mandatory for a competitor to pre-warn a patentee of its commercial intentions. It is counter to a free market and confidentiality of business planning.

Section 8.5.2.1 of the PPR Draft Report states, “Early notification would provide originators with more certainty about the business plans of their competitors, thereby enabling them to engage in steps which hinder generics gaining market share“. GMI A notes that originators most certainly would engage in steps to hinder generic market entry. Such information would provide the originator with huge insight on which to develop and implement monopoly-extending strategies such as comparative marketing campaigns, entering long term supply agreements and transferring the marketing approval or PBS listing to newer products with longer patent life.

At present it may be possible for an originator to estimate the likely timing of generic launch based on expected patent expiry dates. However a requirement to provide advice along the lines of the Panel’s suggestion would provide the originator with far more powerful commercial information:

- the number of generic applicants
- the identity of the generic applicant(s)
- details of the generic product, including product variations or improvements.

Importantly, the proposal for early notification to the originator also does not acknowledge that originators already receive around three months’ notice of market entry of the generic medicine. Originators closely monitor the easily searchable Australian Register of Therapeutic Goods (ARTG). Under the current regime, the patentee effectively receives notice at the time of a generic’s ARTG listing. As most generic medicines are not launched until after pricing reimbursement, the patentee
effectively receives around three months’ notice of generic competition, being the time between registration on the ARTG and reimbursement listing on the PBS.

If the Panel’s suggestion were to be implemented the patentee would obtain a 12-18 month lead time in which to influence the market before generic competition. The Panel’s suggestion would be anticompetitive and is uncommercial given the special nature of this industry where public safety intersects with patent law and competition.

As documented in the Medicines Australia submission (23 January 2013) to the Pharmaceutical Panel Review, “As far as Medicines Australia is aware, in every case since 2007, patent owners have initiated interlocutory and/or infringement proceedings within, on average, 2 to 3 weeks of learning about a generic company’s intention to enter the market whilst there is still a valid patent in place.”

Contrary to the claim made in the Medicines Australia submission, “There is often insufficient time to conduct proper due diligence in order to file a s.26C certificate, if court proceedings are considered necessary”, the existing notification period of around three months (the period between ARTG registration and PBS listing) provides pharmaceutical patent holders with more than sufficient time to seek an interlocutory injunction given current practice.

Further, GMiA expects that early notification would result in a significant increase in the number of interlocutory injunctions being sought by originators.

The Panel states at page xii that if a generic were to provide advice to the originator of its application for regulatory approval, that ‘would provide originators with time to explore their options without immediate recourse to injunctions’. This statement appears to assume that litigation is commenced promptly by a party upon notification and that a court decision at first instance can be obtained prior to ARTG listing. However that assumption is not borne out by GMiA members’ experience where they have voluntarily provided early notification to a patentee. Some of our members regularly follow that approach by way of a confidential notification. Typically the invalidity and/or non-infringement case is disclosed by the generic in an attempt to convince the patentee to clarify its position. Those attempts to negotiate a subsequent market launch (even where the patent is highly questionable) have been singularly unsuccessful.

In particular, there is no legal incentive for the originator to engage in the process or commence proceedings before generic ARTG listing where there is likely to be a PBS price drop upon generic launch. The GMiA refers the Panel to its original submission detailing the prevalence of interlocutory injunctions. Failure or delay to engage has not typically prevented the grant of an interlocutory injunction because the Courts have found that it has not outweighed the alleged irreparable harm which is said to occur from a lowering of the PBS reimbursement price.

Even if one assumes that an originator does issue proceedings promptly, the current legal system moves slowly and in complex cases (which patent cases are) it is highly unlikely that a decision at first instance within 12 months is realistic. Likewise a court is unlikely to order an originator to take steps which would prejudice the proper running of its case.
Consequently, introducing the suggested measure will do nothing to decrease litigation or to diminish the importance or appeal of interlocutory injunction applications to originators. Rather, it would only place the generic medicines sector in a worse position absent some requirement on the patentee to (i) negotiate seriously and/or (ii) commence action early and/or (iii) not to seek interlocutory injunctions.

Various mechanisms have been suggested at page 157 of the Draft Report to inhibit applications for interlocutory injunctions. GMiA supports the following three of these which are consistent with recommendations in GMiA’s original submission:

- making it a mandatory condition of being granted an injunction for pharmaceutical cases that the patentee undertakes to repay any damages to the Government;
- requiring the patentee to repay to the Government an amount based on the lost reduction in PBS subsidy due to the delayed entry to the market of generics;
- requiring the patentee to pay a portion of its profits for the product during the injunction period to a successful challenger.

The GMiA’s original submission detailed the inherent imbalance in the current regime which provides an incentive for patentees to seek interlocutory injunctions, even in relation to patents of questionable validity. The mechanisms listed above lend themselves to clear and concise drafting, and would provide a clear disincentive for the originator to seek interlocutory injunctions and more effectively rebalance the legal and strategic positioning between originators and generics.

As GMiA stated during public hearings for this review, the US Hatch-Waxman regime, which includes the “Orange Book” patent list, is a complex regime unique to that country and not without faults. In particular it has spawned a litigation industry around the rules of the regime which cannot be sustained in a market of Australia’s size.

Accordingly, GMiA argued that Australia should design a system to suit its own needs rather than import aspects of the US system such as patent notification at the time of dossier submission. GMiA notes the Panel recognises the challenges in introducing an Orange Book system (page 170) and therefore strongly cautions against adopting aspects of the US system.

**GMiA Recommendation**

GMiA supports recommendation 8.2 in principle, with the clarification that the function of the register is to provide greater transparency and easier discovery of patents relating to therapeutic goods’, but completely rejects the suggestion that it could be appropriate for generics to advise originators of their application for regulatory approval.
3 GMiA response to remaining draft recommendations

GMiA will address each of the remaining Draft Recommendations.

3.1 Recommendations 3.1 and 3.2

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<th>Draft Recommendation 3.1:</th>
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<td>The Government should expeditiously seek a situation where Australia has strong yet parsimonious IP rights – that is, rights that are strongly enforced and that provide the incentive necessary to underpin an appropriate level of investment in innovation but that are not defined so broadly as to impose costs on innovation or other activity without commensurate benefits.</td>
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<td>For instance such strong yet parsimonious IP rights could provide a desired level of incentive to invest in pharmaceutical innovation without preventing our industry from servicing offshore generic markets, as current law does. Australia should take a leadership role in seeking consensus with jurisdictions with similar interests to identify and pursue a range of changes in international patent law and practice along these lines.</td>
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<th>Draft Recommendation 3.2:</th>
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<td>The Government should ensure that future trade negotiations and renegotiations are based on a sound and strategic economic understanding of the costs and benefits to Australia and the world and of the impacts of current and proposed IP provisions, both for Australia and other parties to the negotiations. The Government should strongly resist changes – such as retrospective extensions of patent rights – which are likely to reduce world economic welfare and lead other countries in opposing such measures.</td>
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GMiA welcomes Draft Recommendations 3.1 and 3.2 which support timely access to competitively priced pharmaceuticals and in supporting innovation and employment in the industry.

3.2 Recommendation 4.1

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<th>Draft Recommendation 4.1:</th>
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<td>As an interim measure, the Government should actively seek the agreement of the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of manufacturing for export.</td>
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GMiA welcomes the intent of Draft Recommendation 4.1, however owing to the “voluntary” nature of the recommendation, GMiA finds it hard to see how this this recommendation could be feasibly
implemented, and how Government could ensure patent holders agree not to enforce patents. Enabling manufacture for export in Australia is a positive step, however this recommendation does not provide certainly for manufacturers of generic medicines.

GMiA reiterates its request in it is original submission that the Panel recommend that manufacture for export (MFE) be expressly exempted from infringement during the patent term extension. GMiA notes that, while it supports the Panel’s Recommendation 5.2 to shorten some extensions of term, implementation of this recommendation will not itself be sufficient to implement MFE.

As stated in the GMiA submission, the consequences of not allowing MFE are significant and waiting for changes in international agreements to be implemented would take some time. GMiA notes that MFE is in the national interest and can be introduced in a way that is consistent with the TRIPS Agreement and AUSFTA.

**GMiA Recommendation**

GMiA recommends that this recommendation be amended before inclusion in the final report of the Pharmaceutical Patents Review, specifically to the effect that section 78 of the Patents Act 1990 is amended to expressly exempt manufacture for export from infringement during the patent term extension.

### 3.3 Recommendation 5.1 and 5.2

**Draft Recommendation 5**

**Option 5.1:**

The current model of using the patents system to subsidise pharmaceutical R&D indirectly should be replaced with a direct subsidy. To this end, the Government should reduce extensions of term for pharmaceutical patents and use part of the associated savings to fund R&D directly. Some of this funding should be targeted to socially beneficial research for which patents provide inadequate incentives to conduct. Such areas include new antibiotics which, once developed, must be used as sparingly as possible to prevent the development of antibodies and pharmaceuticals to address rare diseases, paediatric illnesses and endemic health issues in low income countries.

This option could also include an annual review of the savings delivered through any reduction in the length of extensions of term to be used in allocating funding to the replacement R&D subsidies.

**Draft Recommendation 5**

**Option 5.2:**

The Government should change the current extension of term provisions such that patents receiving an extension of term in Australia will not expire later than the equivalent patents in major trading partners.
Potential ways of achieving this include:

a) Providing an extension expiring up to 5 years after the original patent term or upon the expiry of the equivalent patent extension in one of a list of other jurisdictions including the United States and European Union.

This option ensures Australian extended patents would not expire later than equivalent patents elsewhere. If originators are unable to seek regulatory approval in Australia at the same time as elsewhere, this option would reduce the effective patent life.

b) Changing the method of calculating the length extensions of term to provide an incentive to submit applications for regulatory approval in Australia earlier than is currently the practice. This could be similar to the US method described above.

This option creates an incentive to seek regulatory approval in Australia as soon as possible, reducing delays in access to medicines for Australian health consumers. Under this system, one-to-one compensation is still provided for the time taken to process applications for regulatory approval.

**Recommendation 5.1**

The GMiA supports the review panel’s recommendation to divorce the use of the patent system (via the extension of term provisions) to subsidise research and development by shortening the extension of term and investing more directly into research and development. GMiA supports the conduct of pharma R&D and the grant of valid patents in Australia. Both of these contribute to a vibrant pharmaceutical industry which benefits the GMiA generally and provides a potential pipeline for generic pharmaceutical products. However this recommendation recognises the reality of the modern pharmaceutical industry, ie that it is a global industry, and that the relative size of the Australian market means that extensions of term here will not be sufficient to incentivise global companies to conduct R&D in Australia.

**Recommendation 5.2**

The GMiA supports these recommendations. In relation to Option 5.2(a), GMiA recommends that the expiry of the EOT should expire on the earlier of (a) the expiry date as determined under the current regime and (b) the earliest expiry of an EOT granted for a non-Australian patent(s) in the same patent family in prescribed countries (and then list those countries, suggested jurisdictions are the US and Europe). This would deal with both an Australian-only pharmaceutical substance patent as well as the earlier expiry of overseas extensions of patents where there is a patent family and overseas market authorisation.
GMiA notes that while implementation of this recommendation would enable both earlier generic launch in Australia and commercial export from Australia, it will not be sufficient to implement MFE. GMiA refers the Panel to its request to implement MFE in its original submission.

**GMiA Recommendation**

GMiA recommends the inclusion of Recommendations 5.1 and 5.2 in the final report of the Pharmaceutical Patents Review, provided that Recommendation 5.2 is qualified as described above.

### 3.4 Recommendation 6.2 and 6.3

**Recommendation 6.2:**

Section 76A of the Patents Act should be deleted. The Pharmaceutical System Coordinating Committee recommended in Draft Recommendation 10.1 should consider whether a mechanism for reporting on the use of public and private research funds in pharmaceutical R&D, similar to that established by the PMPRB and superior to s.76A, can and should be developed.

GMiA does not oppose this recommendation.

**Draft recommendation 6.3:**

Section 70(3) should be amended to clarify that the ARTG registration on which an extension of term is based is that of the relevant product, the use of which would infringe the claim. The Panel requests feedback from stakeholders on the effects of clarifying the legislation in this manner.

GMiA submits that by linking the regulatory test to the “relevant product”, an elongation of the EOT will result and delay access to generic forms of that product. The Draft Report has clearly summarised the state of the current law at page 105. However, GMiA submits that the proposed approach, especially in the case of products containing an enantiomer of an earlier approved racemic API, will further reward originators who obtain patents directed to the mere optimisation of existing approved drugs.

In enantiomer cases, the act of simple resolution of a racemate into its constituent enantiomers and patenting of those enantiomers will mean EOTs will be longer because the applicable approval date will be later. Likewise, if formulation patents remain eligible for extensions of term, patents directed to modified formulations of an existing approved drug (for example a rapid release formulation which is the subject of a patent) will be potentially afforded a longer EOT as there will be a different relevant product.

The GMiA discussed in its original submission at page 10 how patents directed to changes to existing drugs can prove powerful tools to delay generic market entry in Australia, even if they are of questionable validity. Providing for longer extensions of term for such products will exacerbate this and
provide originators with more opportunity to structure the market to extend their product monopoly to
the greatest extent, for example through transferring the market or PBS listing to newer products with
longer patent protection at the optimum time. GMiA submits that a more in-depth study is required
into these possibilities before such a recommendation is made.

3.5 Recommendation 7.1 and 7.2

Draft Recommendation 7.1

The Government should ask the Productivity Commission to review the effectiveness of Raising the Bar
Act at the earliest opportunity and not later than three years from the commencement of the Act.

GMiA Members were pleased to see the Intellectual Property Laws Amendment (Raising the Bar) Act
2011 come into full effect in April 2013, and support the Draft Recommendation 7.1 which allows the
effects of this amendment to be assessed by the Productivity Commission.

GMiA Recommendation

GMiA recommends inclusion of Recommendation 7.1 in the final report of the Pharmaceutical Patents
Review.

Draft Recommendation 7.2:

The Government should establish an external patent oversight committee that is tasked with reviewing
grants and decisions issued by IP Australia and auditing the processes involved in making such decisions.

The cost of “bad patents” to generic medicines suppliers, to the public, and to the government are too
significant to ignore. GMiA Members welcome draft recommendation 7.2 which is aimed at improving
the quality of patents coming out of the Australian Patent Office examination process. GMiA respectfully
submits that greater upfront quality control by the APO will minimise reliance on litigation.

GMiA Recommendation

GMiA recommends inclusion of Recommendation 7.2 in the final report of the Pharmaceutical Patents
Review.
3.6 Recommendation 9.1

**Draft recommendation 9.1:**

The Government should actively contribute to the development of an internationally coordinated and harmonised system where data protection is provided in exchange for the publication of clinical trial data.

In principle, GMiA does not oppose this recommendation.

GMiA members support a five year data exclusivity period for all medicines containing an API which has not been included in a product previously listed in the ARTG, and suggest there is no sensible reason to extend the duration or scope of data exclusivity for any product beyond this.

3.7 Recommendation 10.1 and 10.2

**Draft recommendation 10.1:**

The Government should establish a non-statutory Pharmaceutical System Coordinating Committee (PSCC) that reports to Parliament on an annual basis on the success and effectiveness of the patent, marketing approval and PBS systems, particularly where these interface. The PSCC should ensure there is sufficient engagement and coordination between the relevant agencies and take account of costs to government, efficiency of registration and approval processes and respond to issues raised by industry. The PSCC should comprise senior officials from at least DIICCSRTE, IP Australia, DoHA (Pharmaceutical Benefits Division and TGA), DFAT, Finance and Treasury (as chair).

GMiA is not opposed to the establishment of a Pharmaceutical System Coordinating Committee. However, should such a body be established, GMiA strongly recommends industry representation on any potential Committee. Industry representation is essential to ensure that the Committee has the benefit of the input of those with a comprehensive understanding of the complexities and nuances of the delivery of medicines to the Australian community through the PBS.

**Draft recommendation 10.2:**

When drafting the objects clause to be inserted in the Patents Act, as agreed to in the Government’s response to the Senate Community Affairs Committee’s Gene Patents report, the Government should take into account that the purpose of the legislation is to:

- further Australia’s national interest and enhance the well-being of Australians, including by providing reasonable access to healthcare; and
• provide strong, targeted IP protection - but only up to the point at which the costs (to consumers and the impediments of ‘follow on innovation’) are no greater than the benefits of incentivising innovation that would otherwise not occur.

GMiA supports recommendation 10.2.

4 Draft findings of the Panel

4.1 Draft finding 3.1

GMiA agrees that Australian Governments have lacked strategic intent, been too passive in their IP negotiations, and given insufficient attention to domestic IP interests.

While the Government has rightly agreed to only include IP provisions in bilateral and regional trade agreements where economic analysis has demonstrated net benefits, this policy has not always been followed.

GMiA strongly recommends that Australian Governments follow the policy of only including IP provisions in bilateral and regional trade agreements where economic analysis has demonstrated net benefits.

4.2 Draft finding 4.1

GMiA confirms that if MFE had been rendered unambiguously consistent with our international obligations, Australian annual pharmaceutical exports would have been several hundreds of million dollars higher than they are.

4.3 Draft finding 9.1

GMiA strongly agrees that an extension of data protection for biological pharmaceuticals does not provide any benefit.
4.4 Draft finding 10.1
GMiA strongly agrees that the patent system is of obvious significance to the pharmaceutical industry, trade negotiations and health policy in addition to industry and innovation in Australia. The cross-intersection of public policy and the high importance of delivery of medicines to the Australian community is such that Government agencies with the policy and program responsibility in these complex areas must be directed to engage with each other and with the industry to ensure that optimal policy settings for the Australian pharmaceutical system are implemented.

5 Additional items for consideration
A number of recommendations made in the GMiA submission dated January 2013 have not been specifically addressed in the recommendations in the Draft Report. GMiA requests the Panel reconsider the following recommendations in light of the draft report and in preparation of the final report.

These recommendations all support the Review’s intent to balance timely access to competitively priced pharmaceuticals, whilst fostering innovation and supporting employment in research and industry, and redress the current issues of the pharmaceutical patents system in Australia.

6 Conclusion
GMiA thanks the Panel for the opportunity to respond to the PPR Draft Report.

There remain a number of critical issues for the pharmaceutical industry in Australia and GMiA would welcome the opportunity to meet with the Panel to discuss elements of this response.