



Australian Government



PHARMACEUTICAL PATENTS REVIEW

Background and Suggested Issues Paper

November 2012

Review

Background and Suggested Issues Paper

The review panel has released this issues paper to establish the scope of the review and to assist stakeholders in making submissions.

Key dates

Announcement of review	15 October 2012
Release of issues paper	November 2012
Due date for submissions	21 January 2013
Hearings	February 2013
Draft report	March 2013
Final report	April 2013

Submissions

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Further topics and papers for discussion will be published on the website during the course of the review. Interested parties are encouraged to comment on these and post their own material for discussion.

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1. How to use this issues paper

This issues paper outlines the review panel's initial impressions of the key issues. It seeks to begin engaging with anyone who has an interest in this area and to provide a stimulus for written submissions. Chapter 8 provides more information about making a submission. The paper includes questions that may provide ideas for developing your submission. However ultimately we are interested in your views, and you should provide them to us in the clearest way you can. Accordingly you should not be limited by our questions if there are other points that you would like to make.

You are also welcome to contribute to the review by commenting on our blog at <http://pharmapatentsreview.govspace.gov.au>. The review panel will be posting topics and papers on the blog for further discussion during the review.

2. Framework for the review

The role of the Pharmaceutical Patents Review Panel

The review panel has been asked 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 will include an analysis of the current pharmaceutical extension of term provisions, which have not been reviewed since their introduction in 1998. Other issues to be considered include the granting of patents for new formulations, methods and uses of pharmaceuticals, contributory infringement and strategies for extending market exclusivity. The review panel is particularly interested in evidence of whether the current system for pharmaceutical patents supports or hinders innovation, investment and competition. The full terms of reference for the review are available in Appendix A.

What is a pharmaceutical patent?

For the purposes of this review, a pharmaceutical patent is taken to be a patent for a medicine or that directly relates to a medicine. It includes, but is not limited

to, patents with claims for active ingredients, new formulations and methods of production or use. For example:

- a new active ingredient developed to treat a condition
- a new way of formulating the medicine to provide some benefit, such as improving its absorption into the body
- a new method of producing the medicine, which could be more efficient
- a new use for the medicine in treating a different condition.

Pharmaceutical patents include both standard and innovation patents.

Pharmaceutical patents and innovation

The aim of the patent system is primarily economic. It aims to provide sufficient incentives for new inventions to be developed, while ensuring affordable public access to existing inventions. However, patents are not necessary to encourage innovation in fields where the development costs are low. For example, chefs do not need a 20 year exclusive right to their recipes to encourage them to develop new ones.

It is generally accepted that some sort of incentive is needed for the originator pharmaceutical sector. As discussed further in Appendix D, bringing pharmaceuticals from research phase to market can be a particularly expensive and risky business, with only a small percentage of research resulting in a commercially successful product. Whether the patent system is providing appropriate incentives needs to be assessed at a broad level – by whole technologies and sectors – rather than by individual products or companies.

It should also be noted that while the patent system is designed to encourage innovation, patents have their own costs and can limit innovation and affordable access to technology if the correct balance is not found. Further information on patent theory and Australia's patent system is available in Appendices B and C.

An important feature of the patent system is that it involves an exchange. The government grants an inventor an exclusive, temporary set of legal rights for an invention in exchange for the inventor sharing details of the invention with the public, thereby facilitating further innovation in that field.

The term 'evergreening' generally refers to a variety of legal and business strategies used by a patent owner to extend the patent term or market exclusivity for an invention. These strategies sometimes combine the use of the patent system with particular marketing techniques, such as creating 'patent thickets'. Some of the key mechanisms used to extend protection are discussed throughout this paper.

The impact of international agreements

The Australian patent system operates within an international context. Most countries of the world provide a patent system, which have similarities and differences to Australia's system. A country's patent system can influence the attraction and retention of investment and industry activity.

Australia has agreed to a number of international treaties or agreements which impose particular requirements on Australia's patent system, including in relation to pharmaceuticals. These agreements are discussed further in Appendix C and in the main sections of this paper where relevant.

3. Pharmaceutical extensions of term

Objectives

Pharmaceutical extensions of term provisions were first introduced with the *Patents Act 1990* (Cth). Those original provisions were replaced by the current extension of term scheme, which commenced in 1998. The scheme was introduced in recognition that a patent owner is unable to commercially exploit a patent until regulatory approval from the Therapeutic Goods Administration (TGA)¹ is given. The intention was to provide an effective patent term from the date of marketing approval that was “more in line with that available to inventions in other fields of technology”.²

The scheme was also intended to provide a patent system which is in line with other developed nations, recognising the importance of a country's intellectual property system in securing investment in research, development and manufacturing as well as access to pharmaceutical products.³ Australia is obliged to retain a system of extensions for pharmaceutical patents under the Australia-United States Free Trade Agreement (AUSFTA).⁴ However, the Agreement does not specify a particular length for the extensions.

The intended breadth of the provisions is that extensions only be available for patents that include claims to pharmaceutical substances *per se*, but not for delivery systems or administration regimes. Patents that claim a process for producing a pharmaceutical substance are only eligible if the substance is produced by a recombinant DNA process and the substance is new.⁵ Claims which limit the use of a known substance to a particular environment, including claims to substances when used in a new and inventive method of treatment, are not considered to be claims to pharmaceutical substances *per se*. For example, a

¹ A list of abbreviations used in this paper is provided in Appendix E.

² Revised Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill 1998*, page 3.

³ Second reading speech, House of Representatives, 26 November 1997.

⁴ See Appendix C for more details.

⁵ Revised Explanatory Memorandum, page 18.

patent for a system of delivering a known active ingredient is ineligible for an extension.

The introduction of the extension of term provisions was estimated to result in an additional cost to the Pharmaceutical Benefits Scheme (PBS) of \$6 million in 2001-02, increasing to \$160 million in 2005-06, due to delays in the introduction of generic products.⁶

The Revised Explanatory Memorandum to the *Intellectual Property Laws Amendment Act 1998* (Cth) stated that an evaluation of the appropriateness of the extension of term provisions should be undertaken five years after commencement, and an evaluation of their efficiency and effectiveness take place after 10 years. These evaluations form part of this review.

Legal framework

Chapter 6, Part 3 of the Patents Act provides that the term of a standard patent may be extended if the following requirements are met:

- the patent must disclose and claim a pharmaceutical substance *per se*, or a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology
- goods containing, or consisting of, the pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (ARTG)
- the period from the effective filing date of the patent to the date of first regulatory approval must be at least five years, and
- the term of the patent must not have been previously extended.⁷

An application for an extension of term must be submitted to IP Australia within six months of the patent being granted, or of the first inclusion of the pharmaceutical in the ARTG, whichever is later.

A patent which meets these requirements can be extended by up to five years, taking the duration of the term up to twenty-five years. The length of an extension of term is calculated to be the period from the date of filing the patent

⁶ *Ibid*, page 2.

⁷ *Patents Act 1990* (Cth), s.70.

until the date of marketing approval by the TGA, minus five years. Marketing approval typically takes 12 months from application.⁸

Table 1 – Period of extension in Australia

Years from patent filing to TGA marketing approval	Extension of patent term
< 5	0
6	1
7	2
8	3
9	4
10	5
11	5
etc	5

Although the term of the patent is extended on the basis of a specific pharmaceutical substance having regulatory approval, the extension applies to any pharmaceutical substance claimed in the granted patent. During the extension, the exclusive rights of the patent owner are limited to the therapeutic use of the claimed pharmaceutical substance(s). A patent will not be infringed during the period of the extended term if:

- a person exploits the claimed pharmaceutical substance(s) for a purpose other than for a therapeutic use, or
- a person exploits any form of the invention other than a pharmaceutical substance per se.⁹

Chapter 11, Part 1 of the Patents Act provides exemptions from infringement for obtaining regulatory approval for patented pharmaceuticals.¹⁰ Under these exemptions, a patent will not be infringed by a person who exploits the invention solely for the purpose of obtaining inclusion in the ARTG or similar approval in a

⁸ TGA prescription medicines Streamlined Submissions Process newsletter, June 2012.

⁹ Section 78.

¹⁰ Section 119A.

foreign country. The export of pharmaceuticals for obtaining such approvals overseas is only permitted for the patented pharmaceutical substances where the patent term has been extended.

Comparison with other jurisdictions

Around 24 countries grant some kind of extended exclusivity period in the field of medicinal products. This includes Australia, most European countries, the US, Japan, Singapore and South Korea. The main differences between the systems lie in what pharmaceutical inventions are eligible, how the extension is calculated and the maximum extension available. Table 2 on the following page summarises these differences. Countries which do not currently provide for patent term extension for pharmaceuticals include Argentina, Brazil, Canada, China, Ecuador, India, Malaysia, New Zealand and South Africa.

Breadth of inventions covered

Extensions of term are available for active ingredients and for formulations of known active ingredients in Australia, US, Europe, UK and Japan. The US and Japan also provide extensions for uses and methods of manufacture of pharmaceuticals, whereas Australia, UK and Europe do not.

This means that all the above countries would extend a patent for an active ingredient for reducing hypertension, as well as a patent for a formulation that reduces its unwanted side effects. However, of these countries only the US and Japan would extend a patent for a new therapeutic use for the active ingredient or a method of manufacturing it.

Length of extension

Generally, Australia, Japan and European countries provide a maximum effective patent life of 15 years while the US provides up to 14 years:

- Europe's system of Supplementary Protection Certificates (SPC) calculates the extension in the same way as in Australia.
- Japan and the US calculate the extension based on the time taken for regulatory studies to be completed. Japan uses the period from the commencement of clinical trials to marketing approval. The US takes into

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account the full period of time taken to obtain approval from the Food and Drug Administration (FDA) and half the time taken for clinical trials.

Previous studies have indicated that extensions granted in Australia expire later than those granted in other jurisdictions. This appears to be the result of either the different methods of calculating the extension in the US and Japan, or differences in time taken to obtain regulatory approval.^{11, 12}

Table 2 – Comparison of Extension of Term Systems

Country	Extension available	Max Effective Patent Life	Extension for Product	Extension For Use	Extension For Manufacture	Extension For Mixtures of Actives	Calculation of extension (F) [^] See Fig 5 below
AU	Y	15	Y	N	N	Y	$F=A+B+C+D - 5$
US	Y	14	Y	Y	Y	Y	$F=C/2 +D$
EP/UK	Y	15	Y	N	N	Y	$F=A+B+C+D - 5$
JP	Y	15	Y	Y*	Y*	Y	$F=C+D$
CA	N	n/a	n/a	n/a	n/a	n/a	n/a
NZ	N	n/a	n/a	n/a	n/a	n/a	n/a

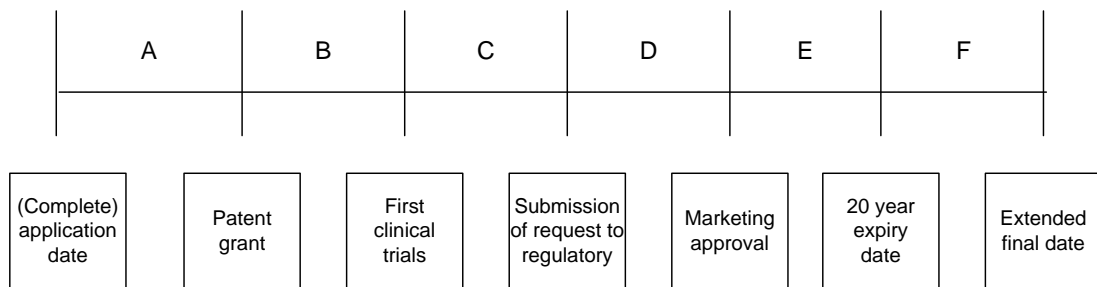
[^] $F \leq 5$ |

* the extension of use and process patents is only given where the working of the claimed invention would require separate approval and is not covered by earlier regulatory approval processes.

¹¹ Research conducted by IPRIA in 2002 on around 20 ‘blockbuster drugs’ found that about 66% of extensions granted in Australia were for longer periods than in the US and UK. On average, patents filed in the US expired 16 months earlier than those filed in Australia. Similarly, patents filed in the UK expired 17 months earlier on average, despite the similar process for calculating the extension. See A Christie et al., *Review of Pharmaceutical Patent Extension and Springboarding Provisions in Various Jurisdictions – Final Report to the Commonwealth Department of Industry, Tourism and Resources*, IPRIA, 2 November 2002.

¹² An analysis of a relatively small sample by IP Australia in 2009 confirmed that extensions in Australia extend the life of the patent beyond that of the equivalent overseas patent in most cases. However, the difference in time between marketing approval in Australia and in Europe is in most cases had fallen to around 6 months.

Figure 1 - General Process for Regulatory and Patent Processing



Note: The scheme represented in Figure 1 is based on clinical trials commencing after the grant of the patent. In the US and Japan, extensions of term are calculated with reference to the first clinical trials or the date of grant of the patent, whichever is later.

Use of the system

From the commencement of the extension of term scheme in 1991 to June 2012:

- there were 721 applications for extensions
- 621 (86%) of these were granted, with some still pending
- durations of extensions ranged from 0 months to 5 years, with an average of three years nine months
- there were 10 oppositions to an extension of term filed, and subsequently five were withdrawn
- the time taken for an application to be granted varies considerably, depending on a number of factors. The median time is around 30 weeks.

Figure 2 – Total extensions of term 1999-2011

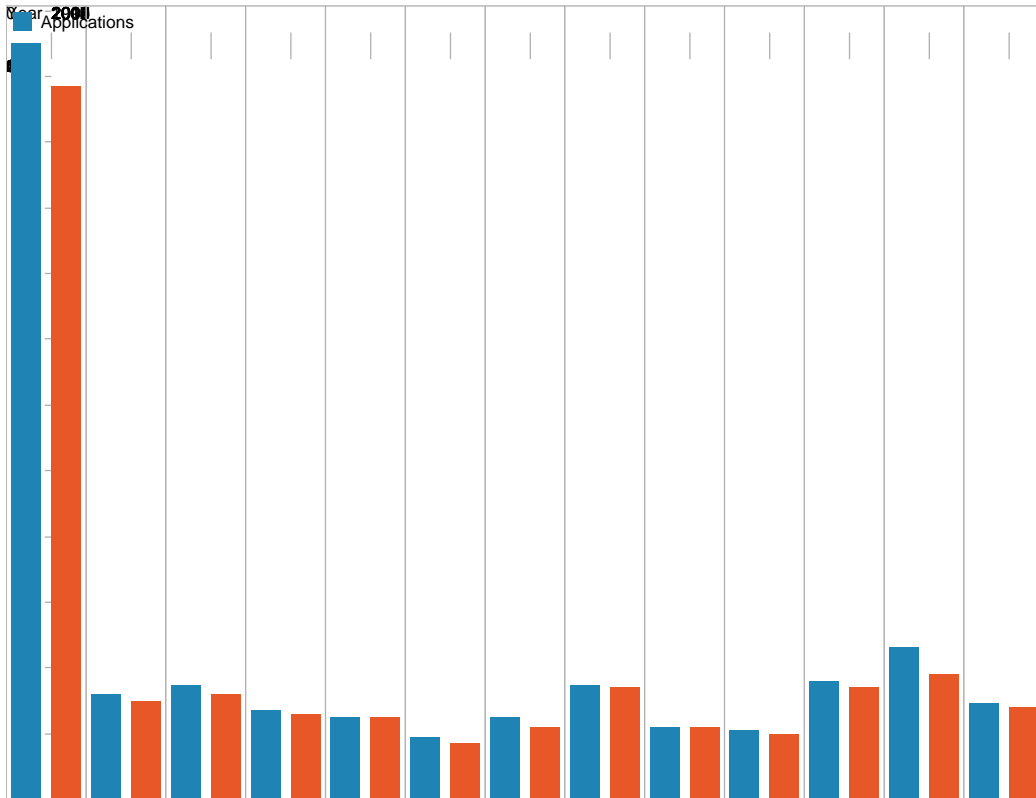
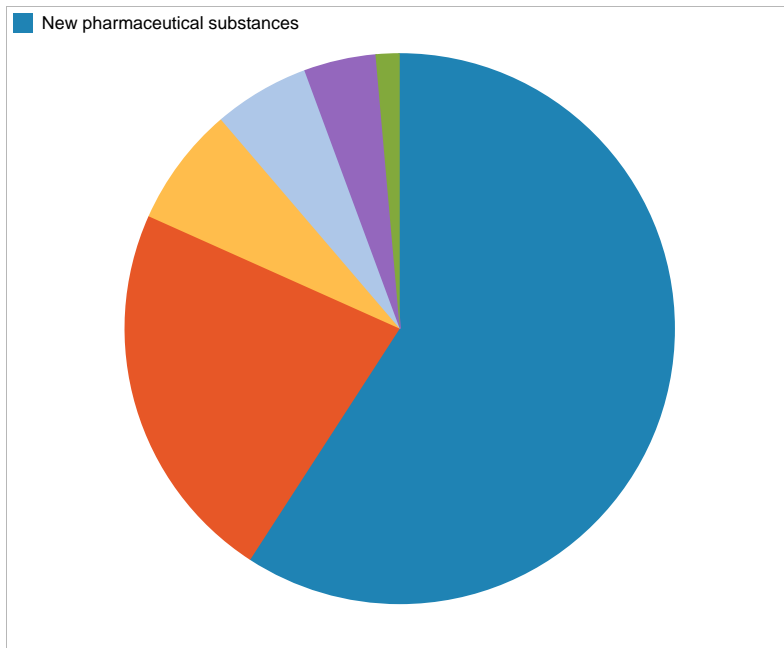


Table 3 - Top applicants for extensions of term

Applicant	No. of applications
Novartis AG	46
Glaxo Group Ltd	28
Merck	28
AstraZeneca AB	24
F. Hoffmann-La Roche AG	23
Pfizer Inc	23
Sanofi-Aventis	20
Schering Corporation	19
Eli Lilly and Company	17
Janssen Pharmaceutica N.V.	17

A random sampling conducted by IP Australia of the types of pharmaceutical patents granted extensions of term has found that around 60% of extensions are for new pharmaceutical substances. Around 28% are for formulations or combinations of known drugs. Figure 3 shows the full breakdown.

Figure 3 – Types of pharmaceutical patents granted extensions of term¹³



¹³ Provided by IP Australia, November 2012. Based on random 10% sample of all granted extensions of term from 1998 to October 2012.

Case study – extension of term

Olanzapine, marketed by Eli Lilly as Zyprexa[®] is an anti-psychotic medication used for the treatment of schizophrenia and bipolar disorder. Zyprexa was the fifth highest selling medication in Australia in 2008¹⁴ and was within the top ten pharmaceuticals globally in 2009.¹⁵ Eli Lilly was granted patent no. 643267 for olanzapine in 1994. TGA marketing approval was provided in 1997 and Eli Lilly obtained an 11 month extension of term in 1999. The extended patent expired in March 2012 and a number of generic versions of olanzapine are now available.¹⁶

Concerns

In recent years a number of concerns have been raised about the length and breadth of protection provided by the extension of term provisions, that is, the duration of the extension and the types of pharmaceutical patents eligible.

The originator sector of the pharmaceutical industry has argued that the provisions are too restrictive for patent owners and are not sufficient to encourage innovation.¹⁷ One such concern is the interpretation of the first regulatory approval date for a substance. For example, the first approval date for a new formulation of a substance may be considered to be the approval date for the original substance on the ARTG. This can mean that, although regulatory approval for the new formulation was obtained more than five years after the filing of the follow-on patent, the follow-on patent may be eligible for little or no extension of term.¹⁸

¹⁴ Medicines Australia – *The Australian Pharmaceuticals Industry – Winds of Change*, 2009.

¹⁵ Medicines Australia – *Medicines Australia Facts Book*, Second Edition, May 2012.

¹⁶ NPS Medicinewise - http://www.nps.org.au/consumers/tools_and_tips/medicine_name_finder.

¹⁷ Medicines Australia, *Time to consider longer patent terms*, media release 15 October 2012.

¹⁸ Flattery-O'Brien, J. and Shoebridge, G. *Mixed messages for patent owners*, *Managing Intellectual Property Life Science IP Focus* (7th ed.), 2009, pp.9-12.

Case study – ‘first regulatory approval date’

The anti-depressant citalopram is a mixture of two enantiomers, or mirror image forms. Lundbeck Australia owned patent no. 509445 for citalopram, which it has marketed as Cipramil[®]. The patent expired in 1993. Lundbeck succeeded in separating the enantiomers and found that the (+) enantiomer, escitalopram, was more than 100 times more active than the (-) enantiomer. In 1992, Lundbeck obtained patent no. 623144 for escitalopram, which it has marketed as Lexapro[®].

In 2003, Lexapro[®] was listed on the ARTG and in 2004 IP Australia granted Lundbeck a five year extension of term. In 2005, IP Australia became aware that the first listing on the ARTG of the (+) enantiomer may have been Cipramil[®] in 1997. This would mean that the extension may have to be reduced and, in any case, Lundbeck’s request for an extension may have been made too late. The case was taken to the Full Federal Court, which found that Cipramil[®] was the first listing of the (+) enantiomer on the ARTG.¹⁹

Lundbeck lodged a new application for an extension of term, accompanied by an application for extra time in which to do so. IP Australia’s decision to grant the extra time has been appealed to the Administrative Appeals Tribunal and no decision has been issued yet. A number of generic versions of Lexapro[®] have been on the market since Lundbeck’s patent expired in 2009.

The practice in Australia has been contrasted with the practices in other countries.²⁰ In Europe, the US and Japan, an enantiomer product is likely to be entitled to an extension of term, even where an extension has previously been granted for a composition comprising a mixture of enantiomers.²¹

¹⁹ *H Lundbeck A/S v Alphapharm Pty Ltd* [2009] FCAFC 70.

²⁰ Summerfield, M. *Pharmaceutical Extensions of Term: Is it Time for a Fix?*, viewed on 24 October 2012 at <http://blog.patentology.com.au/2012/07/pharmaceutical-extensions-of-term-is-it.html>.

²¹ Hayes, C., *Patent term extensions for enantiomeric medicines: a global overview*, *Journal of Intellectual Property Law and Practice*, Vol. 7 No. 3, March 2012, pp.180-185. See also *Ortho-McNeil Pharmaceutical, Inc. v. Lupin*

Arguments have also been made that despite the availability of extension of term, the effective life of pharmaceutical patents is too short to provide the necessary return on investment from developing new medicines.

Conversely, the generic manufacturing sector has argued that the extension of term provisions are too broad and therefore inhibit innovation and competition. It has been said that the original intent of the provisions was that new formulations for active ingredients would not qualify for extensions of term, as they typically do not take as long to obtain marketing approval as the original active ingredient. Others have argued that the interpretation of “pharmaceutical product *per se*” is not clear and, in some cases, decisions appear to conflict with the stated intent of Parliament that extensions generally be restricted to claims for new and inventive substances.²²

A key question arising from these concerns is whether Australia’s thresholds for extensions of term should be higher, lower or the same as those of our major trading partners in order to encourage genuine innovation and investment.

Question 1:

Is the breadth of pharmaceutical patents eligible for an extension of term appropriate?

Question 2:

Is the length of the extension of term provided for appropriate?

Pharmaceuticals, Inc., No. [09-1362](#) (Fed. Cir. May 10, 2010) and Naganuma, T. *Important Decision of Japanese Supreme Court on Patent Term Extension Application*, May 2011, viewed on 24 October 2012 at http://www.asamura.jp/judgments/important_decision.pdf.

²² Sands, P. et al, *Patent term extensions in Australia*, Australian Intellectual Property Law Bulletin Vol. 24, No. 2, June 2011, pp. 35-38.

4. Patent standards

As discussed earlier, the patent system must strike a balance. It must provide sufficient protection to encourage innovation, but not so much protection as to block future or follow-on innovation.

An invention must satisfy a number of criteria to be patentable:

- **disclosure:** public disclosure is a fundamental principle of the patent system and a key criterion is that the patent specification provides sufficient information for the invention to be repeated. In this way the public have access to useful information about new technology and can make and use the invention after a patent is no longer in force.
- **novelty and inventiveness:** a second principle is that patents should only be granted for things that are new and inventive. This ensures that the public are not prevented from doing things that they have previously done, or that would be obvious in light of what has previously been done.
- **usefulness:** to be patentable, an invention must be useful, meaning that it has a practical application and achieves what is promised in the specification.
- **claim scope:** the invention defined in the claims, and thereby the scope of rights obtained, must be commensurate with what is described in the specification.

It is important that the thresholds for these criteria are set at levels where the scope of protection given by a patent is commensurate with what is disclosed to the public and that patents are not granted for trivial or obvious improvements.

The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) makes significant amendments to the Patents Act to raise the thresholds for the grant of patents in Australia (refer to Appendix C). Two key areas of amendment have been to raise the thresholds for disclosure and for inventiveness. These changes are intended to also better align Australian standards with standards elsewhere.

These amendments are the result of extensive consultation with stakeholders and apply to all technologies, including pharmaceutical patents. The higher thresholds

commence in April 2013 and generally apply to patent applications for which a request for examination is made after commencement.

The higher thresholds will need to be in place for a significant period of time before their effect can be determined, particularly given that existing patents granted at the lower thresholds will continue for up to 25 years. It therefore seems premature to assess patent standards in detail and at this stage the panel does not consider them to be a primary focus of this review.

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?

5. Judicial issues

Challenges to Patents

There are a number of processes available to parties who wish to challenge the granting or validity of a patent. These include third party notifications, opposing the granting of the patent, requesting re-examination of the patent, or seeking revocation by the courts.

Third party notification

Section 27²³ of the Patents Act provides for a person to submit information to the patent office showing that the claimed invention is not novel or does not involve an inventive step. This information can only be provided after publication of the application and not more than three months after the publication of a notice of acceptance of the application.

This provision gives third parties access to the examination process, albeit with no direct involvement in providing evidence or responding to arguments put forward by the applicant to defend their application.

Pre-grant opposition

If, following examination, a patent application meets the standards set for patentability, the application is accepted. A three month period then follows, during which time any interested party can file a notice of opposition challenging the grounds on which the patent was accepted. If the granting of a patent is opposed, the patent cannot be granted until the opposition process is complete. An innovation patent can only be opposed once it has been granted and certified. Opposition is intended to provide a faster and less expensive process for settling disputes between patent applicants and third parties than the courts. Oppositions provide the advantage of evidentiary and oral hearing processes, however, the courts still remain the final arbiters.

²³ Similar provisions apply to innovation patents under s.28.

Opposition procedures are administered and managed by IP Australia. The process generally involves the filing of written evidence by each party prior to a hearing of the matter, conducted by a delegate of the Commissioner.²⁴

Re-examination

Section 97²⁵ of the Patents Act provides that where a patent has been granted and the patentee or a third party requests it, a patent application must be re-examined. Re-examination can also be directed by a court where the validity of a patent has been challenged in court proceedings.

Re-examination of a patent can also be initiated by the Commissioner of Patents at any time after acceptance but before grant. The Commissioner may refuse to grant the patent if the re-examination leads to an adverse report.

Currently, re-examination is limited to the question of whether the claimed invention is novel or involves an inventive step, and is based only on publicly available documents and common general knowledge.²⁶ The changes introduced by the Raising the Bar Act, however, expand the grounds for re-examination to all substantive grounds considered during examination, opposition and in court revocation proceedings.

²⁴ *Patents Act 1990*, Chapter 5.

²⁵ Similar provisions apply to innovation patents under s.101G.

²⁶ Advisory Council on Intellectual Property, *Post Grant Patent Enforcement Strategies*, January 2010.

Case study - re-examination process

The following case is an example of how the re-examination process may progress. Re-examination of a patent under the legislation is a discrete act resulting in a clear or adverse report. However, as this example demonstrates, a series of re-examinations may be possible and can progress to opposition where amendments to the patent are proposed.

A request for re-examination of patent no. 732097 relating to a pharmaceutical composition was filed by Freehills Patent and Trademark Attorneys in March 2010. Following this, an adverse re-examination report was issued by IP Australia in June 2010.

A series of re-examinations then followed with submissions provided by Freehills and the patentee. These included proposed amendments to the patent submitted by the patent owner in February 2011. A final re-examination report was issued in June 2011 finding the claims, as proposed to be amended, to be inventive.

The proposed amendments were published in August 2011 and in November 2012 opposition to the amendments was filed by Apotex Pty Ltd. The opposition process is continuing.

Revocation by the courts

Once a patent has been granted, the holder of the patent has the right to enforce the patent and can pursue infringement proceedings in the courts. Alternatively, an aggrieved party can challenge the validity of a patent.²⁷ The Patents Act confers jurisdiction on the Federal Court and the Supreme Court of a State or Territory to hear matters arising under the Act.

International Comparisons

Mechanisms for challenging patents vary internationally. The European Patent Office provides a system for post-grant opposition up to 9 months after publication in which validity of the patent is considered by a three person

²⁷Patents Act, Chapter 11, Part 1 and s.138.

Division. Under recent amendments to US legislation, the US Patent and Trademark Office provides for both pre- and post-grant challenges. Pre-grant submissions can be made in regard to prior art patent references and publications. Post-grant re-examination takes two forms, *ex parte* where the party requesting re-examination does not participate in proceedings following their submission, and *inter partes* where both the patentee and the party requesting re-examination participate in the proceedings. Provisions for an opposition procedure were removed from Japanese patent law in 2003.

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.

Question 4:

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

Infringement

Interlocutory injunctions

Plaintiffs in infringement actions can seek an injunction at an interlocutory hearing to restrain the defendant's allegedly infringing activities until the matter is resolved by the courts. When considering whether to grant an injunction, the court will consider whether an applicant has established that there is serious question to be tried and that the balance of convenience favours the grant of such relief.²⁸

The plaintiff is often required, as a condition of the court granting an interlocutory injunction, to undertake to pay damages, which the court may order to be paid in

²⁸ For example, *Samsung Electronics Co Ltd v Apple Inc* (2011) 286 ALR 257 at [52] – [74].

the event that the plaintiff is unsuccessful at trial. If an interlocutory injunction is denied, the defendant may be ordered to keep an account of profits.

Case study - interlocutory injunctions

The Sanofi-Aventis (clopidogrel)²⁹ and Wyeth (venlafaxine)³⁰ patent cases are two examples where interlocutory injunctions were obtained by the plaintiffs in infringement actions against generic pharmaceutical companies. The courts subsequently found the patents invalid. As a consequence, the generic companies had been inappropriately restricted from entering the market and the originators financially advantaged as a result. As a further consequence, the Commonwealth did not benefit from paying a lower subsidy through the PBS during the period of the injunction. The reason for this is that the listing of the first generic pharmaceutical on the PBS triggers an automatic reduction in the subsidy paid by the Government for all versions of the pharmaceutical product.

Question 5:

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

Contributory infringement

The contributory infringement provisions were included in the Patents Act to harmonise Australian law with its trading partners and to provide patent owners with "a more effective, realistic and just mechanism"³¹ of patent enforcement. In effect, it allows a patent holder to take action against a supplier who facilitates an infringing activity through the supply of a product.

Subsection 117(1) of the Patents Act provides that, where the use of a product by a person would infringe a patent, the supply of that product to the person is an infringement of the patent by the supplier, unless the supplier is the patentee or

²⁹ *Apotex Pty Ltd v Sanofi-Aventis* [2009] FCAFC 134.

³⁰ *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2011] FCAFC 132.

³¹ Industrial Property Advisory Committee. 1984. *Patents, Innovation and Competition in Australia*. Canberra.

licensee of the patent. Subsection 117(2) clarifies that, if the product is not a 'staple commercial product'³², contributory infringement includes circumstances where the supplier had reason to believe that the person would put it to an infringing use.

Case study - contributory infringement

In *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)* [2011] FAC 846, Jagot J ruled that Sanofi-Aventis Australia's patent claiming a method for the treatment of psoriasis using leflunomide was infringed by Apotex in marketing a generic version of leflunomide for the treatment of psoriatic arthritis (PsA) and rheumatoid arthritis (RA). A critical factor in that decision was the evidence of the linked nature of PsA and psoriasis summarised at [126] as "...a person with PsA will almost always have or develop psoriasis, albeit with differing degrees of severity," and that "...if leflunomide is administered to a patient with PsA, that administration would be expected also to prevent or treat the patient's psoriasis, to some extent at least," at [130]. This decision was upheld, on appeal, by the Full Court ([2012] FCAFC 102).

Other cases of significance involving the question of contributory infringement include:

- SNF (Australia) Pty Ltd v Ciba Specialty Chemicals Water Treatments Limited [2011] FAC 452
- Danisco A/S v Novzymes A/S (No 2) [2011] FCA 282
- Northern Territory v Collins [2008] HCA 49
- Bristol-Myers Squibb Co v F H Faulding & Co Ltd [2000] FAC 316

³² Crennan J, in *Northern Territory v Collins* [2008] HCA 49 stated that "The phrase "staple commercial product" means a product supplied commercially for various uses. This does not mandate an enquiry into whether there is "an established wholesale or retail market" or into whether the product is "generally available" even though evidence of such matters may well be sufficient to show that a product is a "staple commercial product". The relevant enquiry is into whether the supply of the product is commercial and whether the product has various uses."

Similar provisions for action against contributory or indirect infringement exist in the laws of other countries including the US, UK, Sweden, Germany, Japan, Canada and Denmark. For example, in the US, contributory infringement of a patent is defined by 35 U.S.C. § 271 (c):

"Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or an apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer."

Question 6:

Is Australian law on contributory infringement appropriate in relation to pharmaceuticals?

Timing of Infringement Proceedings

If a patent is granted, the owner has the exclusive right to exploit the invention from the date of filing the patent application to the end of the patent term. Subsection 120(4) of the Patents Act provides that infringement proceedings must be started within three years from the day on which the patent was granted, or six years from the day on which the infringing act was alleged to have occurred, whichever period ends later. Subsection 122(1) of the Patents Act provides the relief which a court may grant for infringement of a patent. This includes an injunction, subject to such terms as the court sees fit, and at the option of the plaintiff, either damages or an account of profits. Subsection 122(1A) provides that a court may also include an additional amount in an assessment of damages, if the court considers it appropriate to do so and having regard to matters such as the flagrancy of the infringement and the need to deter similar infringements of patents.

In the US and Canada similar provisions exist and any remedy for infringement is only available for acts of infringement committed within six years of the commencement of proceedings.

It has been argued that the six year period is too long a period for a generic company to remain uncertain about whether they will be sued for infringement, particularly given the unpredictability of outcomes from legal proceedings and the high cost of damages if proceedings are successful.

Question 7:

Are the current timeframes in which infringement proceedings must commence appropriate for pharmaceutical patents?

6. Follow-on patenting

Law and practice

Follow-on, secondary or incremental patenting is the practice of patenting further variations and improvements to a patented invention. Australia and many other countries have long provided patents for new uses of known products and new methods of using known products, in accordance with international obligations. The patent system allows innovators to obtain patents on improvements to inventions as long as those improvements meet the same requirements that apply to all inventions, including novelty and inventiveness. The policy aim is to provide an incentive for continued development of, and improvements to, existing technologies.

In the case of pharmaceuticals, such variations can have significant benefits for patients over the original drug and may take the forms of:

- more stable or more active forms of an original drug
- more convenient or effective formulations of the drug, or
- different therapeutic uses of the drug.

Case study – new therapeutic use

In 1994, compounds called pyrazolopyrimidinones were well known for treating heart and vascular disease. Pfizer found that the compounds were also useful for treating erectile dysfunction and obtained patents for the new use worldwide.³³ One of those compounds is sildenafil citrate. Marketed as Viagra[®], it has been extremely successful with annual sales in the billions of dollars.³⁴

Follow-on patents do not prevent the original patent from expiring and generic versions of the original drug from entering the market. However, there are tactics for making market entry more difficult or less rewarding for the competitor.

These are discussed below.

³³ Including Australian patent no. 675571, which expires on 14 May 2014.

³⁴ Reuters, *Pfizer wins Viagra patent battle against Teva*, viewed on 23 October 2012 at <http://www.reuters.com/article/2011/08/15/us-pfizer-idUKTRE77E2H520110815>.

In addition to standard patents, innovation patents may be used as follow-on patents. Innovation patents provide up to eight years protection from the date of filing and are relatively quick and inexpensive to obtain compared with a standard patent. To date few innovation patents have been granted for pharmaceutical inventions. More information on innovation patents is provided in Appendix C.

Competitors are also free to obtain follow-on patents themselves. Although the owner of a follow-on patent may require a cross-licence from the original patent owner to exploit the variation, a follow-on patent can provide the owner with valuable bargaining power, or at least prevent the originator and other competitors from acting in that space.

Concerns

A potential form of 'evergreening' is where a patent portfolio is developed by a single company based on an original patented invention and surrounded by follow-on patents. When combined with particular marketing strategies, this can create a 'patent thicket' and hamper generic market entry.

Large numbers of patents covering related inventions increase the costs for competitors to assess their freedom to operate and obtain any necessary licence agreements. This can result in lost opportunities for both originators and generic manufacturers, particularly in fields where most progress is cumulative.

A number of reviews have looked at the issue of patent thickets in Australia. The 2008 Cutler Review of the National Innovation System found that there was some evidence of patent thickets in particular technologies, especially in electronic and information technologies. It recommended that patent laws be reviewed to ensure that the inventive steps required to qualify for patents are considerable, and that the resulting patents are well defined, so as to minimise litigation and maximise the scope for subsequent innovators.³⁵ As discussed in Chapter 4 and Appendix C, the Raising the Bar Act aims to address some of these concerns by raising patent standards. It also introduces statutory exemptions from infringement for obtaining regulatory approval in all technologies and for

³⁵ *Venturous Australia – building strength in innovation*, Cutler & Company Pty Ltd, 2008, Chapter 7, Recommendation 7.2.

experimental use, thereby providing the research sector with increased certainty and a reduced need to obtain licence agreements to conduct research.

Patent portfolios also enable patent owners to employ a number of tactics that can make it more difficult for competitors to capture market share. One technique is to switch consumers to a new, improved variation of an original drug before the original patent expires and generics can enter the market. This can effectively remove, or dramatically reduce the market for the generic product. Even where the improvement is minor, brand familiarity can play a major role in consumers preferring the new variant of the familiar brand over an unfamiliar generic.

Case study – new formulations

Omeprazole, a proton pump inhibitor used to treat gastrointestinal disorders, is one of the most widely prescribed pharmaceutical compounds in Australia, with 2.3 million PBS prescriptions at a cost to the government of nearly \$65 million in 2010-11.³⁶ Astra Pharmaceuticals markets omeprazole in Australia as Losec[®] under exclusive licence from Aktiebolaget Hässle. Aktiebolaget Hässle's patent for omeprazole expired in 1999, but in 1991 it obtained patent no. 601974 for a specific oral pharmaceutical preparation of omeprazole. The new formulation included two layered coatings to enable the tablets to pass through the stomach and be released in the upper small intestine.

In 1998, Astra Pharmaceuticals sued Alphapharm Pty Ltd for infringement of the new formulation. Alphapharm claimed the patent was invalid and sought its revocation. After decisions of a single judge of the Federal Court and the Full Court, in 2002 the High Court found that the patent was valid and involved an inventive step³⁷ and the parties resolved their dispute over the remaining issues. The patent remained in force until 2007, after which a number of generic competitors entered the market for omeprazole.

³⁶ *Expenditure and prescriptions - twelve months to 30 June 2011*, Pharmaceutical Policy and Analysis Branch, PBS, Table 9(a).

³⁷ *Aktiebolaget Hassle v Alphapharm Pty Ltd* [2002] HCA 59 at [72], [76].

Originators may sometimes move customers onto their own generic version around the time that other generics can enter the market.

Case study - generic pharmaceuticals

Anti-cholesterol drug Lipitor (atorvastatin) is Australia's most widely prescribed drug, with over 10 million prescriptions under the PBS costing the government nearly \$600 million in 2010-11.³⁸ Pfizer's patent for atorvastatin expired on 18 May 2012.³⁹ On 1 April 2012, the first generic version of atorvastatin was listed on the PBS. Pfizer continues to market Lipitor®, but released its own generic version. Pfizer has encouraged pharmacists to switch patients to its generic through a number of means, some of which have been controversial, and including bypassing wholesalers and supplying directly to pharmacists.⁴⁰ A number of generic versions of atorvastatin are now available on the market.

Portfolios can include patents for new methods of manufacturing the original pharmaceutical or diagnostic tests to help prescribe the pharmaceutical. This can be particularly relevant in the field of pharmacogenomics, where genetic testing for variations that affect an individual's response to pharmaceuticals is conducted to determine the best therapy to prescribe.⁴¹

³⁸ *Expenditure and prescriptions - twelve months to 30 June 2011*,

Pharmaceutical Policy and Analysis Branch, PBS, Table 9(a).

³⁹ Granted patent no. 601981, for which a five year extension of term was obtained.

⁴⁰ www.pfizerdirect.com.au/default.aspx; *Pharmacists' fears for direct drug ordering*, Australian Broadcasting Corporation, PM, 7 May 2012, viewed on 23 October 2012 at www.abc.net.au/pm/content/2012/s3497347.htm; <http://theconversation.edu.au/companies-tussle-over-market-share-for-anti-cholesterol-drug-lipitor-and-its-generic-equal-7088>

⁴¹ Altin J, *Pharmacogenomics: A New Frontier for the Evergreening of Pharmaceutical Drugs*, Australian National University College of Law Research Paper No. 08-04, October 2007.

Case study – new method of production

In 2001, Australian biotech company Alchemia obtained a patent relating to generic fondaparinux, the generic version of GlaxoSmithKline's anti-coagulant Arixtra®. Alchemia's patent is for a method of manufacturing fondaparinux in commercial quantities, enabling it to produce the drug more cheaply. Alchemia obtained US marketing approval in July 2011 and achieved sales of \$US33 million in the first six months of 2012, around 40% of the retail market and 6% of the hospital market. The world-wide market for fondaparinux is around \$US500 million.⁴²

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?

⁴² Alchemia confident about fondaparinux, www.news.com.au/business/breaking-news/alchemia-confident-about-fondaparinux/story-e6frfkur-1226487574565.

7. Therapeutic Goods Administration related issues

Data exclusivity

Law and practice

All medicines in Australia are required to be included on the ARTG before they can be sold. Medicines can be either 'registered' or 'listed' on the ARTG. Higher risk medicines must be registered, which involves individually evaluating the quality, safety and effectiveness of the product. Lower risk medicines containing pre-approved, low-risk ingredients and that make limited claims can be simply listed on the ARTG.⁴³

An abbreviated marketing approval process is available for generic pharmaceuticals seeking registration on the ARTG. In this process the clinical data for an original, registered pharmaceutical can be used to obtain registration for a generic on the basis of 'bioequivalence' to the original. This reduces the need for lengthy and expensive clinical trials to be repeated and facilitates competition when the relevant patents expire. In acknowledgement of the considerable investment of time and money in the original pre-approval testing, the *Therapeutic Goods Act 1989* (Cth) provides a data exclusivity period of five years from marketing approval for products registered on the ARTG.⁴⁴ During these five years, the TGA cannot allow the non-public clinical data from the original approval to be relied on by generic competitors in seeking inclusion of the generic product on the ARTG.

Data exclusivity only applies to information provided for registrations on the ARTG.⁴⁵ Listings on the ARTG for lower-risk medicines, such as most complementary medicines, do not receive data exclusivity for any information provided to the TGA. Due to their nature, many listed complementary medicines may also not be eligible for patent protection.

⁴³ Therapeutic Goods Administration. 2012. *Medicines and TGA classifications*. Viewed on 9 November 2012, at <http://www.tga.gov.au/industry/regulation-basics-medicines-classifications.htm>

⁴⁴ Therapeutic Goods Act, s.25A.

⁴⁵ *Ibid.*

Australia's data exclusivity provisions comply with our international obligations. As outlined in Appendix C, the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) requires World Trade Organisation (WTO) Members to "protect test data against unfair commercial use" and disclosure,⁴⁶ while the AUSFTA requires Australia to provide at least five years exclusivity.⁴⁷

Figure 4 on the following page compares data exclusivity periods between Australia, US, Europe and Japan. For chemical (small molecule) drugs:

- Australia and the US - five years exclusivity
- Japan - four years for new indications or formulations to six years for new chemical entities
- Europe - eight years of data exclusivity plus two years of marketing exclusivity.⁴⁸

For complex biotechnology drugs (biologics):

- Australia and Europe – five years, same as for chemical drugs
- Japan – six years, same as for new chemical entities
- US – 12 years, provided by the *Patient Protection and Affordable Care Act 2010*.⁴⁹

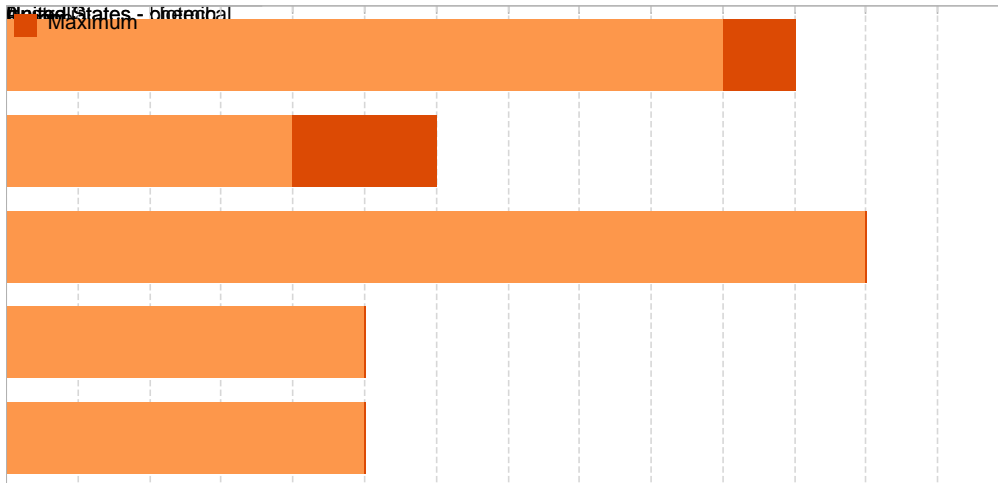
⁴⁶ TRIPS, Article 39.

⁴⁷ AUSFTA, Article 17.10.

⁴⁸ Additional short data exclusivity periods are available in Europe, Japan and the US for developing 'orphan' drugs and paediatric indications. No additional periods are available in Australia.

⁴⁹ The US Government proposes to reduce the period to seven years in order to save the budget \$2.3 billion over the next ten years. This is being strongly resisted by the originator sector. See *Fiscal Year 2013 Budget of the U.S. Government*, US Office of Management and Budget, page 37, available at <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/budget.pdf>.

Figure 4 – Data exclusivity periods



Concerns

For some years, the originator pharmaceutical sector has advocated for the period of data exclusivity to be extended in Australia. They argue that this would bring Australia into line with leading OECD nations, attract more new medicines and foreign investment from global biopharmaceutical companies, and reduce reliance on patent protection, particularly for biologics.⁵⁰ The complementary medicines sector has also advocated that data exclusivity be available for non-prescription medicines.⁵¹ The generic medicines industry considers that Australia's data exclusivity provisions achieve a sensible middle ground and do not need reforming.⁵²

⁵⁰ Medicines Australia, viewed on 22 October 2012 at <http://medicinesaustralia.com.au/issues-information/innovation-industry-policy/data-exclusivity/>.

⁵¹ Expert Committee on Complementary Medicines in the Health System, *Complementary Medicines in the Australian Health System*, Report to the Parliamentary Secretary to the Minister for Health and Ageing, September 2003, Part 6.1.

⁵² For example, see Generic Medicines Industry Association's position of 26 June 2011, viewed on 13 November 2012 at http://www.gmia.com.au/gmia_news_release_26jun11.html.

At present in Australia, data exclusivity periods typically expire well before the expiry of the relevant patents. Patent expiry rather than data exclusivity appears to determine when competitors may enter the market. Even in Europe where longer periods of data exclusivity are available, studies have shown that very few high-selling drugs gain further marketing monopoly from data exclusivity, particularly where the patent term had been extended.⁵³

Case study - data exclusivity

Leflunomide, marketed as Arava® by Sanofi-Aventis Australia, is a medication used to treat rheumatoid arthritis. Although patent no. 529341 for Leflunomide was granted in 1983, the pharmaceutical was not registered with the ARTG until October 1999. Data exclusivity therefore applied until October 2004. The nominal expiry of the patent was December 1999, however the patent was granted an extension of term, resulting in a final expiry date of December 2004. Consequently, the five year data exclusivity period did not extend beyond the patent expiry date, despite the late ARTG registration. It is noted however, that the data exclusivity period in other jurisdictions did extend beyond the patent expiry date, thereby providing a barrier to generic entry into those markets.

Should exclusivity periods be significantly extended in Australia, and/or first marketing approvals take a long time to be granted, then data exclusivity would be increasingly relied upon by originators for protection. For originators, data exclusivity has a number of advantages over patents. It is inexpensive to obtain and requires no active enforcement or litigation activity on the part of the originator. However, data exclusivity has the disadvantage of keeping information out of the public domain. This is in tension with one of the advantages of the patent system, which is to trade off market exclusivity for greater public disclosure of information about patented technologies. If data exclusivity were to be used in place of patenting this could reduce public access to information about new drugs and medical technologies.

⁵³ IMS Health, *Data Exclusivity – The Generics Market's Third Hurdle*, November 2001. This study found that the only drugs that significantly benefited from the data exclusivity provisions are those that do not have an extended term or where the R&D process took an exceptionally long time.

Question 9:

Is the law on data exclusivity appropriate?

Patent certificates

Law and practice

As discussed above, a company applying to have a generic therapeutic good included on the ARTG may rely on the safety or efficacy information provided by an originator company in relation to the original product. Under the Therapeutic Goods Act, where this information is relied upon, the generic company must provide a certificate stating that it believes that it is not marketing, and does not propose to market, the therapeutic goods in a way that would infringe a valid patent, or that the generic company has given the patent owner notice of the application.⁵⁴ There are criminal penalties for providing a false or misleading certificate.⁵⁵

Patent certificates must be provided before the generic good can be registered on the ARTG. Only a minority of patent certificates state that the applicant has given the patent owner notice. Patent certificates are not routinely published by the TGA or made available to the public, so typically the first a competitor learns about an application is when it is successfully registered.⁵⁶

The requirement for patent certificates was introduced in 2005 to comply with the AUSFTA⁵⁷ and is similar to requirements in the US.⁵⁸ One of the differences in law between the two countries is that Australia's Therapeutic Goods Act includes

⁵⁴ Therapeutic Goods Act, s.26B.

⁵⁵ Under s.26B(2), providing a false or misleading certificate is a criminal offence currently punishable by a fine of up to \$110,000 for an individual and up to \$550,000 for a body corporate. Under subsection 22A(4), providing a false or misleading statement in relation to an application for registration of therapeutic goods incurs a penalty of imprisonment for 12 months and/or a fine of \$110,000.

⁵⁶ Information provided by TGA, October 2012.

⁵⁷ AUSFTA, Article 17.10.4.

⁵⁸ *Drug Price Competition and Patent Term Restoration Act 1984* (Waxman-Hatch Act).

provisions⁵⁹ to prevent 'linkage evergreening'. This is where patent owners use the patent certificate requirements to commence vexatious infringement proceedings against generic companies to delay the entry of generic products into the market.⁶⁰

A company applying to have a product included on the ARTG needs to conduct a search of the patent landscape to be able to complete a patent certificate. Such searches would also be necessary early in the process of preparing to enter the market to determine the generic company's freedom to operate in a particular field. Patent office databases, such as IP Australia's AusPat database, provide free basic searching of national patent applications and grants.⁶¹ However, pharmaceutical searching is a complex process, with more than 69 million unique organic and inorganic chemical substances registered in searchable databases⁶²,

⁵⁹ Sections 26C and 26D

⁶⁰ Therapeutic Goods Act. Under section 26C, where a certificate has been provided by a generic manufacturer and the patent owner wishes to begin infringement proceedings, it must first certify that the proceedings are being commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay. If the certificate is false or misleading, or if any undertakings given under the certificate are subsequently broken, the company can be liable for a civil penalty of up to \$10 million for each contravention. Section 26D imposes requirements on a person who applies for an interlocutory injunction to restrain another party from marketing a therapeutic good on the ground that such conduct will constitute an infringement of its patent is subject to certain requirements. The Commonwealth and States and Territories can recover damages where an interlocutory injunction unreasonably delays a generic drug coming onto the market.

⁶¹ AusPat can be accessed from <http://www.ipaustralia.gov.au/auspat/>. The European Patent Office and USPTO also have searchable databases at <http://www.epo.org/searching.html> and <http://www.uspto.gov/patents/process/search/>

⁶² The Chemical Abstracts Service Registry records more than 69 million unique organic and inorganic chemical substances and more than 64million biological sequences, with more than 15,000 new substances indexed each day. Data accessed on 24 October 2012 from <http://www.cas.org/content/chemical-substances>

and no universally agreed nomenclature system. As such, more sophisticated patent searching such as that provided by a range of specialist in-house and commercial searchers is required. These services are routinely used by both originator and generic companies to conduct freedom-to-operate searches.

Concerns

Concerns have been raised about the severity of the penalties for providing a misleading patent certificate, given the difficulty in conducting definitive patent searches. However, the review panel is not aware of any cases where the accuracy of patent certificates provided under s.26B or s.26D have been questioned or legal action taken. The panel welcomes any examples that can be provided.

Also, the effectiveness of the 'anti-evergreening' provisions in the Therapeutic Goods Act has been questioned. It has been suggested that vigorous enforcement of the provisions may lead to US threats of trade retaliation and the instigation of a dispute under the AUSFTA or WTO.⁶³

Question 10:

Are the laws on patent certificates appropriate?

Copyright of product information

Law and practice

A Product Information document (PI) is lodged with the TGA as part of an application for registration of a medicine on the ARTG. The purpose of the PI is to assist medical practitioners, pharmacists and others to correctly prescribe and dispense the medicine. It is important that health professionals receive the same information about a medicine, regardless of the brand.

Section 44BA of the *Copyright Act 1968* essentially provides that, from 28 May 2011, generic manufacturers are able to use the PI of originator companies for a medicine that has been approved by the TGA for registration on the ARTG without

⁶³ For example, Faunce TA and Lexchin J. *'Linkage' pharmaceutical evergreening in Canada and Australia*, Australia and New Zealand Health Policy, 1 July 2007, pp. 9.

infringing the copyright in the PI. This provision was introduced to prevent originator companies from delaying the entry of generics onto the market by denying them a licence to use the PI. The provisions enable the public health objectives in approving PIs of generic medicines to continue and also ensure that the Commonwealth is not subject to additional costs under the Pharmaceutical Benefits Scheme.⁶⁴

Case study - copyright in product information documents

Copyright of PI was one of the issues considered in *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 4)* [2011] FCA 1307 and *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2)*[2012] FCAFC 102. The courts found that Sanofi's copyright was infringed by Apotex before the commencement of s.44BA, as there was no implied licence to use the PI. However, the court found that Apotex's actions after commencement were not infringing. This was partly because s.44BA included within its scope European product information included in the application and subsequently approved by the TGA.

In the US, generic medicines must have the same labelling as the original product and the courts have found that by doing so a generic does not infringe the originator's copyright in the label.⁶⁵

Concerns

Concerns have been raised that s.44BA only applies to acts of using copyrighted PI that occurred on or after 28 May 2011, leaving generic manufacturers open to infringement actions regarding acts before this date. There is also some

⁶⁴ *Therapeutics Goods Legislation Amendment (Copyright) Bill 2011* - Explanatory Memorandum.

⁶⁵ US Code: Title 21 - Food and Drugs § 355(b)(1)(F), Abbreviated new drug applications. *SmithKline Beecham Consumer Healthcare, L.P. v Watson Pharmaceuticals, Inc.* 211 F.3d 21 (2nd Cir. 2000).

uncertainty and concern about the extent of the exception, including whether Consumer Medicine Information (CMI) should be included.⁶⁶

Question 11:

Are the laws on copyright of product information appropriate?

⁶⁶ Recommendation 2 of GMiA's 15 March 2012 submission to the Joint Standing Committee on Treaties inquiry into the Anti-Counterfeiting Trade Agreement, Report 126, tabled 27 June 2012.

8. Submissions

List of questions

The questions below are those appearing in the text of this paper and may provide ideas for developing your submission. As stated earlier, you should not be limited by these questions if there are other points that you would like to make.

Question 1:

Is the breadth of pharmaceutical patents eligible for an extension of term appropriate?

Question 2:

Is the length of the extension of term provided for appropriate?

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?*

Question 4:

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

Question 5:

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

Question 6:

Is Australian law on contributory infringement appropriate in relation to pharmaceuticals?

Question 7:

Are the current timeframes in which infringement proceedings must commence appropriate for pharmaceutical patents?

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?

Question 9:

Is the law on data exclusivity appropriate?

Question 10:

Are the laws on patent certificates appropriate?

Question 11:

Are the laws on copyright of product information appropriate?

How to make a submission

Submissions are due by 5pm on 21 January 2013.

Submissions should be sent as an attachment to pharmapatents@ipaaustralia.gov.au. For accessibility reasons, please submit responses via email in a Word or RTF format. An additional PDF version may also be submitted.

Submissions can also be made by post to the following address:

Terry Moore
IP Australia
PO Box 200
WODEN ACT 2606

Anyone is welcome to make a submission which can be in the form of short letter to the panel or a more substantial document. You should make it clear who the submission is being made by.

Where possible, views and arguments in your submission should be supported with evidence such as data and relevant documentation.

Please note, submissions that have not been identified as confidential will be made available on the review panel's website as described in the privacy statement at the front of this issues paper.

If you have any questions regarding making a submission please contact the review secretariat at pharmapatents@ipaaustralia.gov.au or call (02) 6283 2632.

Hearings

The review panel will be conducting hearings with key stakeholders. If you are interested in meeting with the panel, please make this clear in your submission or notify the review secretariat and provide contact details.

Appendix A: Background

On 15 October 2012, the Hon Mark Dreyfus QC MP, Parliamentary Secretary for Industry and Innovation, announced the establishment of a panel to review the system for pharmaceutical patents in Australia, in particular the pharmaceutical extension of term provisions. The three-member panel comprises:

- Mr Tony Harris, former NSW Auditor-General and Parliamentary Budget Officer, as Chair
- Professor Dianne Nicol, Associate Dean, Research, Law Faculty at the University of Tasmania, and
- Dr Nicholas Gruen, CEO of Lateral Economics.

The current extensions of term provisions were introduced in 1998 with a commitment to evaluate their appropriateness five years after commencement and their efficiency and effectiveness after 10 years. These evaluations will form part of this review. Also, in recent years different sectors of the pharmaceutical industry have raised a number of issues with current Australian law and practice. These are discussed in further detail in this paper. The review is to include a public consultation process and the panel is to provide a final report within six months.

Terms of reference

The review will 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.

Central to this will be an analysis of the pharmaceutical extension of term provisions of the Patents Act 1990 (s.70).

The review will also consider whether there is evidence that the patent system is being used to extend pharmaceutical monopolies at the expense of new market entrants.

In doing this, the review will consider how patents for new formulations are granted, consider the treatment of new methods of manufacturing and new uses of known products, the impact of contributory infringement provisions and the

impacts of extending patent monopolies on entry of generic pharmaceuticals into the market.

Should such evidence be found, the review should provide an assessment of the subsequent impact on competition, innovation and investment.

In conducting the review and making recommendations the panel is to have regard to:

1. The availability of competitively priced pharmaceuticals in the Australian market
2. The role of Australia's patent system in fostering innovation and hence to bringing new pharmaceuticals and medical technologies to the market
3. The role of the patent system in providing employment and investment in research and industry
4. The range of international approaches to extensions of term and arrangements for pharmaceutical inventions
5. Australia's obligations under international agreements (including free trade agreements and the World Trade Organisation agreements)
6. Australia's position as a net importer of patents and medicines

Appendix B: The Economics of Patents: A Brief Overview

This Appendix provides a brief overview of the legal basis for the Australian patent system and the economics of intellectual property rights.

Legal basis

A patent is a temporary, exclusive and legal right conferred to the inventor to exclude others from commercially exploiting the innovation. To be patentable, an innovation must be new, inventive and useful. Patents can be granted for a device, substance, method or process.

The Constitution of Australia defines the powers of the Australian Government. Section 51 states, in part:

The Parliament shall, subject to this Constitution, have power to make laws for the peace, order and good government of the Commonwealth with respect to: ... (xviii) Copyrights, patents of inventions and designs, and trade marks.”

Australian patent legislation is set out in the Patents Act and Patents Regulations 1991. This is covered in more detail in Appendix C. The legislation is largely technology neutral: providing for patents to be granted in all fields of technology, subject to the requirements that the invention is novel, inventive and produces some useful product or effect. The legislation requires for the patent specification to be published.

This legal basis reflects the utilitarian/economic incentive view of intellectual property, in which patent rights strike a balance between needs for invention and creation and needs for diffusion and access. This view recognises that intellectual property has traits of a public good, and it is intangible and based on information. Within this view, intellectual property is recognised as non-rivalrous (one person’s use of it does not diminish another’s use) and non-excludable through private

means (it may not be possible to prevent others from using the information without authorization).⁶⁷

The rationale for patents: A simple premise with important trade-offs

The premise of a patent regime is simple: governments grant an exclusive, temporary, legal right to an inventor for their invention in exchange for the inventor sharing the idea with the public.

The economics of patents involve a trade-off between short run concerns (static efficiency) and long run concerns (dynamic efficiencies). In a static sense, it is in society's interest to permit wide access to new ideas embodied in intellectual property. It may not be possible, however, to prevent others from using the information without authorisation. Since an intellectual effort is potentially valuable but easily copied by others there may be free riding.⁶⁸ As second comers compete with the developer of the information without bearing any of the initial costs, the price is driven down to the marginal cost. With price at marginal cost,

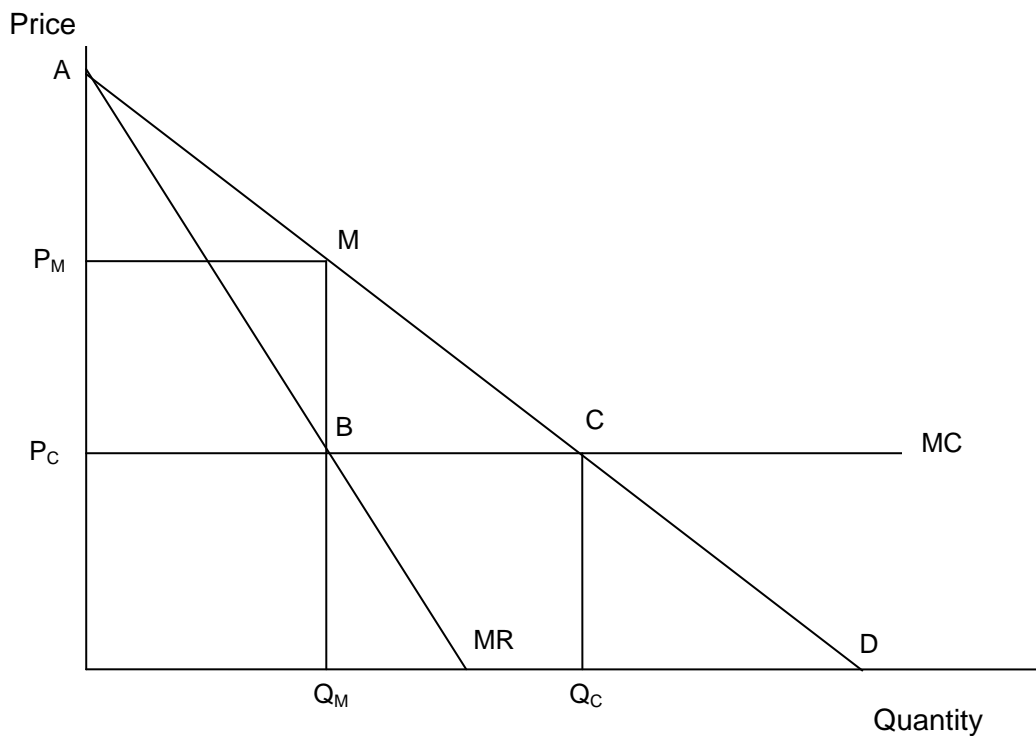
⁶⁷ Broadly speaking, there are three philosophical perspectives on intellectual property. One is the 'natural rights perspective,' in which creations of the mind are entitled to protection just as tangible property is (see Palmer 1990); another is the 'personhood perspective,' in which to achieve proper self development an individual needs some control over resources in the external environment (see Hughes 1988 and Radin 1982); and the third is the utilitarian or economic incentive perspective, described above (see chapter 1 'The Economic Theory of Property,' Landes and Posner 2003).

⁶⁸ In economics, 'free riders' are those who bear less than their fair share of the costs of production (or consume more than their fair share of a resource). This can have adverse economic consequences when it leads to the under-production of a public good or excessive use of common property. Cowen (2012) offers a simple illustration of the free rider problem with an example of fireworks, "even if the fireworks show is worth ten dollars to each person, arguably few people will pay ten dollars to the entrepreneur. Each person will seek to 'free ride' by allowing others to pay for the show, and then watch for free from his or her backyard. If the free-rider problem cannot be solved, valuable goods and services—ones people otherwise would be willing to pay for—will remain unproduced."

the inventor is unable to recoup research and development expenses leaving no commercial incentive for further invention.

This trade-off was presented simply by Maskus⁶⁹ and is illustrated in figure 5 below. Consider a product that has been invented, with a standard linear demand and marginal revenue curve as presented below. Suppose it may be supplied to the market at a price equal to constant marginal cost. Once the product is available, ex-post optimality requires that it sell for marginal cost at point C, generating consumer benefits in the area AP_CC.

Figure 5 - Illustration of the economic trade-off with patents



The solution at C would emerge in a competitive market in which all firms could costlessly imitate the product and sell a close substitute. However, this solution would generate no economic rents for the inventor to cover research and development costs. Subsequently, there would be no such investment and the product would go undeveloped, leaving no consumer benefits.

⁶⁹ Maskus, Keith 2000. *Intellectual Property Rights in the Global Economy*. Institute for International Economics, Washington, DC.

Alternatively, suppose there is a monopoly created by a patent. Then, the firm would offer the product at point M and earn monopoly rents of $P_M P_C B M$. These rents represent a transfer from consumers to the inventor and are a return on the inventor's research and development investment. The economy suffers a deadweight loss of MBC , compared to the competitive (but unattainable) solution at point C. With the patent monopoly, society still benefits from a net gain of the remaining consumer surplus plus monopoly profits less R&D costs.

This illustrates the fundamental trade-off in setting patent rights between the short-run (static) efficiencies and long-run (dynamic) efficiencies. On the one hand, static efficiency requires wide access to users at marginal cost, which may be quite low. On the other hand, dynamic efficiency requires incentives to invest in new information for which social value exceeds development costs. Each public goal is legitimate but taken together present a clear conflict.

Excessively weak property rights satisfy the static goal but suffer the dynamic distortion of insufficient innovation incentives. Society ends up with a sub-optimal level of innovation, slower economic growth, and lower product quality.

Yet excessively strong intellectual property rights favour the dynamic goal but result in insufficient access. Subsequently the economy suffers from inadequate dissemination of new information.

Public health: Legitimate business goals and social and medical needs

Notwithstanding the patent system's role to help spur innovation there may still be market failures that require a further role for government. Public health is one example, particularly in the context of the global economy and in the presence of wide income disparity across countries. Private sector pharmaceutical and biotech firms in high income countries tend to focus their research programs toward commercially viable products.

High income economies have a higher demand for, say, drugs against cancer and heart disease, compared to some low income economies that have a greater

demand for drugs against tropical disease.⁷⁰ If the expected profits are insufficient for a particular drug — even if that drug could save millions of lives in poor countries — a private sector firm is unlikely to invest in such a research and development program.

The profit imperative ensures that drugs chosen for development are those most likely to provide a high return on the company's investment. As a result, drug development and manufacture for use in the industrialized world are often prioritized over ones for use in the developing world where many patients would be unable to pay for them.

In this way, legitimate business goals of pharmaceutical manufacturers do not always align with the social and medical needs of the public. Policymakers must find the appropriate balance between providing incentives for future inventions of new drugs and ensuring affordable access to existing drugs.

Governments around the world recognize this public policy issue. TRIPS contains provisions for the rights of Members to adopt measures for public health and other public interest reasons (Article 8).⁷¹ Countries can implement their intellectual property regimes in a manner that takes account of immediate and long term public health considerations. Also, in recent decades, the role of non-profit entities has become more prominent, as well as public-private partnerships, that work to direct funds to increase access to needed pharmaceuticals and support public health initiatives.⁷²

⁷⁰ See Diwan and Rodrick (1991) illustrate this point with a theoretical economic model.

⁷¹ The World Health Organization and WTO (2002) discuss the importance of further cooperation between health and trade policymakers.

⁷² For instance, the Gates Foundation, with an endowment of over \$30 billion, supports numerous public-private partnerships towards expanding access to medicines and information technology in the developing world.

Appendix C: Patenting practice

International framework

Australia is a signatory to a number of international agreements on intellectual property. These international obligations must be considered when determining Australia's patent system settings.

It should also be noted that the terms of these agreements, and whether domestic legislation complies with those terms, are often subject to interpretation. If another party to an agreement considers that Australia is not complying with the terms of an agreement, it may commence dispute settlement procedures. If the relevant body hearing the dispute finds that Australia has not complied with the agreement, other parties may be entitled to take actions such as imposing trade sanctions against Australia.⁷³

The following summarises Australia's main obligations under its international intellectual property agreements.

Paris Convention

Australia is a party to the Paris Convention, a treaty administered by the World Intellectual Property Organization (WIPO). The Paris Convention applies to all forms of industrial property, including patents, trade marks, and designs. The main features of the Paris Convention are:

- each contracting state must grant the same protection to nationals of other states as it grants to its own nationals⁷⁴
- each contracting state must provide a right of priority based on the first filing date of the application in a contracting state⁷⁵

⁷³ For example, at the request of Ukraine, on 28 September 2012 the WTO Dispute Settlement Body established a panel to consider whether Australia's tobacco plain packaging laws are consistent with international agreements, including TRIPS and the General Agreement on Tariffs and Trade.

⁷⁴ Article 2.

⁷⁵ Article 4. For example, an applicant for a patent can file an application in their home country, and within twelve months, file an application in a second country.

- it sets out common rules which all contracting states must follow.

Patent Cooperation Treaty

Australia is a party to the Patent Cooperation Treaty (PCT) which is administered by WIPO. The PCT provides a scheme whereby an applicant from a contracting state can seek patent protection for an invention in multiple countries by filing a single international patent application. Each country then examines the application according to its own laws and determines whether to grant a patent in that country.

PCT applications have been increasing as globalisation and electronic commerce opens trade opportunities to businesses worldwide. Currently, around 75% of total applications and 83% of pharmaceutical applications filed in Australia are filed through the PCT.⁷⁶

TRIPS Agreement

TRIPS is a trade agreement administered by the WTO. It sets out the minimum standards for intellectual property protection, enforcement, and dispute resolution. Member states are free to decide how they implement their obligations, as long as they are consistent with the minimum standards. The standards most relevant to pharmaceuticals are:

- Public health: members may adopt measures in their laws and regulations that are necessary to protect public health and nutrition, provided such measures are consistent with TRIPS.⁷⁷
- Patentable subject matter: patents are to be available for “any inventions, whether products or processes, in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application”.⁷⁸ Some exceptions to patentable subject matter are allowed, including diagnostic, therapeutic and surgical methods of treatment.

The second application will be regarded as though it was filed on the same day as the first application.

⁷⁶ Data provided by IP Australia, November 2012.

⁷⁷ Article 8.

⁷⁸ Article 27.1.

Members may also exclude patents on morality and *ordre public*⁷⁹ grounds.

- Data exclusivity: where undisclosed test or other types of data must be submitted to obtain marketing approval for a pharmaceutical which utilises new chemical entities, Members must protect the data against unfair commercial use.⁸⁰ See Chapter 7 – data exclusivity.

AUSFTA

AUSFTA came into effect on 1 January 2005. Chapter 17 relates to intellectual property. AUSFTA is commonly referred to as being “TRIPS-plus”, that is, articles in AUSFTA are consistent with and in addition to those of TRIPS. Those requirements most relevant to pharmaceuticals are:

- Parties are to make available an extension of the term of a patent for a pharmaceutical product to compensate the patent owner for unreasonable curtailment of the effective term due to the time it took to obtain marketing approval.⁸¹ The scope of the term ‘pharmaceutical products’ available for an extension and the length of the extension are not stipulated. This issue is discussed in more detail below and in Chapter 3.
- Parties are to allow patent owners to prevent parallel importing of a patented product, or a product that results from a patented process. This right shall not be limited by the sale or distribution of the product outside the Party’s territory, at least where the patent owner has placed restrictions on importation by contract or other means. The purpose of this is to prevent products that have been legitimately sold in another country from being imported into Australia.⁸²

⁷⁹ The term “*ordre public*” comes from French law and is generally considered to include the protection of public security and structures of civil society.

⁸⁰ Article 39.3.

⁸¹ Article 17.9.8.

⁸² Article 17.9.4.

- Parties can permit the use of a patented invention without the authorisation of the patent owner (eg. under a compulsory licence) only under the following circumstances:
 - to remedy an anti-competitive practice, or
 - in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that the patent owner receives reasonable compensation and other conditions apply.⁸³
- Parties are to provide exclusivity for at least five years for safety and efficacy data provided in order to obtain marketing approval for a new pharmaceutical product.⁸⁴ See Chapter 7 – data exclusivity.
- Where a person is permitted to rely on safety or efficacy information originally provided by another person to obtain marketing approval, parties must provide measures in their marketing approval process to prevent the person from marketing the product during the term of the patent, unless by consent from the patent owner (see Chapter 7 - patent certificates). Where a third person is permitted to request marketing approval for a patented product, the patent owner must be notified of the request.⁸⁵

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.⁸⁶

⁸³ Article 17.9.7. Public non-commercial use is not defined but is generally understood to mean use by a government or other non-profit organisation.

⁸⁴ Article 17.10.1.

⁸⁵ Article 17.10.4.

⁸⁶ TRIPS Article 30 and AUSFTA Article 17.9.6.

Domestic framework

Two types of patents are available under the Patents Act and the Patents Regulations – standard and innovation patents.

Standard patent

A standard patent provides the owner with the exclusive right to exploit the invention for up to twenty years from the filing date of the application. However, it is possible for owners of pharmaceutical patents to obtain an extension of term for an additional five years, subject to meeting certain criteria.⁸⁷ Extensions of term are explored in further detail below and in Chapter 3.

In order for an application for a standard patent to be accepted, the patent must meet the following requirements:

- It must be a manner of manufacture within the meaning of s.6 of the *Statute of Monopolies* (that is, the application must be for something that is patentable subject matter)
- It must be novel and involve an inventive step when compared with the prior art base as it existed before the priority date of the claim
- The invention must be useful
- The invention must not have been secretly used in the patent area before the priority date of the claim.⁸⁸

Patentable subject matter can consist of a product or a process. Human beings, and the biological processes for their generation, are not patentable inventions.⁸⁹ Methods of treatment are not excluded from patentability.

In 2011, IP Australia received approximately 25,500 patent applications (over 20,000 of these via the PCT route) and granted 16,500 patents. Around 8% of these are in the field of pharmaceuticals and cosmetics.⁹⁰

⁸⁷ *Patents Act 1990* (Cth), s.70.

⁸⁸ *Ibid*, s.18 (1).

⁸⁹ *Ibid*, s.18 (2).

⁹⁰ International Patent Classification A61K.

Innovation patent

The innovation patent was introduced in 2001 to provide a relatively quick and inexpensive way for small and medium enterprises to obtain patent protection for inventions having a relatively short commercial life, or those which might not be inventive enough for standard patent protection. The maximum term of an innovation patent is eight years from the filing date of the application.⁹¹

For an innovation patent to be certified, and therefore able to be enforced, it must meet the same substantive requirements for patentability as a standard patent, with two exceptions. It need only meet the lower 'innovative step' requirement, rather than the higher inventive step requirement, and it cannot claim plants, animals, and the biological processes for their generation.⁹² This exclusion does not apply if the invention is a microbiological process, or the product of such a process.⁹³

The Advisory Council on Intellectual Property (ACIP) is currently undertaking a review into the innovation patent system.⁹⁴ ACIP is considering the effectiveness of the innovation patent system in stimulating innovation by Australian small to medium business enterprises. It is expected that ACIP will present its interim report to the Government in early 2013.

The courts have interpreted innovative step to be a very low threshold, and so the potential exists for the innovation patent system to be used to secure protection for trivial changes to known products. In response, IP Australia is currently considering increasing the innovative step threshold to an inventive step, as per standard patents. It has not been proposed to change the current system of granting innovation patents before they are examined and certified.⁹⁵

⁹¹ *Ibid*, s.68.

⁹² *Patents Act 1990* (Cth), s.18 (3).

⁹³ *Ibid*, s.18 (4).

⁹⁴ www.acip.gov.au

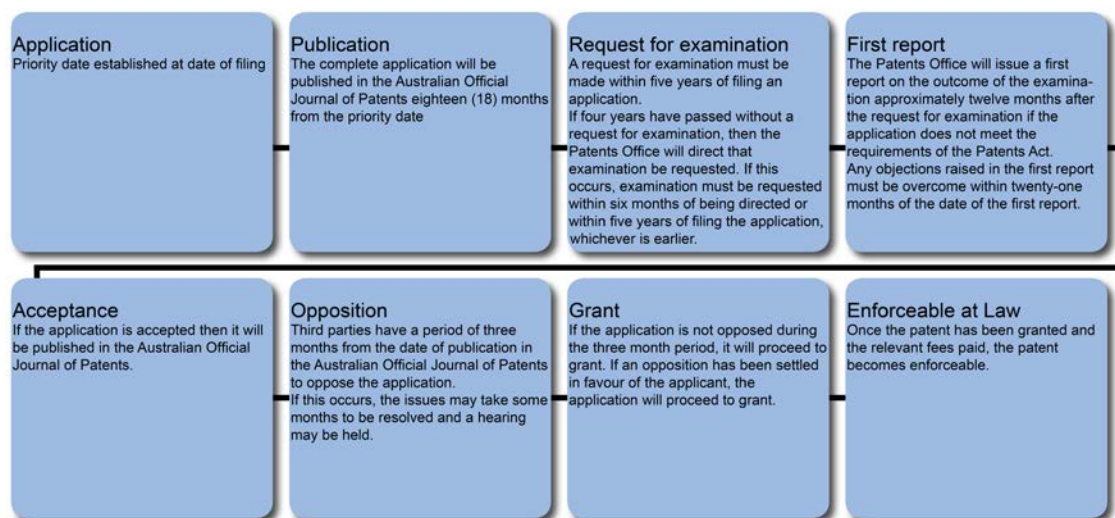
⁹⁵ *Innovation Patents – Raising the Step*, Consultation Paper, IP Australia, October 2012, <http://www.ipaustralia.gov.au/about-us/public-consultations/innovation-patent-consultation/>

In 2011, IP Australia received over 2,000 applications for innovation patents and granted over 1,600. Only around 1% of innovation patent applications are for pharmaceutical inventions.⁹⁶ Presumably this is because the eight year term does not provide a sufficient duration of protection and pharmaceutical companies are more focused on global IP strategies and obtaining patents in multiple jurisdictions. The US, Canada, UK and many European countries do not have innovation patent systems and there is no equivalent of the PCT and an international application system for innovation patents.

Application process

The patent application process has three main stages - application, examination and acceptance. There are opportunities for third parties to be involved in the process at a number of points in the process.

Figure 6 - Patent process



A patent application must include a specification that fully describes the invention and defines the monopoly sought in a set of claims. The description of the invention is an important part of the trade-off between the patent holder and society, as it makes scientific and technical knowledge publicly available in return for exclusive rights. The claims delineate the area of technology that will be the property of the patentee and correspondingly the areas where others are free to operate.

⁹⁶ Data provided by IP Australia, November 2012.

Applications for standard patents are examined before they are granted. Examination ensures that the claimed invention meets the basic patentability requirements including novelty, inventive step and sufficiency of disclosure. Examination is an iterative process where examiners skilled in the relevant technology raise issues of patentability with applicants, or their agents, giving the applicant opportunities to amend their application so that it meets the requirements of the Act. As discussed below, the grounds for examination are being expanded. Applications are accepted if all of the examiners objections are overcome within a specific timeframe. If no oppositions to the grant of patent are filed by third parties within three months of acceptance, the patent is granted.

Recent reforms

The 2008 Cutler Review of the National Innovation System⁹⁷ recommended a number of changes to the Australian patent system. Some of the recommendations are reflected in recent reforms that are designed to raise patent standards to bring the Australian system into line with our major trading partners. On 15 April 2012, the Raising the Bar Act received Royal Assent. The Act includes reforms for patents in all technologies which aim to raise quality, reduce delays, simplify the system and allow access to patented inventions for research and regulatory approvals. The majority of changes commence on 15 April 2013.

Inventive step

One of the primary objectives of the Raising the Bar Act is to strengthen the quality of patents granted by increasing the threshold for the inventive step requirement. Restrictions on the information and background knowledge that can be taken into account when assessing whether an application is sufficiently inventive to justify a patent are being removed. The aim is to raise Australia's standards for inventive step to a level that is consistent with those of our major trading partners.

⁹⁷ *Venturous Australia – building strength in innovation*, Cutler & Company Pty Ltd, 2008.

Usefulness

The Raising the Bar Act also aims to bolster the requirement that a patented invention be useful. The invention will have to work in the way that the patent says it does and the specification must clearly explain how the invention works. These amendments are designed to prevent the grant of patents for speculative inventions that require too much further work before they can be put into practice.

Disclosure

The standards for the disclosure of an invention will also be raised. The amendments address circumstances where the information disclosed in a patent specification, although sufficient to make one thing within the scope of each claim, is not sufficient to make the invention across the full scope of each claim. The changes aim to ensure that granted patents are no broader than the invention which has been disclosed.

Certainty of validity

The reforms aim to increase the certainty in the validity of granted patents. Presently, the Commissioner is limited in the grounds that can be considered when deciding to grant a patent, to revoke a patent or at re-examination. In contrast, the courts are able to consider a wider range of grounds. As a consequence, a patent correctly granted by the Commissioner may subsequently be found to be invalid by the courts. The changes will expand the grounds that the Commissioner can consider, and apply a consistent standard of proof across all grounds.

Research exemption

The reforms introduce a statutory exemption for infringement for research activities. This exemption applies to all tests, trials and procedures that a researcher or follow-on innovator undertakes as part of discovering new information, improving on or testing a patented invention. This gives certainty to researchers: allowing them to conduct their experiments without worrying about patent litigation.

Future agreed reforms

TRIPS Protocol

Many developing and least-developed countries continue to have difficulty obtaining the pharmaceuticals needed to address public health problems such as HIV/AIDS, malaria and tuberculosis. The TRIPS Protocol helps address this by amending the TRIPS Agreement to enable WTO members to grant compulsory licences for the use of a patented pharmaceutical invention to manufacture and export generic medicines to countries in need. The Government intends to introduce legislation in the near future to implement the TRIPS Protocol in Australia.⁹⁸

Patentable subject matter

In 2011, the Government agreed⁹⁹ to ACIP recommendations to clarify the thresholds for patentability in the Patents Act. The changes will define patentable subject matter using clear and contemporary language that embodies the principles developed by the High Court and remove the overlap of this threshold with novelty, inventive step and usefulness. The aim of this amendment is to make the law clearer, not to change it.

The Government also agreed to include exclusions from patentability based on:

- protecting *ordre public* or morality, including to protect human life or health, as permitted under Article 27(2) of TRIPS, and
- inventions the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.

The Government has stated that the development of this legislation will involve comprehensive public consultation.

Compulsory licensing review

Under the Patents Act, a person can apply to the Federal Court for an order requiring a patent owner to grant the person a licence to work a patented invention. The Court may make the order if:

⁹⁸ *Exposure Draft of IP Laws Amendment Bill 2012*, IP Australia, August 2012.

⁹⁹ *Australian Government Response to Senate Community Affairs References Committee Gene Patents Report*, November 2011. page 15.

- the applicant has been unsuccessful in obtaining a licence from the patent owner to work the invention on reasonable terms and conditions and the reasonable requirements of the public have not been satisfied, or
- the patent owner has contravened Part IV of the *Competition and Consumer Act 2010*.

The Productivity Commission is currently conducting a review of the compulsory licence provisions with reasonable access to health care being one of the issues under consideration. The Commission expects to release a draft report in early December 2012 and present its final report to Government in March 2013.¹⁰⁰

General patent law and practice in other jurisdictions

Patent laws in Australia are broadly consistent with those of our major trading partners and countries with similar legal systems. The international framework for intellectual property matters sets out the various requirements which participating countries must comply with, leading to a degree of consistency across jurisdictions. There are similar administrative and judicial avenues for third parties to challenge patents. As discussed above, the Raising the Bar Act substantially increases the alignment between Australian patent standards and those in the US, Japan, Europe and the UK.

The US patent system has recently undergone significant changes. The America Invents Act became law on 16 September 2011 and brings about significant changes in the US system. One of the most significant changes is moving from a first-to-invent system to a first-to-file system. Prior to this, an inventor could challenge a US patent on the grounds that they invented it before another person filed an application for the same invention. This resulted in a number of costly disputes between rival inventors and was out of step with all other jurisdictions, including Australia. This Act also introduced post-grant review proceedings and changes to re-examination processes.

The application of TRIPS is a condition of accession for the 157 members, which includes Australia, and 27 observers of the WTO. The majority of governments that are not WTO members or observers are developing island nations of the Caribbean and Pacific Ocean, as well as North Korea, Turkmenistan and South

¹⁰⁰ www.pc.gov.au/projects/inquiry/patents

Sudan among others. These countries are also net importers of intellectual property.

WIPO has 185 member states, which includes Australia. Non-members include Cook Islands, Kiribati, Marshall Islands, Federation States of Micronesia, Nauru, Niue, Palau, Solomon Islands, Timor-Leste, Tuvalu and the states with limited recognition status in the United Nations.

Appendix D: Australian pharmaceutical industry

Overview

The Australian pharmaceutical industry involves companies operating across the value chain including early-stage research and development (R&D), clinical development, manufacturing, sales and distribution.

Most companies in Australia are global companies with headquarters overseas and can be described as:

- originator medicines companies (developing and distributing original medicines based on small molecules or biologics including biosimilars¹⁰¹);
- generic medicine companies (developing and distributing off patent small molecule and biosimilars medicines);
- research-based biotechnology companies (mostly small start-ups developing new drugs)
- diagnostics companies, and
- contract research, manufacturing and clinical trial service providers.

The distinction between originator and generic medicines companies is blurring as patents on originator medicines expire, originator companies have increasing numbers of generic medicines including biosimilars and business models change.

Diagnostic tests are becoming more important for pharmaceutical companies as many new drugs are only subsidised based on the outcome of an associated diagnostic test.

Size of the pharmaceutical industry

Turnover for the broader Australian pharmaceutical industry has grown from \$10.4 billion in 1999-00 to \$22.5 billion in 2010-11.¹⁰²

¹⁰¹ Biosimilars, or follow-on biologics, are versions of biological drugs (biologics) made after patent expiry. The active ingredient in a biosimilar is not exactly the same as the originator biologic drug due to the complexity of the molecule.

¹⁰² Department of Industry, Innovation, Science, Research and Tertiary Education. 2011. Australian Pharmaceutical Industry Data Card 2011. Accessed online October 2012.

Employment for the industry has also grown from an estimated 34,000 people in 2002-03 to 41,000 in 2010-11 including in sales and distribution.¹⁰³ For the pharmaceutical manufacturing sector alone, employment was 14,489 people at the end of June 2011 representing a 2.2% increase from June 2010 and a total increase of 8.3% over the four years from June 2007.¹⁰⁴

The pharmaceuticals manufacturing sector recorded sales and services income of \$9.3 billion in 2010-11. This was down 2.5% from \$9.6 billion in 2009-10, however, it represented an average compound annual rate of growth (CARG) of 8.5% from \$6.7 billion in 2006-07.¹⁰⁵

Industry value-added for pharmaceutical manufacturing was \$2.3 billion in 2010-11, down 14.6% from \$2.7 billion in 2009-10 and a CARG of 7.9% from \$1.7 billion in 2006-07.¹⁰⁶

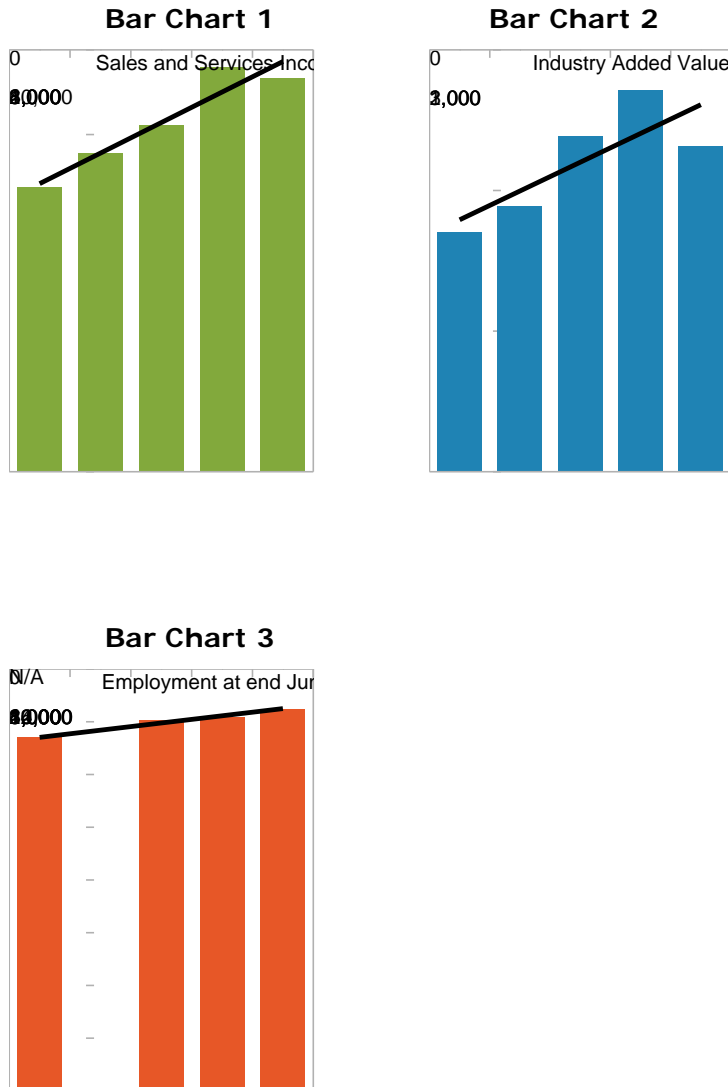
¹⁰³ Department of Industry, Innovation, Science, Research and Tertiary Education. 2011. Australian Pharmaceutical Industry Data Card 2011. Accessed online October 2012.

¹⁰⁴ ABS. *8155.0 – 2010-11*; ABS. *8159.0 – 2009-10*; ABS. *8221.0 – 2006-07*.

¹⁰⁵ Australian Bureau of Statistics. 2012. *8155.0 – Australian Industry 2010-11*; ABS. *8159.0 – Experimental Estimates for the Manufacturing Industry 2009-10*; ABS. *8221.0 – Manufacturing Industry, Australia, 2006-07*.

¹⁰⁶ ABS. *8155.0 – 2010-11*; ABS. *8159.0 – 2009-10*; ABS. *8221.0 – 2006-07*.

Figure 7 – Pharmaceutical sector income, value and employment

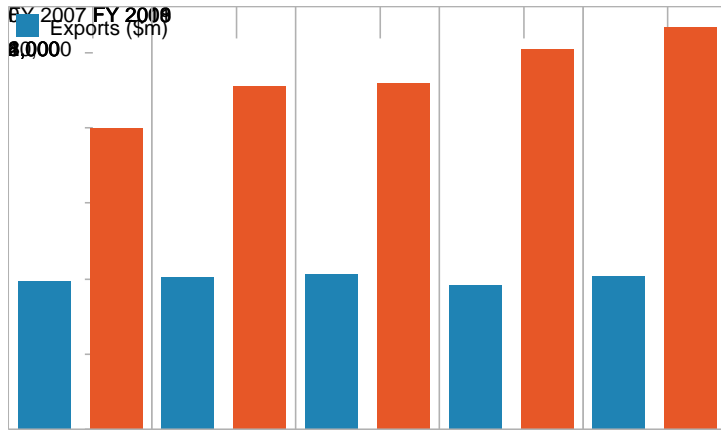


Trade

In terms of international trade, on balance, Australia is a net importer of pharmaceutical products. In 2011-12, pharmaceutical exports totalled \$4.1 billion making it one of the country’s major manufactured exports (pharmaceuticals accounted for an estimated 4.6% of all manufactured exports by value). However, for the same year pharmaceutical imports were \$10.7 billion. In recent

years, growth in pharmaceutical imports has outpaced growth in exports which has remained relatively static.¹⁰⁷

Figure 8 – Pharmaceutical trade



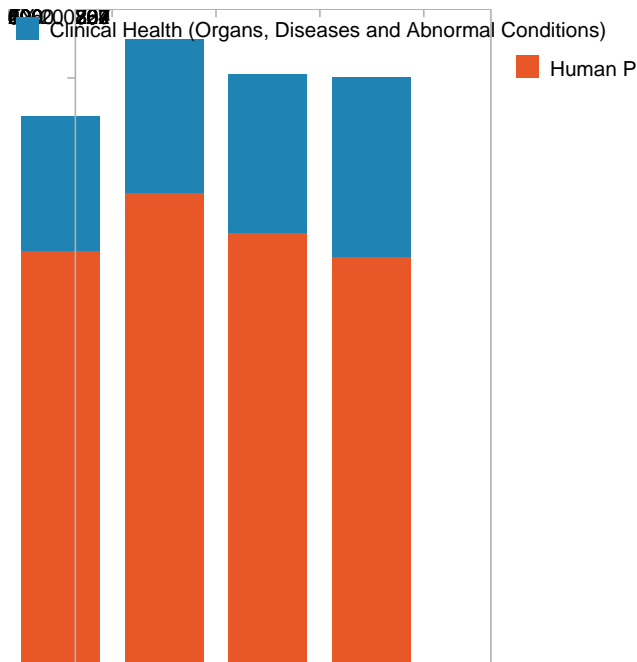
Research and Development

In order to provide new or improved therapeutics and diagnostics, significant research and development is required. Expenditure by businesses on R&D for pharmaceutical development in 2010-11 was \$1.00 billion.¹⁰⁸

¹⁰⁷ Australian Bureau of Statistics. 2012. *5368.0 – International Trade in Goods and Services, Australia 2011-12, September 2012.*

¹⁰⁸ Australian Bureau of Statistics, *8104 – Research and Experimental Development by Socio-Economic Objectives, Businesses, Australia, 2010-11.*

Figure 9 – Pharmaceutical R&D (\$m)



Size of the Australian Market

The Australian market for pharmaceuticals in 2010 was \$14.1 billion and is forecast to grow to \$19.2 billion in 2015. Australia accounts for an estimated 7% of the Asia-Pacific (Australia, China, India, Indonesia, Japan, New Zealand, Singapore, South Korea, Taiwan, and Thailand) market.¹⁰⁹

In 2012, it is estimated that generics represent 30% of the Australian pharmaceutical market by volume and around 10% by value.¹¹⁰

In 2010-11, the pharmaceuticals industry received \$6.4 billion from PBS sales.

Patenting

The development of a pharmaceutical product involves significant investment as well as technical and market risk associated with these products. In order to

¹⁰⁹ Datamonitor. 2012. *Industry Profile – Pharmaceuticals in Australia*

¹¹⁰ Espicom. 2012. *The Pharmaceutical Market: Australia, Opportunities and Challenges*.

justify this investment, sales of pharmaceutical products must provide sufficient returns. The time-limited market monopoly offered by patents is part of the innovation system designed to facilitate the investment needed for new products being developed for the market.

A developer of a pharmaceutical product will typically file for a patent following a period of drug discovery research and/or development. Often such R&D takes many years. This protects the invention and provides a degree of market certainty that makes further development of the product worthwhile. Often in the case of a small biotechnology company, the patent enables the significant investment required for the continuation of the company. After patenting, considerable development is still required before the product can gain regulatory approval to be marketed. The specific business environment of the pharmaceutical industry is significantly affected by the long research and development lead times required for new products and the need for regulation of these products.

In 2011, 7.9% of patent applications at IP Australia were in the technology group 'pharmaceutical, cosmetics'.¹¹¹ The percentages for previous years were: 9.1% in 2010; 8.7% in 2009; and, 9.3% in 2008.

For comparison, in 2009, 4.0% of patent applications worldwide were in the WIPO technology field 'pharmaceuticals' and 4.2% in 2008. At the USPTO, 4.7% of patent applications in 2008 were in the Class: NAICS 3254: 'pharmaceutical and medicines'.

Patents originating from Australia accounted for 67 or 3.3% of the 2,017 patents in the 'biotech, pharmaceutical and cosmetics' category sealed at IP Australia in 2011. Patents originating in the US totalled 876 or 43% of all these patents for the same year.

¹¹¹ International Patent Classification, subclass A61K.

Figure 10 – Countries of origin of pharmaceutical patents

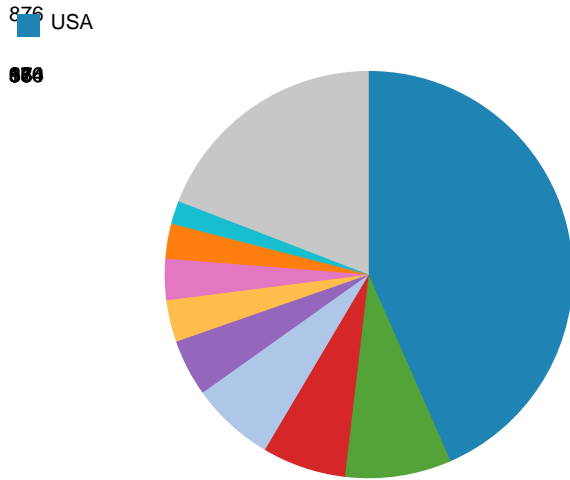
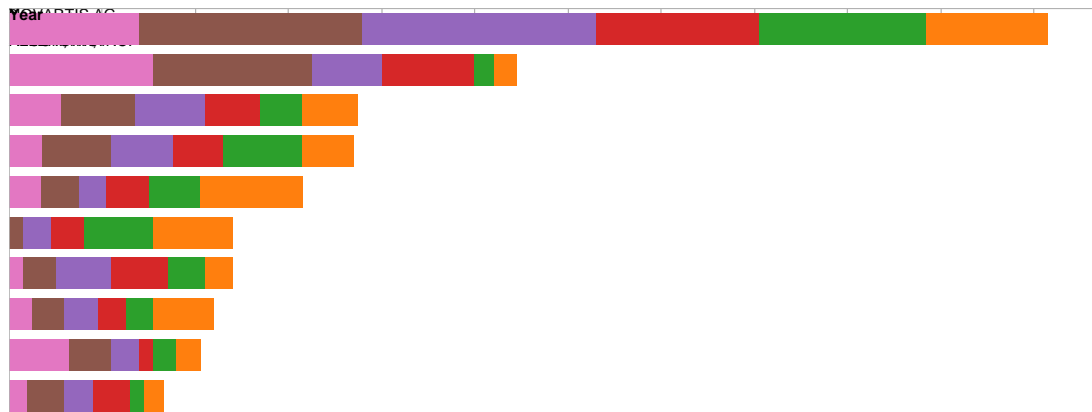


Figure 11 – Top applicants to IP Australia for granted pharma/cosmetic patents (2007-2012)



Clinical Trials

Regardless of how promising a candidate may appear based on preclinical information, the success of bringing a drug to market depends on the demonstration of its safety and efficacy in clinical trials in humans.

There are three stages of clinical trials prior to regulatory processing. A fourth stage is also becoming more common but that takes place after the drug has entered the market.

- **Phase I trials** typically taking 3-6 months, verify the safety of the drug and are generally conducted in healthy people (usually involving 20 to 100 people).
- **Phase II trials** typically taking 6 months – 2 years, consider dosage and efficacy of the drug in relation to the target disease and are conducted in patients (usually several hundred people).
- **Phase III trials** which can take up to 5 years, verify the drug's effectiveness and monitor the development of tolerance or adverse reactions of long term use including interactions with other medications. (The number of patients involved can be several hundred to several thousand).
- **Phase IV trials** gather safety information from a much larger number of users and different patient populations after the drug is available to patients.

A 2010 study examined the drug development pipeline of the 50 largest pharmaceutical companies to investigate the likelihood of pharmaceutical inventions proceeding to the next stage of clinical trials or regulatory review during the period 1993-2004. The study found that approximately 65% of Phase I trials, 40% of Phase II trials and 62% of Phase III trials proceeded and that 92% of submitted marketing applications received regulatory approval. Therefore, around 15% of candidate molecules entering clinical trials made it onto the market. It is important to note that these figures represent the aggregated data and the probabilities varied considerably depending on the therapeutic category being treated.¹¹²

Regulatory Approval

The TGA, an agency of the Department of Health and Ageing, regulates pharmaceuticals and other medicinal products. Before providing approval for a

¹¹² DiMasi, J.A., L. Feldman, A. Seckler, A. Wilson. 2010. Trends in Risks Associated With New Drug Development: Success Rates for Investigational Drugs. *Nature Clinical Pharmacology & Therapeutics* Vol. 87(3) pp 272-277.

pharmaceutical product to be marketed, the TGA requires data to support the quality, safety and efficacy of the product for its intended use. This includes information on how the product is made along with data from clinical and pre-clinical testing.

Once a new therapeutic receives marketing approval from the TGA it is included on the ARTG.

Generics

Generic pharmaceuticals are products containing the same small molecule active ingredient as the originator brand medicine and, in the absence of licensing agreements, can only be marketed once the relevant patents have expired. The introduction of generics to the market usually results in reduced prices through increased competition as well as PBS price reductions discussed below.

The development of a generic pharmaceutical is inherently less costly and less risky than development of the original pharmaceutical. The major drug development work has previously been completed and, subject to the data exclusivity restrictions discussed in Chapter 7, the clinical trial data used in the approval of the original product can be relied on for approval of generic competitor products. However, for inclusion on the ARTG, producers of generic pharmaceuticals are still required to provide data supporting the quality and bioequivalence of the generic to the original product.

Biosimilars

Biosimilars, or follow-on biologics, are versions of biological drugs (biologics) made after patent expiry. They are more complex and expensive to develop than copies of the traditional (small molecule) drugs, called generics, which have exactly the same active ingredients as the original medicine.

Many new medicines are biologics and, as their patents expire, suitable frameworks for assessing and reimbursing biosimilars become more important. The world market in biosimilars has been estimated to be US\$3-5 billion by 2015¹¹³.

¹¹³ Global Industry Analysts. 2011. *Biosimilars: A Global Strategic Business Report*.

There is a well established assessment and reimbursement framework for generics but assessing biosimilars using this framework is not possible.

Countries worldwide are having difficulties developing assessment and regulatory frameworks for biosimilars.

Pharmaceutical Benefits Scheme

The PBS aims to provide reliable, timely and affordable access to a wide range of medicines for all Australians. The PBS Schedule lists medicines available to be dispensed to patients at a Government-subsidised price. Under the PBS, patients pay a set price for all medicines available on the PBS, and a further reduced price for concession card holders, and the Australian Government pays the remaining cost of the product.

An application to have an item listed on the PBS can be made for a medicine for any use for which it is included on the ARTG.

The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent statutory committee that meets three times a year to assess applications for listing on the PBS based on the clinical benefit and cost-effectiveness compared with other treatments or products for the same condition or use. It is assisted by the PBAC secretariat and teams of expert drug evaluators.

The Pharmaceutical Benefits Pricing Authority (PBPA) is a non-statutory committee that meets three times a year following PBAC meetings. It may recommend either a ceiling price or price range for an item that has been approved by the PBAC following negotiation.

The decision to subsidise an item is considered by Cabinet if the net cost to the PBS is greater than \$10 million per year, and then determined by the Minister for Health and Ageing. The Government also exercises a number of controls to manage the overall cost of the scheme.

The prices paid by the Australian Government for PBS listed medicines are reduced in several ways, including the extended and accelerated price disclosure program and statutory price reductions. Under the statutory price reduction, the listing of the first generic version of a pharmaceutical on the PBS triggers an automatic 16% reduction in the subsidy paid by the Government.

The Price Disclosure Program progressively reduces the price of PBS medicines where an interchangeable competitor product is also listed on the PBS. The Government obtains data on the actual ex-manufacturer prices paid by pharmacies for medicines. The approved price (paid by the Australian Government) is adjusted where there is a difference of 10% or more compared with the weighted average disclosed price.

For example, in April 2012 the Minister for Health announced¹¹⁴ that generic versions of 60 different medicines would be significantly cheaper as a result of discounts applied through the extended and accelerated price disclosure program. Several examples were given of savings to patients, including the cholesterol lowering Simvastatin decreasing by up to \$14.64 for a packet of 30, 40 mg tablets. The Minister stated that the reforms will deliver over \$1.9 billion in savings to taxpayers over the next five years.

¹¹⁴ *Patients Save Money on Life-Saving Medicines*, Media release 1 April 2012.

Appendix E: Abbreviations

ACIP	Advisory Council on Intellectual Property
AUSFTA	Australia-United States Free Trade Agreement, entered into force 1 January 2005
ARTG	Australian Register of Therapeutic Goods
FDA	United States Food and Drug Administration
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PI	Product Information
SPC	Supplementary Protection Certificates
TRIPS	World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, signed in Marrakesh, Morocco on 15 April 1994, entered into force 1 January 1995
TGA	Therapeutic Goods Administration
WIPO	World Intellectual Property Organization
WTO	World Trade Organization