GMiA Generic Medicines Industry Association Pty Ltd

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PO Box 222
Pymble BC
NSW 2073

12 May 2011

Ms Julie Dennett
Committee Secretary
Standing Committee on Legal and Constitutional Affairs
c/ email

Dear Ms Dennett

Re: Response to Questions on Notice: Public Hearing concerning
Patent Amendment (Human Genes and Biological Materials) Bill 2010

Please find attached a response prepared by GMiA to a question taken on notice from Senator Boyce at the Public Hearing concerning the **Patent Amendment (Human Genes and Biological Materials) Bill 2010.**

Kind regards,

Kate Lynch
Chief Executive Officer
Generic Medicines Industry Association Pty Ltd

GMiA Generic Medicines Industry Association Pty Ltd

Response to Questions on Notice: Public Hearing concerning
Patent Amendment (Human Genes and Biological Materials) Bill 2010

Please find below a list of molecules that are or have been subject to intellectual property litigation in the last ten years, that took approximately 1-4 years to get to trial (or other resolution) and, we estimate, cost at least $2-3 million (total for all parties).

1. **Alendronate (MSD - Fosamax)**
2. **Aripiprazole (BMS - Abilify)**
3. **Atorvastatin (Pfizer – Lipitor)**
4. **Carvedilol (Roche – Dilatrend)**
5. **Clopidogrel (sanofi-aventis - Plavix)**
6. **Docetaxol (sanofi-aventis - Taxotere)**
7. **Epirubicin (Pfizer – Pharmorubicin)**
8. **Escitalopram (Lundbeck – Lexapro)**
9. **Fentanyl (Janssen Cilag - Durogesic)**
10. **Fexofenadine (sanofi-aventis – Telfast)**
11. **Gemcitabine (Eli Lilly – Gemzar)**
12. **Leflunomide (sanofi-aventis - Arava)**
13. **Olanzapine FCT / ODT (Eli Lilly – Zyprexa)**
14. **Omeprazole (AstraZeneca - Prilosec)**
15. **Oxycodone CR (Mundipharma - Oxycontin)**
16. **Paroxetine (GSK – Aropax)**
17. **Perindopril (Servier – Coversyl)**
18. **Sibutramine (Abbott – Reductil)**
19. **Sildenafil (Pfizer – Viagra)**
20. **Venlafaxine (Wyeth – Efexor XR)**

GMiA overview comment

The ability to challenge a granted patent underpins the integrity and public benefit of the patent system, as there is a limited assessment of the validity of the patent before the patent is granted. The patent system is reliant upon parties with a commercial interest to identify and challenge granted patents that lack merit.

Patents of dubious validity that delay or block the PBS listing of new generic medicines add to the public cost of the Pharmaceutical Benefits Scheme (PBS).

Challenging of patents is a costly and lengthy exercise.

One patent currently under challenge in the Australian Federal Court consists of about 130 pages and 130 separate claims (aripiprazole) demonstrating how complex and broad patents on pharmaceuticals can be. This is illustrative of an increasing tendency for secondary patents to be very broad and challenge to such patents would appear to be in the public interest.

The evaluation of the validity of some patents by the courts, with the benefit of time, resources and additional evidence not available to IP Australia during examination, is in the public interest.

Concomitantly, domestic intellectual property laws must appropriately balance the competing requirements of having new technology disclosed to, and used by, the public at an affordable price and the reward of term specific exclusive rights to patentees to solely benefit from their invention.

The current balance of laws is not in the public's best interest. Patents that were not granted or have been invalidated in other jurisdictions continue to deliver royalties and profits to the owners and licensees of equivalent patents in Australia, resulting in higher prices to the Australian public. Local researchers may be restricted by these Australian patents. Granting of weak patents restricts innovation, competition and diffusion of knowledge AND unnecessarily increases the cost to the public.

GMiA strongly urges the Parliament to support the amendments contained in the exposure draft of the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011. GMiA believes that the proposed amendments bring patent law in Australia more into line with the patent law of its major trading partners.

GMiA urges the Parliament to enact Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 as speedily as possible.

Case studies

GMiA has been able to collate more detail on several molecules in the above list and presents these details by way of case studies.

Clopidogrel (sanofi-aventis - Plavix)

The High Court of Australia on 12 March 2010 dismissed sanofi-aventis' bid to appeal the Full Federal Court's September 2009 judgment in favour of Apotex.

In August 2007, Apotex applied to the Federal Court of Australia for an order revoking Australian Patent No. 597784, in the name of sanofi-aventis, which covers clopidogrel and its pharmaceutically acceptable salts (the Clopidogrel Patent). In August 2008, the Federal Court found that a number of the claims in the Clopidogrel Patent were invalid, but did not invalidate claims for particular clopidogrel salts. Apotex appealed the decision of the Federal Court and on 29 September 2009, the Full Court of the Federal Court of Australia delivered its judgment in this case.

The Full Court found that all of the claims in the Clopidogrel Patent, including claims to a single enantiomer, particular clopidogrel salts and a process for preparing the enantiomer, are invalid for lack of inventive step. In relation to the clopidogrel salts, the Full Court determined that, taking either the racemate or the single enantiomer as the starting point, there was no inventive step involved in creating the salts, as it merely involved the application of common processes with common laboratory acids. The Full Court also upheld the decision of the Court at first instance, insofar as the claims to the single enantiomer and the process for resolving the enantiomer were found to be invalid for lack of novelty.

Apotex is now seeking compensation from sanofi-aventis for the 29 months Apotex has been prevented from marketing its brands.

Olanzapine FCT / ODT (Eli Lilly – Zyprexa).

Following an interlocutory injunction granted by Federal Court Judge John Middleton, Apotex was obliged to inform PBS officials in January 2010 of the withdrawal of its application for 40 olanzapine products which it aimed to start supplying via the PBS in April 2010. Apotex is prevented from launching a competitor product to Zyprexa pending the resumption of its challenge to Lilly's **Zyprexa** patent. Eli Lilly is claiming infringement on a medicine that drew $162 million in PBS outlays in calendar year 2009.

GMiA Generic Medicines Industry Association Pty Ltd

AUSTRALIAN PHARMACEUTICAL PATENT CASES
IN WHICH THE VALIDITY OF THE PATENT WAS CHALLENGED FOR LACK OF INVENTIVE STEP

Where available to GMiA, further details on some molecules are included in the table below.

Product name	Parties	Proceeding number and court	Date proceedings issued	Date proceedings ended	Time
Alendronate *(Fosamax)*	Arrow Pharmaceuticals v Merck	NSD 1211/2002 (Federal Court)[1] NSD 1563/2004 (Full Federal Court)[2] S 244/2006 (special leave application to the High Court)[3]	15 November 2002	10 November 2006	47 months
	Alphapharm v Merck	NSD 2364/2005 (Federal Court (interlocutory	29 November 2005	15 June 2007 (notice of discontinuance was filed - proceedings settled	< 2 years

[1] Arrow Pharmaceuticals Limited v Merck & Co., Inc. [2004] FCA 1282.
[2] Merck & Co Inc v Arrow Pharmaceuticals Limited [2006] FCAFC 91.
[3] Merck & Co Inc v Arrow Pharmaceuticals Ltd [2006] HCATrans 616.

		injunction)[4]		before trial)	
	Merck v Genrx	NSD 1848/2006 (Federal Court (interlocutory injunction)[5]	25 September 2006	14 January 2008 (notice of discontinuance was filed - proceedings settled before trial)	< 2 years
Aripiprazole *(Abilify)*	BMS v Apotex *(application to amend patent)*	NSD 1116/2009 (Federal Court)[6]	2 October 2009	Ongoing	< 2 years
Atorvastatin *(Lipitor)*	Ranbaxy v Warner Lambert Company	VID 926/2005 (Federal Court)[7] VID 93/2007 (Full Federal Court)[8]	10 August 2005	28 May 2008	33 months
Clopidrogrel *(Plavix)*	Apotex v Sanofi-Aventis Spirit Pharmaceuticals v Sanofi	NSD 1639/2007 (Federal Court)[9], [10] NSD 214/2008 (Federal Court)[11]	16 August 2007	12 March 2010	29 months

[4] Alphapharm Pty Ltd v Merck & Co Inc [2006] FCA 1227.
[5] Merck & Co Inc v Genrx Pty Ltd [2006] FCA 1407.
[6] Bristol-Myers Squibb Company v Apotex Pty Ltd [2010] FCA 814.
[7] Ranbaxy Australia Pty Ltd v Warner-Lambert Company LLC(No 2) [2006] FCA 1787.
[8] Ranbaxy Australia Pty Ltd (ACN 110 781 826) v Warner-Lambert Company LLC [2008] FCAFC 82.
[9] GenRx Pty Ltd v Sanofi-Aventis [2007] FCA 1485 (interlocutory injunction application).
[10] Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis [2008] FCA 1194.
[11] Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis [2008] FCA 1194.

	(heard together)				
	Apotex v Sanofi-Aventis and BMS Sanofi-Aventis v Spirit Pharmaceuticals (heard together)	NSD 1311/2008 (Full Federal Court)[12] NSD 1408/2008 (Full Federal Court)[13]	19 August 2008 8 September 2008	13 October 2009	< 2 years
Escitalopram *(Lexapro)*	Alphapharm v Lundbeck *(revocation/infringement)* Arrow Pharmaceuticals v Lundbeck *(revocation/infringement*	NSD 1120/2005 (Federal Court)[14] NSD 1048/2008 (appeal to the Full Federal Court)[15] S 135/2009 (special leave application to the High Court)[16] NSD 954/2006 (Federal Court)[17]	6 July 2005 17 May 2006	11 December 2009	52 months

[12] Apotex Pty Ltd v Sanofi-Aventis [2009] FCAFC 134.
[13] Apotex Pty Ltd v Sanofi-Aventis [2009] FCAFC 134.
[14] Alphapharm Pty Ltd v H Lundbeck A/S (includes corrigendum dated 27 June 2008) [2008] FCA 559.
[15] H Lundbeck A/S v Alphapharm Pty Ltd [2009] FCAFC 70.
[16] Alphapharm Pty Ltd v H Lundbeck A/S & Anor [2009] HCATrans 324.
[17] Alphapharm Pty Ltd v H Lundbeck A/S (includes corrigendum dated 27 June 2008) [2008] FCA 559.

		NSD 1052/2008 (appeal to the Full Federal Court[18] S 151/2009 (special leave application to the High Court)[19]			
	Lundbeck v Secretary of Health and Ageing *(TGA - protected information)*	NSD 1870/2005 (Federal Court)[20]	4 October 2005	24 April 2008	29 months
	Lundbeck v Commissioner of Patents *(extension of term proceedings)* (heard together)	NSD 1078/2006 (Federal Court)[21], [22] NSD 1053/2008 (appeal to Full Federal Court)[23] S 164/2009 (special leave application to the High Court)[24]	6 June 2006	11 December 2009	41 months
Fexofenadine	AMRI v Alphapharm	VID 219/2007 (Federal	20 March 2007	4 May 2011	Ongoing

[18] H Lundbeck A/S v Alphapharm Pty Ltd [2009] FCAFC 70.
[19] Alphapharm Pty Ltd v H Lundbeck A/S & Anor [2009] HCATrans 324.
[20] Alphapharm Pty Ltd v H Lundbeck A/S (includes corrigendum dated 27 June 2008) [2008] FCA 559.
[21] Alphapharm Pty Ltd v H Lundbeck A/S (includes corrigendum dated 27 June 2008) [2008] FCA 559.
[22] Alphapharm Pty Ltd v H Lundbeck A/S (No 2) [2008] FCA 1036.
[23] H Lundbeck A/S v Alphapharm Pty Ltd [2009] FCAFC 70.
[24] Alphapharm Pty Ltd v H Lundbeck A/S & Anor [2009] HCATrans 324.

(Telfast)	AMRI v Arrow Pharmaceuticals (heard together although orders were made on different dates)	Court)[25], [26] VID 883/2007 (Federal Court)[27], [28] VID 279/2011 *(Arrow appeal to Full Federal Court)*	28 September 2007	Ongoing	> 4 years
Leflunomide *(Arava)*	Sanofi-Aventis v Apotex	NSD 1664/2008 (Federal Court)[29], [30]	23 October 2008	Ongoing	Ongoing > 2 years
Omeprazole *(Prilosec)*	Atkiebolaget Hassle v Alphapharm Pty Ltd	NSD 884/1998 (Federal Court)[31] NSD 670/1999 (Full Federal Court)[32] S 287/2011 (High Court)[33]	27 August 1998	12 December 2002	51 months
Perindopril *(Coversyl,*	Les Laboratoires Servier v Apotex *(leave to appeal a*	NSD 1036/2009 (Federal court)[34], [35]	18 September 2009	11 November 2010	13 months (time of appeal only)

[25] Albany Molecular Research Inc v Alphapharm Pty Ltd [2011] FCA 120.
[26] Albany Molecular Research Inc v Alphapharm Pty Ltd (No 2) [2011] FCA 425.
[27] Albany Molecular Research Inc v Alphapharm Pty Ltd [2011] FCA 120.
[28] Albany Molecular Research Inc v Arrow Pharmaceuticals Pty Ltd [2011] FCA 252.
[29] Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd [2010] FCA 601.
[30] Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 2) [2011] FCA 213.
[31] Aktiebolaget Hässle v Alphapharm Pty Ltd [1999] FCA 628.
[32] Aktiebolaget Hassle v Alphapharm Pty Limited (includes corrigenda dated 24 October 2000) [2000] FCA 1303.
[33] Aktiebolaget Hassle v Alphapharm Pty Ltd [2002] HCA 59.

Aceon)	*decision refusing amendments to a patent)*				
	Apotex v Servier	NSD 657/2008 (Federal Court)[36], [37], [38]. [39]	9 May 2008	Ongoing	Ongoing > 3 years
	Servier v Apotex and other generics	VID 139/2007 (Federal Court)[40]	19 February 2007	Ongoing	Ongoing > 3 years
	Servier v Commonwealth of Australia *(Administrative law)*	VID 696/2007 (Federal Court)[41]	6 August 2007	28 January 2009	16 months
	Apotex v Servier	NSD 208/2007 (Federal Court)[42], [43]	14 February 2007	Ongoing	Ongoing > 4 years
Sibutramine *(Reductil)*	Abbott v Apotex	VID 796/2009 (Federal Court)[44], [45]	2 November 2009	14 October 2010	11 months

[34] Les Laboratoires Servier v Apotex Pty Ltd [2009] FCA 1139
[35] Les Laboratoires Servier v Apotex Pty Limited [2010] FCAFC 131.
[36] Apotex Pty Ltd (ACN 096 916 148) v Les Laboratoires Servier (Corrigendum dated 3 October 2008) [2008] FCA 1466.
[37] Apotex Pty Ltd v Les Laboratoires Servier (No 2) [2009] FCA 1019.
[38] Apotex Pty Ltd v Les Laboratoires Servier (No 3) [2009] FCA 1069.
[39] Apotex Pty Ltd v Les Laboratoires Servier (No 4) [2010] FCA 1202.
[40] Les Laboratoires Servier v Apotex Pty Ltd [2009] FCA 1097.
[41] Servier Laboratories (Aust.) Pty Ltd v Commonwealth of Australia [2009] FCA 31.
[42] Apotex Pty Ltd (formerly GenRx Pty Limited) v Les Laboratoires Servier (No 2) [2008] FCA 607.
[43] Apotex Pty Ltd (formerly GenRx Pty Limited) v Les Laboratoires Servier (No 3) [2008] FCA 1139.
[44] Abbott GMBH & Co. KG v Apotex Pty Ltd [2009] FCA 1366.
[45] Abbott GMBH & Co. KG v Apotex Pty Ltd (No 2) [2010] FCA 940.

Sildenafil *(Viagra)*	Eli Lilly v Pfizer	VID 604/2002 (Federal Court)[46] VID 337/2005 (Full Federal Court)[47] M 150/2005 (special leave application to the High Court)[48]	17 September 2002	2 June 2006	44 months
Venlafaxine *(Efexor)*	Wyeth v Alphapharm Wyeth v Sigma Wyeth v Generic Health (all heard together)	NSD 596/2009 (Federal Court)[49], [50], [51] VID 195/2009 (Federal Court)[52], [53], [54] NSD 1124/2009 (Federal Court)[55], [56] NSD 1533/2010 (appeal to Full Federal Court)[57]	19 June 2009 1 April 2009 06 October 2009	Ongoing	Ongoing > 2 years

[46] Eli Lilly and Company v Pfizer Overseas Pharmaceuticals [2005] FCA 67.
[47] Pfizer Overseas Pharmaceuticals v Eli Lilly and Company [2005] FCAFC 224.
[48] Pfizer Overseas Pharmaceuticals & Ors v Eli Lilly & Company & Ors [2006] HCATrans 271.
[49] Alphapharm Pty Limited v Wyeth [2009] FCA 945.
[50] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2010] FCA 1211.
[51] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth (No 2) [2010] FCA 1212.
[52] Sigma Pharmaceuticals (Australia) Pty Ltd (ACN 004 118 594) v Wyeth [2009] FCA 595.
[53] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2010] FCA 1211.
[54] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth (No 2) [2010] FCA 1212.
[55] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2010] FCA 1211.
[56] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth (No 2) [2010] FCA 1212.
[57] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2010] FCA 1258.

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Ms Julie Dennett

Committee Secretary

Standing Committee on Legal and Constitutional Affairs

c/ email

Dear Ms Dennett

Re: Response to Questions on Notice: Public Hearing concerning

Patent Amendment (Human Genes and Biological Materials) Bill 2010

Please find attached a response prepared by GMiA to a question taken on notice from Senator Xenophon at the Public Hearing concerning the **Patent Amendment (Human Genes and Biological Materials) Bill 2010.**

Kind regards,

Kate Lynch

Chief Executive Officer

Generic Medicines Industry Association Pty Ltd

GMiA Generic Medicines Industry Association Pty Ltd

Response to Questions on Notice: Public Hearing concerning

Patent Amendment (Human Genes and Biological Materials) Bill 2010

Improving the process through which to resolve patent disputes

Executive summary

The ability to challenge a granted patent underpins the integrity and public benefit of the patent system, as there is a limited assessment of the validity of the patent before the patent is granted. The patent system is reliant upon parties with a commercial interest to identify and challenge granted patents that lack merit.

In relation to pharmaceuticals, there will be instances where patents, particularly secondary patents, are of questionable validity.

The costs associated with court proceedings are extensive and a party will not take the decision lightly to challenge a patent in the courts. A patent is only likely to be challenged by a commercial entity in the event that there is a high likelihood of success AND a viable commercial return.

Two key factors that are currently impeding the challenge of questionable patents in the Australian jurisdiction are:

A. The declarations of non infringement provisions under the Patents Act (Cwth) 1990 are unworkable principally because of the uncertainty as to whether a generic pharmaceutical company has standing under the current legislation, and in any event no commercial entity will enter into litigation where it is required, as a matter of statute, to meet the patentee's costs; and

B. The ease by which the patentee can obtain an interlocutory injunction is significantly influenced by the Commonwealth Government's policy of statutory price reductions and the Federal Court's view on launching 'at risk' versus 'clearing the way'.

    a. The specific legislative amendment to section 99ACB of the NH Act that governs the statutory price reduction of 16% (previously 12.5%) upon entry of the second brand into a therapeutic classification is currently distorting the court process by providing greater reason for the judge to grant an interlocutory injunction to the patent holder.

    b. GMiA contends that it is not in the public interest for sponsors of generic medicines to be obliged to 'clear the way' of all potentially relevant patents or that lack of such action being taken be a factor for consideration in whether an interlocutory injunction should be granted.

Typically, the interlocutory injunction is not lifted until final determination, including any appeal proceeding from the judgement at first instance, generally two to three years after commencement of proceedings. This has had the unintended consequence of virtually precluding the ability of the sponsor of a new generic medicine to launch on the PBS prior to patent expiry of all the patents related to a particular molecule. This is a consequence of launching 'at risk' in the face of granted patents.

The ability to launch 'at risk', while the court determines the validity or otherwise of a patent, provides the public with the benefit of more affordable medicines earlier.

The current commercial advantage to the patentee of defending potentially invalid patents and consequently delaying the market entry of generic medicines is significant:

1. It protects the patentee's monopoly revenue stream for the period of the delay; and
2. The delay provides sufficient time for a patentee to introduce a downstream version of the medicine (for example, an extended release version or a version based on a salt) and switch doctors' prescribing habits from the original drug to the modified version. This has happened.

Patents of dubious validity that delay or block the PBS listing of new generic medicines unnecessarily add to the public cost of the PBS scheme.

Recommendations

- GMiA urges the Parliament to enact Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 as speedily as possible. This Bill proposes amendments to the declaration of non infringement provisions that are expected to make these provisions workable in the Australian jurisdiction.
- GMiA strongly urges the Parliament to pursue reform that will neutralise the 16% statutory price reduction and the failure to 'clear the way' as a factor in relation to litigation on all patents relating to medicines.

Introduction

Challenging patents is a costly and lengthy exercise.

One patent currently under challenge in the Australian Federal Court consists of about 130 pages and 130 separate claims (aripiprazole) demonstrating how complex and broad patents on pharmaceuticals can be. This is illustrative of an increasing tendency for secondary patents to be very broad and challenge to such patents would appear to be in the public interest.

The evaluation of the validity of some patents by the courts, with the benefit of time, resources and additional evidence not available to IP Australia during examination, is in the public interest.

Concomitantly, domestic intellectual property laws must appropriately balance the competing requirements of having new technology disclosed to, and used by, the public at an affordable price and the reward of term specific exclusive rights to patentees to solely benefit from their invention.

Under the current regulatory and legislative environment, the barriers faced by sponsors of generic medicines are too high and the consequence is that few generic medicines will be introduced into the Australian market, even in cases where the patent is suspected to be invalid. This results in a public loss as potentially invalid patents will not be tested, a fundamental tenet to an effective patent regime. More relevantly, medicines protected by invalid patents will not be subject to market competition, resulting in higher prices to the Australian public.

The current balance of laws is not in the public's best interest. Patents that were not granted or have been invalidated in other jurisdictions, continue to deliver royalties and profits to the owners and licensees of equivalent patents in Australia, resulting in more expensive medicines. Local researchers may be restricted by these Australian patents. Granting of weak patents restricts innovation, competition and diffusion of knowledge AND unnecessarily increases the cost to the public.

It is in the public interest to ensure that sponsors of generic medicines are able to launch new generic medicines and where necessary have an effective avenue to challenge weak patents to help preserve the integrity of the patent system and to ensure that consumers obtain the economic and health benefits of timely generic medicine entry.

A. Declaration of non-infringement provisions

Recommendation

- GMiA urges the Parliament to enact Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 as speedily as possible. This Bill proposes amendments to the declaration of non infringement provisions that are expected to make these provisions workable in the Australian jurisdiction.

A person who wishes to exploit an invention may apply to the prescribed Court for a declaration that the exploitation of the invention would not infringe a claim of a particular complete specification. This is known as seeking a Declaration of Non-infringement.

There is a strong disincentive in the Patents Act (Cwth) 1990 against a sponsor of a generic medicine to seek a declaration of non infringement in Australia because:

a. It is uncertain whether the sponsor has standing. On one view, only a sponsor with its own patent can seek a declaration of non infringement under the Act.
b. The sponsor of the generic medicine will have to pay the costs of the patentee irrespective of the court outcome. It is not surprising that, to the best of the knowledge of members of GMiA, the existing provisions have only ever been used once.

Sections 125 - 127 of the Patents Act (Cwth) 1990 are unworkable (as proven by their lack of use) principally because no commercial entity will enter into litigation where it is required, as a matter of statute, to meet the patentee's costs in any event. If a patentee believes that another party does not infringe having been given notice of the proposed product or process, there is no incentive to the patentee to agree given that irrespective of the outcome of the application its costs are secured. So even if the patentee loses, it is not out of pocket.

GMIA understands there is no similar disincentive given to applicants for non-infringement declarations in Europe or in the USA.

It is commercially unacceptable (especially in the sector represented by GMIA) to basically hand a blank cheque for patentees costs. There is no incentive for the patentee to admit non-infringement given that this could be very damaging to its commercial activities. Basically, there is no reason to distinguish the normal rules for patent litigation from applications for non-infringement declarations. Our major trading partners in Europe and the USA do not have provisions similar to those currently proposed. Consequently, GMIA considers that a fairer approach is for costs to follow the event, as is generally the case for court proceedings.

Further, GMIA believes that any person should be entitled to commence an action seeking a declaration of non infringement whether or not they themselves are a patent applicant.

Intellectual Property Laws Amendment (Raising the Bar) Bill 2011

The Draft Exposure Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 proposes a number of changes to sections 125 - 127 of the Act (see item 72 of Schedule 6 of the Draft Bill) that propose amending the declaration of non-infringement provisions. The main changes are:

i. proposed amendments to s 125 to make it clear that any person can seek a declaration of non-infringement. This reverses the decision in *Occupational and Medical Innovations v Retractable Technologies Inc*[2] where it was held that only a patentee or patent applicant could seek a declaration.
ii. a declaration of non-infringement would also apply to past, present and future acts.
iii. a person may only seek a declaration of non-infringement with respect to a granted patent or a certified innovation patent. This reverses the previous position where a declaration could be sought once a complete specification was open to public inspection.
iv. proposed amendments to s 126 provide that the validity of a patent may be challenged in the same proceedings as for a non-infringement declaration. This reverses the current position.

[2] [2008] FCA 1102

v. the Court would also be allowed to make cost orders as the court thinks fit. This reverses the current position that an applicant has to bear the costs of all parties to the proceedings.

A Court may not make a non-infringement declaration unless the applicant for the declaration:

(i) has previously contacted the patentee seeking an admission that the act has not or would not infringe the patent;

(ii) has provided full particulars of the act; and

(iii) undertaken to pay a reasonable sum for the patentee obtaining advice on whether the acts would infringe the patents. These requirements have not changed materially from the current law (although the word exploit is now replaced with the terminology of doing an act). The main thing is that liability for the costs of the proceeding will be determined using the normal rules courts follow in other patent proceedings.

GMIA supports the proposed changes described above. However, GMIA also submits that s126(1)(a)(iii) of the Patents Act (Cwth) 1990 should be amended so that an applicant should not have to bear the costs of the patentee obtaining initial advice on infringement. No such change has been made to this section of the Act under the exposure draft of the Bill and the original wording is retained.

B Ease of patentee obtaining interlocutory injunctions

Recommendation

- GMiA strongly urges the Parliament to pursue reform that will neutralise the 16% statutory price reduction and the failure to 'clear the way' as a factor in relation to litigation on all patents relating to medicines.

Notwithstanding a strong case by the challenger of the patent, the patentee, as part of patent infringement proceedings, will typically apply to the courts for an interlocutory injunction against the challenger. If granted, this prevents the launch of the generic medicine until the injunction is lifted. Based on recent cases in Australia, the injunction is not lifted until determination of an appeal proceeding from the judgement at first instance, generally two to three years after commencement of proceedings.

In Australia the patentee is required to demonstrate three elements to the court to win an injunction:

1. That there is a serious case to be tried on infringement;
2. That the applicant patentee would suffer irreparable harm for which damages would be an inadequate remedy; and
3. That the balance of convenience is in favour of granting relief.

Members of GMiA are only aware of two exceptions of recent Federal Court decisions where the court has not imposed on an interlocutory injunction on the launch of a generic medicine /

healthcare technology.[1] In recent injunction proceedings in Australia the award of an injunction has turned on the adequacy of damages as a remedy and to balance of convenience. The serious case to be tried hurdle is a relatively low one, and few cases turn on that hurdle.

Recently, sponsors of generic medicines have gone to great lengths to attempt to assuage the courts concerns in relation to the adequacy of damages by offering undertakings not to list on the PBS, to only launch in the private market (which usually accounts for a very small percentage of total sales of the entire molecule) and/or to offer a bond or bank guarantee in respect of damages instead of the court awarding an injunction.

B.1 Influence of the Commonwealth's policy of statutory price reduction

The 16% (previously 12.5%) legislative automatic price reduction has been used by patentees to argue to the court that the launch of the generic medicine 'at risk' will cause irreparable change to the market (that is, loss of established trade and market share to the patentee that prior to generic launch naturally has 100% market share and price reduction triggered by the 16% automatic price reduction on entry of the second brand) that the patentee argues could not be reversed, will cause it irreversible harm and will result in unquantifiable damage.

Generic sponsors to date have been unsuccessful in persuading the courts not to accept such arguments since the change from a monopoly market to a competitive market will by definition result in a loss of market share and loss of revenue to the monopolist. Further, the patentees have argued, and the courts have accepted, that while the Minister may have a discretion to reverse a price drop (triggered by entry of a new generic medicine) under s99AEI of the National Health Act (Cwth) 1954 there is no requirement to do so which prejudices the patentee and means it will not be possible to 'revert to the status quo' should the patent be found to be valid.

In summary, even when the court has found in favour of the generic sponsor that there is a serious case to be tried in relation to invalidity of a patent, the 'inadequacy of damages' to a monopoly market and the 16% automatic price reduction arguments have tipped the balance of convenience finding in favour of the patentee resulting in the court granting the interlocutory injunction. This is notwithstanding that the monopoly and the alleged inadequacy of damages caused by generic competition are derived from a patent about which the court has said there is a serious question as to invalidity.

GMiA agrees that the 16% statutory price reduction triggered upon entry of the second brand on the PBS is an important policy arrangement contributing significantly to the ongoing sustainability of the PBS and should remain in place.

However, the 16% statutory price reduction is currently distorting the court process by providing greater reason for the judge to grant an interlocutory injunction AND it encourages the

[1] [SMITH & NEPHEW PTY LTD v WAKE FORREST UNIVERSITY HEALTH SCIENCES [2009]FCAFC 142], that dissolved an interlocutory injunction on the grounds of the patent's prima facie invalidity; and [sanofi-aventis v HOSPIRA] where Judge Jayne criticised a "lengthy and unreasonable" delay by sanofi-aventis in bringing the case to court and the introduction of the generic medicine would not trigger the 16% statutory price decrease.

commencement of patent infringement proceedings by the patentee for strategic reasons to delay the market entry of the generic medicine.

The delay provides sufficient time for a patentee to introduce a downstream version of the medicine (for example, an extended release version or a version based on a salt) and switch doctors' prescribing habits from the original drug to the modified version. Then, prior to proceedings ending, the original medicine can be withdrawn from the PBS system thus ensuring no reference medicine is available to be used for 'a' flagging purposes by the Sponsor of generic medicines. This practice could effectively prevent certain generic medicines from ever being PBS listed and acts as a significant disincentive to the launch of new generic medicines.

B.2 'Clearing the way' doctrine followed by Federal court of Australia

The Federal Court of Australia in recent decisions has suggested that there is an obligation upon generic sponsors to have 'cleared the way' of **ALL applicable** patents prior to launch of a new generic medicine and that a failure to 'clear the way' by revoking the patent is relevant to whether to grant an interlocutory injunction

Typically, the Sponsor of a generic medicine is not commercially in a position to commence patent proceedings three or more years before launch because:

- The litigating generic company, which will bear the full cost of litigation, is likely to be restrained from taking steps to commercialise, despite all generic companies benefiting. Those generic Sponsors not subject to any injunctive restraint can prepare for launch secretly, thus depriving a successful generic litigant of the fruits of their endeavours.
- The market may change over those years, especially as the originator tries to switch the market to other products.
- There is inherent uncertainty in bringing a generic formulation to market. From time to time bioequivalent studies fail and the TGA may, for unforeseen reasons, not approve an application. It is not commercially feasible to invest in costly litigation three or more years prior to launch. Further, there is an associated risk that, if the generic company embarks upon successful legal proceedings to 'clear the path' but is not successful in developing an approvable generic formulation, the market will open up for their competitors. Ironically they might not even have a product and so may not themselves benefit from the legal action.
- The sheer volume of secondary and tertiary patents surrounding a single pharmaceutical compound and the time and cost involved in patent proceedings in Australia makes it commercially prohibitive for a generic company to commence multiple patent proceedings to 'clear the path' of all potentially relevant patents surrounding a single medicine.
- The legal bar that needs to be hurdled to prove that a patent is invalid on the ground of obviousness is so high as to be itself a disincentive to trying to invalidate a patent early. The height of this bar has been acknowledged in the IP Australia Consultation Paper March 2009 entitled, *Getting the Balance Right* (part 4).

Proposed principle

It is considered critical that generic sponsors of a medicine be able to launch 'at risk' without the prospect of an automatic injunction against them. The 16% statutory price reduction and the failure to 'clear the way' should be 'neutralized' as a factor in relation to litigation on all patents relating to medicines.