



Australian Government

PHARMACEUTICAL PATENTS REVIEW

Draft Report

April 2013

Review

The review panel has released this draft report for further public consultation. The panel will finalise its report after this consultation has taken place.

Key dates

Announcement of review	15 October 2012
Release of issues paper	November 2012
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Final report	30 May 2013

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Preface

On 15 October 2012, the then Parliamentary Secretary for Innovation, the Hon Mark Dreyfus QC MP, announced a review of pharmaceutical patents. The terms of reference of this review are at Attachment A.

The review is to examine whether Australia's patent system is effective in securing timely access to competitively priced pharmaceuticals and in supporting innovation and employment in the industry. An important part of the review is to examine the Australian provisions for extending the terms of eligible pharmaceutical patents.

The Review Panel issued a background paper, with suggested topics related to the review, in November 2012. The Panel invited submissions from interested parties and advised a timetable which would allow for public hearings, a draft report and the completion of a final report for submission to government by the government's date for reporting, 30 May 2013.

Forty-three parties provided submissions and several of these provided further evidence in public hearings which the Review Panel conducted in February 2013 in Canberra, Sydney and Melbourne. In addition, several Commonwealth departments provided oral advice to the Review Panel and its Secretariat. The Review Panel drew on these submissions and testimonies to prepare the Draft Report which follows.

This report and written submissions responding to it will be used to finalise the Panel's report to the Minister for Climate Change, Industry and Innovation, the Hon Greg Combet AM MP.

Overview

The pharmaceutical industry relies on patents more than most: successful pharmaceuticals require significant Research and Development (R&D), yet competitors can cheaply copy those drugs. The patent system restricts such free riding by giving patentees a period of market exclusivity. It allows a reward for past investments and, more importantly, it grants an incentive for continued innovation.

Patents also have negative effects. They may increase prices – and so restrict supply – by more than the amount that would be required to provide the necessary incentives to innovate. This is important for pharmaceuticals because of their importance to human health. And though innovators seeking a patent must disclose considerable information about their inventions - thus providing a platform to others for further innovation - patents can also restrict follow-on innovators.

For these reasons, the question of how much patent protection to offer is crucial. Pharmaceutical patent rights that run for too long or that are defined too expansively will deprive people of drugs because purchasers, including governments, cannot afford them. An overly miserly patent system means patients will suffer because the industry has inadequate incentives to develop new drugs.

International Context

Judgements about patent adequacy and sufficiency are made more complex because the patent system operates within an international system. Some critical features of Australia's patent system have been set by international agreements. Countries that are major net exporters of intellectual property have tended to seek longer and stronger patents, not always to the global good. The acquiescence of Australia and other countries to that agenda means that some features of Australia's patent law are of little or no benefit to patentees.

International agreements also explain in some part why the patent term in Australia has been steadily increasing over time. The life of patent protection, originally 14 years and more recently 16 years, is now set at 20 years by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual

Property Rights (TRIPS). In signing the Australia-United States Free Trade Agreement (AUSFTA) Australia agreed that it would preserve a further extension to patents for pharmaceuticals beyond the 20 years that it had already legislated, without careful regard to whether this was in our own economic interest.

In negotiating such agreements, Australia needs a more active strategic engagement with the issues. While the patent system must be strong to be effective it should also be parsimonious, avoiding restrictions on trade and innovation where it is not necessary for it to deliver incentives to innovate.

Beyond this, international negotiations should address critical issues arising from the limitations of patents in providing incentives to innovate, including the need to develop drugs with high social value and not well rewarded in markets (see below).

There are signs that these past failures are being replicated in the current Trans-Pacific Partnership (TPP) negotiations because small, net importers of intellectual property, including Australia, have not developed a reform agenda for the patent system that reflects their own economic interests – and those of the world. Chapter three offers recommendations about Australia's stance in international forums where patent systems feature.

Chapter four considers two pressing issues covered by international agreements that have materially limited Australia's welfare without providing offsetting benefits to the patentee. One issue concerns Australia's ability to manufacture generic pharmaceuticals for export to countries where there is no applicable patent (MFE). Perversely, if the applicable patent has not expired in Australia, it seems Australian generic manufacturers must establish manufacturing facilities overseas to serve those markets to avoid infringing Australian patent rights. This result offers no obvious benefit to the original patentee in Australia, but it reduces investment and employment in Australia.

The other issue relates to the manner in which current patent law prevents a generic manufacturer stockpiling generic pharmaceuticals for future export to a country or for future sale in Australia, in anticipation of the expiry of an applicable patent. This is an important issue, because the firm that first satisfies the market

acquires strong 'first mover' advantages. This again imposes major restrictions on Australia's ability to manufacture generic pharmaceuticals, while providing negligible benefits to the Australian patentee, for generics can be stockpiled and imported from other countries with weaker, or shorter patent regimes.

The above examples are not new, but they have yet to be rectified. A decade ago, the Productivity Commission identified MFE as an important issue. At that time, the then Department of Industry, Tourism and Resources estimated export losses of \$2.2 billion from 2001 to 2009 unless patent laws were changed. Generic manufacturers continue to ask the government to intervene. In Chapter four, the Panel recommends that the government act on these matters.

Extensions of Term

An important part of the terms of reference of this inquiry is the extension of term that the Australian patent system allows. It applies to some pharmaceuticals for which patentees have taken at least five years from the effective patent filing date to obtain regulatory approval for the pharmaceutical's use. The scheme reflected a similar extension arrangement introduced in 1989 when the standard term of a patent was 16 years. The government then claimed that the extension would "encourage the development of the pharmaceutical products industry in Australia". That arrangement was repealed in 1994 after TRIPS mandated a 20 year patent term. The current scheme dates from 1998. It too aims to attract investment in pharmaceutical R&D in Australia, as well as providing an effective patent term for pharmaceuticals more in line with that available to other technologies.

At the time, the annual cost of the extension to the Pharmaceutical Benefit Scheme (PBS) was estimated to grow from \$6 million in 2001-02 to \$160 million in 2005-06. The cost arises because there is a delayed entry to the pharmaceutical benefits scheme (PBS) of cheaper generic drugs. The estimate for 2012-13 is over \$200 million if the earlier figure is inflated by, say, four per cent per annum.

Another way to measure the cost of the extension scheme is to estimate savings from reducing the length of the extension. AUSFTA requires that Australia has a pharmaceutical extension provision but it is silent as to the length of the

extension. Actual savings obtained from reducing the extension term would be affected by many factors, including price changes caused by increasing sales volumes, the 16 per cent mandated price reduction following the entry of a second drug, the influence of competing generic manufacturers and reductions from price disclosure mechanisms.

The Panel is still developing estimates of savings from reducing patent extension terms, but initial figures suggest they amount to some hundreds of millions of dollars a year. These amounts represent the subsidy which the government decided to provide to the pharmaceutical industry partly to effect an increase in pharmaceutical R&D investment in Australia.

Using the patent scheme to provide indirect subsidies to one industry appears inconsistent with the rationale that patent schemes be technologically neutral. More importantly, particularly where there is already substantial patent protection and where increased patent protection only comes into effect after a patent term has already run 20 years, patents are at the limits of their policy effectiveness and most unlikely to be as effective as direct funding as a policy instrument.

Commercial investment decisions are generally made before or early in the term of a patent and in such circumstances the net present value of some future extension of market exclusivity is much diminished over the course of a normal patent term. In 1984, the Government's Intellectual Property Advisory Committee found it difficult to believe that the prospect of additional returns from an extension of the then 16 year standard patent life could materially influence investment decisions made many years beforehand. This argument remains valid today, and indeed gathers additional force in light of extension of the standard patent term to 20 years.

Even if it were increasing investment, it is difficult to see why a pharmaceutical firm would chose to conduct R&D in Australia, merely because the Government decided to offer an extension of term here. More fundamental issues such as relative costs of R&D and skill availability should influence the location of R&D spending.

It is posited in Chapter five that, if the government wishes to support Australian-based pharmaceutical R&D, it may be more efficient to reduce the five-year extension of patent term and to use some of the savings to provide a direct subsidy than to retain the five-year extension. A dollar of subsidy paid directly to a pharmaceutical research entity as it starts to develop a product may be more efficient in promoting Australian-based pharmaceutical R&D than an equivalent subsidy provided indirectly in the future through the PBS via the extension of patent term. This reflects several factors including the difference in discount rates applicable to government and commercial firms, the effect of subsidising activity at the beginning of product development instead of at the end, and the ability of a subsidy to be linked to spending on pharmaceutical R&D in Australia. Lastly, a direct subsidy has an additional benefit because it can be directed towards investment in pharmaceuticals which are not well addressed by the patent scheme (examples include too little research for new antibiotics – because once developed they must be used as sparingly as possible to prevent the development of antibiotic resistance). Likewise, even with stronger patents, the market cannot provide adequate rewards for pharmaceuticals to address rare diseases, paediatric illnesses and endemic health issues in low income countries.

The introduction of the extension of term in 1998 provided a wind-fall to pharmaceutical companies: they were rewarded with an incentive for work they had already undertaken. But there are problems in reducing the extension of term provisions immediately without compensation. Pharmaceutical research bodies would observe that they had embarked on projects in anticipation of the possible - even if remote - benefits available under those provisions.

Another option which the Panel is considering is to align more closely patent expiry dates in Australia with those in competing countries. The advantages available to first-movers have been discussed above. A disadvantage faced by Australian-based companies manufacturing generic pharmaceuticals is the propensity for patents to expire later in Australia than overseas. This can occur because pharmaceutical companies that have developed drugs (originators) tend first to seek regulatory approval overseas for marketing these drugs. There are also international differences in the speed with which regulators finalise applications for marketing approval. The misalignment of patent expiration can be partly addressed through deeming that the date of regulatory approval, for the

purpose of calculating patent term extensions in Australia, is the date when approval was granted in specified countries. This would encourage originators to align as best they can approval dates in Australia with overseas approval dates. Alternatively, close alignment can be achieved by terminating an extension of term in Australia at the date it is terminated in specified countries. Again, this would encourage originators to achieve the optimum market time for each market.

Chapter six of the report canvasses some technical issues concerning extensions of term. The class of pharmaceuticals that is eligible for extension of term in Australia is narrower than that in many developed countries (on the other hand, there are countries, such as Canada, that do not provide for extensions of term). Originators call for a widening of eligibility to accord with that used in the United States and Europe. In considering these submissions, the Panel takes the approach that it would not recommend more generous patent protection than exists, unless there was evidence that such was justified by national interest considerations.

As mentioned earlier, there is evidence that the current patent term is inadequate to support the development of some drugs, such as those for some paediatric conditions. But for reasons discussed earlier, the Panel believes a direct subsidy would be more effective than additional patent extensions.

The Panel accepts recommendations from many parties that the *Patents Act 1990* (Cth) (Patents Act) be amended to repeal the provision requiring applicants to provide the Department of Health and Ageing with information on Commonwealth money spent on drugs subject to an extension of term. Although these data - much of which appear to be inadequate - have been provided to the Commonwealth since 1999, there is no evidence that they have ever been used. Complying with the requirement is costly and the Panel sees little reason for its continuation.

Similarly, the Panel accepts that there is a technical anomaly with the legislative provision concerning the eligibility of drugs for extension. In one case, a court found that the presence of impurities in an earlier drug shortened the extension

of term available to a patent. The Panel is inclined to support an amendment if it did not risk a costly broadening of eligibility.

A pharmaceutical company can indirectly infringe a patent if it supplies a drug specifically for a purpose which is different to another, patented use but where it is still possible that the drug could be put to the patented use. This infringement can occur even when the company has not induced or supported that use. As a number of submissions recommend, the Panel supports an amendment to the Patents Act to protect a pharmaceutical manufacturer that has taken reasonable steps to avoid indirect infringement.

Evergreening and Follow-on Patents

In most developed countries, including the United States and Europe, there are concerns about pharmaceutical manufacturers using patents and other management approaches to obtain advantages that impose a large cost on the general community. The cost arises because these actions impede the entry of generic drugs to the market. Although some find the term to be pejorative, relevant literature has handily summarised these actions as evergreening: steps taken to maintain the market place of a drug whose patent is about to expire. Chapter seven discusses these and associated matters.

The Panel has little doubt that pharmaceutical manufacturers act to preserve the profitability of their products. A failure to do so would rightly be criticised by shareholders. And it is logical that patentees will seek further patents for improvements to their drugs - so called follow-on patents - with an eye to extending the market life of the original drug. Similarly, patentees are entitled to market these newly patented drugs before the original patent expires.

It is probable that less than rigorous patent standards have in the past helped evergreening through the grant of follow-on patents that are not sufficiently inventive. The newly proclaimed Raising the Bar legislation should moderate this problem somewhat, though the extent to which it will address the problem is unclear at this stage. The Panel, however, sees a need for an external body to audit the patent grant processes to help ensure these new standards are achieved, and the government should ask the Productivity Commission to review the effectiveness of the legislation.

Another approach used to protect a product is to entangle it in a knot of patents, a so-called patent thicket, which raises costs for new entrants. Such thickets would stymie generic manufacturers or developers of new pharmaceuticals. Though opinions will differ as to whether the term ‘thicket’ applies, the interaction of patents, follow-on patents, and drug marketing practices may have an impact on pharmaceutical prices and the costs of the PBS. Those implications are considered below.

Australia’s intellectual property system, like any other, works best when property rights are tightly delineated and there is an efficient adjudication system to resolve disputes. Chapter eight discusses these matters. There are three dispute mechanisms that involve the Patent Office. These non-judicial mechanisms have been affected by recent changes to the law, but they are not typically favoured by disputants as to the validity of individual patents because they lack the certainty offered by courts.

As in other matters heard by Australian courts, patent challenges and patent infringement cases are expensive. Where a generic manufacturer is the potential challenger of a patent, it must consider whether the small size of the Australian market and the relatively small margins from generic drugs make a challenge worthwhile. In addition, although the Commonwealth does not contribute to a challenger’s costs, it can be the major single beneficiary from a finding that a pharmaceutical patent is invalid. The benefits come from reduced drug prices for the PBS. On the other hand, the Commonwealth can incur important additional costs when an originator succeeds in obtaining an injunction for the sale of a generic drug. And the originator, with its higher margins from drug sales, has stronger incentives than its putative opponents to litigate.

The Panel is aware that the Commonwealth has started to seek costs from relevant parties because injunctions - and subsequent findings of patent invalidity can delay price reductions for the PBS. The Panel, however, recommends that the government - as the annual funder of the \$9 billion PBS - should become more closely involved in pharmaceutical patent cases. For example, there are likely benefits to the government from improving incentives for generic manufacturers to test the validity of patents.

As a result of AUSFTA, there are complex procedures that must be followed when a generic pharmaceutical manufacturer wishes to enter the market. Some submissions question the adequacy of these processes and others the impetus they provide to seek injunctions against the sale of the generic. The Panel recommends a mechanism to reduce the risk that generic manufacturers wishing to enter a market will inadvertently infringe a patent. The Panel also wishes to explore mechanisms to reduce the incidence of court proceedings when a generic manufacturers plan to enter the market. It is thus inclined to a system which requires each originator to list its relevant patents for a drug listed on the Australian Register of Therapeutic Goods (ARTG). That listing might not identify all applicable patents but it would capture all of the originator's applicable patents. If such a register was established, the Panel further suggests it could be appropriate for generic manufacturers to advise originators of their application for regulatory approval. That latter step would provide originators with time to explore their options without immediate recourse to injunctions.

Data Protection

When an originator seeks regulatory approval for a drug, it must provide data to the Therapeutic Goods Administration (TGA) demonstrating the drug's safety and efficacy. Although these data remain confidential to the TGA, the TGA may use them after a five year period to approve a generic or equivalent drug. This saves the pointless replication of tests to show safety and efficacy. A number of submissions argue that the five-year period of data exclusivity in Australia is too short.

A number of countries have a five-year exclusivity period; it is also the period Australia agreed under AUSFTA. Other countries, especially in North America and Europe, have longer periods. For many drugs the data exclusivity period is largely redundant because the relevant patent expires later. For some drugs, the data exclusivity period adds to the protection afforded by patent.

It is conceivable that drugs might not be brought to Australia, for example, because regulatory and marketing costs cannot be recouped within five years. Medicines Australia submits that some of its members chose not to supply a total of 13 drugs to the Australian market because of the inadequacy of the data

exclusivity period. However, they are only able to identify three of these, and the Panel's analysis - shown in chapter nine - suggests they are not convincing.

AbbVie offers a more compelling example, but even there the Panel believes that expanding data exclusivity for all or for a wide class of drugs is a poor response to issues affecting a small number of pharmaceuticals. A policy of subsidising drug development discussed above seems more appropriate.

Chapter nine also discusses the desirability of publishing data used for regulatory approval, much as information provided in patent applications must be published. The Panel does not recommend that Australia unilaterally release data submitted to the TGA, such publication has international repercussions, but it recommends that the government work with other countries to achieve that end.

An Integrated Approach to the Pharmaceutical System

In concluding, Chapter ten considers the need for a non-statutory body to oversee and report to government and parliament on the complex inter-relationships and linkages between TGA, PBS, IP Australia, international agreements and industry, budgetary and economic matters. The complexity of these issues- especially as they inter-relate - means that isolated consideration of particular features would likely not give optimum results. Measured by dollars alone, the size of the pharmaceutical industry and the PBS and the economic consequences of patents warrant a mechanism that requires close collaboration between agencies in identifying the best options for the national interest.

Draft recommendations

Draft Recommendation 3.1

The Government should expeditiously seek a situation where Australia has strong yet parsimonious IP rights – that is, rights that are strongly enforced and that provide the incentive necessary to underpin an appropriate level of investment in innovation but that are not defined so broadly as to impose costs on innovation or other activity without commensurate benefits.

For instance such strong yet parsimonious IP rights could provide a desired level of incentive to invest in pharmaceutical innovation without preventing our industry from servicing offshore generic markets, as current law does. Australia should take a leadership role in seeking consensus with jurisdictions with similar interests to identify and pursue a range of changes in international patent law and practice along these lines.

Draft Recommendation 3.2

The Government should ensure that future trade negotiations and renegotiations are based on a sound and strategic economic understanding of the costs and benefits to Australia and the world and of the impacts of current and proposed IP provisions, both for Australia and other parties to the negotiations. The Government should strongly resist changes – such as retrospective extensions of patent rights – which are likely to reduce world economic welfare and lead other countries in opposing such measures.

Draft Recommendation 4.1

As an interim measure, the Government should actively seek the agreement of the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of manufacturing for export.

Draft Recommendation 5

Option 5.1

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

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

Draft Recommendation 5

Option 5.2

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

Potential ways of achieving this include:

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

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

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

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

Draft Recommendation 6.1

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

Draft Recommendation 6.2

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

Draft Recommendation 6.3

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

Draft Recommendation 6.4

Section 117 of the Patents Act should be amended to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement where reasonable steps have been taken to ensure that the product will only be used in a non-infringing manner. Policy should further impose a presumption that “reasonable steps” have been taken where the product has been labelled with indications which do not include any infringing indications

Draft Recommendation 7.1

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

Draft Recommendation 7.2

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

Draft Recommendation 8.1

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

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

Draft Recommendation 8.2

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

Draft Recommendation 9.1

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

Draft Recommendation 10.1

The Government should establish a non-statutory Pharmaceutical System Coordinating Committee (PSCC) that reports to Parliament on an annual basis on the success and effectiveness of the patent, marketing approval and PBS systems, particularly where these interface. The PSCC should ensure there is

sufficient engagement and coordination between the relevant agencies and take account of costs to government, efficiency of registration and approval processes and respond to issues raised by industry. The PSCC should comprise senior officials from at least DIICCSRTE, IP Australia, DoHA (Pharmaceutical Benefits Division and TGA), DFAT, Finance and Treasury (as chair).

Draft Recommendation 10.2

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

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

Draft findings

Draft finding 3.1

In their negotiation of international agreement, Australian Governments have lacked strategic intent, been too passive in their IP negotiations, and given insufficient attention to domestic IP interests.

For example, preventing MFE appears to have deprived the Australian economy of billions of dollars of export revenue from Australian based generic manufactures. Yet allowing this to occur would have generated negligible costs for Australian patentees. The Government does not appear to have a positive agenda regarding the IP chapters of the TPP Agreement which comprehends national and regional economic interests.

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

Draft finding 4.1

Governments appear to have shown little strategic interest in the issue of MFE, despite a number of opportunities to do so and the significant potential advantages MFE could provide for Australia. If MFE had been rendered unambiguously consistent with our international obligations, it is likely that Australia's annual pharmaceutical exports would have been several hundreds of millions of dollars higher than they are.

Draft finding 9.1

The Panel considered whether data protection should be increased for biologics. The Panel is unconvinced that an extension of data protection would be beneficial. The Panel found no evidence to suggest that patents for biologics will be more difficult to obtain than patents for small molecule drugs, or that effective patent life would be substantially reduced by the complexity of biologics.

Additionally, given that the generic manufacturer of a biosimilar cannot rely solely on the clinical data of the reference product to obtain regulatory approval, there is reduced advantage to be gained from granting an additional term of data protection.

The Panel is of the view that given the substantial market opportunity that will arise in the near future for biosimilars, and the corresponding potential for cost savings to the PBS and consumers, competition in this area should be encouraged. At present the Panel does not have sufficient evidence to support an increase in data protection beyond the current five year period for biologics.

Draft finding 10.1

The patent system is of obvious significance to the pharmaceutical industry, trade negotiations and health policy. However, the government agencies with policy and program responsibility in these areas are not engaging sufficiently with each other and are not taking highly relevant issues into account. Each agency needs to be actively engaging from its own perspective – end users, innovation, industry and international implications – in order to optimise policy settings for the pharmaceutical system in what is a complex regulatory and service delivery environment. The areas of government responsible for regulating pricing of pharmaceuticals particularly have the need for and the resources to obtain a well-informed appreciation of the pharmaceutical patent system and its impact on a range of health issues. However, the only area in which they appear to have a strong view is in relation to gene patents.

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1. Introduction

1.1. Focus of the inquiry

The panel has been asked to review the effectiveness of the Australian patent system in providing timely access to affordable pharmaceuticals and medical treatments and supporting innovation.

This includes an analysis of the current pharmaceutical extension of term provisions, which have not been reviewed since their introduction in 1998. Other issues considered include granting of patents for new formulations, methods and uses of known pharmaceuticals; and international IP agreements and strategies for extending market exclusivity.

The Australian pharmaceutical system operates within a wider global system of pharmaceutical research, development and supply. Australia is a small market and a net importer of technology and medicines. The review has considered the Australian system in these contexts and in respect of an environment where many participants are multi-national companies, with far larger markets outside Australia than within. It has also considered how the international agreements to which Australia is a party impact on the pharmaceutical system.

The review recognises the complexity of the system and of the regulatory environment, and interactions between: the IP system; the Therapeutic Goods Administration, which is responsible for the registration of therapeutic goods for supply in Australia; and the Pharmaceutical Benefits Scheme, through which the Government subsidises the cost of most medicines supplied in Australia.

1.2. What is a pharmaceutical patent?

For the purposes of this review, a pharmaceutical patent is taken to be a patent for a medicine or a patent that directly relates to a medicine. A pharmaceutical patent includes (but is not limited to) patents with claims for active ingredients, new formulations and methods of 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 in the body
- a new method of producing a medicine

- a new use for the medicine in treating a different condition.

1.3. Report structure

The draft report has the following structure:

- Setting the scene – the rationale for having a patent system and the value of pharmaceutical patents for innovation and R&D and challenges for developing an optimal system in which the level of protection, and reward, provided by patent rights does not unduly restrict further innovation. (chapter 2)
- The international context – the importance of understanding the economics of IP in national and global economies; the implications for Australia of being a small economy; and the importance of a positive agenda and parsimony when negotiating trade agreements. (chapters 3 and 4)
- Extensions of term – the rationale for having an extension of term scheme, an evaluation of the effectiveness of extensions in encouraging investment in R&D and the impact of extensions on the cost of drugs. (chapters 5 and 6)
- Patent scope and validity – how the patent system is used by pharmaceutical companies to protect investments and maintain market share; patent landscapes around high-earning drugs; the importance of high standards for the grant of a patent and the high costs of litigation. (chapters 7 and 8)
- Data exclusivity and biologics – the term of data protection in Australia; interactions between data protection and patents; and the unique challenges of biologics. (chapter 9)
- Integrating elements of a complex, highly regulated system – regulatory processes in the Australian pharmaceutical system and the silos that administer these processes: developing a more integrated approach to policy development and evaluation. (chapter 10)

1.4. Next steps

The panel invites submissions to this draft report. Following consideration of submissions the panel will finalise its report.

2. The pharmaceutical patent system - setting the scene

2.1. Introduction to the patent system

The patent system encourages investment in innovation by providing a period of market exclusivity during which innovators can try to recoup the costs of developing and bringing new ideas to market. Without this, incentives to innovate may be insufficient because inventors might be unable to prevent others, who have not borne the costs of developing inventions, from exploiting them.

In exchange for market exclusivity, patentees disclose their inventions to the public. This provides public benefit by putting information in the public domain so that others can build on that information.

Patents also increase the price of innovative products to consumers and restrict other innovators' freedom to operate. The challenge is to optimise the system to generate maximum benefits taking into account three factors

- The benefits to society of investments in innovation that would not otherwise have taken place;
- the costs to society of:
 - the costs to consumers of products once they have been produced;
 - the obstacles that the patent system can put in the way of 'follow on' innovators.

Discussion of patent design has typically focused around the optimal patent length – something that typically brings out the tension between the interests of producers and consumers of intellectual property (IP). Here the challenge is to provide just sufficient IP protection to provide incentive enough to produce and commercialise the IP, so that the maximum possible benefit can go to consumers, while still ensuring sufficient producer benefits to create further IP.

In fact, such a fine trade-off is never possible with any accuracy, not just because policy makers lack the requisite knowledge to make it as felicitously as the theory calls for, but also because patents are technology neutral. As a result, policy makers must pick a 'one size fits all' patent length, which will be excessive in

some cases and inadequate in others.

More recently it has become clear that there is more to optimising patent policy than this simple trade-off on patent length. Patents operate not just as a tax on IP consumers but also as a potential barrier to follow-on innovators who wish to further develop existing IP or, to use Newton's famous words, to "stand on the shoulders of giants".

We have been through a period in which, for a variety of reasons, patenting was associated with the benefits of innovation in too simple and automatic a manner. The result of such a mindset seems to have involved the granting of a sharply increasing number of patents and an expansion of patenting to areas not originally envisioned as patentable, for example software and business methods.

Too many patents can be a serious impediment to innovation, as innovators must spend their scarce resources identifying patents they may be infringing – even if their own innovations were independently discovered. This has been a particular problem in software where major firms in IT such as Apple, Google and Microsoft now spend large amounts suing each other.

The pharmaceutical industry has very different characteristics to software, which are discussed more fully later in this report. Nevertheless as this report documents, the design of the IP system is of considerable importance for efficiency, raising considerations well beyond the simple length patents run or the ease with which existing rights can be enforced. Our task is to optimise the design of the patent system to maximise the gains relative to the costs.

Patent systems have existed in one form or another for a number of centuries. Australia's current patent system developed from the English system and the Statute of Monopolies of 1624 which established a legal system for the grant of patents for a maximum of fourteen years for any new 'manner of manufacture'. The objective of the statute was to allow monopolies and curb abuses of monopoly power: monopolies were only to be granted in exchange for communicating the invention to the public and were for a finite period of time.¹

¹ State Library of Victoria Research Guide – Patents accessed at <http://guides.slv.vic.gov.au/content.php?pid=87344&sid=649913> on 15 March 2013.

Today, patents sit alongside a number of other government administered systems for supporting innovation, including tax incentives, direct government funding for R&D and prizes, awarded for solving specific problems.

Australian patent legislation is set out in the *Patents Act 1990* and the *Patents Regulations 1991*. The legislation is largely technology neutral: providing for a twenty year patent to be granted in all fields of technology, subject to the requirements that the invention is novel, inventive and produces a useful product or effect. Patent specifications, which include the description of the invention and the claims that define the patent monopoly, are published soon after the patent application is filed.

Despite the fact that patents are available for inventions in all technologies, it is arguable whether the patent system is of general benefit across the full range of technologies. Where a technology is relatively inexpensive to develop and can be quickly brought to market, innovators may be better served by simply entering the market quickly: recouping their costs through first mover advantage. Specific industries and the public may also benefit through fewer patents impeding their freedom to operate. In this respect patents are a blunt instrument, with generally the same duration and extent of rights being granted regardless of the development costs or market size of the invention.

There is another weakness in the patent system: it might not stimulate innovation in certain areas of public interest because the commercial return, even after the grant of a patent, provides insufficient incentive. For example, pharmaceutical companies would be reluctant to invest considerable research funds for drugs for illnesses where the prospects of cost-recovery are small.

Patent protection is also a blunt instrument because a standard term patent is provided irrespective of the profitability of a particular invention or inventor. Some inventors might be able to recoup their costs quickly. Others might need a longer monopoly period than the patent system provides to become profitable.

Opinions differ on the value of patenting in different industries, but there is general agreement that, of all the industries where patents are used, patents are of particular value for pharmaceuticals.²

Pharmaceuticals are an example of a technology where:

- R&D costs are high;
- the risks of failure, particularly at a late stage of the development process, are high;
- the time between initial discovery and market entry is long; and
- products have traditionally been relatively easy to reverse engineer.

Although there can be disagreements about the details of a patent system, there is general agreement that the system encourages investment in pharmaceutical innovation. As noted by Dr Moir in her submission to the review:

The pharmaceutical industry is the major exception to the substantial empirical evidence that in most industries the patent system is the least useful means of ensuring good returns to innovation investment.³

In recognition of these specific challenges for pharmaceutical technologies, particularly the ease of copying and the time taken to enter the market, and to support investment in pharmaceutical R&D, extensions of term of up to five years are available in Australia for pharmaceutical patents. Again, these concessional extensions, available only to pharmaceuticals, might be more or less generous than is required to promote inventiveness.

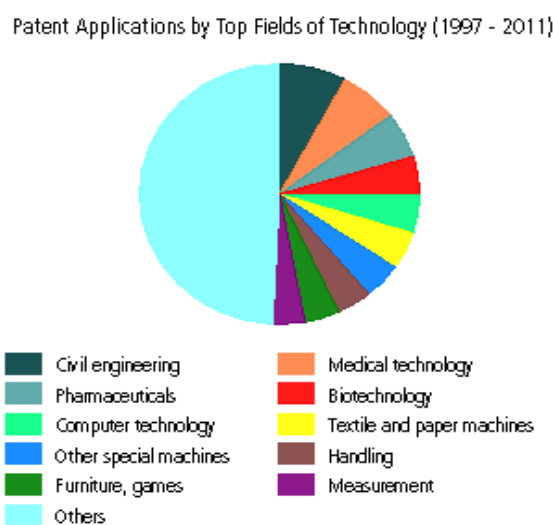
² Mansfield, E. (1986) "Patents and Innovation: An Empirical Study", *Management Science*, 32, 173-181; Cohen, W.M. et al (2000) "Protecting their intellectual assets: appropriability conditions and why U.S. manufacturing firms patent (or not)" NBER Working Paper Series, <accessed at <http://www.nber.org/papers/w7552.pdf> on 8 March 2012>; Higgins M.J. et al (2009) "Balancing innovation and access: patent challenges tip the scales" *Science*, 326, 370-371.

³ Dr Moir's submission to the Pharmaceutical Patents Review (PPR), made February 2013.

2.2. Pharmaceutical patents

In Australia, pharmaceuticals represent the third largest technology area for patent application filings. Pharmaceutical inventions represented 5.7% of the patent applications filed between 1997 and 2011. This compares to 7.5% in the UK, 6.0% in the US, and 6.0% in Canada.⁴

Figure 2.1: Patent applications by top fields of technology (1997-2011)



Source: WIPO statistics database; last updated: 12/2012

As is the general case for patent applications filed in Australia, the majority of pharmaceutical applications are made by foreign applicants, with 4.4% of the applications filed between 2007 and 2011 made by Australian residents. In the same time period, US applicants accounted for 47.6% of the foreign applications, followed by Chinese applicants with 7% and German applicants at 6%.⁵

Most pharmaceutical patent applications are filed by multi-national research pharmaceutical companies (all of them originators), with Novartis, Merck, Sharp and Dohme and Wyeth being the three largest filers of pharmaceutical patent applications between 2007 and 2011: filing 357, 119 and 118 applications

⁴ WIPO statistics accessed at <http://www.wipo.int/directory/en/> on 6 March 2013.

⁵ Data obtained from IP Australia records on 30 September 2012. Pharmaceutical applications are those classified in IPC A61K.

respectively, out of a total of 11,468 pharmaceutical applications.⁶ However, other entities such as universities, small biotechnology companies and manufacturers of generic pharmaceuticals (generics) also file patent applications.⁷

Universities and publicly-funded research institutes are important sources of the early stage research that leads to new drugs and medical treatments.⁸ It is estimated that in Australia in the 2010-11 financial year, 59% of health and medical research funding was sourced from Government (\$3,297 million). Of the remainder, 5% was sourced from private non-profit organisations, principally research institutes and Cooperative Research Centres (\$259 million) and 22% from business (\$1,220 billion).⁹ A significant proportion of this funding, both government and industry is expected to be spent on pharmaceutical research.¹⁰

Patenting is important to these institutions, and to small biotechnology and pharmaceutical companies, because patents can be used to attract investment or income through licensing deals, or as a bargaining chip in negotiations with industry and research partners. As noted by Walsh et al (2003):

⁶ Ibid.

⁷ A generic pharmaceutical is a product containing the same active ingredient as the originator brand medicine. In the absence of licensing agreements generics can only be marketed once the relevant patents have expired. Generics file only small numbers of applications. For example in 2007-2011 the 3 generic manufacturers Apotex, Alphapharm and Hospira filed 10, 10 and 2 standard patent applications respectively in the pharmaceutical technologies field.

⁸ Walter and Eliza Hall Institute submission to the PPR, made January 2013

⁹ Research Australia 2010-2011 Funding Health and Medical Research in Australia and 2011 report *Shaping Up: Trends and Statistics in Funding Health and Medical Research*, accessed at <http://www.researchaustralia.org/health-medical-research/funding-hmr> on 20 March 2013.

¹⁰ For example, ABS figures for 2008-09 show that 62.6% of business spending on health and medical research was spent on pharmacology and pharmaceutical sciences, medical biochemistry and metabolomics and clinical sciences.

Patents can play a vital role in facilitating the transactions that are needed to take research from the developmental phase to downstream product delivery.¹¹

The same observation was made by the Walter and Eliza Hall Institute (WEHI) in their submission to the Senate Community Affairs Committee review of Gene Patents:

Researchers in the public sector are accepting more and more that patenting is an essential component of commercialisation, and that commercialising patents is necessary for investment in R&D and for ensuring that products that benefit the public are developed. Public institutes do not have the skills or capital to transform research results into marketable products in the form of pharmaceuticals, therapeutic proteins and diagnostics and require public sector involvement to make possible public access to these developments. Consequently, WEHI works with other organisations to achieve these outcomes through effective licensing practices and effective collaborations.¹²

Within the university sector, patents are often used to achieve broader university goals. As explained by Ms Harrison-Smith of Monash University in public hearings, income from licensing of pharmaceutical technologies to industry is used by the university to fund research to address public and community health issues that might be of less interest to originators.

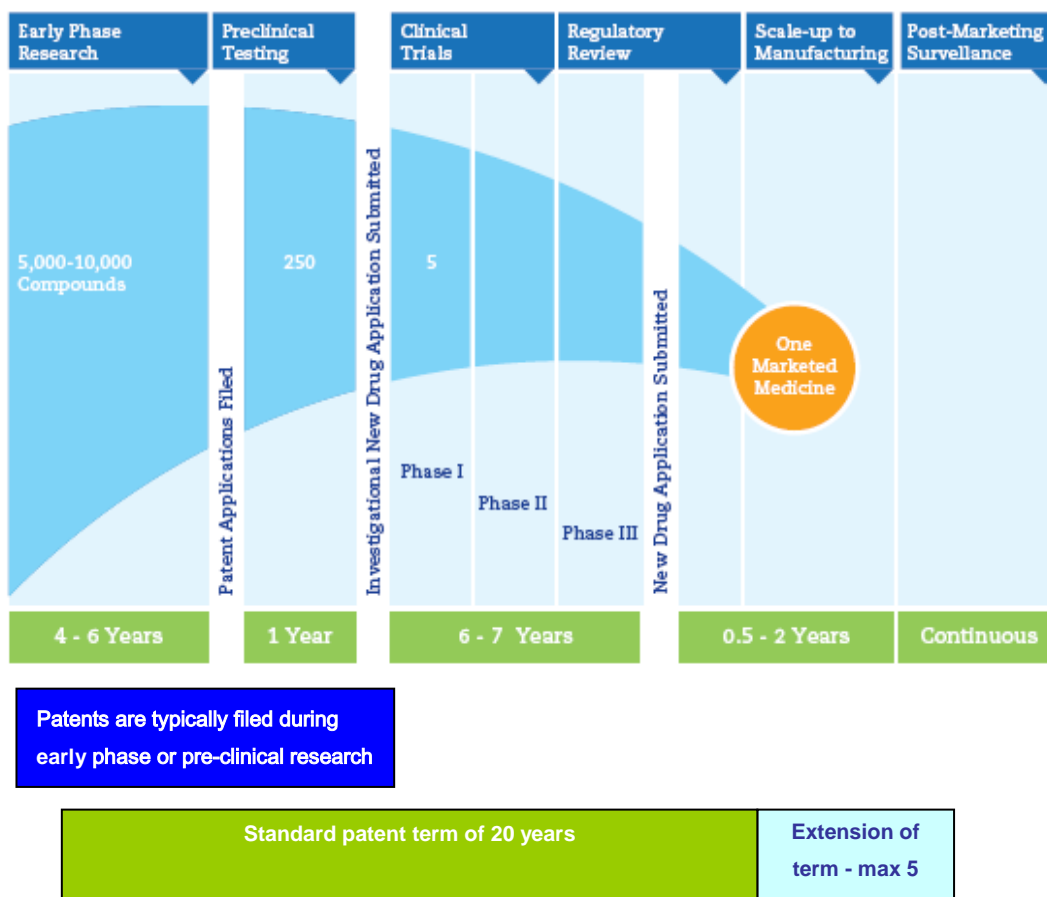
¹¹ Walsh J.P et al (2003) *Effects of Research Tool Patenting and Licensing on Biomedical Innovation* in Cohen, W.M. and Merrill, S.A. (eds.) *Patents in the Knowledge Based Economy*.

¹² Submission 21 to the Senate Community Affairs Committee review of Gene Patents (WEHI), accessed at http://aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/completed_inquiries/2008-10/gene_patents/submissions/sublist.htm.

2.3. The pharmaceutical lifecycle

Figure 2.2 below provides an overview of the development process for pharmaceuticals, demonstrating the long lead time and high costs in bringing new pharmaceuticals to market and the high failure rates for potential new products.

Figure 2.2 – Pharmaceutical development



Source: International Federation of Pharmaceutical Manufacturers and Associates (2012), *The Pharmaceutical Industry and Global Health: Facts and Figures 2012*

The overwhelming majority of submissions to the review acknowledge the importance of the patent system in encouraging investment in bringing new drugs and treatments to market. Where differences arise, it is mostly about the extent of protection provided by the patent system.

In their submission, Bristol Myers Squibb quotes the International Federation of Pharmaceutical Manufacturers & Associations:

IP rights are the lifeblood of pharmaceutical innovation. IP provides assurance to an innovator of approved new products or indications that it has the opportunity to generate revenues sufficient to justify its substantial R&D investments and ensure sustainable future innovation.¹³

The Generic Medicines Industry Association (GMiA) also states:

Pharmaceutical patents play an important role in encouraging the innovation of new pharmaceutical [sic] and it is imperative that innovation is directed to the invention of products that improve health outcomes.¹⁴

In their submission, Medicines Australia quotes an average cost of \$1.5 billion and 12 to 15 years to bring a new drug to market.¹⁵ A significant proportion of this, on average \$700 million per medicine, is typically spent on clinical trials.¹⁶ While submissions from originators stress the importance of the patent system for a sustainable, innovative pharmaceutical industry, none address the current and future state of industry profitability or asset growth.

Despite the high costs of drug development, the rewards for bringing a new drug to market can be very substantial. This is reflected in high overall profitability for research pharmaceutical companies. Spitz and Wickham (2012) found that international and US research pharmaceutical companies trading on the US exchange enjoyed profits more than 3.2 times greater than non-pharmaceutical companies between 1988 and 2009.¹⁷ Similarly, a 2006 Congress Budget Office report found that using standard accounting principles the industry's return on

¹³ Bristol Myers Squibb submission to the PPR, paragraph 4, made January 2013.

¹⁴ GMiA submission to the PPR, pg 8, made in February 2013.

¹⁵ Medicines Australia submission to the PPR, pg 1, made in January 2013.

¹⁶ Medicines Australia submission to the PPR, pg 14, made in January 2013.

¹⁷ Spitz J. and Wickham M. (2012) *Pharmaceutical High Profits: The value of R&D, or oligopolistic high rents?* American Journal of Economics and Sociology 71, p 1-36.

assets had consistently been 2 to 3 times higher than the median for *Fortune* 500 firms.¹⁸

The general health of the industry in Australia is reflected in a compound annual growth in revenues of 9.5% for the period spanning 2006-2010, with a market of \$14.1 billion in 2010, and forecast growth to \$19.2 billion in 2015.¹⁹

2.4. Generic pharmaceuticals

The generic sector is an important element of the pharmaceutical industry, with generic pharmaceuticals accounting for 30% of the Australian pharmaceutical market by volume and around 10% by value in 2012 and domestic manufacturing and exports contributing over \$300 million to the Australian economy.^{20,21} In addition, generic pharmaceuticals play a key role in reducing the cost of medicines to consumers and to the government.

The development of a generic pharmaceutical is inherently less costly and less risky than the development of the original pharmaceutical. The major drug development and testing phases have previously been completed and, subject to some restrictions, the clinical trial data used to obtain regulatory approval of the original product can be relied on for approval of the generic product. This enables generic manufactures to market drugs at substantially reduced prices.

Entry of generic products onto the market produces substantial cost savings for the Government's Pharmaceutical Benefits Scheme (PBS), because market entry of the first generic version of a pharmaceutical listed on the PBS triggers an automatic 16% reduction in Government subsidy and ongoing reductions through

¹⁸ October 2006 US Congress Budget Office Study *Research and Development in the Pharmaceutical Industry* accessed on 23 March at Needs content <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf>.

¹⁹ Datamonitor. 2012. *Industry Profile – Pharmaceuticals in Australia*.

²⁰ Espicom. 2012 *The Pharmaceutical Market: Australia, Opportunities and Challenges*.

²¹ GMiA submission to the PPR, pg 4, made in February 2013.

the Price Disclosure system. Under the Price Disclosure system, manufacturers are required to provide information to government showing the market price of their drugs. Where there is a significant price difference between the government price and the market price of a drug, the PBS price will be reduced to match the market.

In submissions to the review, GMiA states that the sector is currently driving savings to the PBS (Government contribution) of an estimated \$1.4 billion over 2005-2009.²²

The prospect of competition from generic medicines also encourages further innovation by originators which would no longer have exclusive market share once a generic enters the market place. This competition encourages originators to innovate to maintain a dominant position in the market.

2.5. Challenges for the pharmaceutical system

The pharmaceutical system currently faces a number of challenges.

A first challenge arises from the argued or apparent combination of reduced revenues from established drugs and increased costs of bringing new drugs to market. To the extent this is occurring, the amount that pharmaceutical companies have to spend on researching and developing new drugs decreases, reducing the rate at which new drugs are developed and brought to market.

Threats to industry revenue come from what is referred to as the 'patent cliff'. This term is used to describe the expected sharp decline in pharmaceutical company revenues as leading drugs come off patent.²³

A significant proportion of total drug revenue earned by pharmaceutical companies comes from a relatively small number of drugs. In Australia, in the 2011-12 financial year three drugs accounted for 16.7% of total cost to the

²² GMiA submission to the PPR, pg 5, made in February 2013.

²³ DeRuiter J. and Holston P.L. (2012) *Drug Patent Expirations and the "Patent Cliff"* U.S. Pharmacist, accessed at <http://www.uspharmacist.com/content/s/216/c/35249/> on 13 March 2013.

Government through the PBS. These were Atorvastatin (\$593.3 million), Rosuvastatin (\$359.2 million) and Ranibizumab (\$307.8 million).²⁴ Each of these drugs is patented, with the key patent on Atorvastatin expiring in 2012, patents on Rosuvastatin²⁵ due to expire in 2020 and the key patent on Ranibizumab due to expire in 2020.²⁶

With patent expiry come cheaper generic versions of the drugs, driving prices down and eating into the patentee's market share. When combined with the automatic 16% PBS price reduction and ongoing Price Disclosure reductions, this leads to price reductions of on average 25%, but in some circumstances well over 50%.²⁷

A number of submissions to the inquiry also refer to the increased costs of bringing a drug to market. A 2012 study by the UK Office of Health Economics reported a general consensus in the literature that there has been a steady increase over the past ten years in the cost of bringing a new drug to market. The report estimated an increase from approximately \$1 billion US in 2003 (in 2011 figures) to over \$1.5 billion US in 2011.²⁸

²⁴ Department of Health and Ageing publications - Expenditure and Prescriptions 12 months to June 2012, accessed at <http://www.pbs.gov.au/statistics/2011-2012-files/expenditure-and-prescriptions-2011-2012.pdf> on 9 March 2013.

²⁵ Note that 3 key Rosuvastatin patents were recently found invalid before a single judge of the Federal Court *Apotex Pty Ltd v AstraZeneca AB (No 4)* [2013] FCA 162 (5 March 2013).

²⁶ Patent expiry data obtained from AusPat.

²⁷ Department of Health and Ageing Price Reductions for Second Main Cycle, accessed 20 March 2013 and Grattan Institute Report Australia's Bad Drug Deal: High Pharmaceutical Prices accessed at <http://grattan.edu.au/publications/reports/post/australias-bad-drug-deal/>.

²⁸ UK Office of Health Economics *The R&D cost of a new medicine*, December 2012, accessed at <http://www.ohe.org/publications/article/the-rd-cost-of-a-new-medicine-124.cfm>.

Reasons given for the increased costs included decreasing success rates, from a 1:5 success rate in the 1990s to 1:10 in the 2000s, and increased development times, from an average of 6 years in the 1990s to 13.5 years in the 2000, as companies tackle complex and intractable diseases such as cancer and Alzheimer's.²⁹

Recently it has been reported in the media and academic literature that, in response to the current or imminent threat to their income streams, a number of pharmaceutical companies have announced reductions to their in-house R&D programs.³⁰

In submissions at public hearings, a Pfizer representative explained that the company's reported reduction in research staff was associated with a large expected fall in revenues as the patents over its block-buster drugs expired. The Pfizer representative also noted that pharmaceutical companies were looking more to out-source research activities and to look to research done by research institutes and universities to identify promising new drugs.³¹

This model presents opportunities for a country such as Australia to capitalise on its strong medical and biotechnology research sectors. However, success relies on there being sufficient funding for the research in the first place, from Government, philanthropic or industry sources, and effective mechanisms to capture the benefits from the IP generated through the research and from the industry partnerships and collaborations that develop.

It also requires sufficient funding for the pre-clinical and phase 1 and 2 clinical trials that follow-on from the initial research work. This work is often undertaken by research institutes and small biotechnology firms using a mixture of public and private sector funding.

²⁹ Ibid.

³⁰ Tang W. (L) (2013) *Revitalizing the patent system to incentivise pharmaceutical innovation: The potential of claims with means-plus-function clauses* Duke Law Journal 62, p 1069-1108.

³¹ Pfizer's oral submission to the PPR, Sydney Hearings, 12 February 2013.

In their submissions to the review, Medicines Australia, AusBiotech and representatives from research pharmaceutical companies argue that, in the face of such challenges, any diminution in the levels or duration of IP protection in Australia would risk driving investment in pharmaceutical manufacturing and research offshore, damaging the Australian economy, and increasing the risk of Australian accessing new medicines.

Key factors influencing the amount of R&D conducted in Australia are the relative costs of conducting R&D, access to skilled researchers and the presence of strong medical infrastructure to support laboratory research and clinical trials. The importance of research reputation for attracting industry funding for clinical trials was stressed by representatives from both Monash University and Murdoch Children's Research Institute in their submissions at public hearings. Both explained that the strong reputations of researchers at Monash and Murdoch, and a successful collaboration history, play a significant part in attracting industry R&D funding for clinical trials.

Both representatives considered that patent protection also played some part in attracting funding, because industry partners were more inclined to invest where there was patent protection. However, where the investor is an international company and the market is global, a patent portfolio that spans major markets such as the US and Europe is likely to be of far more importance than the relative strength or duration of patent protection in Australia. In particular, it is unlikely that the length of patent term extensions should be a key determinant in the decision whether or not to conduct research in Australia.

Similarly, it is difficult to see how features of Australia's patent system would have a decisive influence on the availability of drugs in the country. It is unlikely, all other things being equal, that the strength or duration of patent term would be the major factor in deciding whether or not to bring a drug to Australia.

But, as exemplified by Medicines Australia, and other submissions from the originator industry, the amount of R&D the industry would undertake in Australia is linked to the robustness of the country's patent arrangements. The view is that the industry would favour countries depending on the strength of their patent

protection, even if that decision entailed a less than efficient allocation of research funds. There is, however, no precision as to what constitutes an adequate patent system and no guarantee about the amount or share of R&D which would be funded by the originator industry in a country with a strong patent system.

A relationship between patent protection and research is also evident in some of the announcements of past governments, which have stated that lengthening the duration of patent protection for pharmaceutical inventions is for the purpose of increasing pharmaceutical research or to promote the production of new drugs in Australia.³² The effectiveness of this extension of patent protection is considered at chapter 5.

On the other hand, submissions from the generic manufacturers argue for reduction of the length and scope of extensions to address the second challenge to the pharmaceutical system, which is to control the cost of medicines to ensure that Australians and the Australian Government, through the PBS, can continue to enjoy access to medicines and a high standard of medical care. Australian governments have significantly increased PBS funding in order to meet the large costs of modern drugs. As more medicines become available, particularly as more expensive biological medicines come onto the market, and the population ages, the costs to the PBS and Australian tax payers will likely increase further.

In its submission, GMiA and members of the generics industry argue that current levels of IP protection create barriers to generic entry to the market stifling the development of a productive generic industry and delaying the advantages that generic products bring in terms of driving the cost of pharmaceuticals down and reducing costs to the PBS. GMiA also argue that originator pharmaceutical companies operate globally and that high IP standards are not required in

³² Revised Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill 1998*.

Australia, as the small market here has an insignificant effect on the overall incentive to innovate.³³

2.6. Optimisation

As indicated at the outset of this chapter, the challenge is to optimise policy so as to encourage innovation that would not otherwise have taken place but to do so only to the point at which such benefits continue to outweigh the costs of such measures to consumers, in higher prices, and to innovation more generally, by obstructing 'follow on' innovation.

Evidence supports the view that the originator industry is facing a challenging period. That, however, does not of itself justify patent extensions which must be in Australia's wider interests.

For a start, the Australian originator industry represents a small part of what is a world industry. Even a large increase in pharmaceutical industry revenues in Australia would not materially lift the international industry's total revenue flows. Moreover, there is no assurance that any increase in revenues provided to the Australian industry would be directed to additional R&D and there is no guarantee that it would lead to increased research effort in Australia. These decisions tend to be made internationally and are subject to many factors.

Evidence also supports the view that the generic industry is facing challenges from the ways in which originators use the IP system to maintain their market advantage. In a technology where the costs and failure rates in bringing a drug to market are high it is no surprise that, and there are good business reasons why, an originator would make every reasonable effort to extend the period and scope of market protection for an existing drug.

One practice is to file subsequent patents for improvements and modifications to an original drug. This is a legitimate practice and the further patents can produce substantial benefits in improved bioavailability or efficacy, new indications or

³³ GMiA public submission to the Pharmaceutical Patents Review, made February 2013.

more efficient and cost effective manufacturing processes. However, the practice can also frustrate generic entry to the market, resulting in consumers and the government paying more than they should for medicines. This process is colloquially called ‘evergreening’ and is discussed further in chapter 7

2.7. The extending scope and length of patents

Further challenges to optimising the patent system arise from the increases in term and scope of protection and decreases in patent thresholds.

For instance, although patents were primarily granted for mechanical inventions and industrial processes, the scope of patenting has gradually broadened, and in the last few decades has been extended by judicial decision to areas like business methods, software and biological materials.

Likewise patent lengths for pharmaceuticals were further extended in 1999 with extensions of the standard patent term of 20 years of up to 5 years for inventions relating to eligible pharmaceutical substances. Extensions are discussed in chapters 5 and 6.

A broader example, one relevant to all technologies in Australia, is a gradual lowering of patent thresholds in Australia as compared to patent thresholds elsewhere. Addressing this divergence has been the focus of reforms introduced by the *Raising the Bar Act 2012*. Patent thresholds are discussed in chapter 7.

A more pervasive example, and one whose relevance extends beyond pharmaceuticals, is that of IP provisions in trade agreements. As a member of TRIPS, Australia agreed to set minimum standards for IP protection, including extending the patent term from 16 to 20 years.³⁴

In 2005 the AUSFTA came into effect. In agreeing to AUSFTA Australia agreed to “TRIPS-plus” provisions that further strengthen IP protection. In its 2010 report

³⁴ The TRIPS Agreement came into force on 1 January 1995. Changes were implemented into Australia law by the *Patents (World Trade Organization Amendments) Act 1994*.

Bilateral and Regional Trade Agreements the Productivity Commission suggested that there had been clear net costs to Australia in adopting IP requirements agreed to in the TRIPS and AUSFTA agreements and recommended that the Government avoid the inclusion of IP in future agreements unless overall net benefits could be demonstrated.

A number of submissions raised concerns about the constraints imposed by trade agreements, particularly in light of Australia's participation in current negotiations on the TPP. International agreements are discussed in chapters 3 and 4.

2.8. Regulatory complexity

A further challenge for the pharmaceutical system arises from regulatory complexity. The pharmaceutical system in Australia is regulated at a number of different levels.

It is indirectly regulated through the patent system, which gives a patentee control over who can enter the market during the life of their patent. The market advantages from patent protection also extend beyond the life of the patent because of the brand reputation and market power established by the patentee, or their licensee, during the period of market exclusivity prior to expiry of the patent.

The system is also directly regulated through the market regulatory approval process administered by TGA. A pharmaceutical product must obtain TGA approval before it can be registered on the ARTG and marketed.

The PBS provides a further layer of indirect market regulation. Under the PBS, patients pay a set price for all medicines listed on the PBS, and a further reduced price for all concession card holders. The Australian Government pays the remaining cost of the product. An application to have a drug listed on the PBS can be made for a medicine for any use for which the medicine is listed on the ARTG.

Although listing of a drug on the PBS is not a prerequisite for marketing the drug, listing has the practical effect of increasing the size of the market for the drug because, in the absence of PBS subsidies, consumers might not be prepared to

pay, or be able to pay, the prices charged for the drug. In this respect, the Australian market is very different to the US market.

The challenge is to ensure that these layers of regulation work together to maintain a pharmaceutical system that:

- encourages investment in finding new medicines and treatments and/or bringing them to the Australian market;
- provides Australian consumers with safe and efficacious medicines without undue delays; and
- supports a level of competition sufficient to promote affordable pricing of medicines for consumers and the Government.

Against the background of these challenges this report looks at what policies are in Australia's best interests, economically and socially, and examines key aspects of the pharmaceutical patent system to determine whether it is meeting its objectives.

3. International context

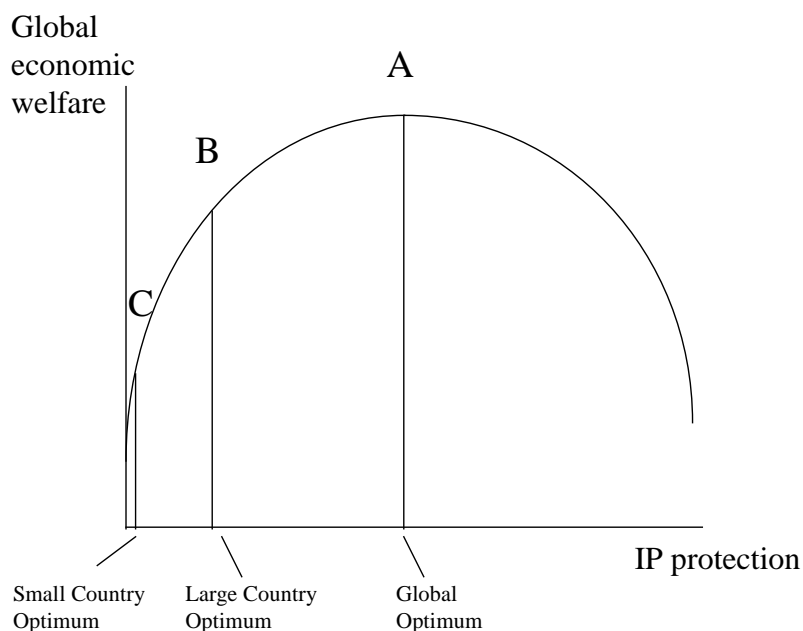
3.1. Background

The same policy dilemmas posed by IP within national economies arise in a similar, though somewhat different, form between countries. Generally the task is not to prohibit free riding altogether; for once new knowledge is brought into existence it should be spread as widely as possible. Rather, it is to ensure that investors in R&D are able to capture sufficient returns from their investment to ensure that it continues to occur. While the logic of providing incentives to invest in R&D justifies robust IP protection, the logic of maximising its social value also requires that IP protection be limited, both in time and in scope.

A small country can have very little influence on the global economics of IP production by changing its own IP protection policies. Given that Australia contributes less than 2 per cent of the world economy, extensions of Australian IP rights on their own are unlikely to influence a global firm's decisions as to whether or not to invest in IP. However, if global IP protection is inadequate, all countries have an interest in together agreeing to each provide sufficient minimum incentives to encourage investment in the production of IP. That is, although every country has an interest in free riding off others', each also has a collective interest in restricting their own free riding on others, if other countries do likewise in return.

Figure 3.1 illustrates the discussion above. If we consider some aspect of IP – the best example for our purposes is the length of patent terms – then no country 'internalises' all the benefits of longer patent terms, but large countries internalise them more. As a result their incentives when acting unilaterally are to have greater IP protection than small countries but still less than the global optimum.

Figure 3.1: Unilateral IP Protection



Source: IC, 1996) Gruen, N., I. Bruce, and G. Prior, (1996), *Extending Patent Life: Is It in Australia's Economic Interests?*, Canberra: Industry Commission, Industry Commission Staff Information Paper (June).

Given this, the economics of IP protection for Australia differs depending on the perspective one takes. Because Australia's share of the world market is small, when it is considering its interests unilaterally, and where it is considering incentives to generate IP of global significance, as it is for the pharmaceutical industry, it will generally be in its interests to have lower rather than higher IP protection. This does not exhaust its interests, however, because Australia also has an interest in a healthy global IP regime.

In this inquiry, the Panel has taken as its framework Australia acting unilaterally within a multilateral system. That is, it has not recommended action which might be in the global interest if all countries took it, unless it is also in Australia's interests unilaterally. This does not exhaust the issue, however, for one of the Panel's concerns about the past conduct of IP policy in the international arena is that Australian has been too passive in articulating its broader interests, the job of which is to 'internalise' the global economic interest by seeking all country's agreement to standards of IP.

Australia is a signatory to a number of international agreements that have IP aspects to them. The TRIPS Agreement and the AUSFTA are the agreements of most relevance to this review. AUSFTA is an example of what is known as a “TRIPS-Plus” agreement. That is, it sets minimum IP standards that are higher and more extensive than those in TRIPS. Australia has agreed that its patent system will be consistent with the terms of these agreements.

Differences between international agreements and domestic law

To comprehend our own and others’ obligations under international agreements we must appreciate the differences between sovereign domestic law and international law without the presence of a sovereign.

If a subject breaches the domestic law of a sovereign, it risks any sanctions that the law may contemplate as well as a range of civil harms. If the law were ambiguous in some way one might reasonably say that it was “risky” to proceed in a way that could give rise to penalties or civil liabilities.

The situation is quite different regarding international agreements. Firstly, an international agreement is an agreement between sovereign states. It does not directly bind firms or persons in the countries which are signatory to the agreement. Rather, an international agreement creates obligations on the parties to the agreement (states) to each other, to each make domestic arrangements that realise the intent of the agreement. This affects both the efficacy and speed with which disputes may be heard, the consequences of that breach for different parties and the entire legal process by which relief may be sought by one party and delivered to another. It also changes the sense in which we might consider who is ‘at risk’ when there is disagreement about the correct meaning of the words of an agreement.

Consider a situation in which a firm seeks to act in a particular way within a country which is signatory to the agreement, in a situation in which other firms either in that country or in the country of another signatory to the international agreement disagree with its interpretation of the agreement. For the matter to be ‘litigated’ or otherwise dealt with under the international agreement it must be raised between states. This means that any individual party must persuade that state that its case should be pursued. Where a remedy is sought by one state for breach of an international agreement by another, it will be sought initially by conciliation and discussion. Where agreement cannot be reached it may be

referred to a panel. If the matter is not resolved between the parties during the panel hearing, the panel will provide an opinion. If the panel finds that there has been a breach, the matter returns to the states for resolution. Where resolution cannot be reached one state may impose sanctions contemplated in the agreement on the other.³⁵

Rather than the agreement being thought of as “the law” between states, as if there were some international sovereign, such agreements might be better thought of as mediating an ongoing relationship between the parties rather like a memorandum of understanding would do between firms within a sovereign legal system.

None of this is to suggest that Australia should be cavalier about its obligations to other countries under the agreements to which it is a party. The Australian Government should not generally endorse action that is probably in breach of international agreements. But we should not be afraid to take a proactive, strategic approach to the negotiation of international agreements. And we should remember that, in all this, the real risk takers are the firms taking action which might ultimately be disciplined by resolution under an international agreement. For those firms will be making investments and establishing trade patterns which might ultimately be disrupted by a state taking action that may adversely affect them.

³⁵ Even here there is no certainty of action because sanctions cost the country imposing them often as much or more than the country on which they are imposed. As Guzman points out:

In contrast to domestic law, where contractual violations are sanctioned through zero-sum payments from the breaching party to the breached-against party, sanctions for violations of international agreements are not zero-sum. To the extent that sanctions exist, they almost always represent a net loss to the parties.

Andrew T. Guzman, *The Design of International Agreements*

<http://ejil.oxfordjournals.org/content/16/4/579.full>

Chapter 4 discusses the specific issues of manufacturing for export (MFE) and stockpiling of patented products. It finds that it would be in Australia's national interest, and other countries', to change their domestic law to allow these activities to occur. However, the words of both TRIPS and AUSFTA tend to presuppose that, at the time they were negotiated and agreed, domestic patent law provided optimal reward for invention without unduly restricting further innovation. As a result it seems likely that acting in Australia's and the global interest on MFE and stockpiling would be inconsistent with TRIPS and/or AUSFTA. Alternatively, if exceptions permitting MFE and stockpiling were legislated in Australia, they would need to be heavily constrained in scope and therefore in value in order to be brought into consistency with the international framework.

The impact of constraints placed on Australia by current agreements highlights the importance of Australia's Government representatives – at both the official and political level – having a broad strategic economic understanding of Australia's national interests regarding IP when negotiating agreements containing substantial IP content. This point was made in the Productivity Commission (PC) 2010 research report *Bilateral and Regional Trade Agreements*.³⁶ There the PC indicated that it was not convinced that the approach adopted by Australia in relation to IP in trade agreements has always been in the best interests of either Australia or (most of) its trading partners. The PC noted that there does not appear to have been any economic analysis of the specific provisions in AUSFTA prior to its finalisation, despite clear net costs to Australia and other countries on some issues. A PC staff paper³⁷ also subsequently identified substantial net costs to Australia in extending the patent term from 16 to 20 years under TRIPS.

The PC recommended that the Government avoid the inclusion of IP matters as matter of course in future bilateral and regional free trade agreements. IP provisions should only be included in cases where a rigorous economic analysis

³⁶ Productivity Commission, *Bilateral and Regional Trade Agreements*, November 2010, Part 14.1, Recommendation 4.

³⁷ Productivity Commission, *Bilateral and Regional Trade Agreements*, November 2010, p.263.

shows that the provisions would likely generate overall net benefits for the agreement partners. The Government agreed with this recommendation and noted that it is consistent with the approach in its Trade Policy Statement.³⁸ The Statement sets out the Government's trade policy objectives and mentions that economic modelling is typically the basis on which free trade negotiations are justified.³⁹

³⁸ *Gillard Government Trade Policy Statement, Attachment: Government responses to recommendations of the Productivity Commission report on bilateral and regional trade agreements*, April 2011.

³⁹ *Gillard Government Trade Policy Statement*, page 8.

Trans-Pacific Partnership Agreement

Several other free trade agreements are in force and a number are currently under negotiation, including the TPP between Australia and several other countries in the Asia-Pacific region, including the US. The Australian Government states that the conclusion of the TPP is its highest regional trade negotiating priority. It is intended that the TPP will be a living agreement that remains relevant to emerging issues.⁴⁰ Although TPP negotiations are confidential, documents leaked in 2011⁴¹ suggest that the US Government is generally aiming to increase the value of US patent rights by seeking agreement that other TPP countries adopt measures that increase IP rights. Some of the reported proposals directly relate to the issues considered in this review. These include:

- patent term extensions being available for methods of making or using a pharmaceutical product;
- the exportation of a patented pharmaceutical being only allowable for the purpose of obtaining marketing approval;
- providing a transparent system to identify the patents covering an approved pharmaceutical product or method of use, and the provision of notice to the patentee of the generic applicant's intentions to obtain marketing approval. The patentee may seek to delay the grant of marketing approval to enable disputes to be resolved, but in such cases a reward is provided to a successful challenger of the validity of the patent;
- providing data protection for three years for new clinical information relating to a previously approved product; and
- basing prices paid by other TPP Governments for pharmaceuticals, such as through the PBS, on competitive market-derived prices, rather than therapeutic value.

⁴⁰ Gillard Government Trade Policy Statement, page 11.

⁴¹ Trans-Pacific Partnership Intellectual Property Rights Chapter (Selected Provisions), September 2011 and Transparency Chapter-Annex on Transparency and Procedural Fairness for Healthcare Technologies, 22 June 2011.

3.2. Submissions

Concerns have been raised by the generic pharmaceutical sector⁴² and others⁴³ during the TPP negotiations that increasing IP protection for pharmaceutical innovations is not in the interests of Australia or Australia's neighbours in the region. It has been argued that the adoption of US laws by smaller economies reduces the flexibility for these governments to adopt laws appropriate to their own circumstances and impedes their ability to deliver affordable health care. At the time some argued that the adoption of various TRIPS-Plus measures in AUSFTA delay competition from generic manufacturers and increase costs for consumers, with little benefit in terms of added incentives for originators to invest in Australia.

Similar concerns are expressed in submissions to this review, with GMiA remarking on what it considers to be a trend to include pro-patentee provisions in international trade agreements, including the TPP. It argues that new overarching international IP obligations will wrongly upset the balance between patentee interests and public interests:

⁴² GMiA Briefing Paper – *Trans Pacific Partnership Agreement*, GMiA, September 2012, available at <http://gmia.com.au/wp-content/uploads/2013/01/GMiA-Briefing-TPPA.pdf>; Alphapharm submission to DFAT on TPPA, 14 March 2011.

⁴³ For example, Gleeson, D, *Analysis of the June 2011 leaked TPP Transparency Chapter Annex*, submission to DFAT, 7 September 2012; Faunce, T et al., *Potential Impact of the TPPA on Public Health and Medicine Policies*, submission to DFAT, undated; Maxmen, A, *Trade deal to curb generic-drug-use*, *Nature*, Vol. 489, No. 7414, 6 September 2012; Flynn, et al., *Public Interest Analysis of the US TPP Proposal for an IP Chapter*, 6 December 2011, <http://infojustice.org/tpp-analysis-december2011>; Medecins Sans Frontiers, *How the Trans-Pacific Partnership Agreement Threatens Access to Medicines*, September 2011, <http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf>; Oxfam, *Oxfam Analysis of US Proposals for IP and Pharmaceutical Pricing Provisions in Trans-Pacific Partnership Agreement Negotiations*, <http://www.citizen.org/documents/Oxfam-Paper-on-the-TPPA-Leaked-IP-Chapter.pdf>.

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

Australian generic medicine manufacturers will suffer if generic medicine penetration in FTA member countries is delayed by prolonged patent monopolies, protracted data protection regimes, patent term adjustments, removal of pre-grant opposition and onerous patent linkage regimes.⁴⁴

Similarly, Alphapharm argues that, by signing up to TRIPS and TRIPS-Plus treaties, Australia has limited its capacity to maximise the goal of best-priced access to pharmaceutical products, except where patents have expired.⁴⁵

In contrast, while submissions do not directly comment on the appropriateness of including IP provisions in trade agreements, they argue for strong IP protection of the level required under TRIPS and AUSFTA in order to adequately support innovation and investment in new pharmaceuticals. For example, in public hearings Pfizer submitted that originator pharmaceutical companies do not view markets as either important or unimportant based on population size, but rather as having overall strong or weak IP protection which either warrant or do not warrant investment in new products. Pfizer contends that weakening IP protection such as reducing the length of extensions of term would affect decisions on whether to conduct R&D and clinical trials in Australia.

3.3. Analysis

In the past Australia has taken a leading role in the shaping of international trade agreements, most notably with the Cairns Group of countries.⁴⁶ We initiated and played a leading role within this group to better reflect our interest and the global interest in lower trade barriers for agricultural products. We have also taken an active role in some aspects of international patent law, for instance regarding the

⁴⁴ GMiA, Submission to the Pharmaceutical Patents Review, p.12.

⁴⁵ Alphapharm, Submission to the Pharmaceutical Patents Review, p.3.

⁴⁶ www.cairnsgroup.org.

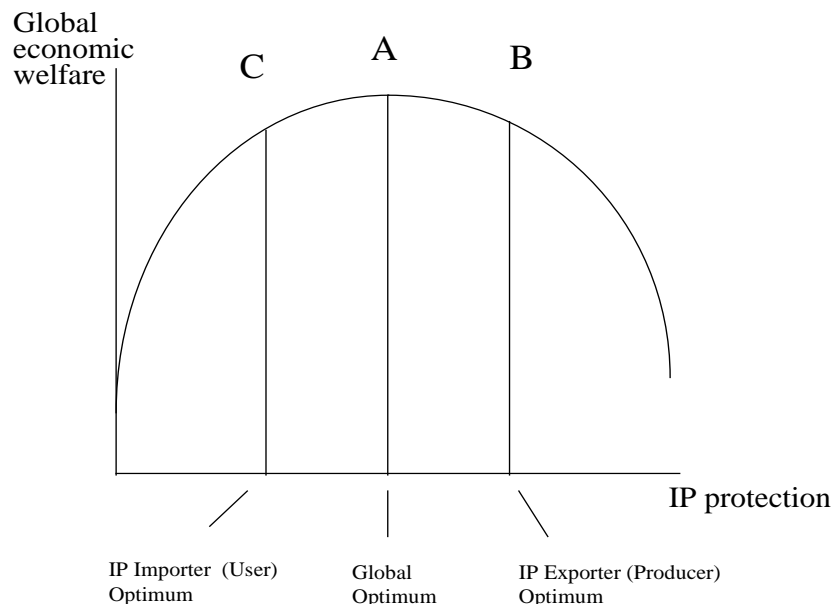
publication of patent information, the international consistency of the 'grace period' in which a patentee does not invalidate their patent by self-publishing their patented idea.

But no government agency offered evidence to the Panel suggesting that the Australian government has clear strategic goals for Australia in IP negotiations other than to minimise changes to its own IP system. To engage in such negotiations effectively, Australian Government agencies and politicians need a much deeper and strategic understanding of what aspects of the existing international IP system require improvement, particularly where the Australian and the global interest are in harmony. As the Panel outlines in this chapter, there are plenty of opportunities for improvement, though they require international co-ordination.

Countries' strategic interests differ not just when considering IP policy unilaterally, but also in a multilateral context. In this regard a critical consideration is not so much whether countries are large or small, but whether they are net importers or exporters of IP. In this regard there is a large imbalance, for the US is the world's greatest IP exporter. In pharmaceuticals, Europe is also a large net exporter of IP. IP net exporters have an interest in seeking minimum global standards of IP that are stronger than the global optimum. This is because their exporters gain more from extensions of IP than their buyers of imports lose from the same measures. Net IP importers have the converse interest in a level of IP protection somewhat lower than the global optimum. These ideas are represented in Figure 3.2.

Though Australia has an interest in somewhat lower levels of IP protection than IP exporters, we should not see our vigorous pursuit of those interests as somehow undermining the global interest in strong and clear IP rights. Australia has little long-term interest in encouraging some global 'free-for-all' that would undermine the incentive to invest in new knowledge. Ideally, defending our interests as an IP importer, and joining and coordinating with other countries with similar interests to do likewise would help balance the interests of IP exporters and so move the global regime nearer to the global optimum in IP standards.

Figure 3.2: Multilateral IP protection



Source: IC, 1996) Gruen, N., I. Bruce, and G. Prior, (1996), *Extending Patent Life: Is It in Australia's Economic Interests?*, Canberra: Industry Commission, Industry Commission Staff Information Paper (June)..

As a system stretching back many centuries, there are numerous aspects of IP regimes that remain poorly designed. Yet international IP agreements have tended to be made without regard to such matters. One consequence is that aspects of this poor design have been built into international agreements, for instance as presuppositions about the definition of the patent right itself. As a result, intellectual agreements lock us into a number of inefficiencies which have clear costs to Australia and yet which confer benefits on other countries that are either small or negligible.

3.3.1. The importance of parsimony in defining property rights

Other things being equal, the more precisely property rights are defined the better. Thus we go to great lengths to delineate the boundary between different suburban blocks in a city or farms in the country. But often there are a penumbra of rights existing around a particular property right.

Traditionally in many legal systems, real property rights to the surface of land extended below that land and above it as denoted in the Latin maxim: *Cuius est solum, eius est usque ad caelum et ad inferos* ("For whomever owns the soil, it is theirs up to Heaven and down to Hell.") Over time, this penumbra of rights became progressively unworkable. Mining rights were better handled as independent rights interacting with surface rights – rather than entirely determined by them. Similarly, the rise of aviation made the earlier doctrine unworkable as a framework for managing airspace rights. Yet it often takes a long time before a problem is properly recognised, let alone solved. In the US the above principle of Roman law remained influential until 1942, decades after aviation was born.

Something similar, though perhaps not as dramatic, is occurring in IP law. When patents were first codified in the Statute of Monopolies in English Law in 1624, the infrastructure of modern government was absent. In that world, the penumbra of rights around the monopoly of sale in a market assisted in enforcing that central right. Just as property in land at that time carried with it exclusive rights "up to heaven and down to hell", so a patent involved not just the right to sell a product into the domestic market, but the right to 'work', 'make' and 'import' such goods.

The rights to work, make and import may still be valuable in the context of certain patents, particularly those that protect processes. Today, however, unauthorised domestic sales of pharmaceuticals would be quickly detected and dealt with without the need to prohibit unauthorised manufacture and import of such goods. Further, if such prohibitions were still helpful in detecting breach or otherwise addressing public policy objectives, they could be provided with carve outs for MFE or for stockpiling in anticipation of patent expiry either domestically or offshore.⁴⁷ Further, global trade is vastly more extensive and complex and

⁴⁷ MFE is the term used to describe manufacture of generic pharmaceuticals for export while an Australian patent is in force. Stockpiling describes the process of manufacturing generic pharmaceuticals while an Australian patent is in force for the purpose of entering the domestic or a foreign market immediately on patent expiry.

thus the costs of too broad a specification of property rights are greatly increased over earlier, simpler times.

In addition to the obvious inefficiencies of requiring cascades of permissions even where they are not necessary to enable policy to deliver an important economic right, over-specified or poorly specified rights can contribute to unnecessary 'border disputes' and to strategic behaviour around the boundary. Thus the penumbra of rights can be used to make life a little more difficult for emerging competitors, and so they are.

To take the case of stockpiling, the net effect of precluding stockpiling for the Australian market during the patent period is to give domestic originators another month or two of exclusivity. If policy makers had really intended to do this, it would have been far more efficient to do so explicitly with an extension of the patent term for that period. This would keep the law out of making unnecessary and expensively litigated distinctions and qualifications, in this case the extent of production permitted before patent expiry. The case of MFE is even more unfortunate because it appears that patent holders regard it as important to preserve the holdup value of their exclusive right to manufacture even though it is of no positive benefit to them. In each case, such a refocusing of rights would have been relatively straightforward to negotiate as a *quid pro quo* for the extensions of IP rights sought and negotiated in recent years. Unfortunately such considerations have not been put forward with any force by the parties.

More tightly defined rights would also reduce perverse, unintended consequences such as those in which the prohibitions on stockpiling and MFE make firms in countries with weaker IP protection better placed to supply generic drugs to countries with strong IP protection than those countries' domestic manufacturers themselves.

The next chapter canvasses arguments that AUSFTA prevents Australia from changing its law to permit Australian companies manufacturing drugs which remain under patent in Australia to export pharmaceuticals to countries where the corresponding patents have expired. Preventing Australian firms from exporting to such markets offers negligible benefit to the patent holder in Australia or anywhere else, as the firm prohibited from MFE will still manufacture

but it will do so from another country. If this interpretation of AUSFTA is correct it is contrary to the trade-expanding goal of trade agreements generally, it imposes a substantial cost on Australia, and yet it has no discernable benefit to the other signatory to the agreement, the US.

In a sense the discovery of potential gains without costs is good news, for it identifies an agenda which should unite countries wishing to expand trade between them in mutually beneficial ways. But to do so we must take a more strategic view of our role in international negotiation on such matters. As mentioned earlier, Australia has taken important steps to stimulate trade in agricultural produce, such as establishing the Cairns Group of like-minded countries. Using the same approach, it can also pursue important advances in the international patent system. This chapter outlines a number of areas in which such progress might be made.

The Panel generally agrees with the approach agreed to by the Government of only including IP provisions in bilateral and regional trade agreements where economic analysis has demonstrated net benefits. The Panel accepts that it may not always be practical for the Government to conduct thorough economic analysis of individual proposals as they are being negotiated and amended. However, the Government should have a broad strategic understanding of what is in Australia's economic interests as a basis for negotiations.

The Government's stated approach has not always been followed, as illustrated by Australia's negotiating position with regard to the Anti-Counterfeiting Trade Agreement (ACTA), which focuses on copyright and trademarks, rather than patents. In recommending that ACTA not be ratified by Australia, the Joint Standing Committee on Treaties (JSCOT) found that the National Interest Assessment (NIA) conducted for the agreement was inadequate in providing an economic assessment of its costs and benefits for Australia. It recommended that one be undertaken. It also recommended that NIAs of treaties clearly intended to

have an economic impact have such an assessment done, or a statement explaining why one was not necessary or possible.⁴⁸

Of even more concern is that there is no evidence that current negotiations for the TPP Agreement are being based on a broad economic understanding of what approach to IP is in Australia's and other countries' interests. With its outstanding record of transparency and public independent economic analysis through such institutions as the Productivity Commission, Australia is well placed to take a leadership role in negotiations such as TPP and should make the most of such opportunities as they arise.

⁴⁸ Joint Standing Committee on Treaties, *Report 126*, June 2012, page 12 and recommendations 1-2, 8.

Draft Findings 3.1:

In their negotiation of international agreements, Australian Governments have lacked strategic intent, been too passive in their IP negotiations, and given insufficient attention to domestic IP interests.

For example, preventing MFE appears to have deprived the Australian economy of billions of dollars of export revenue from Australian based generic manufactures. Yet allowing this to occur would have generated negligible costs for Australian patentees. The Government does not appear to have a positive agenda regarding the IP chapters of the TPP Agreement which comprehends national and regional economic interests.

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

Increasingly global markets mean that policies and laws need to be implemented in multiple jurisdictions to be effective and to avoid adverse consequences for individual countries. For example, Australia could publish data that has been provided in support of regulatory approval once the data protection period has expired in order to facilitate transparency and further research (see Chapter 9). If it were the only country to do so, this could result in originator pharmaceutical companies not bringing some new products to the Australian market in order to avoid their clinical trial information being disclosed. However, if a number of jurisdictions were to adopt this approach, there would be no such adverse consequences for Australia.

There is a wide range of fronts on which international IP law and practice could be improved. These changes would be in the interest of most if not all countries and also in the global interest, though there would likely be some commercial interests which would oppose changes to the *status quo*. The Australian Government should take a leadership role in seeking consensus with other jurisdictions to identify such improvements. Examples might include:

- economically examining the breadth of exclusive rights provided by a patent, and the length of protection, to see whether they continue to be

appropriate or whether they should be rationalised, reduced or expanded;⁴⁹

- ensuring that the disclosure requirements for patent specifications are sufficient, particularly in fields like biologics (see Chapter 9);
- enabling manufacturing for export during the patent term and extension period (see Chapter 4);
- enabling stockpiling of patented pharmaceuticals for sale after the expiry of the patent (see Chapter 4);
- enabling data provided in support of regulatory approval to be published upon the expiry of the data protection period (noting the European proposal and that this currently appears to be allowable under AUSFTA Article 14.10.1(e)). This is discussed in Chapter 9;
- seeking international agreement not to extend IP rights retrospectively;
- seeking international agreement to building independent economic analysis into the negotiating process with an agreement between countries that they would not pursue IP changes where such analysis indicated that this was clearly contrary to global economic interests;
- seeking international agreement to funding pharmaceutical innovation in areas with large public benefits, particularly, but not exclusively in developing countries but where patent protection is relatively ineffective in generating such innovation. The Panel proposes that Australia make its contribution in this area and fund it from reductions in the term of patent extensions.

Australia has pioneered the provision of domestic economic transparency delivered by bodies such as the Productivity Commission and its predecessors. It should offer to provide independent analysis and advice to other countries in the region on IP matters to assist them in negotiating international agreements. It

⁴⁹ The rights provided by a patent have changed little for hundreds of years, despite economies and markets changing dramatically in that time. Over the same period the maximum term of a patent has increased significantly with little regard for whether this is appropriate for all modern technologies.

should also champion the cause of transparent deliberative processes involving appropriate expertise into the negotiation of international economic agreements.

Draft Recommendation 3.1:

The Government should expeditiously seek a situation where Australia has strong yet parsimonious IP rights – that is, rights that are strongly enforced and that provide the incentive necessary to underpin an appropriate level of investment in innovation but that are not defined so broadly as to impose costs on innovation or other activity without commensurate benefits.

For instance such strong yet parsimonious IP rights could provide a desired level of incentive to invest in pharmaceutical innovation without preventing our industry from servicing offshore generic markets, as current law does. Australia should take a leadership role in seeking consensus with jurisdictions with similar interests to identify and pursue a range of changes in international patent law and practice along these lines.

Draft Recommendation 3.2:

The Government should ensure that future trade negotiations and renegotiations are based on a sound and strategic economic understanding of the costs and benefits to Australia and the world and of the impacts of current and proposed IP provisions, both for Australia and other parties to the negotiations. The Government should strongly resist changes – such as retrospective extensions of patent rights – which are likely to reduce world economic welfare and lead other countries in opposing such measures.

4. Manufacturing for export and stockpiling

4.1. Current law

As discussed in Chapter 3, TRIPS and AUSFTA are the international agreements to which Australia is a signatory that are of most relevance to this review. The TRIPS Agreement requires patentees to be given specific exclusive rights, including the right to prevent others from making the patented product or using the patented process.⁵⁰ The TRIPS Agreement and the AUSFTA allow exceptions to these rights; provided that they do not unreasonably conflict with a normal exploitation of the patent and that they do not unreasonably prejudice the legitimate interests of the patentee, taking account of the legitimate interests of third parties.⁵¹ TRIPS also requires technology neutrality – generally prohibiting the exclusion of specific technologies from rights provided by the patent system. However, it does allow optional exclusions for medical methods of treatment, for plants and animals, and for inventions the commercial exploitation of which would be contrary to *ordre public* or morality. The latter allows, amongst other things, exclusions from patenting for the protection of human life or health.⁵²

Australian law is compliant with the TRIPS Agreement and so it gives a patentee exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit it. ‘Exploit’, for a product invention, includes making, hiring, selling or otherwise disposing of the product, using it or importing it. For a process invention, exploit includes using the process to do any of these acts.⁵³

⁵⁰ Article 28(1) of the TRIPS Agreement reflects domestic Australian law, requiring that patent laws of member states should include certain rights. The rights are, for product inventions, the right to prevent others from making, using, offering for sale or selling the product, or importing it for these purposes. For process inventions, the right to prevent others from using the process and using, offering for sale or selling the product obtained directly from the process, or importing it for these purposes.

⁵¹ TRIPS Agreement Article 30 and AUSFTA Article 17.9.3.

⁵² TRIPS Agreement, Article 27.

⁵³ *Patents Act 1990*, s.13(1) and Schedule 1 Dictionary.

There are some exceptions to these rights which are permitted under TRIPS and AUSFTA because they do not unreasonably conflict with the normal exploitation of the patent. Thus AUSFTA provides an exception enabling a Party who is not the patent holder to seek marketing approval for the relevant pharmaceutical products. It also provides that, if Australia permits exportation, the product shall only be exported for the purposes of meeting marketing approval requirements of Australia.⁵⁴ A Side Letter between the parties to AUSFTA elaborates on this requirement stating that, where an extension of term has been granted, the use and export of the patented product to obtain marketing approval in Australia *or in another country* is not an infringement.⁵⁵ No other exceptions are specified.

Accordingly, Australian law provides that a person who exploits an invention solely for the purpose of obtaining inclusion in the ARTG or similar approval in a foreign country will not infringe a pharmaceutical patent.

Manufacture for export and stockpiling

On a literal interpretation of Australian law, manufacturing a patented product or using a patented process solely for export to another country where the corresponding patent does not exist or has come to the end of its term (MFE) is most likely not allowed without the authorisation of the patentee. MFE would involve one or more of the exclusive rights of the patentee - making, hiring, selling or otherwise disposing of the patented product, using it or importing it. The exception from infringement for regulatory approval of a pharmaceutical does allow manufacturing of a patented product for export to another country, but only in very limited circumstances that would not apply to MFE generally. In recent years a number of manufacturers of generic pharmaceuticals have asked Australia's Government to change the law to enable some types of manufacturing

⁵⁴ AUSFTA Article 19.9.6.

⁵⁵ Side Letter from the Australian Minister for Trade to the US Trade Representative about the application of IP rights in Chapter 17 of AUSFTA, 18 May 2004.

for export.⁵⁶ It seems likely that similar entreaties would have been made to other governments as the prohibition of MFE is widespread if not universal, and widely seen to be required by TRIPS.

A literal interpretation of Australian law also suggests that stockpiling a patented product during the term of the patent without the patentee's permission, for sale upon expiry of the patent, currently also constitutes patent infringement.⁵⁷ This is because the exclusive rights of a patentee include making a patented product or keeping it for the purpose of hiring, selling or otherwise disposing of it. It is worth noting that 'keeping' is not one of the exclusive rights mandated under TRIPS. So in this respect Australian law appears to provide a higher standard of IP rights than that required by TRIPS.

It could be argued that the intended purpose of TRIPS, AUSFTA and Australian law was to provide patentees with the exclusive rights to commercialise their inventions domestically and during the term of the patent, not to prevent export to other countries or preparation for patent expiry. There is little evidence that those drafting or negotiating TRIPS deliberated on the prospect that, by including within patent rights the exclusive right to manufacture, rather than focusing it more tightly on the essentially valuable right which is the right to sell in the domestic market, they were preventing MFE. However, the guidance available on the interpretation of TRIPS (discussed in detail below) is that because the right to 'make' has been legally interpreted as fundamental (even though the overwhelmingly important substantive right is the right to sell into the domestic market) MFE without the patentee's permission breaches the patent right.

⁵⁶ For example, Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program: Research Report*, 2003, Part 8.3; Submission by Hospira, GMiA, Mylan, Ausbiotech and others to the Joint Trade Sub-Committee *Inquiry into Trade and Investment Relations with Asia, the Pacific and Latin America*, 15 February 2009.

⁵⁷ *Patents Act 1990*, s.13(1) and Schedule 1 Dictionary.

4.2. Submissions

A number of submissions argue that the pharmaceutical extension of term system has created a major barrier to export. The Australian patent extension provisions prohibit Australian-based manufacturers from exporting without the permission of the patent holder to countries where relevant patents have expired or never existed. Submissions argue that this prohibition disadvantages Australian generic manufacturers relative to generic manufacturers in other countries which are not subject to equivalent prohibitions. If an Australian-based company wishes to manufacture drugs for a foreign market where the relevant patent has expired, it must under current government policies establish the relevant manufacturing facility outside Australia.

In her submission Dr Moir argues that not allowing MFE is a well-known inefficiency in the current system that probably does not even benefit the patentee as the overseas market will be supplied by companies which are not impeded in this way.⁵⁸

GMiA claims that the consequences of not allowing MFE are very significant. Global launches of medicines will be delayed for Australian generic manufacturers, depriving them of the early mover advantage and making it difficult for them to compete.⁵⁹ GMiA also argues that allowing MFE would have no impact on the commercial interests of Australian patentees because the generics are currently being manufactured in countries where the patent has expired, such as India, Israel, Canada, South Africa and China. In public hearings GMiA and Alphapharm claimed that, while Australian generics are finding it increasingly difficult to compete on price, they can compete on quality, reliability and indivisibilities, in that they can achieve economies of scale for specific health needs.

In their submission GMiA argues that MFE can be introduced in a way that is consistent with the TRIPS Agreement and AUSFTA. Israel is cited as an example of a country that has designed its patent extension system to remove barriers to

⁵⁸ Hazel Moir, Submission to the Pharmaceutical Patents Review, p.14.

⁵⁹ GMiA, Submission to the Pharmaceutical Patents Review, p.19-21.

trade. In public hearings, GMiA also advocated that it should not be an infringement to stockpile products during the patent term for export or sale upon expiry of the patent. This would enable the local generics industry to enter Australian and foreign markets immediately upon patent expiry and thus allow competition on an even playing field with foreign generic industries.

Conversely, Medicines Australia, Abbvie and Interpat argue that the intent of the extension of term provisions was not to limit the rights of patentees during the extension period. They consider that introducing an exception for MFE would contravene Australia's international obligations to provide rights to patentees and a 20 year patent term under Articles 28 and 33 of TRIPS, and to compensate patentees for curtailment of the effective patent term under Article 17.9.8(b) of the AUSFTA.⁶⁰

In public hearings Medicines Australia, a number of originator companies, IPTA and FICPI argued that allowing MFE could result in less R&D being conducted in Australia. Pfizer and Merck, Sharp and Dohme (MSD) also argued that MFE would also adversely affect patentees by assisting generic providers to develop their Australian manufacturing base prior to patent expiry. Presumably this would provide Australian generic providers with a wider range of expertise and economies of scale, making them more competitive in the domestic market.

In public hearings MSD also noted that allowing MFE would run the risk of stockpiling and so supply to the domestic market immediately upon expiration of the patent, contrary to current law or AUSFTA. It could be difficult to determine whether the manufacture and storage of a product was for export or to prepare for domestic sale.

4.3. Analysis

4.3.1. *TRIPS and Canada's stockpiling case*

In 2000 there was a WTO dispute between European countries and Canada regarding Canada's exceptions for the regulatory approval and stockpiling of pharmaceutical patents. The decision in this case provides some guidance on the

⁶⁰ Medicines Australia, Submission to the Pharmaceutical Patents Review, p.10.

way in which the exceptions to patent infringement provided under the TRIPS Agreement may be interpreted.

At the time, Canadian patent law provided that it was not an infringement of a patent to make, construct, use or sell the patented invention solely for obtaining regulatory approval for any product in Canada or another country.⁶¹ Where a person was doing any of these things to obtain regulatory approval, it was also not an infringement to make, construct or use the invention, during the six months prior to the expiry of the patent, for the manufacture and storage of articles intended for sale after the expiry of the patent.⁶² The European Communities alleged that Canada's legislation was not TRIPS compliant because it did not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection.

The dispute was heard by a panel established by the WTO Dispute Settlement Body.⁶³ The WTO dispute resolution panel found⁶⁴ that the regulatory review exception was compliant with TRIPS because it was a 'limited' exception and therefore allowed under Article 30. However, the WTO dispute resolution panel found that the stockpiling exception constituted a substantial curtailment of the exclusive rights provided to the patentee to such an extent that it could not be considered to be a limited exception within the meaning of Article 30. The panel

⁶¹ *Patent Act*, Section 55.2(1).

⁶² *Patent Act*, Section 55.2(2), *Manufacturing and Storage of Patented Medicines Regulations*.

⁶³ WTO dispute panels work like tribunals and usually consist of three independent experts from different countries, chosen in consultation with the countries in dispute. The panel's report is passed to the Dispute Settlement Body which can reject it by consensus, otherwise it becomes a ruling. Rulings can be appealed based on points of law but not on new issues or the re-examination of existing evidence.

⁶⁴ Canada – Patent Protection of Pharmaceutical Products, Complaint by the European Communities and their Member State, WT/DS114/R, 17 March 2000.

could not accept Canada's argument that the curtailment of the patentee's legal rights is 'limited' as long as the exception preserves the exclusive right to sell to the ultimate consumer during the patent term. Implicit in the Canadian argument is a notion that the right to exclude sales to consumers during the patent term is the essential right conveyed by a patent, and that the rights to exclude 'making' and 'using' the patented product during the term of the patent are in some way secondary.⁶⁵

If one investigates the question as to which exclusive rights associated with a patent are substantively important to patentees, it is quite clear that the right to sell into the domestic market is the essential right. If one were to auction off the various rights enjoyed by the patentee, the right to sell would constitute the overwhelming source of the patent's commercial value. The WTO panel sought an answer to this question not with regard to the substantive value of the various rights, but rather from the words in the TRIPS Agreement. It said:

The Panel does not find any support for creating such a hierarchy of patent rights within the TRIPS Agreement. If the right to exclude sales were all that really mattered, there would be no reason to add other rights to exclude 'making' and 'using'. The fact that such rights were included in the TRIPS Agreement, as they are in most national patent laws, is strong evidence that they are considered a meaningful and independent part of the patent owner's rights.

Lawyers would differ in their assessment of the merits of this reasoning. Some would endorse it as a sound 'literal' interpretation of the agreement's words. Others would argue that such interpretation should take their context within an understanding of the substance of the commercial and policy issues. However whether the 'right' decision might have been reached from an interpretation of the words in TRIPS, the Pharmaceutical Patents Review Panel is in a different position from the WTO panel. Where the WTO panel interpreting the words of a specific agreement, this Panel is considering the merits of our laws and Australia's role in influencing the content of the international agreements to which we and

⁶⁵ WT/DS114/R, para 7.33.

other countries bind ourselves. In this context this report supports strong IP rights which are nevertheless parsimoniously delineated around their policy objectives, which in the case of pharmaceutical products is to deliver a commercial monopoly on domestic sale as discussed in the previous chapter.

In 2001, in response to the WTO Panel's opinion Canada repealed its stockpiling exception. According to the Canadian case, a stockpiling exception would have to be strictly limited in quantity and duration to be consistent with TRIPS. The reasoning in the Canadian case also suggests that a broad MFE exception applying during the original patent term would not be permissible under TRIPS, but a more limited exception for MFE may be acceptable. One could argue that an exception that was limited to the extension of term period and only for export to countries where the patent would not be infringed would be acceptable under TRIPS. Such an exception may be consistent with the criteria set out in Article 30 as follows. The exception:

- must be "limited". The dispute panel found that "limited" meant "only a small diminution of the rights in question"⁶⁶ and restricting the exception to the extension period in a manner that does not commercially affect the patentee may satisfy this. However, in light of the stockpiling decision it is possible that a limit on quantity would be required;
- must not "unreasonably conflict with a normal exploitation of the patent". The dispute panel found that the normal exploitation of the patent "is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity".⁶⁷ An exception limited to the extension of term period and only for export to countries where the patent would not be infringed may satisfy this, as there would be no commercial effect on the patentee, either in domestic or foreign markets. The exception would simply enable the manufacturing of generics that is currently taking place in other countries to take place in Australia; and

⁶⁶ WT/DS114/R, para 7.30-7.34.

⁶⁷ WT/DS114/R, para 7.55.

- must not “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”. The dispute panel found legitimate interests to be broader than simply legal interests and to include policy considerations, such as enabling experimentation to occur under an experimental use exception.⁶⁸ An MFE exception may meet this criterion because the patentee does not have a legitimate interest in hampering the Australian generics export industry from Australia with no benefit to itself.

4.3.2. AUSFTA

Little guidance is available on the intent and interpretation of AUSFTA regarding MFE and stockpiling. One can argue that MFE would not be consistent with AUSFTA. The Side Letter explaining that MFE for regulatory purposes is permitted does not mention other forms of MFE during the extension period. Though some differ, many argue that this means that, MFE more generally is unlikely to be consistent with AUSFTA. Similarly, a general exception for stockpiling is unlikely to be consistent with AUSFTA as it contains the same limits on exceptions as TRIPS which are likely to be interpreted in the same way. A limited exception for the stockpiling of products made for the purpose of obtaining marketing approval may be consistent with AUSFTA; however its value to generic manufacturers would also be limited.

Given the current difficulties under AUSFTA and the clear benefits of both MFE and stockpiling and the limited costs in the case of stockpiling and the negligible costs in the case of MFE, the Panel considers that Australia should vigorously pursue the cause of both exceptions in bilateral, plurilateral and multilateral international forums, as recommended in Chapter 3.

⁶⁸ WT/DS114/R, para 7.61, 7.68, 7.69, 7.77, 7.82.

4.3.3. Other jurisdictions

The Panel is not aware of any jurisdiction that allows MFE during the standard 20 year patent term.⁶⁹ The situation in Israel is discussed below. The US does not allow MFE for normal commercial purposes and explicitly prohibits the export of the components of a patented invention in such a way as to encourage their assembly outside of the US.⁷⁰ The Panel is not aware of any jurisdiction that is a WTO member and allows general stockpiling, as opposed to limited stockpiling in order to seek regulatory approval.

Israel and extensions of patent term

Israel has strong pharmaceutical and biotech industries, with domestic revenues of \$US1.9 billion and exports of around \$US6 billion in 2012.⁷¹ The industry comprises over 1,000 life sciences companies (biopharma and medical devices). Over 150 of these are biotechs, with this increasing by 17% per annum, and 80 are pharmaceutical companies. In total, around 80 new companies are formed every year.⁷² The number of clinical trials is currently at around 2,500 per annum.⁷³ Israel's originator sector is growing, with multinationals increasingly looking to acquire innovative local start-ups.

Israel's Teva Pharmaceutical Industries Ltd is one of the 10 largest pharmaceutical companies in the world with over \$20 billion in annual sales. It produces active pharmaceutical ingredients (APIs), new formulations and over-

⁶⁹ A number of countries allow limited MFE in accordance with Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This enables pharmaceutical products to be exported under compulsory licence to developing and least-developed countries experiencing a public health problem. The Australian Government will introduce a Bill this year to implement this system.

⁷⁰ 35 U.S.C. 271(f)(1).

⁷¹ Business Monitor International, *Israel Pharmaceuticals and Healthcare Report Q3 2012*, Israel Export & International Cooperation Institute, *Developments and Trends in Israeli Exports, January – September 2012*.

⁷² State of Israel, Ministry of Industry Trade and Labor, *Life Sciences in Israel*, 2011.

⁷³ Clinical Trials Department, Ministry of Health.

the-counter products in 75 production facilities around the world.⁷⁴ Teva is also the world's largest generics provider, with 4.2 million prescriptions for its generics filled daily in Europe and the US.

Israeli patent law allows exportation for the purpose of obtaining marketing approval, and in the past some have claimed that this exception has been used by generic manufacturers for general manufacturing for export.⁷⁵ Israel's extension of term system seems to allow generic manufacturers to export as soon as a corresponding foreign patent expires. Essentially, the extension period for an Israeli patent expires no later than the first expiry date of an extension for the equivalent patent in any one of 21 reference countries.⁷⁶

Israel's system is consistent with international agreements. Notably, the Israel Free Trade Agreement with the US does not contain any requirements similar to Article 17.9.8(b) of the AUSFTA about adjustments to the patent term to compensate patentees. The Israel FTA entered into force in 1985 and has only a very brief provision on intellectual property.⁷⁷ Nonetheless, Israel's extension of term system has drawn criticism from the US for a number of years. The Office of

⁷⁴ www.tevapharm.com.

⁷⁵ A. Christie et al., *Review of Pharmaceutical Patent Extension and Springboarding Provisions in Various Jurisdictions*, 6 November 2002, 4.6.1.

⁷⁶ *Israeli Patents Law, 5727 – 1967*, s.64A – 64Q. The calculation of the extension is complex. The 21 reference countries are Australia, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Holland, Iceland, Ireland, Italy, Japan, Luxembourg, Norway, Portugal, Spain, Sweden, Switzerland, UK and US.

⁷⁷ *Israel Free Trade Agreement*, Article 14 merely states "The Parties reaffirm their obligations under bilateral and multilateral agreements relating to intellectual property rights, including industrial property rights, in effect between the Parties. Accordingly, nationals and companies of each Party shall continue to be accorded national and most favored nation treatment with respect to obtaining, maintaining and enforcing patents of invention, with respect to obtaining and enforcing copyrights, and with respect to rights in trademarks, service marks, trade names, trade labels, and industrial property of all kinds". The Agreement has not been renegotiated.

the United States Trade Representative has Israel on its Special 301 Priority Watch List, along with countries such as China, India and Russia, due to several longstanding issues with its regime for pharmaceutical patents. To resolve this, Israel has committed to “strengthen” its laws on a number of matters, including patent term extensions.⁷⁸

4.4. Policy

The Productivity Commission (PC) considered MFE in 2003.⁷⁹ In its submissions, the Department of Industry, Tourism and Resources (DITR) estimated that up to 70% of pharmaceutical patents expire later in Australia than in other countries. DITR also estimated that, without MFE, export revenue of \$2.2 billion would be lost from 2001–2009. The PC considered that MFE would have little impact on the rights of patentees and concluded that there was a compelling economic case to allow MFE during the patent extension period. The PC also observed that it appeared this would be consistent with the TRIPS Agreement.

Originators claim that the extent of IP protection provided in a country is one of the factors considered when deciding where to conduct R&D. However, the Panel considers that constraining MFE in Australia is of negligible value to the owner of an Australian patent, whether this be an international pharmaceutical company or not. This is because it is not possible to stop the manufacture of generics in countries where the patent has expired.

As discussed in Chapter 3, the Panel considers that IP rights need to be targeted and parsimonious. Precluding MFE is not consistent with this. The biggest benefit which the parties to the AUSFTA can hope to derive from having a no-export clause is to curb the growth of a generic export industry in the other party. This outcome, of course, is the opposite of what countries should be seeking from trade agreements: to increase world and national incomes by freeing industry development from artificial, income-reducing constraints. It also undermines the

⁷⁸ Office of the United States Trade Representative, *2012 Special 301 Report*, pages 6, 36.

⁷⁹ Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program: Research Report*, pp 8.10.

outcome that champions of strong IP claim— namely that strong IP underpins local investment. In the situation where MFE is not allowed the opposite is the case, because local generic manufacturers are put at a disadvantage vis-à-vis generic manufacturers in other jurisdictions. Moreover any benefit to either party to the AUSFTA of reducing investment in the generic pharmaceutical industry in the other is negligible, because, the former party is unlikely to gain the investment. In all the situations of which the Panel is aware, the investment has gone to countries with lower levels of IP protection and/or no patent extensions such as India, Canada, New Zealand and Israel.

In Chapter 3 the Panel recommended that the Government take an active leadership role in pursuing changes to IP laws internationally that are in its national interest. This is likely to take some time to achieve. For MFE, an interim approach is to introduce an exception that is likely to be consistent with international agreements, as discussed above. The Panel considers that such an exception would be too limited to be of significant value.

A preferred option is that the Government actively seek the agreement of the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of MFE. This would enable MFE to occur without changes to international treaties or domestic law being necessary. This may be feasible due to the advantages this would provide to generic manufacturers and minimal disadvantages to patentees. Patentees may be encouraged to agree through a sense of corporate social responsibility and in order to avoid contributing to a situation in which countries which have, at the urging of pharmaceutical companies, agreed to extend patent protection only to see investment for export being lost to countries providing shorter periods and/or less expansive patent protection. This is not in their interests, and most assuredly not in the interests of those countries which have responded to their entreaties.

Draft Recommendation 4.1:

As an interim measure, the Government should actively seek the agreement of the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of manufacturing for export.

MFE has been raised as an issue in Australia several times since the commencement of TRIPS in 1995. As discussed above, in 2003 the PC considered MFE in response to concerns raised by the generic pharmaceutical sector and recommended that the matter be addressed. Around the same time, negotiations were underway between Australia and the US on the AUSFTA, resulting in its commencement in 2005. Export for regulatory approval was an issue, resulting in the provisions outlined above. However, there is no clear evidence that MFE was actively considered during negotiations for AUSFTA, or for implementation domestically.

In the mid 2000s and then again in the late 2000s, generic manufacturers lobbied the Government to enable it to export patented pharmaceuticals to generic markets. Hospira provided to the Government detailed analysis of market share foregone in other countries. The Government response was simply that MFE was not possible under its international obligations. Yet throughout this period there is no evidence of Australian officials raising the issue in international forums or in their discussions with the US under AUSFTA. It does not appear that officials are giving the matter a high priority in their negotiations around the provisions of the TPP.

Draft Finding 4.1:

Governments appear to have shown little strategic interest in the issue of MFE, despite a number of opportunities to do so and the significant potential advantages MFE could provide for Australia. If MFE had been rendered unambiguously consistent with our international obligations, it is likely that Australia's annual pharmaceutical exports would have been several hundreds of millions of dollars higher than they are.

The Panel considers that not allowing stockpiling is also inconsistent with a parsimonious approach to IP rights. It is perverse that generic manufacturers in other countries can stockpile in their own markets and so be ready to enter the Australian market as soon as the patent expires, whereas Australian manufacturers cannot. The laws against MFE and stockpiling are both examples of over specification of IP rights which generates substantial costs with small to negligible benefits to originators. They are not consistent with Australia's economic interest and nor with the world's.

As in the case of MFE, the options available to the Government regarding stockpiling include the introduction of an exception that is consistent with international agreements. However, it is not clear that an exception of any value would be consistent with AUSFTA. Again, this demonstrates the need for the Government to negotiate international agreements to ensure Australia's interests are taken into account.

5. Extension of term – length of extension

5.1. History of pharmaceutical patent extension of term provisions

Apart from the current extension of term provisions for pharmaceutical patents that was introduced in 1998, a number of other provisions have existed for extensions in certain circumstances. For example, the *Patents Act 1903* and *Patents Act 1952* allowed for an extension to patent terms on the grounds of inadequate remuneration from the patent or lost opportunity to exploit the patent due to war.

In its 1984 report on the Australian patent system, the Industrial Property Advisory Committee (IPAC) recommended the removal of extensions of term for standard (16 year) patents. In support of this recommendation the Committee stated:

In the view of the majority, in the absence of contrary empirical evidence, it strains credulity to contemplate that research or innovation investment decisions, made early in the life of the invention, could ever be materially influenced by the prospective availability of an extension after expiration of the initial 16 year term to compensate for inadequate remuneration, particularly when allowance is made for discounting. On the other hand, such extensions would increase social costs.⁸⁰

The Government accepted the recommendation and repealed the general extension of term provisions through the *Patents Amendment Act 1989*. At the same time, the Government introduced patent term extensions specifically for pharmaceuticals. The Minister for Science, Customs and Small Business at that time, the Hon Barry Jones, said:

⁸⁰ Industrial Property Advisory Committee. 1984. Patents, Innovation and Competition in Australia. [Available Online: <http://www.acip.gov.au/library/Patents.%20Innovation%20and%20Competition%20in%20Australia.pdf>]

The Government wanted to proceed with the patent term issue because of its importance as an element of its policy package to encourage the development of the pharmaceutical products industry in Australia.⁸¹

These extension of term provisions were incorporated in the *Patents Act 1990* and later repealed by the *Patents (World Intellectual Property Organization) Act 1994* when the standard patent term was increased from 16 years to 20 years. At that time however, the Government reaffirmed it was 'committed to providing an effective 15-year term for those [pharmaceutical] patents and is working closely with industry to that end.'⁸²

The current scheme was introduced through the *Intellectual Property Laws Amendment Act 1998* in recognition that a pharmaceutical patentee is unable to commercially exploit a patent until regulatory approval from the Therapeutic Goods Administration (TGA) 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".⁸³

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.⁸⁴ Australia is obliged to retain a system of extensions for pharmaceutical patents under the AUSFTA.⁸⁵ However, the Agreement does not specify a particular length for the extensions.

⁸¹ *Patent Amendment Act 1989*, House of Representatives Second Reading Speech, 2 May 1989.

⁸² *Patents (World Trade Organization Amendments) Bill 1994*, House of Representatives Second Reading Speech, 18 October 1994.

⁸³ Revised Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill 1998*, page 3.

⁸⁴ *Intellectual Property Laws Amendment Bill 1997*, House of Representatives Second Reading Speech, 26 November 1997.

⁸⁵ See Appendix C for more details.

5.2. How the scheme works

The provisions for extensions of term are set out in chapter 6, part 3 of the *Patents Act 1990*. They provide for extensions of term of a standard patent 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.

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 for up to five years, taking the duration of the term up to 25 years. The length of an extension of term is calculated to be the period from the date of filing the patent until the date of marketing approval by the TGA, minus five years. This allows for a maximum patent life of 25 years and a maximum effective market life, or period from marketing approval to patent expiry, of 15 years.

5.3. The stated policy objective

The explanatory memorandum of the bill introducing the current extension of term provisions stated that:

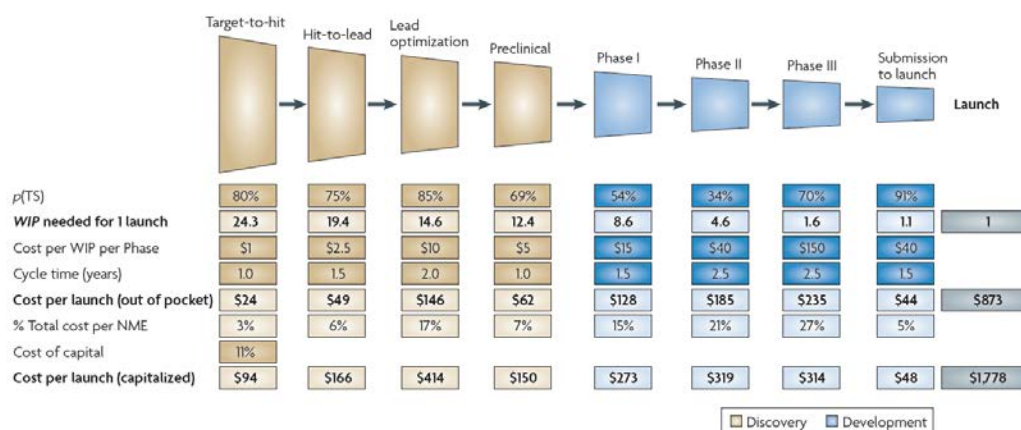
The objective of this proposal is to provide an 'effective patent life' – or period after marketing approval is obtained, during which companies are earning a return on their investment – more in line with that available to inventions in other fields of technology. It is also intended to provide a patent system that is competitive with other developed nations.

Other statements in the explanatory memorandum explain that 'competitive' is meant in the sense of attracting investment in pharmaceutical R&D to Australia.

Providing a new pharmaceutical product to the Australian market involves considerable costs. Therefore, pharmaceutical companies require an appropriate return on the outlays associated with gaining regulatory approval and supplying the Australian market. The extension of term scheme has been referred to as compensating pharmaceutical companies for the cost and time taken to meet regulatory requirements including clinical trials.

Figure 5.1 from Paul et. al. provides an analysis demonstrating the stages and cost of developing a new pharmaceutical product including an indicative breakdown of the costs at each stage of the process.

Figure 5.1: Pharmaceutical R&D Cost Analysis by Paul et al (2010)⁸⁶



While the extension of term scheme compensates companies for the time taken to obtain TGA approval, the regulatory requirements to formalise to some extent what these companies would consider ethically and legally prudent in any case. Under existing consumer laws, pharmaceutical companies would not expose themselves to risks associated with providing an unsafe or ineffective medicine to the market. Therefore, while no one should doubt the importance and necessity of a robust regulatory system, it would be inaccurate to consider the activities

⁸⁶ Paul, S.M. et al. 2010. How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge. *Nature Review Drug Discovery* 9(3) 203, 206.

required to meet the regulatory requirements of the TGA as a delay which would otherwise not occur. It is reasonable to say, however, that the need to ensure safety and efficacy delays the marketing of a new drug and thus reduces the value of a patent and that government regulation of safety and efficacy may add additional costs and delay.

Furthermore, extending patent terms in Australia is an imperfect policy tool for encouraging pharmaceutical innovation because of its limited capacity to provide an increased incentive to innovate as described below.

As discussed in the 1984 IPAC Report, one shortcoming of such a scheme is that the projected value of an extension at the time of making an investment decision, the net present value (NPV), is relatively small. The additional returns provided by the patent extension have to be discounted for the cost of capital over time and the inherent risk associated with bringing a new pharmaceutical product to market.

5.3.1. Value of extensions versus R&D subsidies

In table 5.1 below we examine the economics of assisting pharmaceutical R&D with two different mechanisms. The first is a patent extension and the second is a government subsidy. Consider two policy means of encouraging investment in Australian pharmaceutical innovation. There are a wide range of possible investments that investors can make, and only some of them will pay off. Two policy mechanisms are considered for trying to get investors to expand their investment in more marginal projects. The first is expanding patents from 20 to 25 years. The second is to subsidise pharmaceutical R&D.

We then compare the NPV of future projects with and without a patent extension to determine the incremental improvement in the economics of the R&D project brought about by the patent extension. We assume no inflation such that a dollar at the end of the 25 years is worth the same as a dollar at the beginning. We examine commercial real discount rates of 9, 13 and 15 per cent reflecting a risk tolerant investor in the former case and a risk averse investor in the latter case, discounting heavily because of the riskiness of the project.

The table reports how these discount rates affect the NPVs of extensions of the patent term. Looking at just those drugs in the Australian system that are protected by patents, we assume, for illustrative purposes, that each year they are on the market and receive patent protection, the value of the patent is one hundred million dollars of additional revenue. Given this, the NPV of the last \$500 million dollars in the patent extension period (from years 21 to 25) would be worth between \$70 and \$20 million (See Row 7).

In fact, however, the extension is only granted in its full form if the drug has taken ten years or more to come to market. In this situation, the last five years of the patent increase the patent life by fifty per cent. Yet because of the passage of time, the extension increases the NPV of the project *ex ante* by just over half this amount in the most optimistic scenario – with the lowest discount rate – ranging down to 16.5 per cent for a higher discount rate.

The patent extension is a liability on government, which will be collected in twenty years. Accordingly, to assess the cost to government of the patent extension at the time its incentive effects are being assessed by investors, we need to apply the government's discount rate to its future costs. The government's discount rate is much lower, and can be approximated by its cost of capital. Using a range of real discount rates of 1.5 to 4.5 per cent the net present cost (NPC) of the patent extension to the government at the commencement of the patent term, discounted by its discount rate is between \$355 and \$182 million (See Row 16).

Taking the lowest reasonable discount rate for the pharmaceutical firm and the highest discount rate for the government – ie the comparison that puts the patent extension in its best possible light – a government subsidy of \$182 million at the outset of the patent term in subsidies to R&D would have the same NPC to the government as a patent extension, but could be expected to provide more than double the incentive to the pharmaceutical firm to invest. Even assuming that the subsidy suffered from a 'deadweight cost' of 20% representing the cost of tax collections, the government subsidy still has twice the policy efficacy of the patent extension in increasing incentives to invest in pharmaceuticals.

Now let us consider how much additional investment in pharmaceutical R&D such incentives might generate in Australia. To illustrate, we assume an 'additionality' of 50 per cent - that is, for each dollar of additional NPV the firm sees it invests an additional 50 cents in R&D, though the number chosen here does not change the basic result or relationships being illustrated.

In the case of the patent extension, Australia's assistance is provided no matter where the R&D investment occurs. If Australia's pharmaceutical industry is around 2 per cent of the global industry, and we assume that firms are responding only to the economic incentives they face, the additional investment in R&D on the relevant project is about fifty times more likely to take place outside Australia than in Australia. Thus even at the most favourable discount rate, the \$70 million in NPV produces a 2 per cent chance of capturing the additional investment of \$35 million. This has an expected value of \$700,000 (Row 20). This compares with an expected increase in investment from a \$180 million subsidy of \$90 million. Again assuming a 20 per cent deadweight loss attributed to the distortions involved in additional taxation to fund a direct subsidy, the subsidy produces around \$72 million of extra Australian investment, which is more than one hundred times the expected Australian investment brought about by the patent.

An alternative approach would be to relax the assumption that global firms will base R&D investment wherever it is most efficient for them and instead assume that firms choose to reward Australia for its adoption of patent extensions and disfavour other countries that do not have patent extensions. For the purposes of illustration, we suggest that, instead of attracting 2 per cent of the investment promoted by the additional assistance Australia provides with patent extensions, the firm directs 25 per cent of the additional assistance produced by Australia's patent extension to Australia. Even under this very favourable assumption, and with the other assumptions remaining at their most favourable as with the examples above, the subsidy is ten times more efficient in stimulating pharmaceutical investment in R&D.

Now consider the effects of removing the last four years of the patent extension. On the most conservative assumptions as above, this will reduce the NPV of the patent extension by \$53 million dollars. On the additionality assumptions above this will produce a reduction in investment of around \$500,000 or \$6.6 million assuming some reduction in the reward the pharmaceutical industry gives to Australia for having patent extensions (rows 25 and 26).

On the other hand, the reduction in the four-year patent extension has reduced the NPC to the government by \$142 million dollars. If we apply half these savings to a subsidy scheme less a 20 per cent deadweight cost of revenue collection, on assumptions that are least favourable to the government scheme we get an additionality of \$28.5 million, which is 57 times the amount of additionality conceded from the shortening of the patent extension (assuming firms invest purely commercially), or over four times the amount of additionality if we assume that firms will disfavour Australia as a result of the lower patent incentives.

In short, because the cost of a patent extension is mostly borne by the PBS, and because of differences in the cost of capital for originators and for government, it is more efficient for the government to provide an up-front subsidy instead of an extension of a patent to achieve the same impact on originators' financial position. In addition, a subsidy is considerably more efficient at meeting the government's goal – more pharmaceutical R&D in Australia – than an extension of a patent.

Table 5.1: The Economics of Assisting Pharmaceutical R&D

	Additionality	50%		
		Low	Medium	High
1	Commercial Discount Rate	9%	13%	15%
2	1. NPV (Patent no EOT)	\$912,854,567	\$702,475,158	\$625,933,147
3	2. NPV (Patent with EOT)	\$982,257,960	\$732,998,498	\$646,414,909
4	3. First 10 years' NPV	\$641,765,770	\$542,624,348	\$501,876,863
5	1. - 3.	\$271,088,797	\$159,850,810	\$124,056,285
6	2. - 3.	\$340,492,190	\$190,374,150	\$144,538,046
7	Difference in NPV	\$69,403,394	\$30,523,340	\$20,481,761
8	Difference in NPV (%)	7.6%	4.3%	3.3%
9	Difference in reduced NPV (%)	25.6%	19.1%	16.5%
10	Social Discount Rate	1.50%	3%	4.50%
11	1. NPC (Patent no EOT)	\$1,716,863,879	\$1,487,747,486	\$1,300,793,645
12	2. NPC (Patent with EOT)	\$2,071,961,120	\$1,741,314,769	\$1,482,820,896
13	3. First 10 years' NPC	\$922,218,455	\$853,020,284	\$791,271,818
14	1. - 3.	\$794,645,423	\$634,727,202	\$509,521,827
15	2. - 3.	\$1,277,315,697	\$1,106,587,567	\$973,299,069
16	Difference in NPC	\$355,097,241	\$253,567,283	\$182,027,251
17	Difference in NPC (%)	20.7%	17.0%	14.0%
18	Difference in reduced NPC (%)	44.7%	39.9%	35.7%
19	Additionality (patent)	\$34,701,697	\$15,261,670	\$10,240,881
20	Additionality (in Aust 2%)	\$694,034	\$305,233	\$204,818
21	Additionality (in Aust, 25%)	\$8,675,424	\$3,815,418	\$2,560,220
22	Additionality (Subsidy)	\$177,548,621	\$126,783,642	\$91,013,626
23	Loss of NPV from 4 yr reduction	\$53,033,587	\$22,843,491	\$15,168,693
24	Additionality with patent	\$26,516,794	\$11,421,745	\$7,584,347
25	Additionality (in Aust 2%)	\$530,336	\$228,435	\$151,687
26	Additionality (in Aust 25%)	\$6,629,198	\$2,855,436	\$1,896,087
27	Redn in NPC from 4 yr redn	\$281,947,446	\$199,812,355	\$142,348,509
28	Additionality (Subsidy)	\$140,973,723	\$99,906,178	\$71,174,254
29	With 40% NPC going to subsidy	\$56,389,489	\$39,962,471	\$28,469,702

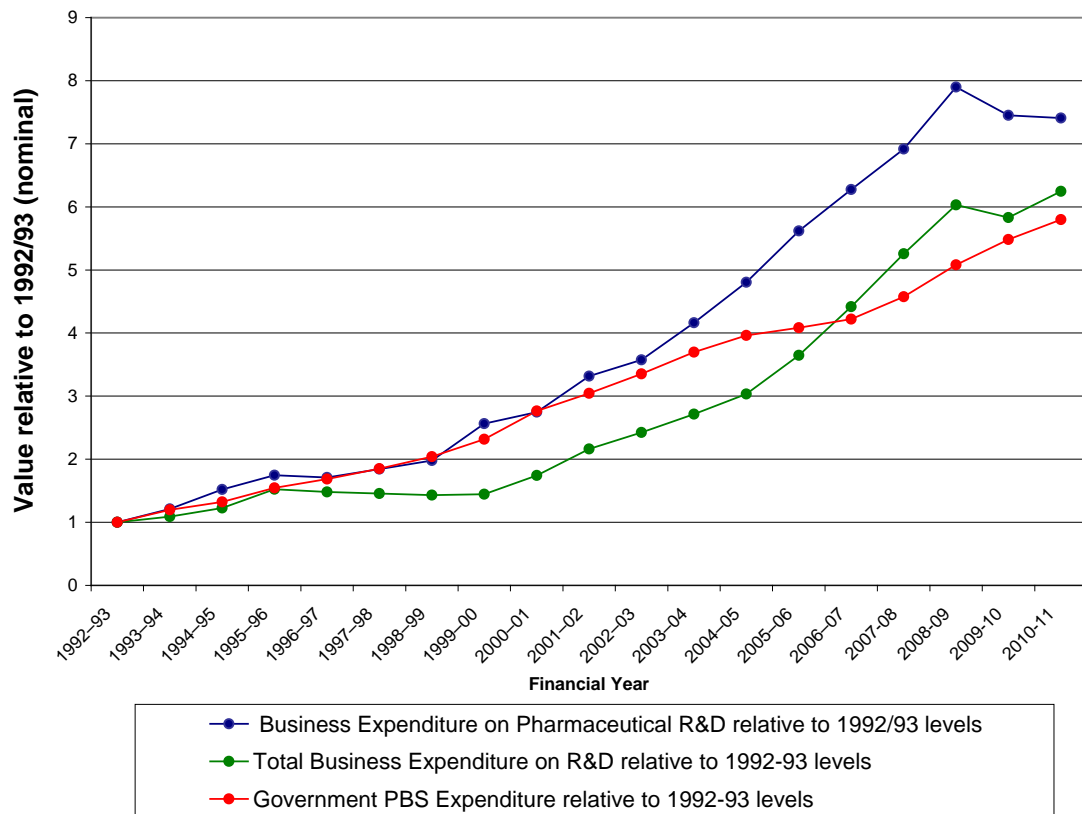
5.4. The costs of pharmaceutical R&D

Significant R&D is required to bring new or improved therapeutics and diagnostics to the market and these activities are costly. The total cost of developing new drugs has been reported as being more than \$1 billion. Most of these costs are incurred overseas, but business expenditure in Australia on R&D for pharmaceutical development in 2010-11 was \$1.00 billion.⁸⁷

Figure 5.2 compares the growth in business expenditure on pharmaceutical R&D with that of total business expenditure on R&D in Australia as well as the Government expenditure on the PBS. For the purposes of this comparison, the graph plots the value of each of these expenditure series relative to the expenditure in the first year of the graph (1992-93). Up to 2010-11, growth in business spending on pharmaceutical R&D and on total R&D has exceeded the growth in PBS expenditure but there has been little difference in the growth in business pharmaceutical R&D and in total business R&D since 1999-00.

⁸⁷ Australian Bureau of Statistics, *8104 – Research and Experimental Development by Socio-Economic Objectives, Businesses, Australia, 2010-11*. The total is calculated from the addition of two objectives: Human Pharmaceutical Products and Clinical Health (Organs, Diseases and Abnormal Conditions).

Figure 5.2: Growth in Business Expenditure on Pharmaceutical R&D in Australia⁸⁸



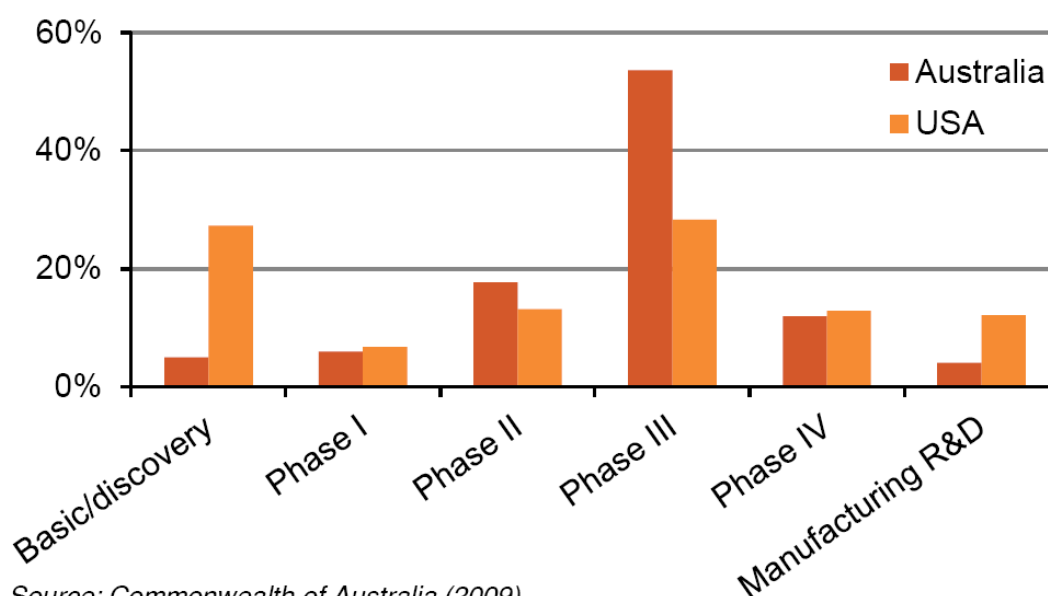
While much of this expenditure can be expected to come directly from companies, some may also be provided through government grants⁸⁹ and/or be supported by government through the R&D Tax Incentives.

⁸⁸ Australian Bureau of Statistics, *8104 – Research and Experimental Development by Socio-Economic Objectives, Businesses, Australia, 2010-11*; Australian Government Department of Health and Ageing. 2012. *Expenditure and prescriptions twelve months to 30 June 2012*, Table 15(b) PBS, Government Cost – History.

⁸⁹ Australian Bureau of Statistics, *8104 – Research and Experimental Development by ANZSIC06 industry subdivision by source of funds, Businesses, Australia, 2010-11*.

Figure 5.3 is reproduced from the recently released report by The Grattan Institute, *Australia's bad drug deal: High pharmaceutical prices*.⁹⁰ The figure compares the investment in different stages of pharmaceutical development, as a percentage of the overall investment, between Australia and the US. The majority of pharmaceutical R&D investment in Australia is in phase III trials and, as a proportion of the total investment, is much higher than in the US.

Figure 5.3: Types of Pharmaceutical R&D, Australia and US, 2008
(reproduced from Duckett et. al.)



Source: Commonwealth of Australia (2009)

Extensions of term provide some compensation for the costs of bringing drugs to market, but the extent of this compensation would only be a small percentage of total R&D expenditure. Furthermore, when considering the global market, of which Australia has only a small share, the value of an Australian extension of term as compensation of the total costs of R&D is further diminished.

⁹⁰ Duckett, S. J. with Breadon, P., Ginnivan, L. and Venkataraman, P. 2003. *Australia's bad drug deal: high pharmaceutical prices*, Grattan Institute, Melbourne. p 30.

The estimated annual cost for 2005-06 caused by the provision of an extension and the delay in the entry of generics was \$160 million.⁹¹ In current dollars, with an inflator of four per cent, the equivalent figure for 2012-13 is over \$200 million. Another way to estimate these costs is to examine the impact of generics on PBS spending and the savings which might be achieved by reducing the term of extensions.

5.5. Effect on PBS expenditure of generic products entering the market

Several factors can affect PBS expenditure by the Government for pharmaceuticals. These include (among other factors) the subsidy paid for a pharmaceutical, volume of scripts and the proportion of scripts that are concessional.

A review of government reimbursement prices for over 50 drugs suggests there is no single narrative that reflects how the government subsidy per script changes over time. Drugs vary in their numbers of dosages and deliveries offered over time, and dosages enter and exit the market throughout time while each dosage may have a different price. Supply and demand side factors can also be expected to play a role.

What can be said generally from this sample is that, as might be expected, the average subsidy paid by the Government per script is lower after the extension of term expires and a generic medicine enters the market compared to the date it is first listed on the PBS. There are a number of factors that contribute to this reduction.

Figures 5.4, 5.5 and 5.6 show the total PBS expenditure for three illustrative patented pharmaceuticals, from the first listing of the pharmaceuticals on the PBS (or the earliest date from which data are available) to after the extended patents expire. They also show the number of manufacturers, relative volume and the subsidy paid by the Government per script over the period. The figures are provided to demonstrate some of the key factors in the change in

⁹¹ Revised Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill 1998*, pg 2.

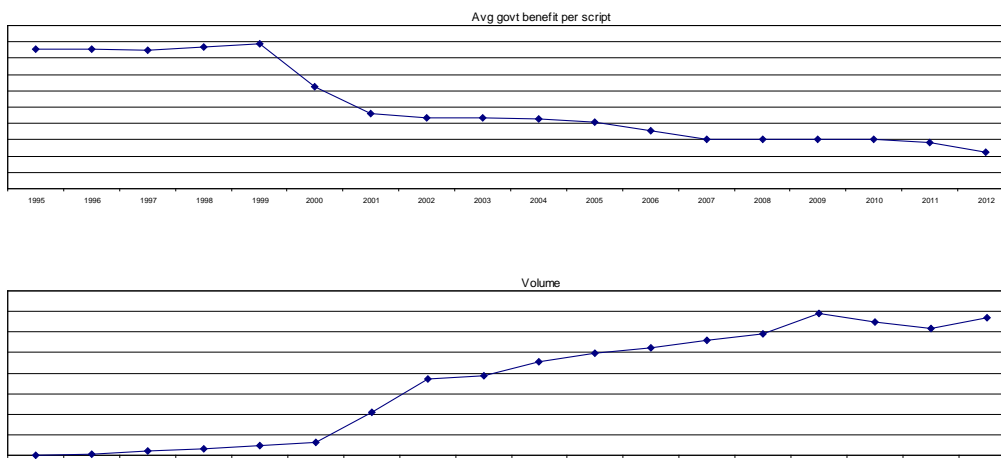
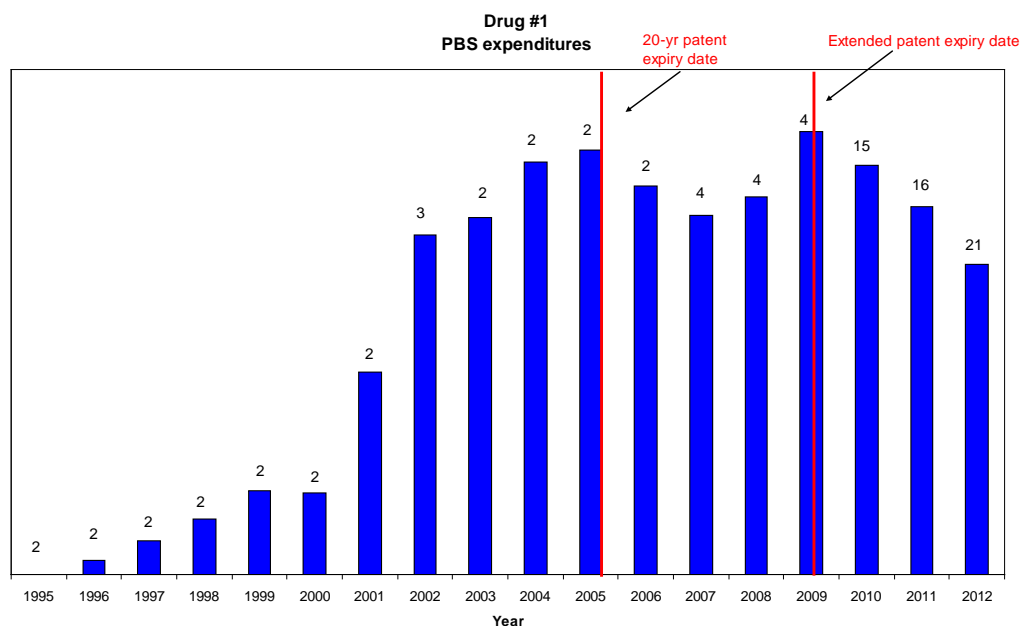
government subsidy per script; the actual expenditure and volume figures have been removed.

Figures 5.4 and 5.5 indicate that after the patents expire, PBS expenditure decreases due to reduced subsidies paid by the Government. A key factor affecting the average government subsidy per script in these cases is the regulated price reductions, namely the mandated 16 per cent price reduction that occurs once a second brand of a drug is listed on the PBS and the further price reductions that can occur with price disclosure.

The number of manufacturers also has an effect on the Government subsidy per script. Since their introduction as part of the PBS pricing policy, the regulated price reductions referred to above ensures the Government benefits decline as competition increases through reduced subsidies.

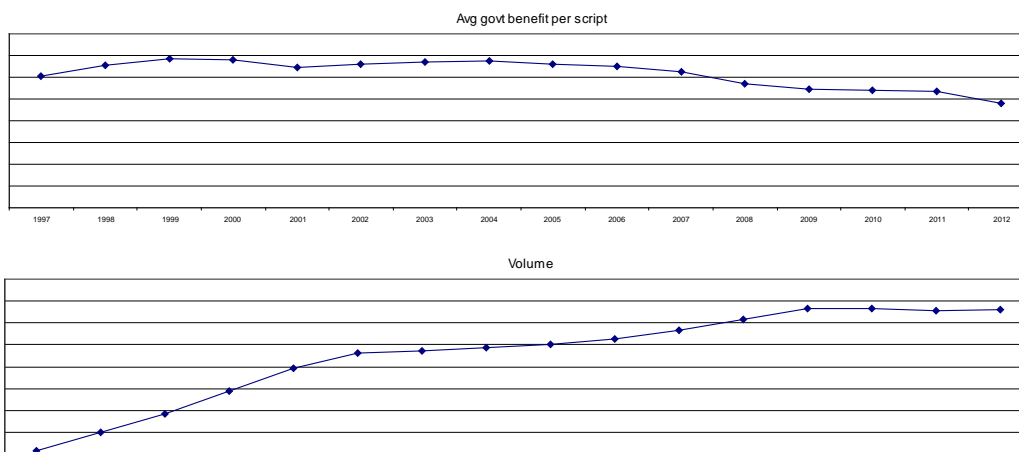
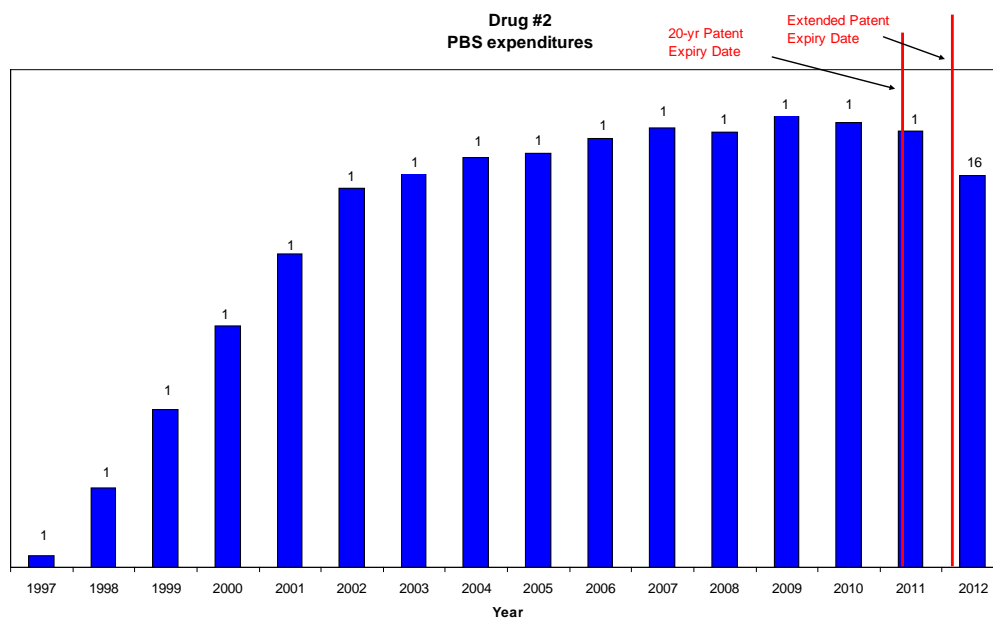
Figures 5.4 and 5.5 also indicate that volume can be an important factor in the Government subsidy paid, regardless of patent status.

Figure 5.4: PBS Expenditure for Example Drug #1



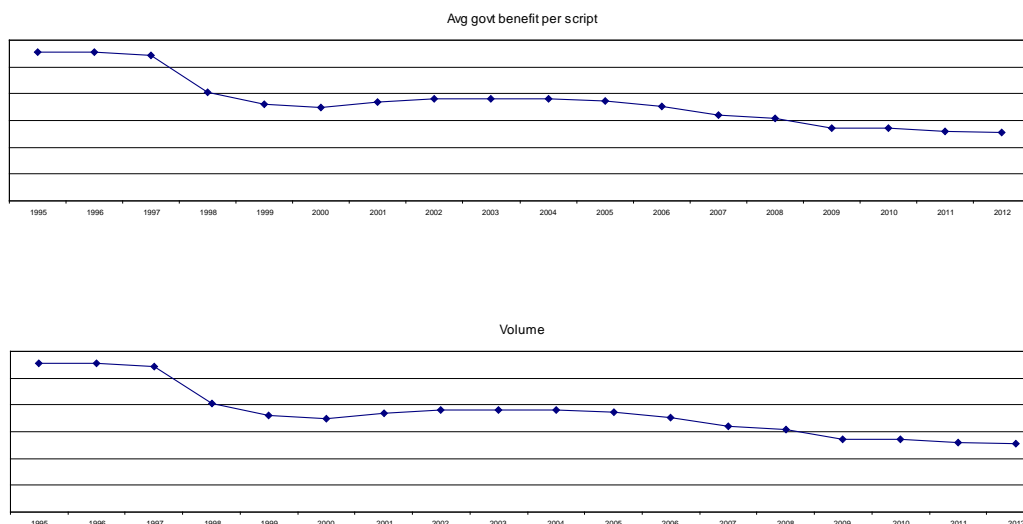
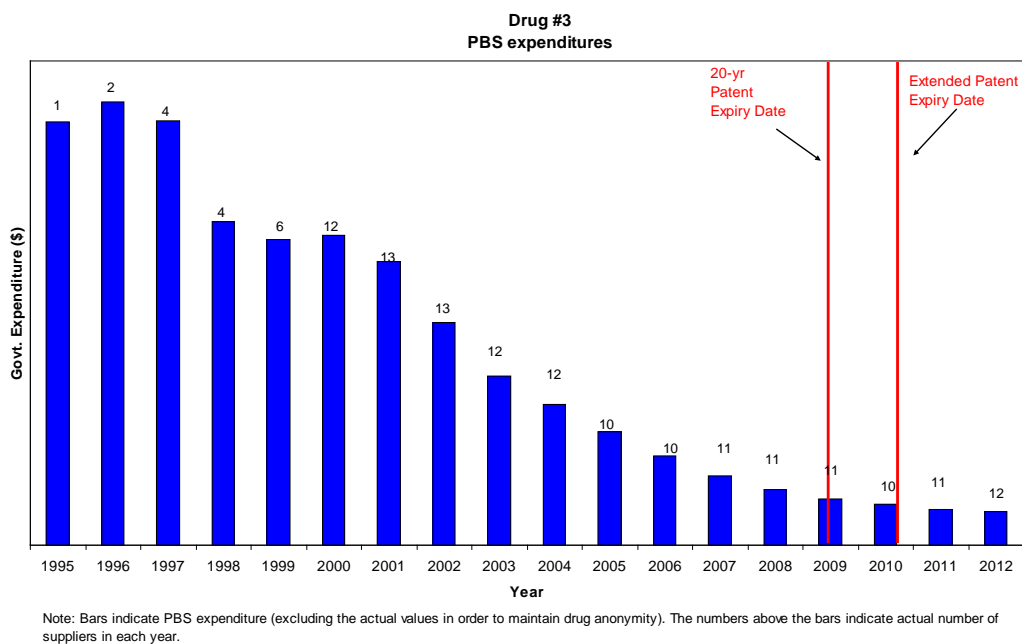
For the drug described in Figure 5.4, the Government subsidy dropped sharply in 2001 when volume increased substantially. The next visible price decline occurred in 2006 (during the beginning of the patent extension) as the number of suppliers increased and volume continued to increase. A major price decline then occurred in 2012, a few years after the extended patent expired and many additional manufacturers were listed on the PBS.

Figure 5.5: PBS Expenditure for Example Drug #2



In Figure 5.5, there remained a single supplier until the extension expired in 2012. The price declined during the patent term as volume steadily increased and again when the extended patent expired in 2012 and many additional manufacturers were listed on the PBS.

Figure 5.6: PBS Expenditure for Example Drug #3



In Figure 5.6, the first main price decline occurred in 1998 as the number of suppliers increased. This price decline occurred even as volume also declined, although this could be associated with another dosage for this particular drug entering the market during this time (the graph only represents one dosage of the drug). The number of manufacturers increased prior to the original patent term expiry and the price appears to have reached its low in 2009.

The volumes shown in these figures do not include 'under-copayment scripts' i.e. those where no Government benefit is paid. The average subsidy per script is

also affected by the relative mix of general and concessional subsidies in any one year which was not available in the data used to produce these figures.

The figures and discussion above indicate that volume, number of manufacturers and the regulated price reductions are key factors in the average Government subsidy per script. Patent expiry date can significantly affect the last two of these, though as shown in Figure 5.6, this is not always the case.

5.6. Cost of extension of term provisions to the PBS

At the time that the extension of term provisions were introduced, the estimated additional cost to the PBS was \$6 million in 2001-02, increasing to \$160 million in 2005-06, due to delays in the introduction of generic products.⁹² This cost was calculated based on delays in the automatic reduction in the Government subsidy that occurs with entry of the first generic drug onto the market. This cost did not account for the further reductions in PBS expenditure that occur through the Price Disclosure system, discussed in chapter 2.

This section considers the potential savings from a reduction to the maximum available length of extensions of term. These calculations are based on a number of assumptions and are provided to give the reader a sense of magnitude. These estimates should be viewed as stylised estimates rather than actual projected savings to the PBS from a change in the extension of term.

5.6.1. Figures used in calculations

The total expenditure by the PBS in 2012 was \$9.2 billion.⁹³ In any given year, an estimated 2.6% of the total PBS expenditure is on drugs having an extension of term which will expire within the next year⁹⁴. This is based on an average across 2008 to 2011.

⁹² Revised Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill 1998*, pg 2.

⁹³ PBS Expenditure for 2012, accessed at <http://pbs.gov.au/info/browse/statistics#Expenditure> on 30 April 2013.

⁹⁴ IP Australia estimates of PBS expenditure on the subset of drugs with extended patent terms expiring between 2008 and 2011. Source data obtained from the Department of Health and Ageing.

The price changes that follow a drug going off patent and a generic competitor entering the market vary considerably. However, for the purposes of this estimate, the following assumptions have been made:

- the 16% statutory price reduction is applied when the generic drug enters the market. For the purposes of this estimate, generic entry is taken to be soon after patent expiry. This is often the case for costly drugs where there is high PBS expenditure; and
- per the accelerated price disclosure program, an additional price reduction is applied to the already reduced price approximately 18 months after the drug is subject to generic competition. For the purposes of this study, we (conservatively) assume a 23% price reduction from price disclosure, which is the minimum saving, agreed to in the MOU between the Department of Health and Ageing and Medicines Australia in 2010.

The timing of each price reduction is determined by the extension of term expiry and hence both are included in these calculations. For the purposes of these calculations, the long run price reduction is assumed to be 35% (the combined effect of the 16% and additional 23% price reductions). This estimated price reduction is clearly conservative as it represents the minimum average saving across the PBS agreed to in the MOU between the Australian Government and Medicines Australia.

The length of an extension of term can be up to 5 years. Table 5.1 shows the distribution of the length of extensions of term for all extensions granted since the current scheme commenced in 1999 (approximately 560).

Table 5.2: Distribution of extended patents by length of extension of term

Length (years)	5	4-5	3-4	2-3	1-2	0-1
Percentage of all extended patents	47%	11%	11%	11%	12%	7%

Source: PBS data and IP Australia calculations.

Thus, 47% of all patent extensions granted since 1999 had an extension of the maximum five years, 11% had an extension greater than 4 years and less than 5, and so on. For the purpose of these calculations, we apply this distribution

evenly across all years. The estimates are provided for reducing the maximum from 5 years to 4, 3, 2, 1 and 0 years.

Calculations

The average value of PBS expenditures on drugs with EOT expiring in any given year:

$$\begin{aligned}
 & \textbf{\$9.2 bn PBS expenditures 2011-12} \\
 & \times 2.6\% \text{ (share of PBS expenditures on drugs with} \\
 & \quad \text{extension expiring in any given year)} \\
 & = \\
 & \textbf{\$240 mln PBS expenditures on drugs with EOT expiring in} \\
 & \quad \text{any given year}
 \end{aligned}$$

Potential savings from decreasing a 5-year extension to 4 years:

$$\begin{aligned}
 & \text{For patents with the maximum 5-year extension:} \\
 & \quad \textbf{\$240 mln PBS expenditures 2011-12} \\
 & \quad \times 47\% \text{ (share of patent extensions affected)} \\
 & \quad \times 1 \text{ (average length of reduction in years)} \\
 & \quad \times 35\% \text{ (long run price reduction)} \\
 & = \\
 & \quad \textbf{\$39.5 mln estimated savings}
 \end{aligned}$$

+

$$\begin{aligned}
 & \text{For patents with an extension greater than 4 years and} \\
 & \quad \text{less than 5:} \\
 & \quad \textbf{\$240 mln PBS expenditures 2011-12} \\
 & \quad \times 11\% \text{ (share of patent extensions affected)} \\
 & \quad \times 0.5 \text{ (average length of reduction in years)} \\
 & \quad \times 35\% \text{ (long run price reduction)} \\
 & = \\
 & \quad \textbf{\$4.6 mln estimated savings}
 \end{aligned}$$

=

$$\begin{aligned}
 & \textbf{\$44.1 mln} \\
 & \text{Potential savings from decreasing a 5-year extension to 4} \\
 & \quad \text{years}
 \end{aligned}$$

The above methodology was applied to calculate potential savings from a reduction in the maximum extension length from 5 years to 4, 3, 2, 1 and the entire removal of extension of term. The summary of estimates is presented below.

Table 5.3: Estimated potential savings from reductions in extension lengths⁹⁵

	Estimated Savings (\$m)
Reduction in extension length from 5 to 4 years	
For patents with the maximum 5-year extension:	39.5
For patents with an extension greater than 4 years and less than 5:	4.6
Total	44.1
Reduction in extension length from 5 to 3 years	
For patents with the maximum 5-year extension:	79.2
For patents with an extension greater than 4 years and less than 5:	14.2
For patents with an extension greater than 3 years and less than 4:	4.7
Total	93.4
Reduction in extension length from 5 to 2 years	
For patents with the maximum 5-year extension:	118.8
For patents with an extension greater than 4 years and less than 5:	23.6
For patents with an extension greater than 3 years and less than 4:	14.2
For patents with an extension greater than 2 years and less than 3:	4.6
Total	142.5
Reduction in extension length from 5 to 1 years	
For patents with the maximum 5-year extension:	158.4
For patents with an extension greater than 4 years and less than 5:	33.1
For patents with an extension greater than 3 years and less than 4:	23.6
For patents with an extension greater than 2 years and less than 3:	13.7
For patents with an extension greater than 1 years and less than 2:	5.0
Total	191.4

⁹⁵ Source: PBS data and IP Australia calculations. Note that numbers may not sum precisely due to rounding.

Reduction in extension length from 5 years to 0	
For patents with the maximum 5-year extension:	198.0
For patents with an extension greater than 4 years and less than 5:	42.5
For patents with an extension greater than 3 years and less than 4:	33.1
For patents with an extension greater than 2 years and less than 3:	22.9
For patents with an extension greater than 1 years and less than 2:	14.9
For patents with an extension greater than 1 years and less than 2:	3.1
Total	240.6

The estimates presented here reflect a static analysis and do not take into account other factors that would be affected if patent extensions were shortened, such as firm behaviour. Hence, these savings figures should be viewed with caution.

These data suggest that there may be substantial savings from even a small reduction in the extension of term. When considered in light of the small value to originators of a longer extension in Australia, because of the small size of the market, in global terms, and the potentially damaging impacts longer extensions can have on the broader pharmaceutical industry through retarding development of a viable generics sector, there is an argument for considering options for reducing extensions. However, there are other factors to consider, including the possibility that large pharmaceutical companies will reduce their investment in Australian research organisations and biotechnology companies if the extension of term is reduced. This point is discussed further later in this chapter.

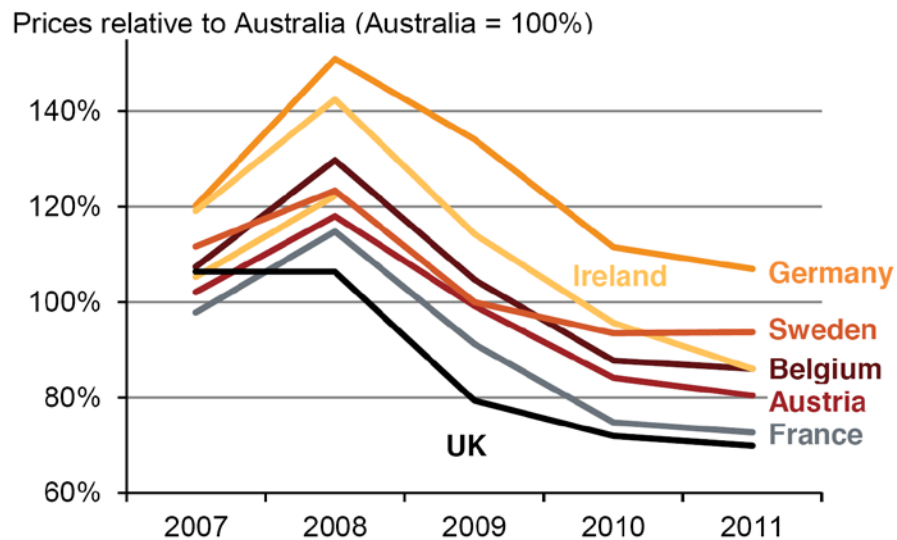
5.6.2. Findings from Duckett et al

The Panel notes the recent finding of Duckett et. al. that Australia's drug prices are 'high by international standards'.⁹⁶ Figure 5.7, reproduced from Duckett et. al., shows that prices set by the PBS for pharmaceuticals have risen significantly in recent years compared to those paid in comparable markets. The report indicates that this results mainly from the higher prices paid by PBS for generic

⁹⁶ Duckett, S. J. with Breadon, P., Ginnivan, L. and Venkataraman, P. 2003. *Australia's bad drug deal: high pharmaceutical prices*, Grattan Institute, Melbourne. p 33.

drugs. Australia's higher exchange rates over the period have also contributed to these higher prices.

Figure 5.7: Australia's pharmaceutical prices relative to selected countries, 2007-2011 (reproduced from Duckett et. al)⁹⁷



Duckett recommends changes to Australian pricing policies and actions to encourage the use of cheaper pharmaceutical products where possible. These changes would increase Government savings from the current approach to price reductions from generic pharmaceutical competition.

The estimated savings shown in Table 5.2 from reducing the maximum length of patent extensions are based on the current pricing policies for drugs with generic competition. If the changes proposed by Duckett et. al. were to be implemented, the savings from a reduction in extension of term would be substantially increased.

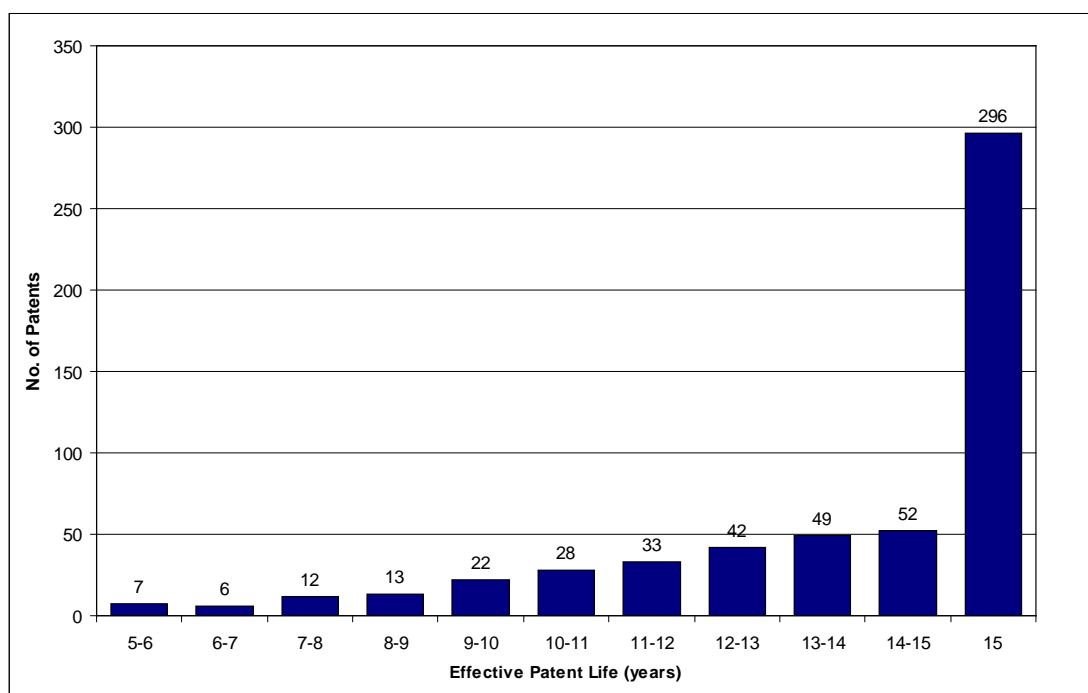
⁹⁷ Ibid p.5.

5.7. Evidence of whether 15 year effective term is being achieved

A number of submissions to the review argue that the scheme is not achieving its original policy intent because many patents granted an extension are not provided the full 15 year effective life.⁹⁸

More than half of all patents extended under the current provisions have received the maximum effective patent life after marketing approval of 15 years, and the remainder have received less than 15 years having been granted the maximum 5 year extension.

Figure 5.8: Effective Patent Life Provided Under Current Provisions – Frequency Histogram⁹⁹



The data on patent extensions granted by IP Australia indicate that the median effective patent life provided by the extension of term has remained at or close to 15 years each year since its introduction (see Figure 5.9). For drugs which have been accorded an extension, this is the maximum period provided under the

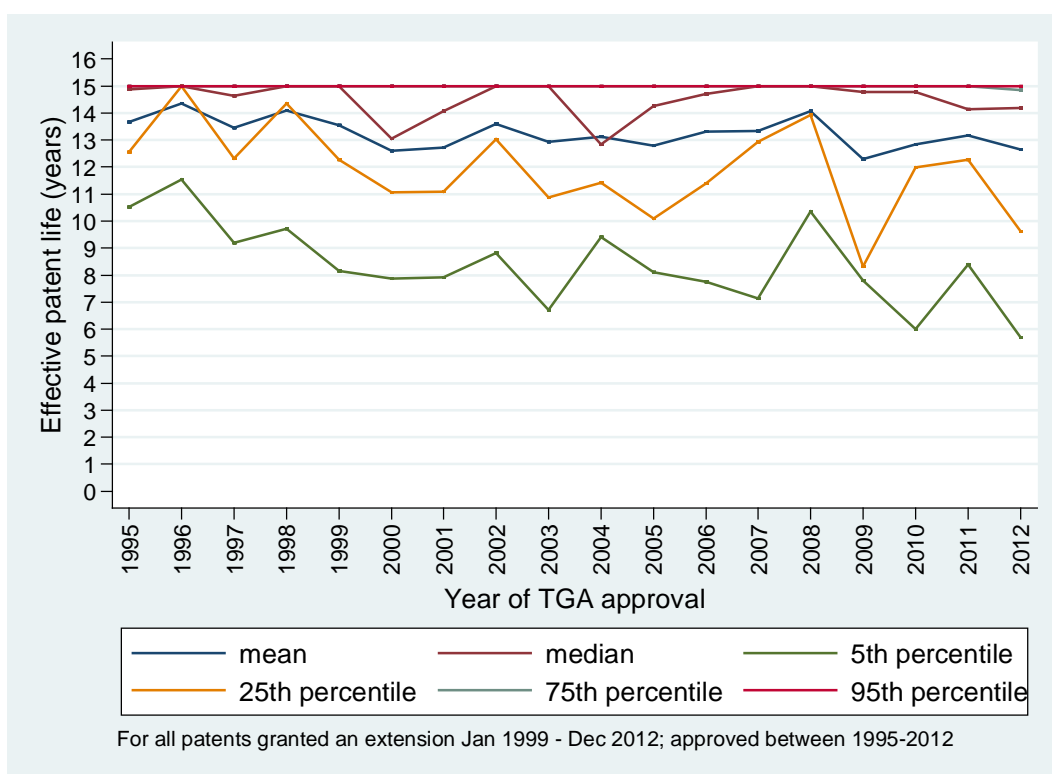
⁹⁸ Medicines Australia, Submission to the Pharmaceutical Patents Review, p.6; IPTA, Submission to the Pharmaceutical Patents Review, p.2.

⁹⁹ Source data: IP Australia.

scheme. However, the effective patent life may be decreasing for the 25% of patents receiving the shortest effective patent life. This suggests that where there are unusually long delays, the period of delay may have increased slightly over time.

Comparing these patents, where possible, with equivalent patents in the US and UK, there appears to be a relatively even mix of cases where the delay in gaining regulatory approval is specific to Australia and where the delay is seen worldwide.¹⁰⁰

**Figure 5.9: Effective Patent Life Provided Under Current Provisions
– Percentiles by Year**



Merck, Sharp and Dohme propose a possible mechanism to give more extended patents a 15 year effective life, which is also suggested in a number of other submissions:

¹⁰⁰ Source data: IP Australia, United States Patent Office, UK Patent Office.

... the five year cap on the length of an extension of term should be either totally removed or increased to ensure that all the eligible pharmaceutical patents achieve 15 years of effective term.¹⁰¹

Regardless of arguments whether this was truly the policy intent, or whether the intent is more correctly stated as a scheme that allows extensions more in line with those granted elsewhere and up to a maximum of 15 years, there are important considerations that should be taken into account in considering any adjustment to the terms granted under the scheme.

More extended patents could be provided with an effective life of 15 years if the existing limit was changed. Where extended patents do not receive a 15 year effective patent life, it is because the maximum extension of 5 years has been granted. IPTA submits that if the limit on the length of extensions under section 77(2) were increased from 5 years, or removed, more patents would be provided with a 15 year effective life.¹⁰² This approach is suggested in a number of submissions.¹⁰³ However, this would also mean allowing total patent terms of up to 20 years plus the allowable limit (with the possibility of 35 years in some cases if the limit was removed entirely). The existing method of calculating the length of extensions set out in section 77(1) would maintain a maximum effect patent life of 15 years.

5.8. Changes since 1998

This section will consider what, if any, changes have occurred since the extension of term provisions were introduced, including consideration of the time taken for TGA approval and PBS listing as well as the cost of pharmaceutical R&D.

The current method of calculating extensions takes account of the time taken in assessing applications for registration by the TGA. Therefore, this time would only be of concern where the five year maximum extension prevents a 15 year

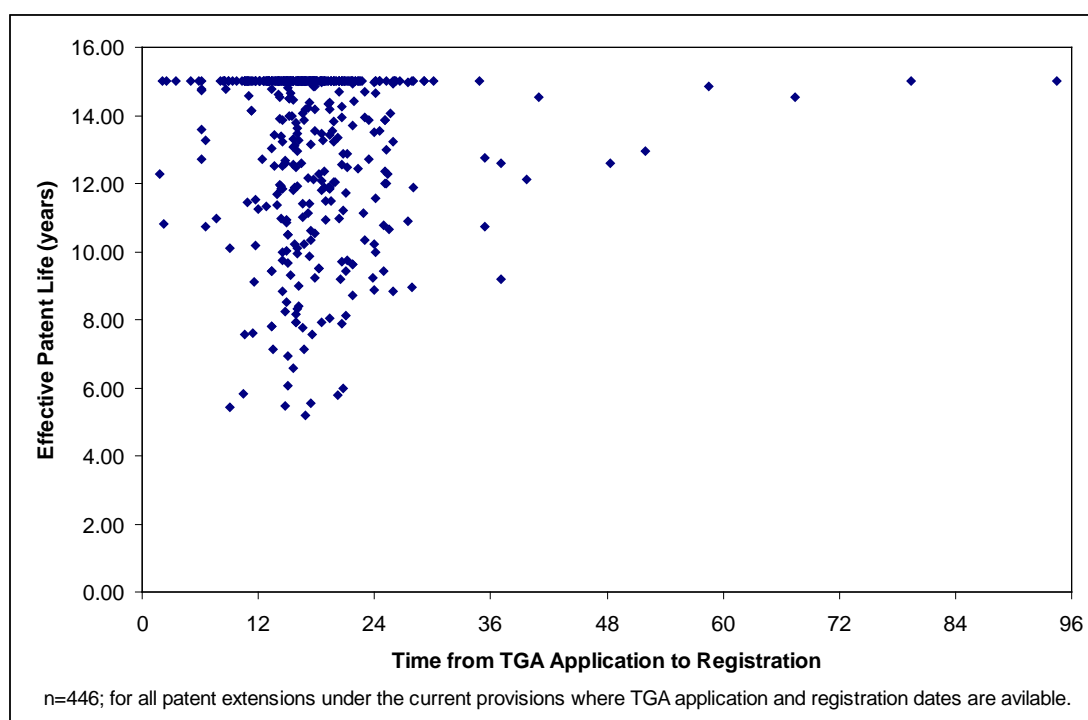
¹⁰¹ Merck Sharpe & Dohme, Submission to the Pharmaceutical Patents Review, p.3.

¹⁰² IPTA, Submission to the Pharmaceutical Patents Review, p.13.

¹⁰³ IPTA, AusBiotech, Medicines Australia, INTERPAT, Abbvie, Lundbeck, Pfizer, Merck Sharp and Dohme, CSL, AIPPI.

effective patent life being provided. As shown in Figure 5.10, the time taken for TGA approval has not been a significant factor in determining the effective patent life provided under the current extension of term provisions.

Figure 5.10: Effective Patent Life vs TGA Approval Time¹⁰⁴



In its submission to the Review, AusBiotech suggested that the time taken to get PBS listing after ARTG registration is increasing, reducing the exclusive marketing period of pharmaceuticals on the PBS.

In Australia there has been a decade-long trend in increased delays, with the average time between a positive TGA recommendation and PBS listing increasing steadily from 13.6 months in 2000 to 34.2 months in 2009.¹⁰⁵

However, this is not supported by other studies or data collated on extension of term pharmaceuticals. *Pretium's Drug Tracker*¹⁰⁶ found that the time taken from

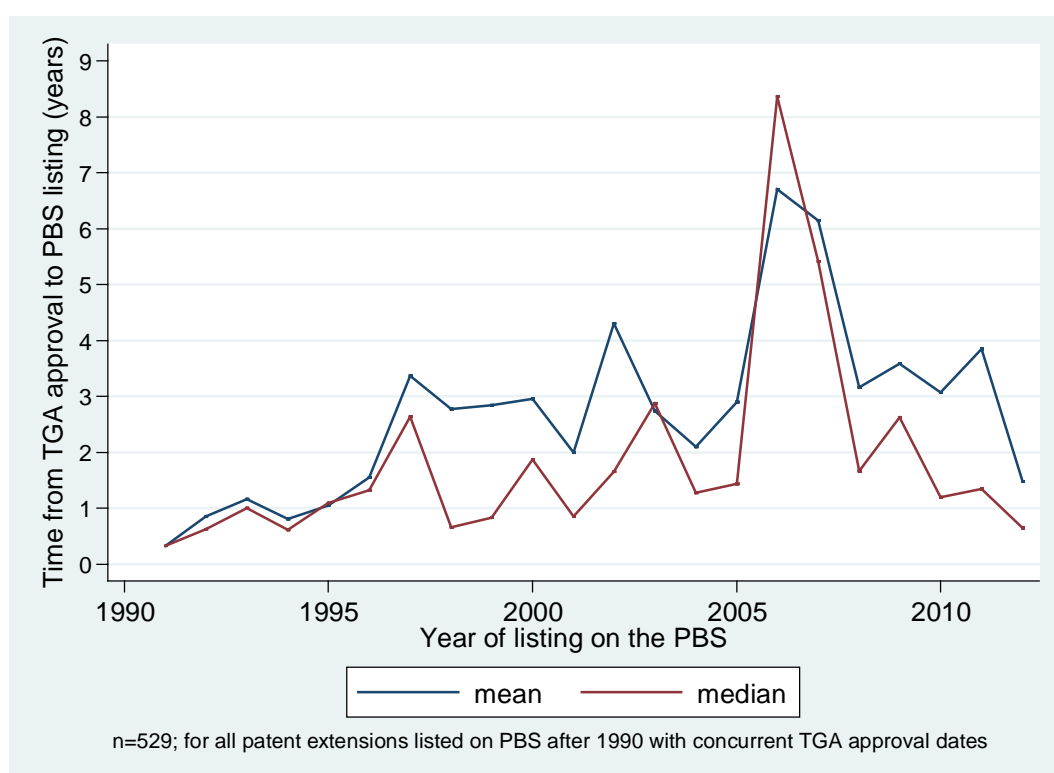
¹⁰⁴ Source data: IP Australia, Therapeutic Goods Administration.

¹⁰⁵ AusBiotech, Submission to the Pharmaceutical Patents Review, p.2.

ARTG registration to PBS listing for all pharmaceuticals increased from 10 months in 2000 to 24 months in 2008 and then decreased to 15 months in 2010.

Furthermore, data on just those pharmaceuticals granted an extension of term indicate that while there was a significant spike in the median time taken for drugs listed on the PBS in 2006, this has decreased in recent years and is in line with the long term average.¹⁰⁷

Figure 5.11: Time from TGA approval to PBS Listing by Year Where an Extension of Term was Granted



These data do not show the impact of the recently introduced parallel processing system allowing TGA and PBS assessments to occur concurrently rather than sequentially. Through parallel processing, a submission to the Pharmaceutical Benefits Advisory Committee (PBAC) may be made at any time from the date of

¹⁰⁶ Pretium. 2011. Drug Tracker. Available Online:
<http://www.pretium.com.au/drugtrackerPDF/Drug%20Tracker%20-%202011%2009.pdf>

¹⁰⁷ Source: IP Australia, Department of Health and Ageing.

lodgement of a TGA registration dossier. However, in practice the risk of discrepancy between TGA and PBAC outcomes may lead applicants to wait until part way through the TGA assessment process before making a PBAC submission. The data above do not take account of the requirement for cabinet approval for some new items on the PBS. The net effect of these two changes on average duration from ARTG registration to PBS listing is uncertain at this stage.

Medicines Australia argues that the exclusive period which pharmaceutical companies have to sell their products starts, in practical terms, from the time they receive PBS listing rather than the date of ARTG inclusion. The reason is that in practice there may be little market for a drug not listed on the PBS. Australian consumers, who are accustomed to paying the substantially reduced prices for PBS listed drugs, might be unwilling or unable to pay the higher prices charged where there is no subsidisation.

Therefore, Amgen advocates:

... incorporating delays due to the reimbursement process as a factor in calculating the term of patent extension in order to achieve an effective patent life of 15 years.¹⁰⁸

It is important to note, however, that not all pharmaceutical products are sold through the PBS and hence the proposal to use the date of PBS listing would not be applicable in many cases. Of the 621 applications for pharmaceutical patent extensions of term accepted to the end of 2012, over a third of the pharmaceuticals were not subsequently listed on the PBS. Calculating the effective patent life from the time of PBS listing would also provide an unparalleled distinction between pharmaceutical and non-pharmaceutical technologies. Inventions in other technology areas are not without their own difficulties during the marketing phase. Furthermore, no evidence has been provided to demonstrate that such a change would improve the policy outcomes of the scheme.

¹⁰⁸ Amgen, Submission to the Pharmaceutical Patents Review, p.5.

AusBiotech is among a number of submitters arguing that the cost of R&D has increased since the extension of term provisions were introduced:

A recent report from the UK Office of Health Economics (December 2012) reviewed research published over the last three decades, and confirmed what the industry has known anecdotally for some time: the costs and times of R&D are increasing.¹⁰⁹

While estimates of the typical cost for new drug development vary greatly, overall the literature supports a trend of increasing costs over time.¹¹⁰ Meanwhile pharmaceutical companies argue that they no longer have sufficient time in which to generate the necessary returns from their R&D investment.

5.9. Analysis of changes since the introduction of extension of term provisions

Based on the data presented above, it does not appear that there has been a significant change in the effective patent life provided for pharmaceuticals since the introduction of the current extension of term provisions in 1998. Further, the time taken to get PBS listing after ARTG registration has not increased significantly in that time, despite fluctuations within that period.

Available estimates in the literature suggest that the cost of pharmaceutical R&D is increasing. However, no evidence was provided that the industry as a whole is suffering from inadequate profitability and that longer periods of patent protection are needed.

Therefore, there does not appear to be an argument for increasing the length of extensions of term on the basis of a change in the average exclusive market period available.

¹⁰⁹ AusBiotech, Submission to the Pharmaceutical Patents Review, p.2.

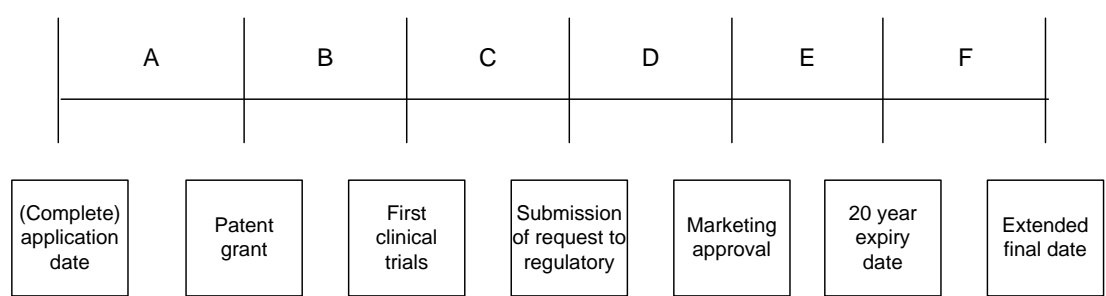
¹¹⁰ UK Office of Health Economics. 2012: The R&D Cost of a New Medicine.

5.10. Comparison of extension length internationally

In this section, extensions of patent term provided in Australia are compared with those in the United States (US) and the United Kingdom (UK). The comparison uses IP Australia's database of extended pharmaceutical patents and matched, where possible, with the equivalent patents in the US and UK. The resulting dataset contained 340 and 339 extended patents where matches were identified in the US and UK respectively and 169 patents where extensions were provided in all three jurisdictions.

Before presenting the results of these comparisons, a summary of the differences in methods of calculating pharmaceutical patent extensions in key jurisdictions is provided.

Figure 5.12: General Process for Regulatory and Patent Processing



Note: The scheme represented in Figure 5.12 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.

Table 5.4: Comparison of Extension of Term Systems

Country	Max Effective Patent Life	Calculation of extension
AU	15	$F = A + B + C + D - 5$
US	14	$F = C/2 + D$
EP/UK	15	$F = A + B + C + D - 5$
JP	15	$F = C + D$

Figure 5.13 and Table 5.4 show that the effective life of extended pharmaceutical patents in Australia is the same as in the UK at the median and longer than those in the US by 12 months at the median.

Figure 5.13: Difference in effective patent life between Australia and other jurisdictions¹¹¹

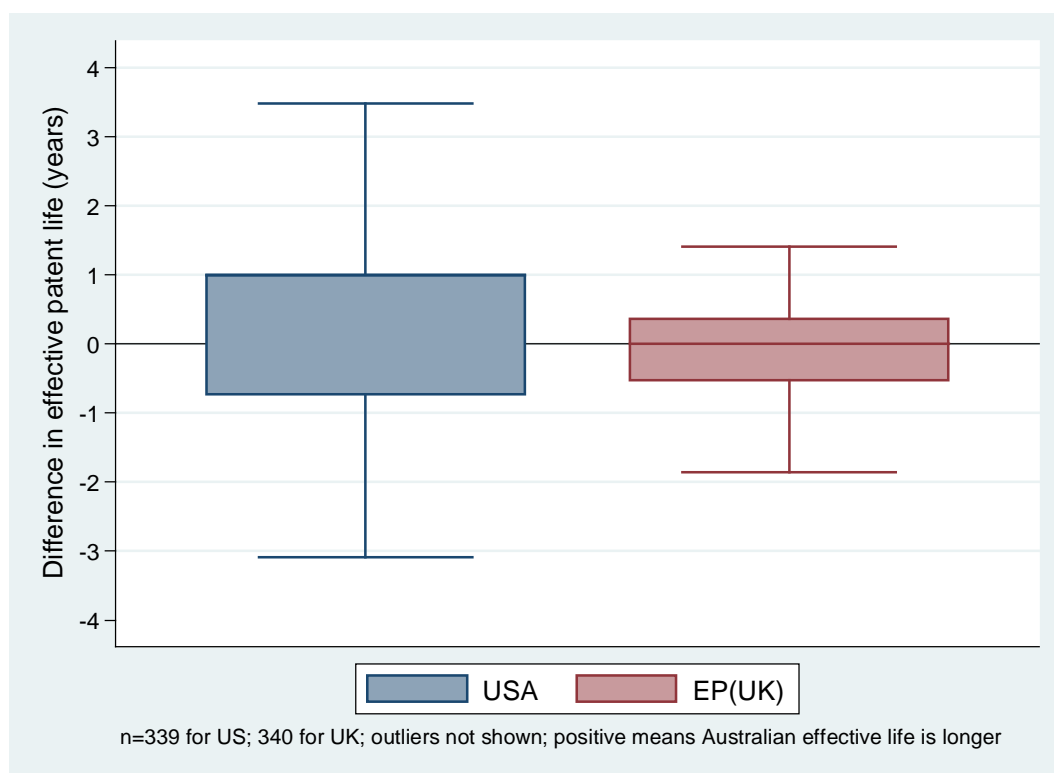


Table 5.5: Difference in effective patent life between Australia and other jurisdictions

	United States	United Kingdom
Mean	5 months	0.5 months
Median	12 months	0 months

*Note: (a positive result represents longer period in Australia)

¹¹¹ Source data: IP Australia.

It is worth distinguishing between situations where the extended Australian patent receives a full 15 years effective patent life (53% of extended patents) and those where, because the 5 year limit is reached, an effective patent life of less than 15 years is granted (47% of extended patents).

Where a full 15 year effective patent life is provided in Australia (i.e where the 5 year limit is not reached), the corresponding UK patent is granted a similar effective patent life. However, in these cases, the US patents always receive a shorter effective patent life as the US provisions aim to provide 14 years rather than 15 years.

This situation changes, however, where the Australian patent extension reaches the 5 year limit and is not provided a 15 year effective patent life. In these cases, the effective patent life in Australia is typically, though not always, shorter than that provided in the US and UK.

The comparison above considers the length of the effective patent life, irrespective of the patent expiry dates. Figure 5.14 and Table 5.5 show that the length of pharmaceutical patents extensions in Australia is the same as in the UK at the median and longer than in the US by 18 months at the median. Because these patents share the same filing date, these observations will also be true for the patent extension expiry dates.

Figure 5.14: Difference in patent term extensions between Australia and other jurisdictions¹¹²

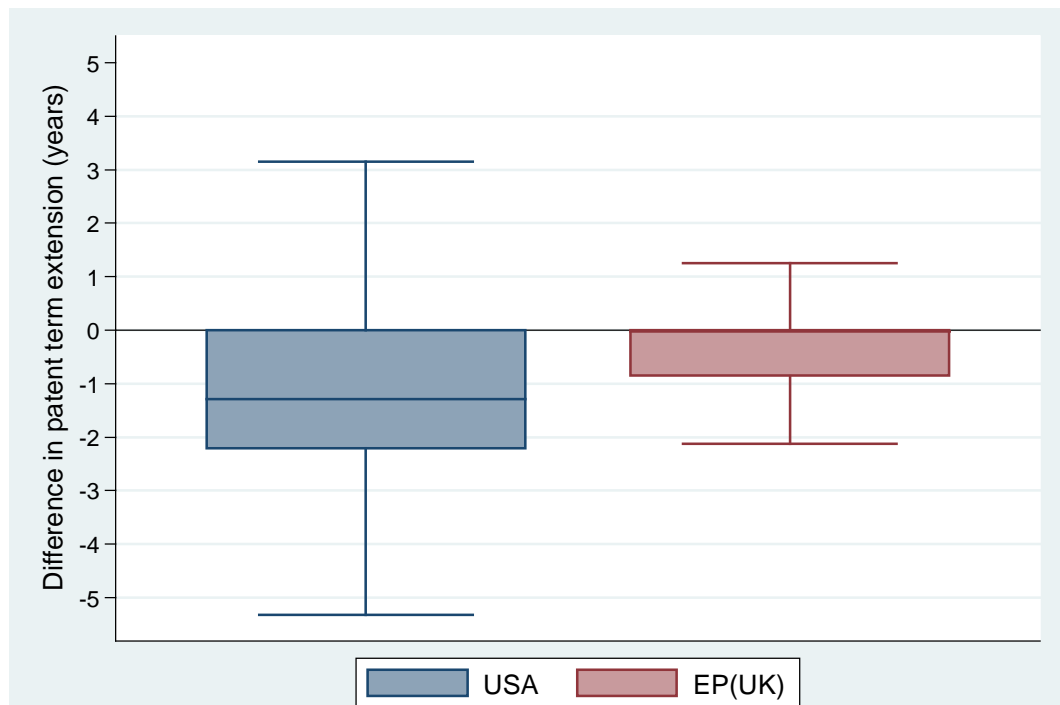


Table 5.6: Difference in extension length (and hence expiry date) between Australia and other jurisdictions

	United States	United Kingdom
Mean	18 months	6 months
Median	18 months	0 months

The difference in regulatory (FDA and TGA) application dates is a significant factor in explaining the difference in the extension length and expiry date of extended patents between Australia and the United States. The mean difference in the dates of TGA and FDA application is 39 weeks. This, along with a mean difference of 12 weeks in the assessment timing, results in a mean difference in regulatory approval dates of 51 weeks.¹¹³

¹¹² Source data: IP Australia.

¹¹³ Source data: IP Australia.

5.11. Analysis of the length of extensions of term

Encouraging and attracting investment in pharmaceutical R&D in Australia has been a key stated objective of the extension of term provisions. It is not clear, however, how the provisions achieve this objective, nor has the case been made in submissions to this review that they do in fact meet this objective. The extension of term provisions provide increased certainty around the available return from the Australian market on investment in an industry characterised by high R&D costs and considerable technical uncertainty. However, pharmaceutical companies operate globally and can, and presumably do, conduct their R&D activities wherever it is most commercially favourable to do so. R&D location decisions may be made separately from marketing decisions. Key factors in R&D location decisions include the cost of conducting R&D and access to the necessary resources including expertise.

This reasoning is consistent with the views of Duckett et. al.

... cutting Australian drug prices might have a marginal impact on total, global pharmaceutical research. However, this impact would be very small. Investing the savings from lower drug prices in better healthcare, access to more drugs, in other services, or in tax reductions would almost certainly create a bigger positive impact.¹¹⁴

An important factor not considered above is the potential for pharmaceutical companies to use the location of R&D activities as a 'negotiating tool' with countries to ensure favourable policy settings. These R&D activities provide economic benefits in the country in which they are located. Therefore, linking R&D location decisions with the countries with the most favourable market policies could be used as a mechanism to pressure nations in their decision making.

¹¹⁴ Duckett, S. J. with Breadon, P., Ginnivan, L. and Venkataraman, P. 2003. *Australia's bad drug deal: high pharmaceutical prices*, Grattan Institute, Melbourne, p.31.

Draft Recommendation 5**Option 5.1:**

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

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

Australia provides an effective patent life largely in line with the UK and longer than the US. Due to later dates of regulatory approval, as a consequence of both later TGA application dates and longer TGA processing times when compared to the FDA, Australian patents generally have longer extensions resulting in later patent expiry dates.

While this does not necessarily result in a longer exclusive period in the market in Australia compared to the US and UK, it does have other implications, especially for the Australian generics industry. In particular, as discussed in previous chapters, generic manufacturers wanting to compete in markets where the patents have expired are not able to do so from Australia if the patent is still in force in Australia. Also, if the patents expire later in Australia then Australian manufacturers may be disadvantaged if overseas-based manufacturers are positioned to enter the Australian market immediately (and before their Australian competitors) due to their advantage in supplying other markets beforehand.

Draft Recommendation 5

Option 5.2:

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

Potential ways of achieving this include:

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

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

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

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

6. Extension of term – scope including technical problems

6.1. Current scope for extension of term

Under existing Australian provisions, patents with claims to active ingredients or new formulations of a known active ingredient are considered to be eligible for an extension. This is similar to, but not the same as, the US, Europe, UK and Japan. In these jurisdictions, extensions are also available for uses and methods of manufacture of pharmaceuticals,¹¹⁵ whereas in Australia they are not.

6.2. Divergence from original intent of the pharmaceutical patent extension of term provisions

This section will consider whether the current understanding of the law has diverged from the original intention of the legal provisions for extension of term. In an area as complex as pharmaceuticals, it is inevitable that both the patent office and judiciary will be called upon to interpret and apply the extension of term provisions.

The explanatory memorandum accompanying the legislation that introduced the current extension of term provisions states that:

...extensions of term would usually be restricted to new and inventive substances.¹¹⁶

GMiA argues that this was intended to limit eligibility to patents claiming new active ingredients:

[The] Explanatory Memoranda accompanying the 1998 amendments and in 2006 also made it clear that this regime was intended to relate to “new drugs”. Particularly, to provide an economic incentive for businesses to invest in the development of new chemical entities as

¹¹⁵ Article 1(c) European Community Regulation 469/2009.

¹¹⁶ Revised Explanatory memorandum to the *Intellectual Property Laws Amendment Bill 1998*, page 18.

active pharmaceutical ingredients (APIs) for potential therapeutic use.

¹¹⁷

Conversely, originator companies argue that new formulations containing known active ingredients can and should be considered to be new and inventive and are thus correctly considered eligible for extensions of term. Bristol Myers Squibb (BMS) states:

It appears that the original intention behind section 70 of the *Patents Act* was that it would apply to "new and inventive substances", which BMS submits may often apply to new formulations.¹¹⁸

The definition of "pharmaceutical substance" provided in the *Patents Act 1990* refers to "*a substance (including a mixture or compound of substances) for therapeutic use*". This definition has not yet been the subject of judicial consideration. It has, however, been the subject of Patent Office decisions, where it was found that the definition encompasses not only a mixture or compound of substances, but also a compound with a controlled spatial configuration, such as a biphasic tablet or thermoplastic ring containing a diffused active ingredient.¹¹⁹ However, to meet the definition a level of integration or interaction between component parts of the compound is necessary.

6.3. Analysis

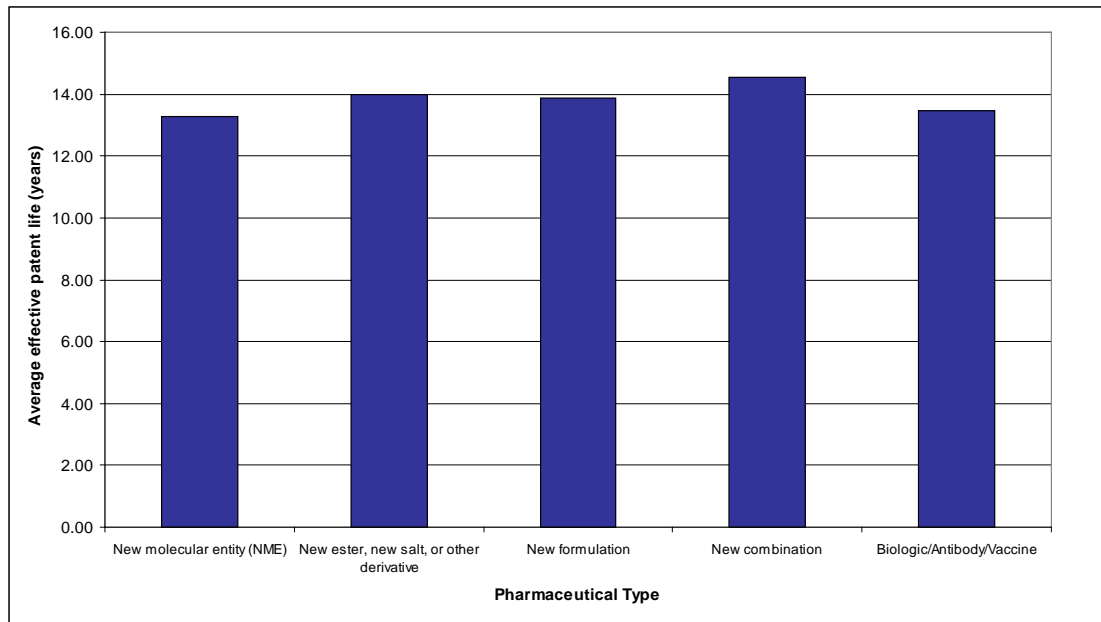
The current approach, allowing for extensions to patents claiming active ingredients as well as new formulations, appears reasonable on the basis that products based on these inventions are desirable, require considerable R&D and are prevented from entering the market until regulatory approval is given. This is supported by data demonstrating that the time taken to obtain regulatory approval is similar for new actives, new formulations, new compositions and biologics (see figure 6.1 below).

¹¹⁷ GMiA, Submission to the Pharmaceutical Patents Review, p.14.

¹¹⁸ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [15].

¹¹⁹ *Sanofi-Aventis* [2007] APO 35 and *N.V. Organon* [2009] APO 8.

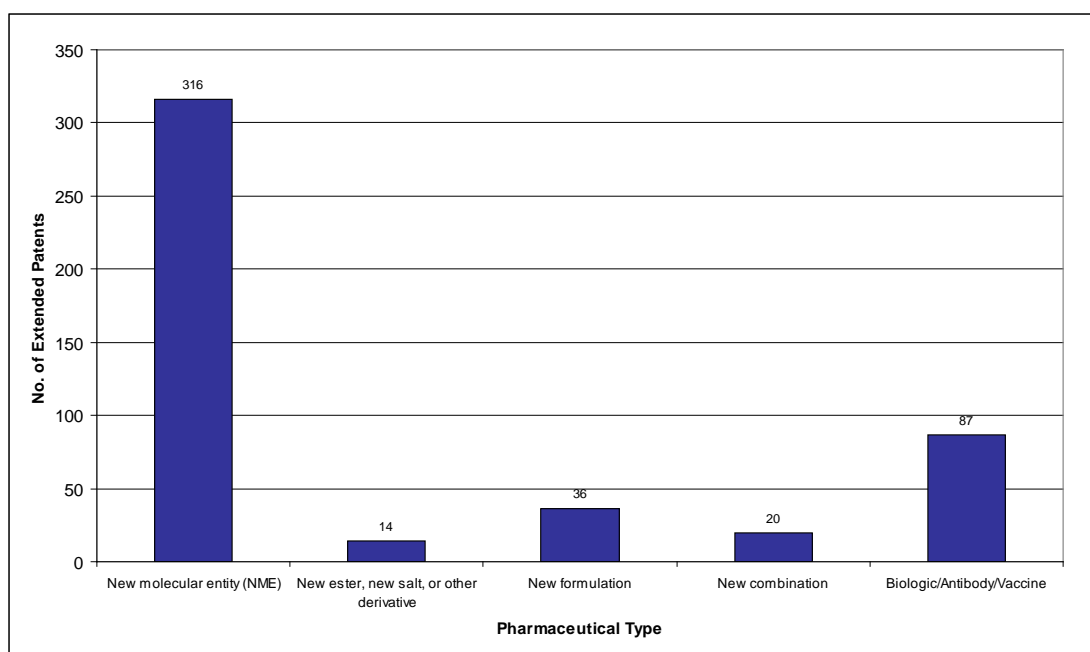
Figure 6.1: Average Effective Patent Life for Extended Patents by (Equivalent FDA) Pharmaceutical Classification¹²⁰



Notwithstanding arguments from generic manufacturers that the scope of pharmaceutical patents eligible for an extension of term is too broad, data from IP Australia indicate that new active ingredients make up the vast majority of extended patents 6.2 below. Limiting extensions to patents on new active ingredients would therefore have little effect in reducing the overall cost of pharmaceuticals.

¹²⁰ IP Australia Data.

Figure 6.2: Number of Extended Patents by (Equivalent FDA) Pharmaceutical Classification¹²¹



Some submissions argue that extensions should be available for patents claiming new methods of use or manufacture for a number of reasons:

- allowing extensions for such patents would more closely match the extension of term schemes in the US, Europe and Japan¹²²;
- '[t]here is often the same public health interest in developing new therapies using known substances as there is in identifying new active ingredients ... [and] [t]he investment in developing new formulations

¹²¹ IP Australia Data. Note: this is based on a reduced set of 473 extended patents where was possible to match each to the equivalent FDA pharmaceutical classification.

¹²² Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [14].

and new therapeutic uses may be comparable to that involved in developing the original active ingredient,¹²³

- springboarding provisions, i.e. provisions exempting from patent infringement those steps necessary for obtaining regulatory approval, cover a broader range of pharmaceutical patents than they did when the extension of term provisions were introduced. IPTA argue ‘... it would seem appropriate to expand the types of patents which may be eligible for a patent term extension accordingly.’¹²⁴

Novartis also suggests that the extensions of term provisions could be expanded to allow veterinary pharmaceuticals to be granted extensions on the basis of the time taken to obtain regulatory approval from the Australian Pesticides and Veterinary Medicines Authority.¹²⁵

On the other hand, Alphapharm argues that the scope of patents eligible for an extension of term should be limited ‘...to the earliest patent to claim that substance in a pharmaceutical composition contained in a therapeutic good (the first pharmaceutical patent).’¹²⁶

Given that additional clinical trials may also be required where regulatory approval is sought for a new use of a previously registered pharmaceutical, the rationale for the current scope of patents eligible for extensions of term may also apply to patents for new uses. However, no evidence has been provided to the panel that such inventions are subject to the same extent of cost, delay and risk as pharmaceutical products or that these new uses are not being developed and made available to the Australian market due to a lack of incentive.

The guiding principle for any change to the intended scope of pharmaceutical patents eligible for an extension of term is that changes should only be made if it

¹²³ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [16].

¹²⁴ IPTA, Submission to the Pharmaceutical Patents Review, p.8.

¹²⁵ Novartis, Submission to the Pharmaceutical Patents Review, p.3.

¹²⁶ Alphapharm, Submission to the Pharmaceutical Patents Review, p.11

is clearly in the national interest to do so. Convincing evidence to warrant expanding the scope of extensions to method patents has not yet been provided to the Panel.

Furthermore, with respect to the argument that extensions should be available in Australia for methods of use and manufacture to more closely match the Australian scheme with schemes in the US, Europe and Japan, expanding or reducing the scope of the pharmaceutical extension so that Australian legislation matches that in other countries for its own sake does not represent a sound argument for doing so. As stated previously, it should only be done where it is clearly in the national interest.

Draft Recommendation 6.1:

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

6.4. Multiple extensions based on one ARTG listing

In public hearings, GMIA proposed that only one patent should be able to be extended per ARTG registration, as is the case in the US. Under the US system, applicants are required to nominate which patent will receive an extension based on the FDA approval. This means that it is not possible to receive extensions to multiple patents for a single approval.¹²⁷

Under the Australian scheme, provided that various timing requirements are satisfied, there is no barrier to the extension of multiple patents on the basis of a single, first ARTG registration. As shown in Table 6.1, there have been 77 instances identified (covering 179 patents, which is 32% of all extended patents) where this has occurred.

¹²⁷ 35 USC 156(c)(4).

Table 6.1: Frequency of Instances of One or Multiple Patent Extensions based on a single ARTG Registration¹²⁸

No. of Patents per ARTG Registration	1	2	3	4	5	6
No. of Instances	381	60	11	5	0	1

Necessarily, where there is more than one patent receiving an extension of term for the same ARTG listing, all patents have been filed more than five years prior to the pharmaceutical receiving ARTG approval. Therefore, the approved product typically incorporates the multiple inventions disclosed in the patents.

Multiple extensions per ARTG-registered product may increase the total length of the monopoly granted in relation to the product. However, restricting extensions to only one extension per ARTG-registered product would be unlikely to prevent this, because in most cases it could be expected that the patent selected for the extension would be the one that provides the longest effective patent life.

The above analysis suggests there does not appear to be a strong case for applying the US approach where only one patent can be extended per ARTG listing as it is unlikely to make a practical difference when a product will become subject to generic competition.

6.5. Clarity of ‘pharmaceutical substance per se’

A number of submissions also raise concerns about the clarity of the current provisions. In particular concerns are raised in respect of the clarity of the term ‘pharmaceutical substance *per se*’ and the language used in paragraph 70 (3) (a) to describe the relationship between the pharmaceutical substance and the goods listed on the ARTG.

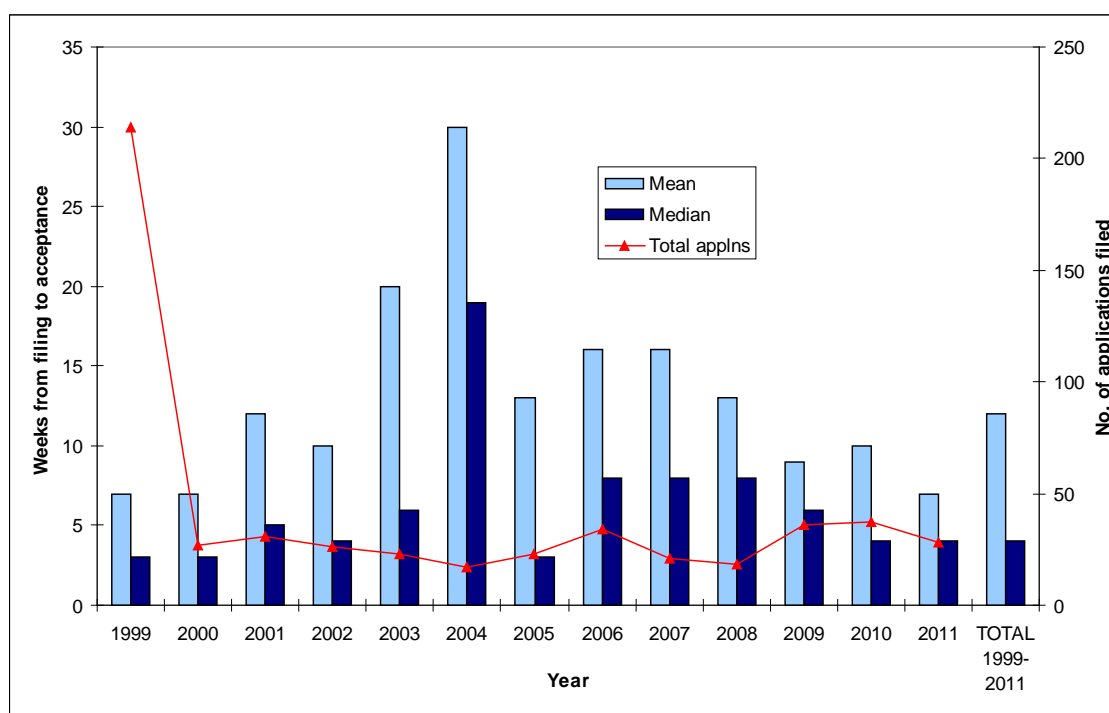
These issues are discussed later in this chapter in section 1.8, which deals with technical corrections and clarifications of the legislation.

¹²⁸ IP Australia data.

6.6. Efficiency of pharmaceutical patents extension of term scheme

Figure 6.3 shows the mean and median processing times by IP Australia for all accepted extension of term applications under the current provisions. The median time for IP Australia to accept an extension of term application was four weeks in 2011 and this is also the long-term median time for acceptance since the current provisions came into effect.

Figure 6.3: Processing Times and Volume of Accepted Extension of Term Applications¹²⁹



The estimated average cost of administering the extension of term scheme is \$809.64 per application including time taken to process applications and hearings where applicable.¹³⁰

There were 599 applications, including those accepted or refused, from the commencement of the current scheme in 1999 to October 2012 giving an estimated total administrative cost for the scheme of \$484,974 to October 2012.

¹²⁹ IP Australia data.

¹³⁰ IP Australia data.

There were 227 applications in total in 1999 due to the commencement of the scheme. Following this initial spike, the average number of applications per year from 2000 to 2011 was 28.8. Therefore, the estimated average cost of administering the extension of term scheme since 2000 is \$23,277 per year.

Based on the data above, the Panel is satisfied that the administration of the extension of term scheme is reasonably efficient.

6.7. Extensions for drugs needing greater incentives - paediatric, orphan, antibiotics

Some submissions advocate providing additional extensions of patent term for medicines where greater incentives are needed. These included medicines for paediatric indications, antibiotics and "orphan" drugs.¹³¹ The development of paediatric medicines, it was argued, presents further challenges for the industry that should be acknowledged through appropriate policies. Evidence was given of a decline in the development of antibiotics over the last 30 years and it was suggested that patent term extensions could be provided to signal to innovators that they will be given adequate opportunity to recoup their investment.

The US and Europe provide additional extensions for paediatric medicines. Under the European Supplementary Protection Certificate (SPC) scheme, an additional six month extension is available where paediatric clinical trial data is required for regulatory approval. Similarly, in the US an additional six month extension is available for pharmaceuticals in return for performing paediatric studies requested by the FDA.

However, it is questionable whether extensions of patent term in Australia are an appropriate, or even sufficient, mechanism for addressing this issue. Firstly, the Australian market is very small in comparison to the larger markets in the US and Europe. Therefore, additional market exclusivity would provide only a very small increase in the level of remuneration for pharmaceutical developers. Secondly, in the case of antibiotics, new treatments are increasingly being held in reserve as a

¹³¹ Pfizer submission, Dr David Lim submission, Merck Sharp and Dohme submission.

last resort in order to combat the issue of antibiotic resistance. Therefore, additional years of market exclusivity alone are unlikely to provide an adequate incentive for the development of new antibiotics. Moreover, as we have seen earlier in this report, a small extension will have little material impact on the estimated net present value of a potential investment in R&D at the beginning of the inventive process.

With respect to these categories of pharmaceuticals, and also personalised medicines, a more efficient approach would be to provide assistance in the form of additional grant funding or support for clinical trials that would reduce the costs of bringing these drugs to market, rather than relying on extended market monopolies to compensate companies for the cost of bringing drugs to what may only ever be a small market (as discussed in chapter 5).

6.8. Technical clarifications and corrections

6.8.1. Section 76A of the Patents Act

6.8.1.1. Current law

Section 76A of the Patents Act provides that for each approved extension of patent term, the patent holder must file a return with Department of Health and Ageing (DoHA). The return must detail the amount and origin of any Commonwealth funds spent in the R&D of the drug subject to the extension.

Section 76A of the Patents Act was introduced in 1999 at the same time as the current extension of term provisions. At the time, the government was planning to invest \$800 million over ten years to assist the pharmaceutical sector with R&D, with the intention of retaining pharmaceutical research and manufacturing in Australia.¹³² The extension of term provision was intended as a further measure to encourage investment in R&D in the pharmaceutical industry. The

¹³² Senator M. Lees, Second Reading Speech, Intellectual Property Laws Amendment Bill 1998, 9 July 1998, p.5323.

reporting requirements in s.76A were meant to assist the government to evaluate whether extensions of term were in fact achieving this objective.¹³³

In 1998, the Department of Health said that access to the information provided by patentees would be governed by the *Freedom of Information Act 1982* but that collective information would be publicly available.¹³⁴ To its knowledge, the Panel is the first to obtain such collective information.

6.8.1.2. Submissions

IPTA argues in its submission that the purpose of the provision was unclear and, as it served no useful purpose, it should be deleted.¹³⁵ Dr Jacinta Flattery-O'Brien of Shelston IP made similar comments in public hearing. A submission received from Dr Charles Lawson outlines the legislative history of s.76A. Dr Lawson submits that there was insufficient evidence to justify patent extensions of term and the s.76A requirements were introduced to help address this. He also says that the collected data should be made available to the public so that it's usefulness could be determined.¹³⁶

6.8.1.3. Analysis

There is a similar requirement to s.76A in Canadian patent law, and this provides a useful example of how data could be collated to provide information on pharmaceutical R&D. Canada's Patent Act provides that patentees must provide information about revenue, licensing and R&D expenditure to the Patent Medicine Prices Review Board (PMPRB).¹³⁷ Each year, the PMPRB must report on the percentage of R&D expenditure undertaken by pharmaceutical patentees.¹³⁸ It

¹³³ Explanatory Memorandum to the Intellectual Property Laws Amendment Bill 1997, p.9.

¹³⁴ IP Australia, *Patents Manual of Practice and Procedure, Vol. 2 National*, 3.23.13.

¹³⁵ IPTA, Submission to the Pharmaceutical Patents Review, p.13.

¹³⁶ Dr C. Lawson, Submission to the Pharmaceutical Patents Review, p.1.

¹³⁷ Patent Act, (R.S.C., 1985, c. P-4), s.88

¹³⁸ Patent Act (R.S.C., 1985, c. P-4), s.89.

should be noted that Canada does not have extension of term provisions and that this information is provided for all patented pharmaceutical products.

Reported Canadian data includes the source of R&D funding in a given year. The PMPRB Annual Report for 2011 shows that in 2011, from a total expenditure of \$991.7m, \$879.2m (88.6%) was provided from company funds, while \$28.7m (2.9%) was provided from federal and provincial governments.¹³⁹

DoHA has provided the Panel in confidence with a summary of the information provided to it under s.76A. Only 384 returns were provided to DoHA between 2000-01 and 2011-12, compared with around 500 extensions of term being granted from 1999 to 2010-11. Some returns list worldwide expenditure on R&D, or composite figures over multiple years. In only three of the 12 years collected were Commonwealth funds reported to have been spent on the R&D for the patented products.

The average total R&D spent on each patented pharmaceutical varies greatly year by year, with an overall average of only \$A1 million per return. This figure appears low. This may be because patentees have interpreted the provisions to refer to a single financial year.

The Panel considers that the information provided is of only limited value. It relates only to R&D spending on a drug that has already completed the market approval process and is unlikely to be at a stage where it is the subject of substantial R&D activity. It is also less likely to be at a stage where there is significant Government R&D funding, again because it has arguably moved beyond the early R&D and clinical trial phases that precede market approval. Providing the return places a burden on patentees that is not balanced by any significant advantage to Government or the public in terms of better understanding or evaluation of the effectiveness of the extension of term scheme.

¹³⁹ Patent Medicine Prices Review Board, Annual Report 2011, accessed at <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1625&mid=1552>.

The Panel considers that s.76A is not meeting its policy objective. The usefulness of the information currently being provided is limited and does not justify the burden placed on patentees. However, the Panel is not aware of any good sources of data on R&D spending on pharmaceuticals, including Government-funded components. Other sources for R&D spending are limited. The Australian Bureau of Statistics (ABS) reports that around \$1 billion is spent on R&D in pharmaceuticals in Australia each year.¹⁴⁰ The ABS provides a breakdown of this by source, including Government grants. However, the pharmaceutical development portion is not clearly identifiable.¹⁴¹ Figures provided to the Panel by the Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education show that virtually all of the R&D being reported by the ABS under the industry code 'Human Pharmaceutical Products Manufacturing' is being claimed under the Department's R&D Tax Concession and R&D Tax Incentive programs.

In Chapter 10 the Panel recommends that the Government establish the Pharmaceutical System Coordinating Committee (PSCC) to report annually on the effectiveness of the pharmaceutical regulatory systems. Rather than simply remove the s.76A requirements, the PSCC should assess whether they can and should be replaced with a useful reporting mechanism.

Recommendation 6.2:

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

¹⁴⁰ Australian Bureau of Statistics, *8104 – Research and Experimental Development, by Socio-Economic Objectives, Businesses, Australia, 2010-11*.

¹⁴¹ Australian Bureau of Statistics, *8104 – Research and Experimental Development, by ANZSIC06 subdivision – by source of funds, Businesses, Australia, 2010-11*.

6.9. Section 70(3) and “contains or consists”

6.9.1. Current law

In order to be eligible for an extension of term, a patent must claim a pharmaceutical substance per se or a pharmaceutical substance produced by a process involving the use of recombinant DNA technology.¹⁴²

The period of the extension is calculated based on the ‘first regulatory approval date’, which is defined in the legislation as the date on which goods “*containing, or consisting of, the substance*” are first listed on the ARTG.¹⁴³

6.9.2. Submissions

A number of submissions raise concerns that goods “containing” the patented substance could include products in which the substance is present as only an impurity or minor contaminant. If this broad interpretation of the word ‘containing’ is adopted, there will be circumstances where the period of the extension for the patented substance is calculated from the date of listing of a product that is not covered by the patent.

IPTA and others argue that this outcome is contrary to the policy intent, which is to provide an extension based on the time taken to gain regulatory approval for a product that is covered by the patent. This results in some patentees getting a foreshortened effective patent life because the first regulatory approval date will not be relevant to any substances protected by the patent.¹⁴⁴ Australia’s approach is different to the approach taken in other jurisdictions. For example, in the US an extension is based on the first regulatory approval date of the product.¹⁴⁵ The same approach is taken in the EU.¹⁴⁶

¹⁴² *Patents Act 1990* (Cth), s.70(2).

¹⁴³ *Patents Act 1990* (Cth), s.70(5).

¹⁴⁴ IPTA, Submission to the Pharmaceutical Patents Review, p.10.

¹⁴⁵ 35 USC 156(a)(5)(A).

¹⁴⁶ European Community Regulation 469/2009, Article 3(d).

Submissions refer to two court decisions, *H Lundbeck A/S v Alphaparm Pty Ltd* [2009] FCAFC 70 and *Merck & Co Inc v Arrow Pharmaceuticals Ltd* [2003] FCA 1344 to illustrate their concerns.

In *Lundbeck* the court found that an extension for the product Lexapro, a purified form of the enantiomer escitalopram, should have been based on the earlier listing of Cipramil: the racemate containing citalopram and escitalopram. Cipramil had been registered on the ARTG six years prior to the registration of Lexapro. Despite finding that escitalopram was novel and inventive in light of Cipramil the court found that the relevant date for the extension of term was the date of listing of Cipramil: Cipramil being a product 'containing' escitalopram.

In *Merck* it was held that where an earlier ARTG registration contained the substance for which an extension was sought, even as a mere impurity, it was the earlier registration that was relevant for the first regulatory approval date.

Many submissions suggest that s.70(3) should be amended so that the relevant ARTG listing is related to the product claimed by the patent. The Law Council submits:

Section 70 should be amended so that the basis for an extension is the first inclusion on the ARTG of a therapeutic good the marketing of which would otherwise infringe the claims of the relevant patent.¹⁴⁷

6.9.3. Analysis

The stated purpose of the extension of term provisions in the explanatory memorandum to the amending legislation was to compensate pharmaceutical companies for the time taken for pharmaceutical products to reach the market. It was envisaged that the provisions would provide an effective patent life that was closer to those available in other fields of technology, and would ensure that Australia had a patent system that was comparable with other developed

¹⁴⁷ Law Council of Australia, Submission to the Pharmaceutical Patents Review at [15].

nations.¹⁴⁸ In light of the *Lundbeck* and *Merck* cases, it is arguable that the provisions are inconsistent with the original intentions of the Parliament.

While the *Lundbeck* decision has been criticised for interpreting “contains” too broadly, this interpretation currently stands. The High Court of Australia considered that the approach taken was not attended with sufficient doubt to warrant grant of an application for special leave to appeal.¹⁴⁹ The question then arises as to whether the legislation should be amended to be more consistent with the original intentions.

The *Lundbeck* case can be contrasted with the position in the EU and the US, where Lundbeck has successfully obtained extensions for its enantiomer patents. In both the US and the EU, the first regulatory approval date is based on the first permitted commercial marketing or use of the product. In the US, if the drug for which an extension is sought can be considered a separate product to that of an earlier registration, and is subject to its own regulatory approval process, then generally it will be entitled to an extension of term.¹⁵⁰ The differences between Australian law and law in other jurisdictions have lead to an entirely different outcome despite the facts of a case being substantially similar.¹⁵¹

Australian law should only be amended where this is in the national interest, not simply to align with other jurisdictions. However, in the case of s.70(3), it appears that the current law has produced unintended consequences and that US and EU law tends to result in more appropriate outcomes. Under current Australian law the presence of impurities or enantiomers can limit the availability of extensions of term that from a policy perspective appear to be warranted. It can also result in extensions being obtained in reliance on an ARTG listing which bears little relation to the patented product.

¹⁴⁸ Explanatory Memorandum to the Intellectual Property Laws Amendment Bill 1997 p.4.

¹⁴⁹ *Lundbeck v Alphapharm* [2009] HCA Trans 324 at [955].

¹⁵⁰ *Ortho-McNeil Inc v Lupin Pharmaceuticals Inc*, 09-1362, (Federal Circuit, May 2010).

¹⁵¹ H. Lundbeck A/S, Submission to the Pharmaceutical Patents Review p.3.

The Panel considers that clarifying s.70(3) so that the relevant ARTG listing is related to the product claimed by the patent may result in better outcomes in certain specific cases and should reduce uncertainty. However, an amendment would only be warranted if it addressed important continuing inefficiencies and would involve negligible net costs

Draft recommendation 6.3:

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

6.10. Contributory Infringement**6.10.1. Current law**

Contributory infringement is a form of indirect infringement. In general terms, contributory infringement may occur where a person contributes to infringing conduct, or directs another party to engage in infringing conduct.

Section 117(1) of the Patents Act provides that, if use of the product by a person would infringe a patent, the supply of that product from one person to another is an infringement of the patent by the supplier, unless the supplier is the patentee or licensee of the patent.

Section 117(2) further provides that the “use of a product by a person” refers to:

- (a) the use of a product that is capable of only one reasonable use; or
- (b) any use of a product that is not “a staple commercial product”, if the supplier had reason to believe that the person would put it to that use; or
- (c) the use of the product in accordance with any instructions or any inducement to use the product, provided by the supplier.

These provisions were introduced to harmonise Australian law with its trading partners and to provide patentees with a “more effective, realistic and just

mechanism”¹⁵² to enforce their patents. It enables a patentee to take infringement action against a small number of suppliers rather than against a large number of users of the product. The criteria for contributory infringement appear to be based on recommendations made by the Industrial Property Advisory Committee¹⁵³ and the equivalent US provisions.¹⁵⁴

6.10.2. Submissions

Submissions received from the originator pharmaceutical sector indicate broad support for the existing provisions. Although the provisions are technology neutral, they are of particular importance to the pharmaceutical sector.

There is general agreement in submissions that contributory infringement provisions are particularly important in cases of method of treatment for a particular disease. For example, IPTA submits that it would be inappropriate for patentees to take infringement action against physicians or patients who were using the patented treatment method in circumstances where supply of the patented product for the claimed use had been made by a third party.¹⁵⁵

GMIA submits that s.117 needs to be amended to ensure that where the approved product information does not include a patented use as a treatment indication, and does not otherwise recommend the use of a product in an infringing manner, the use of the non-patented indication does not amount to infringement. This is commonly referred to as a “carve out”.¹⁵⁶ The use of a carve out is currently sufficient to avoid liability for patent infringement in the EU¹⁵⁷ and

¹⁵² Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, Canberra, 1984.

¹⁵³ Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, Canberra, 1984.

¹⁵⁴ 35 USC 271(c).

¹⁵⁵ IPTA, Submission to the Pharmaceutical Patents Review, p.18.

¹⁵⁶ GMIA, Submission to the Pharmaceutical Patents Review, p.35.

¹⁵⁷ European Community Directive 2001/83/EC, Article 11.

the US.¹⁵⁸ This was recently confirmed in the case of *AstraZeneca Pharm LP v Apotex Corp.*¹⁵⁹

The result of a carve out is that a generic manufacturer can supply a drug for a treatment indication which is not covered by a patent without being liable for infringement of a patent covering another indication for the drug.

Submissions from originator companies also support the use of carve outs. Novartis submits that where a supplier has taken reasonable steps to ensure a product is not put to an infringing use, such as carving out a particular indication, then this should be prima facie evidence that a supplier is not engaged in infringing conduct. This would not, however, preclude the patentee from arguing that there was in fact an infringing use of the product, irrespective of any carve out.¹⁶⁰

Additional concerns have been raised about the drafting of the legislation and the meaning of “staple commercial product”. Both generic manufacturers and originators seek clarification of this term and are concerned about the judicial interpretation of it in the recent decision of *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2)* [2012] FCAFC 102.

According to the courts’ interpretation, most pharmaceuticals would not be considered to be staple commercial products because they would only have a small number of uses. Contributory infringement will therefore often be a question of whether a generic manufacturer had reason to believe that the end user would use the product in an infringing way, even where the product information does not include that use. It should be noted that this matter is currently on appeal before the High Court of Australia.

¹⁵⁸ 21 USC 355(j).

¹⁵⁹ 669 F.3d 1370 (Fed.Cir.2012).

¹⁶⁰ Novartis, Submission to the Pharmaceutical Patents Review, p. 4.

6.10.3. Analysis

The current contributory infringement provisions are unclear and lead to uncertainty for both patentees and generic manufacturers.

Patentees should be able to continue to take action against suppliers who have clearly directed a user to use a patented product in an infringing manner. However, where a product has patented and unpatented indications, a supplier should be able to supply the product for the unpatented indications without fear of infringing. Without this, originators may be able to prevent generics from supplying products for treatments that are off patent by obtaining patents for new treatments using the same drug.

The Panel supports the use of carve outs to provide greater certainty for originators and generic manufacturers. The legislation should be amended to provide that, in the absence of clear directions from a supplier to use a product in an infringing manner, the supply of the product with instructions that only direct a person to use it in non-infringing ways will not amount to infringement.

Supplying product information specifying that the product should only be used for a non-patented indication should be considered to be taking a “reasonable step” for the purposes of avoiding infringement actions. Other “reasonable steps” may include package labelling and advertising material clearly stating the non-infringing purposes for which the product can be used. Ultimately what constitutes a “reasonable step” will depend on the circumstances, and in the event of any infringement proceedings, would be a matter for the court. However policy can reduce uncertainty by providing ‘deemed to comply’ status to certain practices. Thus for instance policy should specify that clear labelling of indications which does not include infringing uses will create a presumption against contributory infringement.

If a carve out is introduced, the Panel considers that there is sufficient guidance in court decisions regarding the meaning of “staple commercial product” and is not persuaded that further change to the legislation is required on this issue.

Recommendation 6.4:

Section 117 of the Patents Act should be amended to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement where reasonable steps have been taken to ensure that the product will only be used in a non-infringing manner. Policy should further impose a presumption that “reasonable steps” have been taken where the product has been labelled with indications which do not include any infringing indications.

6.11. Types of pharmaceutical inventions that can be extended

6.11.1. Pharmaceutical substance per se

6.11.1.1. Current law

Section 70(2) of the Patents Act provides that an extension of term can only be granted for a “pharmaceutical substance per se”, or for one or more “pharmaceutical substances when produced by a process involving the use of recombinant DNA technology.”¹⁶¹

A pharmaceutical substance is defined in Schedule 1 of the Act as:

A substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:

- (a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or
- (b) action on an infectious agent, or on a toxin or other poison, in a human body;

but does not include a substance that is solely for use in *in vitro* diagnosis or *in vitro* testing.

¹⁶¹ *Patents Act 1990* (Cth), s.70(2).

The purpose of this was to limit extensions to pharmaceutical substances and not delivery systems, new uses of known pharmaceutical substances, or methods of manufacturing a pharmaceutical substance.¹⁶²

6.11.1.2. Submissions

Concerns are raised in submissions about the meaning of the term “pharmaceutical substance per se”. For example, the Law Council of Australia submits that the complexity of the provisions has led to inconsistent interpretation in the decisions of the Australian Patent Office and the courts.¹⁶³ GMIA submits that judicial interpretation of the phrase “pharmaceutical substance per se” has led to a broad definition that encompasses items which might otherwise not be considered a pure pharmaceutical substance, such as a layered bi-phasic tablet and a thermoplastic ring adapted to the slow release of a steroidal mixture.¹⁶⁴

6.11.2. Judicial interpretation

6.11.2.1. The meaning of substance per se

The case of *Boehringer v Commissioner of Patents* was an appeal from a single judge of the Federal Court to the Full Federal Court.¹⁶⁵ The single judge’s decision was the first to consider the construction of s.70(2)(a).¹⁶⁶

The patent in question claimed a container comprising an aerosol or spray composition for nasal administration of a pharmaceutical substance. The court concluded that an extension of term would only be available for new and inventive substances where the claim is for a pharmaceutical substance as such,

¹⁶² Explanatory Memorandum to the Intellectual Property Laws Amendment Bill 1997, p.18.

¹⁶³ Law Council of Australia, Submission to the Pharmaceutical Patents Review at [2]–[8].

¹⁶⁴ GMIA, Submission to the Pharmaceutical Patents Review, p.17.

¹⁶⁵ *Boehringer Ingelheim International v Commissioner of Patents* [2001] FCA 647.

¹⁶⁶ *Boehringer Ingelheim International GmbH v Commissioner of Patents* [2000] FCA 1918.

as opposed to a substance forming part of a method or process. The court held that it was the legislative intention of the parliament to foster primary R&D in new and inventive pharmaceutical substances, and not the way such substances are made or used. As the patent was for a mode of treatment involving the pharmaceutical substance, it did not satisfy s.70(2)(a).

6.11.2.2. Method and process claims

In *Prejay Holdings & Anor v Commissioner of Patents*,¹⁶⁷ the Full Federal Court considered whether a method of treatment could be considered a pharmaceutical substance per se. The patent in question claimed a method of treating menopausal disorders using a pharmaceutical substance known as Premia, which was administered in continuous and uninterrupted dosage units.

The court followed the reasoning established in *Boehringer*, finding that the claim was a method of use and not a pharmaceutical substance per se. The court also held that a pharmaceutical substance per se must itself be the subject of a claim in the relevant patent. As such, a substance claimed only in the context of a claim for a method or process does not satisfy s.70(2)(a). The court stated that the policy adopted in s.70 was to confine extensions to patents that claim the invention of the substance itself.

6.11.2.3. Inconsistency in judicial decisions

GMIA submits that inconsistency in the subsequent application of the principles established in *Boehringer* and *Prejay* have led to a broadening in scope of the extensions.¹⁶⁸ Two cases that are often given as examples are discussed below.

6.11.2.4. N.V. Organon

This IP Australia decision found that a thermoplastic ring used to deliver a slow release steroidal formulation for contraceptive purposes was a pharmaceutical substance per se. The hearing officer considered that the diffusion of active ingredients (which were not new) through the thermoplastic materials in the core and skin regions conferred a level of integration or interaction between the

¹⁶⁷ *Prejay Holdings & Anor v Commissioner of Patents* (2003) 57 IPR 424.

¹⁶⁸ GMIA, Submission to the Pharmaceutical Patents Review, p.16.

component parts that was considered more characteristic of a pharmaceutical substance of itself, rather than a pharmaceutical substance combined with another element or thing.

This decision has been criticised as incorrect.¹⁶⁹ It was expressly disapproved by the AAT in *Lohmann*,¹⁷⁰ with the Tribunal finding the decision was inconsistent with previous judicial reasoning on the issue. The AAT found that it is the active ingredient in a product, rather than the product as a whole, which is considered the pharmaceutical substance for the purposes of s.70(2)(a). The AAT found that the correct characterisation of the patent claim was as a new method of delivery of known active ingredients.

6.11.2.5. Sanofi Aventis¹⁷¹

This IP Australia decision found that a bi-layered tablet comprising an immediate release layer and a prolonged release layer was a pharmaceutical substance per se. The hearing officer found that the combination of the layers formed a pharmaceutical compound and that therefore the tablet was a pharmaceutical substance per se. The two layers brought the mixtures into a form suitable for administration and it was the combination of the layers that gave the compound its effectiveness. The hearing officer concluded that it was the synergistic combination of the layers which provided the essence of the invention, and therefore that it was a new and inventive pharmaceutical substance per se.

A number of commentators have criticised this decision, arguing that the proper characterisation of the claim was as a method of administration, not a

¹⁶⁹ G.McGowan and B. Fitzpatrick, 'Pharmaceutical Extension Law in the 21st Century', *Intellectual Property Forum*, 8 March 2012, pp.69-76; P.Sands and E.Iles, 'Patent term extensions in Australia', *Intellectual Property Law Bulletin*, Volume 24, No.2, June 2011, pp.35-38.

¹⁷⁰ *Re LTS Lohmann Therapie Systeme AG & Schwarz Pharma Ltd v Commissioner of Patents* (2010) 118 ALD 425; [2010] AATA 809.

¹⁷¹ [2007] APO 35.

pharmaceutical substance per se.¹⁷² The decision in *Sanofi* has not been considered by a higher court.

6.11.2.6. Analysis

The Panel considers that the decisions in *Boehringer* and *Prejay* appear consistent with the original policy intent of the legislation. These decisions have been affirmed many times and have not been overturned. However, the IP Australia decisions of *Sanofi* and *NV Organon* show that interpreting the term “pharmaceutical substance per se” can be complex. Both of the decisions have been the subject of substantial criticism. Considering the decision of the AAT in *Lohmann*, it appears unlikely that *NV Organon* would have survived further challenge in a higher court. It is less clear whether the *Sanofi* decision would be considered incorrect by a higher court.

Originator companies argue that consideration should be given to whether Australia’s legislation should be amended to be similar to that in the EU and the US. The Panel considers that this would broaden the scope of products that are currently eligible for an extension and this issue is discussed below. Given the complexity of pharmaceutical technology, there would be some advantage to maintaining the status quo. A new definition could create new uncertainty until interpreted by the courts.

The Panel is of the view that the courts have provided sufficient direction on the meaning of the term “pharmaceutical substance per se” and that the principles established by the Federal Court are consistent with the policy intent of the legislation. The Panel does not support any change to the current legislation.

¹⁷² For example, G.McGowan and B. Fitzpatrick, ‘Pharmaceutical Extension Law in the 21st Century’, *Intellectual Property Forum*, 8 March 2012, pp.69-76, p.73.

6.11.3. Scope of pharmaceutical inventions eligible for extensions

6.11.3.1. Submissions

As discussed above, extensions are available for pharmaceutical substances and new formulations, but not for methods of use or processes to manufacture a pharmaceutical substance.

Submissions from originator companies argue that the scope of extensions should be broadened to include methods of use and methods of manufacture. This is because it can take significant time to develop new indications and obtain regulatory approval for them. Originators also argue that broadening the scope of the extensions would bring Australia's legislation and practice into alignment with major trading partners such as the USA and the EU.¹⁷³ In both the US and the EU an extension is available for a wider range of pharmaceutical products. For example, in the US, an extension can be obtained for an active pharmaceutical ingredient (API), a method of using an API, or a process to manufacture an API.¹⁷⁴ The EU also permits extensions of term for an application of the pharmaceutical substance, or a process to obtain the substance.¹⁷⁵

Submissions from generic manufacturers oppose any broadening of extensions to methods of use or manufacture. They argue that a new treatment method has a shorter development and regulatory approval time, and therefore should not be entitled to an extension.¹⁷⁶ Generic manufacturers also submit that it would be inconsistent with the legislative intention to allow extensions for new methods of use and manufacture.¹⁷⁷

6.11.3.2. Analysis

The Panel considers that the policy intention of the provisions is clear and that the narrow approach taken in the case law is consistent with Australia's national interest and the original policy intent. No evidence has been provided to the

¹⁷³ H.Lundbeck A/S, Submission to the Pharmaceutical Patents Review, p.5.

¹⁷⁴ 35 USC 156(a).

¹⁷⁵ European Community Regulation 469/2009, Article 1(c).

¹⁷⁶ GMIA, Submission to the Pharmaceutical Patents Review, p.16.

¹⁷⁷ GMIA, Submission to the Pharmaceutical Patents Review, p.16.

Panel to demonstrate that the development and marketing of new methods of use and manufacture of pharmaceuticals in Australia is adversely affected by such inventions being ineligible for an extension of patent term. Where it is not clear that change is in the national interest, there is no merit in adopting overseas practices for the sake of aligning our policies and laws with those of other countries.

7. Evergreening and follow-on patents

The term ‘evergreening’ has no generally agreed definition. It is not a term originating from or commonly used in patent law. Rather, it is often used in literature to describe the utilisation of patent law and regulations, in order to maximise or extend the protection surrounding intellectual property.¹⁷⁸ Although the concept is not limited to any particular technology, it is most commonly used in relation to the pharmaceutical industry and in reference to strategies employed by originator pharmaceutical companies to prolong patent royalties over high-earning drugs.¹⁷⁹ It is important to note that the term ‘evergreening’ is not used in this report in a pejorative way; rather it is used to describe the legitimate patenting and business strategies that pharmaceutical companies use to maintain their dominant share of a drug market.

Evergreening can be used to extend both the breadth and duration of patent rights. A common evergreening strategy is the accumulation of multiple patents surrounding a single pharmaceutical product. These “follow-on” patents are generally directed towards various embodiments of the original active pharmaceutical ingredient (API) and may cover new formulations, derivatives, delivery systems, methods of use and methods of production. In terms of breadth, the presence of multiple patents with over-lapping scope around a single product may contribute to so-called “patent thickets”. Such a strategy can be effective in obstructing the entry of competitors into the market by reducing and rendering uncertain the space in which they may operate. Furthermore, as follow-on patents have a later expiry date than the original patent, these patents may extend the duration of the patent protection awarded to a single pharmaceutical product.

¹⁷⁸ Varying definitions are provided in: Faunce, T. & Lexchin, J. Australia and New Zealand Health Policy, 2007, 4:8; Bansal, I.S. et al. Journal of Intellectual Property Rights, 2009, 14: 299; Thomas, J.R. CRS Report for Congress R40917, 2009 (http://www.ipmall.info/hosted_resources/crs/R40917_091113.pdf).

¹⁷⁹ Ibid.

In addition to the accumulation of a patent portfolio, a number of business and marketing strategies have been associated with evergreening in the pharmaceutical industry. A commonly cited example of this is life-cycle management (including what has been called prescription switching), in which an originator pharmaceutical company uses marketing processes to extend the life of the original pharmaceutical. Prescription switching occurs when prescribers are invited to switch prescriptions from an older variety of a drug in which the patent is due to expire, to a new – patent protected – variety,¹⁸⁰ the intentions being to reduce demand for generic versions of the original pharmaceutical and to extend the period of market exclusivity available to the originator pharmaceutical company.

Views on the extent and validity of evergreening practices in the pharmaceutical industry are polarised. One particular view is that originator pharmaceutical companies game the patent system to prolong patent protection and delay market entry of generic drugs. This behaviour increases the cost of pharmaceuticals (particularly to the Government) and delays the entry of more affordable generic versions, which in turn affects the profitability of the Australian generic pharmaceutical industry.¹⁸¹

On the other hand, maintaining a patent portfolio is an essential element of the business strategy of any company operating within the IP system. To this extent, originator pharmaceutical companies are legitimately using the patent system to protect and enforce their IP rights.¹⁸²

This chapter refers to original (i.e. first), and later patents filed in relation to the same pharmaceutical substance. For the sake of clarity and conciseness, the

¹⁸⁰ Thomas, J.R. CRS Report for Congress R40917, 2009
(http://www.ipmall.info/hosted_resources/crs/R40917_091113.pdf);
Submissions by Alphapharm, GMiA, Dr. Hazel Moir.

¹⁸¹ These views are reflected in submissions received by Alphapharm, GMiA, Dr. Hazel Moir, AFTINET.

¹⁸² Views reflected in submissions from originator pharmaceutical companies and IP professionals.

terms 'original patent' and 'follow-on patent' will be used. Original patent refers to the first patent application disclosing the active pharmaceutical ingredient (API). Follow-on patent will refer to any subsequently filed patent directed towards that API. Thus, the term follow-on patent provides an indication of time-frame only and is not intended to impart any observations regarding the quality or validity of such patents.

7.1. Patentability standards

A commonly voiced concern in submissions to this inquiry, and in discussions of evergreening and follow-on patents, is that patent standards are too low, particularly in relation to incremental or cumulative improvements upon previous technology or products.¹⁸³ Such criticisms of patentability standards are often directed towards the level of inventiveness required (i.e. inventive step) for the grant of a patent.

With regard to pharmaceutical patents, the consequence of low patentability thresholds can be the grant of low quality patents for minor modifications of existing drug products, which do not provide any advance over the existing product.¹⁸⁴ The ability to gain such patents may permit originator pharmaceutical companies to accrue large numbers of follow-on patents in relation to a single drug product.

In order to be patentable, an invention must satisfy a number of criteria:

- **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

¹⁸³ Submissions from GMiA, Alphapharm, Dr. Hazel Moir, AFTINET.

¹⁸⁴ Submissions from, for example, Alphapharm, GMiA, Dr. Hazel Moir.

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 will achieve 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 that which is disclosed to the public and that patents are not granted for trivial or obvious improvements.

The GMiA submission provides a summary of the effect of the granting of low-quality patents:

When a “bad” patent (i.e. one which on a robust assessment is not valid) is granted by the APO, the following occurs:

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

considering this to be relevant to a prima facie assessment of patent validity¹⁸⁵.

Where appropriate rigour is not applied at the APO level, the public health consequences are very significant. The supply of generic medicines is wrongly delayed in Australia, and the cost to the PBS and the public is very significant.¹⁸⁶

7.1.1. Raising the bar

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. These changes are also intended to better align Australian standards with standards elsewhere.

These amendments are the result of extensive consultation with stakeholders and applicable to all technologies, including pharmaceuticals. The higher thresholds commence in April 2013 and generally apply to patent applications for which a request for examination is made after commencement.

The Act raises patent standards in three important areas:

1. **disclosure and utility** – there must be sufficient information disclosed for the public to make and use the invention. In addition, a specific, substantial and credible use for the invention must be disclosed.
2. **inventive step** – all published information is taken into account during the examination of a patent and is assessed against background knowledge of a skilled person, regardless of where that person resides.
3. **standard of proof** – a consistent standard of proof is applied in all decisions. The Commissioner must be satisfied, on the ‘balance of probabilities’, that a patent, if granted, will be valid.

¹⁸⁵ See Yates J in *Novartis AG v Hospira Pty Ltd* [2012] FCA 1055 (28 September 2012) paragraphs 51, and 92 – 94.

¹⁸⁶ GMiA Public Submission, p. 30.

These changes will make it harder for applicants to obtain patents for trivial advances or obvious variations, thereby limiting the opportunities for patent portfolio-type evergreening.

Submissions received in relation to the Raising the Bar amendments are generally positive. Originator pharmaceutical companies welcome moves to provide strong and valid IP protection for their property.¹⁸⁷ Similarly, generic companies acknowledge attempts to achieve the right balance between strong IP rights, the encouragement of innovation and the interests of both patentees and society as a whole.¹⁸⁸

However, a further consensus is that these higher thresholds will need to be in place for a significant period of time before their effect can be determined. These standards will only apply to applications for which examination is requested on or after 15 April 2013. As the effects of evergreening practices are generally observed towards the end of the life of a patent, it may be a number of years before the impact of Raising the Bar on the pharmaceutical system can be determined. It would therefore be premature to suggest any changes within this area at this time.¹⁸⁹

In view of the time periods involved, the Panel considers that it would be prudent to review the effectiveness of the Raising the Bar amendments at the earliest date feasible. A full analysis of the effects of the new provisions should be undertaken by the Productivity Commission. The panel considers that three years, following the commencement of the Raising the Bar Act, should be sufficient time to gather evidence for a review.

Draft Recommendation 7.1

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

¹⁸⁷ Submissions by Amgen, Medicines Australia, Bristol-Myers Squibb, Merck Sharpe & Dohme, Novartis.

¹⁸⁸ GMiA public submission, p. 22.

¹⁸⁹ This view is also reflected within many submissions.

7.1.2. Other means for improving patent quality

The grant of low quality patents may not only be a result of the existing legislation, but could also be a result of the application of this law by IP Australia.

Submissions from GMiA and Alphapharm suggest that quality issues in the patent examination process may be contributing to the grant of low quality patents.

The Panel is aware of the existence of quality systems within IP Australia which are specifically aimed at improving the quality of the examination process.¹⁹⁰ However, other than the review of office decisions provided by courts (in the few cases that are taken to such a level), there appears to be a lack of any external and continuing review of patent grants and decisions applied by IP Australia.

The Panel considers that an external auditing process would be of benefit in this regard. The grant of poor quality pharmaceutical patents can cost the Government significant money in PBS subsidies. The establishment of an external auditing committee would be a small cost in comparison to the potential savings that could occur through the associated improvement in, and maintenance of, patent quality.

It is envisaged that such a committee could review patent grants and decisions issued by IP Australia. The audit committee could further monitor judgments from the courts and play a role in shaping future patent law reforms and policy.

Draft Recommendation 7.2:

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

7.2. Evergreening strategies and concerns

A key concern about evergreening strategies is that they delay the entry of generic drugs to the market. Unreasonable delays to generic entry may have significant effects, including increased costs to the consumer and the Government

¹⁹⁰ <http://www.ipaustralia.gov.au/about-us/corporate/quality/iso-certification/>.

via delays in PBS subsidy price reductions and loss of revenue for generic pharmaceutical companies, as discussed in chapter 5.

A 2009 European Commission report investigating competition in the pharmaceutical sector found that originator pharmaceutical companies use a variety of practices to prolong the commercial life of their products and that the cumulative use of these practices contributes to delays in generic entry into the market.¹⁹¹

The practices cited in the EU Commission report include:

- patent filing strategies and specifically, the filing of numerous patent applications for the same medicine, forming patent thickets or clusters;
- patent litigation, particularly in relation to “secondary” patents¹⁹² to prevent generic market entry; and
- life-cycle management strategies, which include the progression or switch to a second generation pharmaceutical covered by later patents.

The report also noted the extent to which various strategies were used depended on the commercial importance of the pharmaceutical, with more strategies being used in relation to the highest selling medicines.¹⁹³

The findings of the EU Commission report appear to have some bearing on the Australian pharmaceutical industry. Each of the points summarised above has been raised as a concern in submissions received by the Panel.¹⁹⁴

GMiA submits that follow-on patents are being used to delay the entry of generic medicines following the expiration of the original patent. Furthermore, GMiA

¹⁹¹ EU Commission Pharmaceutical Sector Inquiry Report – 8 July 2009, p. 10-15.

¹⁹² Referred to as follow-on patents in this report.

¹⁹³ EU Commission Pharmaceutical Sector Inquiry Report – 8 July 2009, page 15.

¹⁹⁴ Submissions provided by GMiA, Alphapharm, Dr. Hazel Moir and AFTINET each express concern about the purported use of evergreening tactics by originator pharmaceutical companies.

states that the density of patent thickets is a pertinent consideration for generic companies attempting to enter the market, as litigation costs and compounded risks increase exponentially with each additional potentially relevant patent.¹⁹⁵

Alphapharm has provided its own interpretation of the term evergreening, wherein it is “understood to mean the extension of patent protection around a medicine or related medicine(s) beyond 25 years from the date the API is patent protected in Australia”.¹⁹⁶ Relying on this definition, Alphapharm has provided a number of examples of pharmaceuticals which meet its criteria of having patent protection beyond 25 years.

Specific examples cited by Alphapharm include: Losec (omeprazole) and Nexium (esomeprazole), which are claimed to have over 48 years of patent protection; Cipramil (citalopram) and Lexapro (escitalopram), which are claimed to have over 46 years of patent protection; and Fosamax (alendronate), which is claimed to have over 36 years of patent protection.¹⁹⁷

Alphapharm also cites Efexor (venlafaxine), Efexor-XR (venlafaxine extended-release) and Pristiq (desvenlafaxine) as an example of the use of marketing tactics for the purpose of evergreening, wherein it is claimed that “doctors are encouraged through marketing to prescribe the newer medicine (more expensive) instead of the older medicine (less expensive)”.¹⁹⁸

Representatives of the originator pharmaceutical industry express concerns over the use of so-called pejorative terms, such as evergreening, follow-on/secondary patents and patent thickets, for describing legitimate business and patenting strategies that are conducted within the legal framework of the patent system and which are no different to the practices employed in other technological areas. Particular emphasis is placed on the term “evergreening” when used in the context of follow-on patents. A number of submissions note that follow-on

¹⁹⁵ GMiA public submission, pages 44-46.

¹⁹⁶ Alphapharm public submission, p. 4.

¹⁹⁷ Alphapharm public submission, p. 7.

¹⁹⁸ Ibid.

patents have no less merit than any other patent, because they are required to meet the same patentability thresholds.¹⁹⁹ Members of the IP profession also voice similar concerns.²⁰⁰

7.3. Follow-on patenting and patent thickets

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 original patent protects the invention and provides a degree of market certainty that makes further development of the product worthwhile.

After initial patenting, considerable development may still be required before the product can gain regulatory approval to be marketed. During this development period, further patent applications may be filed. These further applications can contain variations of the originally filed invention that provide improvements or solve problems not envisaged at the original time of filing.

In this context, such follow-on patenting is a legitimate use of the patent system. Cumulative innovation is one of the tenets of the patent system and indeed, science as a whole. While these patents may prevent competitor entry into the market, this is the nature of IP protection. Furthermore, while patent protection may be used to exclude innovation by others,²⁰¹ “inventing around” a patent can lead to new innovation, which of itself may be worthy of patent protection.

Submissions to the Panel debate the degree to which follow-on patents restrict market entry of generic versions of originally patented technology. For example, IPTA submits that follow-on patents do not interfere with the manufacture and use of drugs described in the original patent.²⁰² GMiA argues this point, stating “it is certainly not correct that follow-on patents do not prevent generic versions of the original drug from entering the market”.²⁰³ GMiA further presents a table

¹⁹⁹ Bristol-Myers Squibb, Medicines Australia, AIPPI, Amgen, MSD submissions.

²⁰⁰ IPTA, Law Council of Australia.

²⁰¹ Within the scope of the claims and without the permission of the patentee.

²⁰² IPTA submission, p. 18.

²⁰³ GMiA public submission, p. 44.

providing 12 instances wherein follow-on patents were used to gain court-ordered injunctions and delay generic entry.²⁰⁴

A number of submissions received by the Panel argue that low patentability standards are permitting the grant of low quality patents over non-inventive variations of an original pharmaceutical product. They argue that ease with which originator pharmaceutical companies can obtain these patents over trivial modifications increases the number of follow-on patents surrounding a single product and that this is a major contributor to the patent density surrounding pharmaceuticals.²⁰⁵

7.3.1. Patent thickets

The European Patent Office recently published a report from a workshop focussing on patent thickets.²⁰⁶ In their definition of a patent thicket, the authors included the criteria that multiple patents for similar technology need be held by multiple parties.²⁰⁷ Furthermore, they suggested that it is the blocking effects of these multiple overlapping patents, held by multiple parties, that contribute to a patent thicket.

The report further discussed literature distinguishing between complex and discrete technologies²⁰⁸ and provided data indicating that patent thickets are significantly more likely to occur in complex technologies. The chemical and

²⁰⁴ GMiA public submission, Table 3.

²⁰⁵ Submissions by GMiA, Alphapharm, Dr. Hazel Moir, AFTINET.

²⁰⁶ EPO Economic and Scientific Advisory Board Workshop on Patent Thickets, 2013

([http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/\\$FILE/workshop_patent_thickets_en.pdf](http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/$FILE/workshop_patent_thickets_en.pdf)).

²⁰⁷ Ibid - A patent thicket usually involves (1) multiple patents on (2) the same, similar, or complementary technologies, (3) held by different parties, making it difficult to negotiate intellectual property rights (for example, licensing agreements) to the point where some scholars feel it might be socially inefficient.

²⁰⁸ The distinction between complex and discrete technologies is explained in terms of patented products (or processes) requiring the marketing of few "patentable elements" (discrete) or many such elements (complex).

pharmaceutical technology sectors were specifically listed as examples of discrete technologies and it was stated that in the pharmaceutical industry, “thickets were thought to be less prevalent and less problematic”.²⁰⁹

The Panel considers that the submissions do not support a case for the presence of pharmaceutical patent thickets in Australia. The “patent thickets” described in submissions to the Panel generally referred to the patent portfolio of a single originator company in relation to a single pharmaceutical. This type of portfolio does not fall within the meaning of a patent thicket as summarised above, and certainly does not appear to be comparable to voluminous patent thickets commonly discussed with regard to software and electronics, particularly in the US patent system.

The Panel, however, does not wish to undermine the concerns expressed in submissions regarding this area and notes these concerns generally echo those presented in the EPO report in relation to patent thickets:

patent thickets raise entry costs for new entrants, reducing the system's benefits for society. In such a situation, it is argued that strategic use of the patent system by applicants may be interfering with the goals of the system, by obliging innovators to spend inordinate resources on transaction costs to bring new technology that builds on prior work to market.²¹⁰

The strategic use of the patent system, as referred to above, is a key point. The patent system is highly complex and regardless of whether or not patent thickets are actually present, the ability of companies to employ such strategic behaviours should be the focus of discussion. This point is expanded upon in the Analysis section of this Chapter.

²⁰⁹ Ibid - In comparison to complex technologies such as electronics semi-conductors. Page 8, Annex 1 – Figure 3.

²¹⁰ Ibid - page 5.

This report will address further discussion of this issue in terms of original and follow-on patents, rather than as “thickets”: the meaning of which clearly differs between various interested parties.

7.3.2. Case studies

Certain pharmaceuticals have been raised in multiple submissions as examples of evergreening practices. A summary of two of these examples, venlafaxine and omeprazole, is provided below.

Venlafaxine/Desvenlafaxine

Venlafaxine is the API in the antidepressant marketed as EFEXOR.

The original patent 567524 was filed in 1983, granted in 1988 and expired in 2008, having been granted an extension of term of 5 years. The patent is directed towards a related group of chemical compounds characterised by a generalised formula, one of which is venlafaxine. EFEXOR was first registered on the ARTG in 1994, eleven years after it was first patented. This gave EFEXOR an effective marketing life of 14 years.

The key follow-on patents are 727653 and 2002250058.

Follow-on patent 727653, directed towards a specific extended release formulation, was filed in 1997, granted in 2001 and will expire in 2017. Extended release venlafaxine was marketed as EFEXOR-XR after gaining ARTG inclusion in 1998. The drug was listed on the PBS in 2005.²¹¹

²¹¹ A second follow-on patent 2003259586 (divisional status derived from 727653) directed to a method of using venlafaxine formulation resulting in extended release of drug was partially revoked. Wyeth may have to pay compensation arising from interlocutory injunctions they obtained in 2009

Follow-on patent 2002250058, directed towards desvenlafaxine, was filed in 2002, granted²¹² in 2008 and will expire in 2023, having gained an extension of term of 1.52 years. Desvenlafaxine is the active metabolite of venlafaxine and is marketed as PRISTIQ.

Alphapharm submits that venlafaxine related medicines enjoy undue market exclusivity of over 39 years.²¹³

The Panel has seen no evidence to suggest that the EFEXOR-XR (extended release) and PRISTIQ (desvenlafaxine) patents restricted generic versions of venlafaxine from entering the market once the original Efexor patent expired. Rather, it is possible that the removal of the original Efexor pharmaceutical from the ARTG was a strategy for preventing any generics from relying upon this listing for bioequivalent registration.²¹⁴ This issue, however, has already been addressed by the TGA and such practices are no longer possible.²¹⁵

Extended release venlafaxine generics are available on the market, as generic companies are able to use alternative release formulations not covered by the EFEXOR-XR formulation patent. Similarly, any remaining follow-on patents relating to venlafaxine/desvenlafaxine were apparently unable to provide any barrier to generic marketing of extended release venlafaxine. It would therefore appear that claims of 39 years of market exclusivity are somewhat overstated.²¹⁶

²¹² The patent was granted on the basis of a particular succinate salt, which is stated in specification as having improved bioavailability compared to previously disclosed fumarate salts.

²¹³ Alphapharm public submission, page 14.

²¹⁴ Such practices were referred to in Dr. Hazel Moir's submission, page 11. Bioequivalency is discussed further in Chapter 9.

²¹⁵ The Therapeutic Goods Regulations were amended such that generic drugs wishing to gain ARTG entry on the basis of bioequivalency can rely on any previous listing, even if it is no longer on the Register - *Therapeutic Goods Amendment Regulation 2012 (No. 3) - Schedule 9, Part 1, subitem 1(1)*.

²¹⁶ However, the Panel notes that the entry of these generics was only made possible following the successful challenge of the 2003259586 patent. This patent

The Panel considers, however, that there do appear to be life-cycle management strategies utilised in this instance. Alphapharm asserts that there is no improved health outcome of Efexor-XR over Efexor, nor any improved health outcome of Pristiq over Efexor, and further submits that a shift in prescriptions has occurred as a result of marketing campaigns directed towards physicians.²¹⁷ Further discussion of these strategies is included in the Analysis section of this Chapter.

Omeprazole/Esomeprazole

Omeprazole and Esomeprazole are structurally related compounds. Omeprazole is the API in LOSEC, a drug for treating gastrointestinal disorders.

The original patent 529654 was filed in 1979, granted in 1984 and expired in 1999. The patent is directed to a large group of chemical compounds characterised by a generalised formula, one of which is omeprazole. LOSEC was approved for marketing in 1988.

Esomeprazole is the S-enantiomer of omeprazole and is marketed as NEXIUM. NEXIUM was approved for marketing in 2001.

The key follow-on patents are 563842, 601974, 676337 and 695966.

Follow-on patent 563842, directed towards omeprazole salts, was filed in 1984, granted in 1987 and expired in 2009, having been granted an extension of 5 years.²¹⁸

Follow-on patent 601974, directed towards a specific oral formulation of omeprazole or salts thereof, was filed in 1987, granted in 1991 and expired in

broadly covered any method of extending the release of the drug, but the court ruled they were only entitled to specific embodiments. Issues surrounding patent challenges are addressed Chapter 8.

²¹⁷ Alphapharm public submission, page 7.

²¹⁸ The patent was extended based on Nexium (Esomeprazole magnesium trihydrate) though the patent did not disclose any specific enantiomer of omeprazole.

2007. Generally accepted as the patent protecting LOSEC, this patent was challenged and the validity was upheld in the High Court. Broad level generic entry did not occur until expiry of this patent.

Follow-on patent 676337, directed towards esomeprazole salts, was filed in 1994, granted in 1997 and will expire on 27 May 2014. This was the first patent to disclose the S-enantiomer of omeprazole.

Follow-on patent 695966, directed towards multiple unit tablet formulations of omeprazole/esomeprazole, was filed in 1995, granted in 1998 and will expire on 7 June 2015.

Ranbaxy has applied to the Court for revocation of the 676337 and 695966 patents. AstraZeneca cross-claimed for infringement and was granted interlocutory injunction.²¹⁹ The matter is yet to be decided in the Court.

The combination drug Vimovo, comprising esomeprazole and naproxen, is the subject of three patents. These three patents were granted to Pozen, Inc. Despite the patents being owned by a third-party, Astra Zeneca sponsored the introduction of the pharmaceutical to the ARTG, presumably under a co-licensing agreement.

Patenting practices that take place during pharmaceutical development have previously been discussed in section 7.3 of this Chapter. The development of omeprazole appears to be an example of where multiple patents are filed during

²¹⁹ VID 1008/2011 Federal Court order dated 23 February 2012 - Upon Astra's undertaking among other things to pay reasonable compensation if Ranbaxy were successful, the Court ordered that Ranbaxy be restrained from exploiting the invention of the two patents with its product magnesium esomeprazole or applying for listing of the Ranbaxy product on the PBS, until the Court proceedings were finalised.

the development phase of a pharmaceutical, with three key patents being filed before the pharmaceutical was brought to market.²²⁰

IPTA addresses this case study in their submission. Referring to the omeprazole formulation patent,²²¹ IPTA states:

This case study illustrates the important work carried out by pharmaceutical formulation scientists in devising formulations for the delivery of active agents to their site of action. To exert its biological action, omeprazole needs to pass through the stomach and be released in the upper small intestine. Since omeprazole degrades rapidly in acid, there were difficulties involved in providing a formulation which allowed the active agent to pass through the acidic environment of the stomach. The originator eventually arrived at a formulation which achieved the desired effect and allowed the production of a commercial formulation which would achieve the desired biological effect.²²²

Bristol-Myers Squibb also summarises this type of cumulative innovation in broader terms:

research and development does not stop once the original patent applications are filed, or even once the product is launched. Innovative pharmaceutical companies engage in ongoing research and development regarding product improvements, in order to make the best form of the treatment accessible to patients. Such improvements may take the form of new formulations, improved delivery systems, methods of treatment, and new uses for known active ingredients. To the extent to which this

²²⁰ 529654 (API patent), 563842 (omeprazole alkaline salts) and 601974 (omeprazole formulation).

²²¹ 601974.

²²² IPTA submission, page 20.

ongoing research and development results in new patentable inventions, new patents are applied for.²²³

The omeprazole formulation patent (601974) was challenged and found to be valid in the High Court.²²⁴ This appears to be an example of where further innovation, following the original patent, was required in order to bring an efficacious pharmaceutical to the market. This cumulative innovation provided an advance over the existing technology at the time and, as the High Court resolved, was therefore subject matter worthy of a patent.

On the other hand, the validity of the esomeprazole patent,²²⁵ which was filed towards the end of the omeprazole API patent life, is yet to be determined judicially. As this patent is specifically directed to the S-enantiomer of omeprazole, it does not extend the patent life of the original omeprazole pharmaceutical.²²⁶ Whilst this, again, appears to be contrary to suggestions of evergreening of the original pharmaceutical patent, the Panel is of the opinion that the life-cycle management strategies at play are worthy of consideration.

The Panel notes that enantiomer patents for atorvastatin and clopidogrel have been found invalid, and revoked in recent years.²²⁷ The pending decision²²⁸ regarding the omeprazole enantiomer may provide guidance as to whether this type of follow-on innovation is considered worthy of patent protection.

The Panel considers that the issue of the inventiveness of enantiomer patents (and other patents involving modifications and improvements) warrants further

²²³ Bristol-Myers Squibb submission, paragraph 30.

²²⁴ *Aktiebolaget Hassle v Alphapharm* [2002] HCA 59.

²²⁵ 676337.

²²⁶ The entry of generic omeprazole pharmaceuticals to the market is evidence of this.

²²⁷ Albeit on different grounds – Clopidogrel patent 597784 revoked on grounds of novelty and inventive step, Atorvastatin patent revoked on grounds of false suggestion.

²²⁸ Federal Court – VID 1008/2011.

investigation and monitoring. Mechanisms for review of patent office decisions and evaluation of recent changes to inventive step are discussed at section 7.1 of this Chapter.

7.4. Follow-on patents by third-parties

Follow-on patents are usually discussed with regard to the originator pharmaceutical company which brought the pharmaceutical to the market and which, it would be expected, wishes to obtain the maximum possible length of patent protection surrounding that pharmaceutical.

Research by IP Australia has found that for omeprazole/esomeprazole and simvastatin, a large proportion of follow-on patents are filed by third-party applicants (i.e. other than the originator company). These are generally filed after market entry of a pharmaceutical.²²⁹ A similar finding has also been published in regard to formulation patents surrounding atorvastatin (Lipitor).²³⁰

Case study – Omeprazole and Simvastatin

Omeprazole is the subject of a large number²³¹ of follow-on patents. It was found that more than half of these are from applicants other than the original patentee.²³²

The following timeline of Omeprazole/Esomeprazole illustrates early patenting by the originator, before and shortly after the release of omeprazole. Later patenting was dominated by third parties.

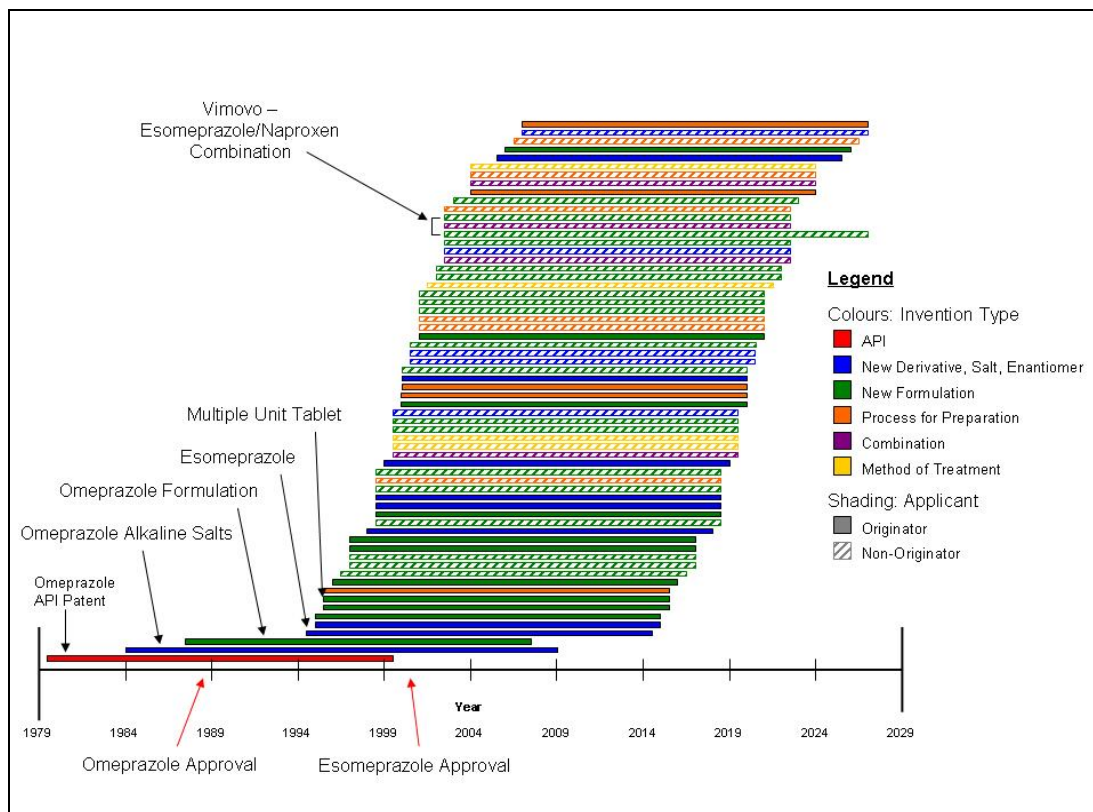
²²⁹ Whereas filings before market entry appear to be exclusively by originators.

²³⁰ Howard, L. 'Formulation patents in pharmaceutical development', The Journal of Generic Medicines, 2008, Vol. 5, No. 4, pages 365-370 (see Figure 1).

²³¹ In comparison to the majority of other pharmaceuticals studied by the Panel

²³² Data obtained from AUSPAT and the FDA Orange Book. Analysis by IP Australia. For the sake of clarity, only in-force patents are included in Figure 7.3.1.

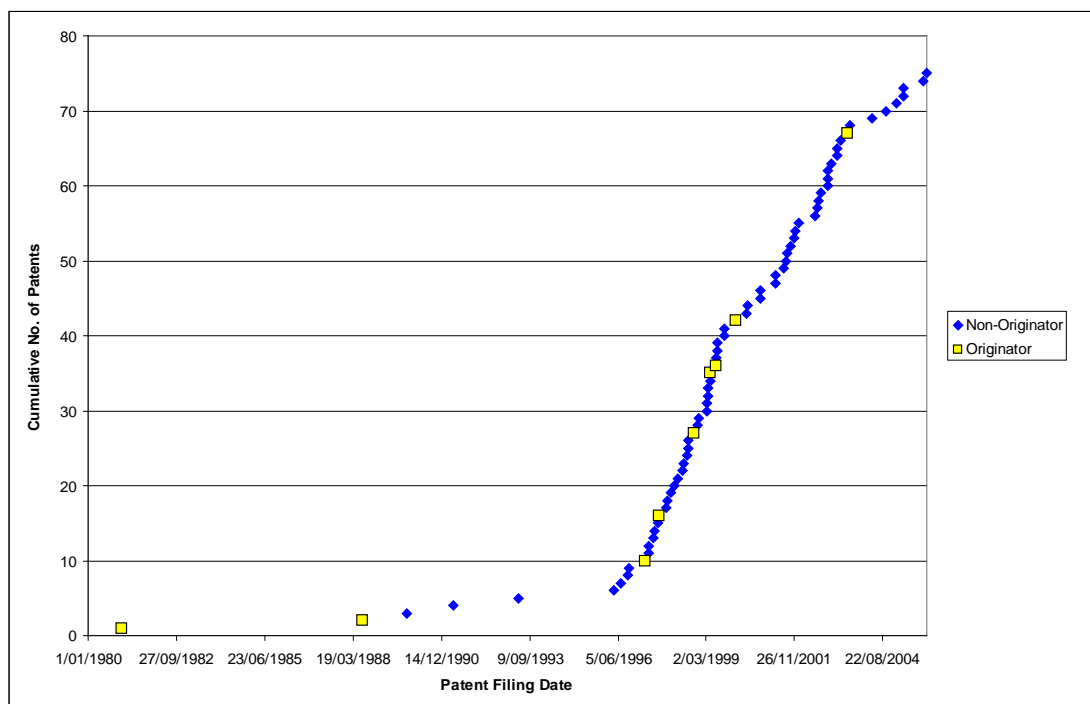
Figure 7.3.1: Omeprazole patent timeline



A similar pattern was observed for simvastatin.²³³ As seen in the previous omeprazole example, follow-on patenting following market approval²³⁴ was dominated by third parties.

²³³ Ibid.

²³⁴ Marketing approval was granted on 19 July 1990.

Figure 7.3.2 : Simvastatin patents - Originator vs. Non-Originator

7.4.1. Analysis

The expiry of a pharmaceutical patent marks the period of transition between a protected and non-protected market. The high value returns associated with successful pharmaceuticals have the inevitable effect of inviting the use of business strategies to maximise these returns.

The Panel considers that the types of behaviours demonstrated by originator pharmaceutical companies is consistent with what would be expected when operating in a complex legal environment and dealing with high levels of risk, high costs and high returns. It is further expected that originator pharmaceutical companies will utilise every means within the system in which they operate in order to gain the maximum level of protection for their high- value products. This could be viewed as a corporate responsibility and it follows that anything less would be a failure of these companies to act in the best interests of their shareholders.

This has, however, the unfortunate effect of blurring the lines of transition between the protected and non-protected market. The legal and regulatory systems in place in the pharmaceutical environment further increase the overall complexity and, therefore, costs of operating in such a space.

The granting of follow-on patents surrounding an API is one of the main criticisms of the pharmaceutical patent system. The ability of originator pharmaceutical companies to amass a patent portfolio around a single product is an effective strategy for frustrating competitors by increasing uncertainty around entry into the market.

While some follow-on pharmaceutical patents are found to be invalid by the courts,²³⁵ this does not mean that all forms of follow-on patenting are invalid. Furthermore patents filed prior to the launch of a pharmaceutical product may well be necessary in order to protect new innovations arising during the developmental process.

Additionally, it appears that it is not only originator pharmaceutical companies that are utilising these follow-on patents. As can be seen from the omeprazole and simvastatin examples in Figures 7.3.1 and 7.3.2, non-originator companies appear to dominate follow-on patenting after the marketing of a successful pharmaceutical product.

It is worth reiterating at this point that these companies, irrespective of whether or not they are originator pharmaceutical companies, are legitimately operating within the confines of the various legal and regulatory systems in place in Australia (and indeed, the international community). It is inefficiencies within these systems that permit the behaviours addressed in this chapter. Therefore, rather than addressing behaviours of the companies working within this system, it would be more effective to address the inefficiencies within the system that permit these behaviours.

In the case of the patent system, follow-on patents must be examined and found by IP Australia to be novel and inventive in order to meet the requirements of the Patents Act. The Panel is of the opinion that patentability standards are key to this issue, and that incorrect thresholds in the past may well have provided undue patent protection in certain instances. These standards must be set at a level that restricts the grant of follow-on patents to truly novel and inventive subject matter which contributes to cumulative innovation.

²³⁵ Most recently, patents covering rosuvastatin were found to be invalid by the Federal Court – *Apotex Pty Ltd v AstraZeneca AB (No 4)* [2013] FCA 162.

Before continuing the discussion in relation to patentability standards, the Panel observes that a number of issues raised in regard to evergreening practices may be more appropriately dealt with by reviewing processes involved in regulatory systems outside of the patent system. Changes to the patent system alone will do little to affect the marketing strategies utilised by pharmaceutical companies.

The pharmaceutical market in Australia, gives end users little influence in determining the success of a drug. In effect, the only customer capable of having any significant impact on the pharmaceutical market is the PBS. Intermediaries, physicians and pharmacists, also have a strong influence on the choice of drugs for patients from those within the PBS range.

The Panel considers that it may be of benefit for the Pharmaceutical Benefits Advisory Committee (PBAC) to have regard to the patent landscape surrounding a pharmaceutical, when forming its recommendation regarding acceptance into the PBS.²³⁶ To the Panel's knowledge, this is currently not a consideration for the PBAC.

This approach may be beneficial in minimising the effects of life-cycle management strategies employed by originator pharmaceutical companies. For example, in cases where prescription switching is a strategy - analysis of the patent landscape may identify a new drug as a follow-on innovation, covered by a patent that expires at a significantly later date than the patent relating to the current PBS drug.

As discussed in section 7.3.2 of this Chapter, submissions to the Panel claim that venlafaxine/desvenlafaxine is an example of such prescription shifting and that the later product (desvenlafaxine) provides no improved therapeutic outcome²³⁷. Therapeutic relativity sheets, published by the PBAC in relation to these pharmaceuticals, do not refute this assertion and indicate that the listings of venlafaxine extended release and desvenlafaxine on the PBS were recommended on the basis of cost effectiveness and minimisation, rather than improved efficacy

²³⁶ This role need not be performed by the PBAC alone. See section 10 of this report discussing inter-authority co-operation.

²³⁷ Submissions by Alphapharm, Dr. Hazel Moir.

or therapeutic outcomes.²³⁸ Alphapharm estimates that the cost of the prescription shift to desvenlafaxine will amount to \$257 millions by the end of the desvenlafaxine patent in 2023²³⁹.

The Panel suggests that while a comparison of an existing PBS listed drug and a new derivative drug might indicate a case for cost-minimisation at single dosage level, broader considerations that take the patent landscape into account could potentially alter the cost comparison dramatically. Due to the extended patent protection of the new derivative drug, the PBS could stand to pay substantially more in subsidies should the new drug be approved for PBS listing. The figure of \$257 million, provided by Alphapharm in relation to desvenlafaxine, suggests the scale of savings that may be achieved. This is, of course, based on the assumption that there are no improved therapeutic outcomes being provided by the new drug and where cost minimisation and provision of alternatives, for the purpose of providing choice, are the only considerations.

²³⁸ Venlafaxine was accepted initially on the basis of cost minimisation compared to fluoxetine. It was subsequently accepted that it was more effective than the SSRIs for some patients. Following the presentation of further data to the PBAC at its June 2003 meeting, venlafaxine was then accepted as being of acceptable cost effectiveness compared to the selective serotonin re-uptake inhibitors (SSRIs) (at the prices then applying). Venlafaxine modified release capsules were accepted for listing on the basis that the 75 mg and 150 mg once daily is similar to the 37.5 mg and 75 mg plain tablets twice daily, respectively. Desvenlafaxine was recommended for listing for major depressive disorders on a cost minimisation basis with the parent drug venlafaxine. The equi-effective doses are desvenlafaxine 50 mg and venlafaxine 75 mg. Special pricing arrangements apply.

(PBS Therapeutic Relativity Sheets: ATC N06 – Psychoanaleptics Effective Date: 04/06 (<http://www.pbs.gov.au/info/industry/pricing/pbs-items/therapeutic-relativity-sheets>)).

²³⁹ Alphapharm public submission, page 7.

8. Challenges to patent grants and validity

Efficient and effective mechanisms for challenging patents are an important element in maintaining a robust and appropriately balanced intellectual property system. There are a number of processes available to parties who wish to challenge the granting or validity of a patent. These include challenges involving the Commissioner of Patents: third party notifications, opposing the grant of the patent and requesting re-examination of the patent, or seeking revocation by the courts. Parties may also settle disputes without recourse to the Commissioner or the courts, such as through licensing agreements.

Patent litigation in Australia is an expensive process. Alphapharm's submission provides an average cost of between \$4.5 million and \$7 million for a patent challenge, depending on the outcome.²⁴⁰ Novartis provides a typical range of between \$750,000 to \$2 million, commenting that the cost of patent litigation in Australia is disproportionately large in relation to the size of the pharmaceutical market.²⁴¹ It is not clear to the Panel why these estimates differ to such a large degree.

Non-judicial third-party challenge systems aim to provide a rapid, inexpensive alternative to litigation and additional mechanisms to ensure the validity of granted patents. Opportunities to object to the grant of a patent are available during the patenting process – prior to the acceptance of a standard patent application, after acceptance and after sealing.

²⁴⁰ Alphapharm public submission, page 8.

²⁴¹ Novartis submission, page 4.

8.1. Third party challenge provisions

8.1.1. Third party notification

Section 27²⁴² 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.²⁴³ 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 is a mechanism for ensuring examiners give due regard to the relevant prior art during the examination process. It 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.

From 2003 to 2010, there have been, on average, two s.27 notices filed per annum in regard to pharmaceutical technologies.²⁴⁴ There were 29 s.27 notices filed in 2011 for pharmaceutical technologies. However, all but three of these were filed by a single third party and were in relation to applications for lower-tech, traditional knowledge patents, rather than small molecular entity or biologic type pharmaceutical patents. Only four notices were filed in 2012. As such, there does not appear to be an increasing trend in s.27 filings.²⁴⁵

²⁴⁴ In comparison to an average of 35 per annum in all technologies. IP Australia data, March 2013.

²⁴⁵ Similar provisions apply to innovation patents under s.28. Only two s.28 notices were filed in regard to pharmaceutical technologies between 2003 and 2012.

8.1.2. Opposition

If IP Australia considers that 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.²⁴⁶ 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.²⁴⁷ 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. An office decision on an opposition can be appealed by a patent applicant or an opponent to the Federal Court.²⁴⁸

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.²⁴⁹

The Raising the Bar Act has introduced changes to the opposition procedures that are intended to enable patent oppositions to proceed more expeditiously. These include stricter conditions for filing divisional applications²⁵⁰ and extensions of time to prevent exploitation of the system and thereby, public uncertainty.

²⁴⁶ *Patents Act 1990* (Cth), s.59.

²⁴⁷ *Patents Act 1990* (Cth), s.101M.

²⁴⁸ *Patents Act 1990* (Cth), s.60(4).

²⁴⁹ *Patents Act 1990*, Chapter 5.

²⁵⁰ *Patents Act 1990*, Section 141 – the Commissioner can refuse withdrawal of an opposed application and filing of a divisional application to continue its prosecution; Section 79B – restriction to filing of divisional application within 3 months of acceptance of parent or no later than acceptance of the divisional. This ensures the divisional application cannot be filed or converted late in opposition proceedings.

Only a very small proportion of accepted applications - less than 1% - are opposed. From 2003 to 2012, there have been, on average, 88 oppositions filed per year and approximately 17% are in relation to pharmaceutical patents.²⁵¹ It can take 2-3 years before an opposition progresses to hearing by a delegate of the Commissioner.²⁵²

8.1.3. Re-examination

Section 97²⁵³ 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 of a patent can also be initiated by the Commissioner of Patents at any time after acceptance but before grant. If re-examination leads to an adverse report, the Commissioner may refuse to grant the patent. Furthermore, re-examination can be directed by a court where the validity of a patent has been challenged in court proceedings.

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.²⁵⁴ 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.

Since 2001, there have been 117 re-examination requests filed by third parties. Thirty three of these requests (28%) were in relation to pharmaceutical technologies. The average time for resolution of the re-examination proceedings was 48 weeks (median time of 44 weeks). The average time taken to issue a first re-examination report was 13 weeks (median time of 11 weeks).²⁵⁵

²⁵¹ IP Australia data, March 2013.

²⁵² IP Australia data, March 2013.

²⁵³ Similar provisions apply to innovation patents under s.101G.

²⁵⁴ Advisory Council on Intellectual Property, *Post Grant Patent Enforcement Strategies*, January 2010.

²⁵⁵ IP Australia data, March 2013.

In the pharmaceutical area, about 49% of the third party re-examination requests resulted in successful narrowing of the scope of the granted patent, while 28% of challenges were unsuccessful to the extent that the scope of the claimed monopoly remained unchanged.²⁵⁶

8.1.4. Submissions – third party challenges

A number of submissions acknowledge changes to the re-examination and opposition provisions as a result of the Raising The Bar Act. Some suggest improvements to the opposition system, such as by introducing post-grant opposition.²⁵⁷ However, there is a general consensus that any reform to these systems would be premature before the consequences of the Raising The Bar changes have been assessed.

GMiA submits that non-judicial systems of examination (including third party notification), pre-grant opposition, and re-examination overall provide a relatively rapid and inexpensive means for challenging and determining the validity of a patent claim. However, GMiA submits:

Even in light of [the Raising The Bar changes], the systems do not provide the required certainty or a workable alternative to litigation... In reality, the only issues that are likely to be settled at this stage are those that are clearly untenable. All others will be subject to re-hearing in Court.²⁵⁸

More specifically, GMiA makes the following points:

- re-examination findings are not subject to challenge or opposition, and the proceedings are ex parte²⁵⁹ so the public has little/no involvement in the examination process. The Panel notes that the patentee can appeal an adverse re-examination finding, and any party can oppose an amendment to the patent arising from re-examination;

²⁵⁶ The remaining 23% of re-examinations have related court proceedings.

²⁵⁷ Novartis Submission, page 3.

²⁵⁸ GMiA public submission, page 29.

²⁵⁹ The third party is precluded from any further participation in the re-examination process.

- appeal on oppositions/re-examinations to Courts serve to delay public certainty regarding the scope of the patent, and also delay infringement/revocation decisions on the other criteria for validity that are currently not grounds for re-examination or opposition. The Panel notes that the Raising The Bar amendments are reducing these limitations; and
- time and resource constraints restrict the ability of patent examiners to perform robust examination. There is therefore no assurance of examiners granting strong, defensible patents.

GMiA suggests that these constraints may undermine trust in IP Australia's internal examination processes, resulting in parties preferring to have their validity concerns heard by the Courts.²⁶⁰ However, in public hearing submissions Jacinta Flattery-O'Brien of Shelston IP suggested that unsuccessful opposition or re-examination challenges may hold some weight in later litigation proceedings (to the detriment of the challenger), as it is seen as a re-affirmation of the validity of the patent by IP Australia.²⁶¹

8.1.5. Analysis

A major limitation of the pre-grant opposition system to date is that it typically takes two to three years before a hearing is held. The Raising The Bar changes need time to take effect before their success in reducing this period can be determined. The Panel notes that the Advisory Council on Intellectual Property (ACIP) briefly considered the introduction of a post-grant opposition system in 2010. ACIP found that most countries that have an opposition system have a post-grant one. Over 5% of all patents granted by the European Patent Office are opposed using its post-grant system, a significantly higher proportion than in Australia. However, ACIP found little justification for Australia to move to a post-

²⁶⁰ GMiA Public Submission, page 27.

²⁶¹ Jacinta Flattery-O'Brien, Shelston IP, Sydney hearings, 12 February 2013.

grant system and recommended that the situation be monitored.²⁶² The Government accepted this recommendation.²⁶³

Third party re-examination has rarely been used as an approach to resolving patent disputes. It takes IP Australia an average of 13 weeks to issue a first re-examination report. The Panel suggests that re-examination may be used more by the pharmaceutical industry if this period was reduced. However, the *ex parte* nature of re-examination may be the most significant factor against its use. For example, a patentee may appeal the decision of the Commissioner on re-examination to the Federal Court. A third party, however, has no right to appeal against the decision of the Commissioner on re-examination. The only recourse for a third party is to apply for revocation under s.138 of the Patents Act.

It appears that the attractiveness of non-judicial third party challenge mechanisms is limited because they do not provide an acceptable degree of certainty to either the patentee or third party. Re-examination decisions may be appealed by the patentee and opposition decisions may be appealed by both the patentee and third party. Lengthy delays may result and prolong the period of uncertainty. This is not an issue that can be addressed, because IP Australia decisions must be subject to appeal.

The Panel considers that IP Australia should continue to tighten up its opposition and re-examination processes to reduce delays. Until these forums become more useful and used, the main available opportunities for improving mechanisms for challenging patents lie in the court system.

²⁶² ACIP, *Post-Grant Patent Enforcement Strategies final report*, January 2010, 7.1, Recommendation 9.

²⁶³ *Australian Government Response to the ACIP Report: A Review of Post-Grant Patents Enforcement Strategies*,
http://www.acip.gov.au/reviews_completed.html.

8.2. Court challenges

Once a patent has been granted, the patentee has the right to enforce it and can pursue infringement proceedings in the courts. Alternatively, an aggrieved party can challenge the validity of a patent in the courts through revocation proceedings.²⁶⁴ It is often the case that revocation is raised as a counterclaim in infringement proceedings as well an action in its own right. 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.

GMiA states in its submission that a significant burden is placed on generic medicine suppliers because they bear the burden of removing inappropriate patent barriers through the Courts. The high cost of litigation and relatively small market in Australia means that the patent litigation “investment” in Australia is not capable of reaping comparable commercial returns for suppliers of generic medicines as it does elsewhere. GMiA submits:

The risks associated with pharmaceutical patent litigation are very significant, often requiring two if not three levels of judicial review (i.e., Federal, Full Federal and High Courts). The risks facing the generic litigant in Australia are greater than those overseas due to the Australia-specific patent law challenges outlined [in GMiA’s submission], including in particular the high likelihood of an injunction being granted.²⁶⁵

Injunctions are discussed in more detail below. GMiA also submits that, at present, the only incentive for generic sponsors to bring a pharmaceutical patent challenge is market access, which will then be open to all comers. The benefit of the generic litigant’s success also flows directly to the government and to the Australian public. GMiA states that if appropriate incentives were put in place, more proceedings would be commenced in Australia, and more invalid patents will be revoked.

²⁶⁴ Patents Act, Chapter 11, Part 1 and s.138.

²⁶⁵ GMiA Public Submission, pages 39-40.

As mentioned above, Alphapharm states that the average legal cost for patent litigation is \$4-5 million, with that cost increasing to \$7.5 million should the challenge prove unsuccessful. Before patent litigation is initiated, a reward to risk ratio of 10:1 must be demonstrated. Alphapharm further states that whilst the generic companies behind the litigation absorb most of the risk, it is the Commonwealth that stands to save hundreds of millions of dollars should the patent challenge prove successful. Alphapharm claims that the lack of an incentive system to encourage generic companies to mount challenges will lead to fewer patent challenges.²⁶⁶

Originator pharmaceutical companies submit that patentees are fully entitled to enforce and defend their IP and their concerns generally focus around issues with interlocutory injunctions and the timing of notifications.

8.3. Interlocutory Injunctions

Applicants 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.²⁶⁷

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

The most recent guidance on the matters that the courts consider when granting interlocutory injunctions in patent cases is the *Novartis AG v Hospira* decision.²⁶⁸

²⁶⁶ Alphapharm Public Submission, pages 8-9.

²⁶⁷ For example, *Samsung Electronics Co Ltd v Apple Inc* (2011) 286 ALR 257 at [52] – [74].

²⁶⁸ *Novartis AG v. Hospira Pty Ltd* [2012] FCA 1055.

In this case the court granted an injunction because damages would not have been an adequate remedy. This was primarily because the generic would have entered the market and triggered the 16% statutory reduction in the subsidy for the F1 (original) pharmaceutical. The statutory reduction is discussed in Chapters 2 and 5.

Medicines Australia states that interlocutory injunctions are “a vital means of protecting patentees from unpredictable and irreversible effects of patent infringement while the validity of a patent is being tested in court”.²⁶⁹ The “irreversible effects” described by Medicines Australia largely refer to the 16% statutory price reduction in the PBS subsidy. Further price reductions may also result from generic competition in the market. The original pricing is highly unlikely to be reinstated should the generic pharmaceutical be found to be infringing. Although the 16% price reduction may be overturned by Ministerial discretion, such discretion has never been exercised. For this reason originators argue that the status quo ought to be maintained until a court decision is reached.²⁷⁰

Medicines Australia and Bristol-Myers Squibb emphasise that interlocutory injunctions are only provided if a patentee can satisfy the Courts that the conditions outlined above exist. Furthermore, they argue that the availability of interlocutory injunctions is consistent with the presumption of validity in favour of registered patents under Australian law.

GMiA submits that the balance of convenience persistently falls against generic companies. GMiA states that disproportionate interlocutory relief is being granted against generic sponsors, largely in response to claims from the originator company that it will encounter immediate adverse effects under the PBS pricing legislation. GMiA claims that in the last 8 years, 22 interlocutory injunctions concerning pharmaceuticals and medical devices have been sought and that injunctions were granted in 18 of these cases.

²⁶⁹ Medicines Australia submission, page 12.

²⁷⁰ Bristol-Myers Squibb, Medicines Australia submissions.

Medicines Australia's submission also discusses the number of recent cases involving interlocutory injunctions. It states that since 2007, at least 20 interlocutory injunctions have been granted by the Federal Court in view of the 16% price reduction in PBS subsidy. Medicines Australia makes the following point:

That two of these 20 injunctions were granted in cases where patents were subsequently revoked does not in any way undermine the necessity of interlocutory injunctions as a means of preventing third parties from causing irreparable harm to patent owners in the vast majority of cases where patents are in fact upheld.²⁷¹

The Panel notes that in recent years the US courts have raised the thresholds to be met before granting an injunction from what appears to have been a low base.²⁷² Also, the US Patent and Trademark Office and US Department of Justice have proposed that, for patents relating to industry standards, injunctions should be discouraged and voluntary licensing on fair, reasonable and non-discriminatory terms should be encouraged.²⁷³

8.3.1. Timing issues

A number of submissions raise concerns regarding timing issues in regard to interlocutory injunction applications. Bristol-Myers Squibb states that due to a lack of any early notification process, interlocutory injunctions are required to be pursued urgently in order to prevent generic PBS listing. It is submitted that a preferable system would be to provide earlier notification to the patentee to allow early adjudication of disputes, potentially avoiding interlocutory rulings.²⁷⁴ The

²⁷¹ Medicines Australia submission, page 12.

²⁷² *eBay, Inc. and Half.com v. MercExchange LLC*, 547 US 388 (2006). The Supreme Court ruled that permanent injunctions should not be issued as a matter of course and that a four-factor test must be used.

²⁷³ United States Department of Justice and United States Patent & Trademark Office, *Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments*, 8 January 2013.

²⁷⁴ Bristol-Myers Squibb submission.

issue of early notification is considered in more detail in the discussion of patent certificates below.

8.3.2. Costs to PBS of invalid patents

Where a patentee has undertaken to pay damages as a condition of obtaining an interlocutory injunction and the patent has been found invalid, the patentee may be liable to pay damages to the Government. These would involve the foregone savings to the PBS budget resulting from delay in generic entry into the market and reduction in the Government subsidy. Damages could total in the millions of dollars, depending on the value of the product and the period of the injunction.

As discussed by Medicines Australia above, in recent years there have been two cases of injunctions being granted for PBS-listed products and the patents subsequently being revoked – Sanofi-Aventis' patent for clopidogrel (Plavix)²⁷⁵ and Wyeth's patent for venlafaxine (EFEXOR XR).²⁷⁶ In both cases the Department of Health and Ageing is currently seeking compensation from the patentees.

GMiA supports the Government seeking such damages, as this may deter originators from seeking interlocutory injunctions.²⁷⁷ Conversely, Medicines Australia submits the following:

The Australian Government ought not be seeking to recover its damages under an undertaking as to damages in cases to which it was not a party. Putting aside legal arguments about the ability of the Australian Government to claim damages pursuant to the usual undertaking as to damages, on one view, such recovery is bad public policy. To the extent that the Australian Government is able to recover damages pursuant to the usual undertaking as to damages, the quantum of such claims will act as a significant deterrent to patentees enforcing their rights in Australia

²⁷⁵ *Apotex Pty Ltd v Sanofi-Aventis* [2009] FCAFC 134.

²⁷⁶ *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2011] FCAFC 132.

²⁷⁷ GMiA submission, page 34.

and will, therefore, result in fewer pharmaceutical products coming to market in Australia.²⁷⁸

The issue of originator companies deciding not to bring products to the Australian market due to insufficient IP protection is discussed in Chapter 2 and 9.

8.4. Analysis

The Panel notes that litigation in general is slow and expensive in Australia. In recent years the Government has introduced a number of measures to address this.²⁷⁹ However, more needs to be done to reduce costs, particularly those associated with discovery and expert witnesses. The use of administrative decisions needs to be encouraged and use of the courts discouraged. One possible solution that the Panel will consider further is to change the law so that, if an administrative determination is made, this can only be challenged in court if the challenger meets all costs.

One difficulty with a solution of this nature is that there is a risk that it could actually result in fewer administrative decisions, with challengers going straight to the courts. Also, because the current pre-grant opposition process is early in the life of a patented pharmaceutical product, competitors typically do not yet know the value of the market and whether it is worthwhile opposing the grant of the patent. Post-grant opposition may provide a more appropriate option because it can be commenced at a stage when the competitor knows the value of the product.

The Panel would welcome suggestions to improve the usefulness and use of non-judicial forums.

Interlocutory injunctions are vital to rights owners to prevent irreparable damage from being done. It is clear from court decisions in these matters that the statutory price reduction and ongoing price disclosure systems of the PBS are

²⁷⁸ Medicines Australia Submission, page 13.

²⁷⁹ *Strategic Framework for Access to Justice*, 2009,

<http://www.ag.gov.au/LegalSystem/Pages/Accessjustice.aspx>.

important factors in court decisions as to whether interlocutory injunctions are granted in pharmaceutical cases. The Panel recognises that it is for the courts to judge each case on its merits. However, changes to the patent certificate requirements may result in fewer injunctions being necessary and reduce costs for all parties. This issue is explored in more detail below under Patent Certificates.

The Panel considers that the incentive available to generic manufacturers to challenge patents in the courts is low due to a number of factors. The Australian market is relatively small compared with the US, Europe and Japan and the profit margins of generic manufacturers are lower than originators. This is exacerbated by the lack of special reward or period of market exclusivity for a successful challenger. Because its margins over production cost are slimmer than the originator, a generic manufacturer 'internalises' only a small proportion of the benefits of successfully challenging a patent. Therefore it is often in a competitor's interest to wait and hope that another competitor incurs the cost and risk of a challenge.

The Panel considers that some form of extra incentive may be necessary to provide competitors with sufficient encouragement to challenge potentially invalid patents, without removing all the risk for challengers and thereby creating inefficiencies and a litigation industry. There is little evidence to suggest that introducing reasonable incentives to challenge patents would discourage the introduction of new products to the Australian market. The Panel invites stakeholders to provide any examples where this might occur.

The Panel notes that in the US the first generic manufacturer to successfully challenge a patent that has been listed in the Orange Book will receive six months of market exclusivity. It therefore obtains a first mover advantage to some extent, although generic products authorised by the patentee can still enter the market.²⁸⁰ A mechanism of this nature has the advantage of being simple to administer and is discussed in more detail below under Patent Certificates.

²⁸⁰ The Orange Book is discussed in more detail below in regards to patent certificates.

Arguably the need for such incentives in the US is questionable due to the large market.²⁸¹ However, the Panel considers that there may be a stronger argument for such an incentive in Australia where the returns available to a generic manufacturer following a successful patent challenge are substantially less.

The Panel also considers that it is appropriate that the Government continue to seek damages from the owners of invalid patents that have resulted in significant costs to the PBS by delaying the entry of generic versions. The Government, through the PBS, is the party most affected by the actions taken by patentees to prevent generic entry. Given this, it is appropriate that the Government seek compensation for the higher price it has been forced to pay because of delay in the automatic price reduction. Although some submissions argue that the risk of paying damages to the Government could result in delay in the timely introduction of new products to the Australian market, little evidence has been provided to support these arguments.

However, the Panel considers that the recovery of damages in isolation is insufficient. The PBS is the party that 'internalises' most of the benefits of a successful challenge to a patent through reduced subsidies. Therefore the Government should take a more active role where another party is challenging the validity of questionable patents that incur significant costs to the PBS. For example, the Government could put in place mechanisms for assessing the validity and significance of particular patents to the PBS budget.

Possible mechanisms include:

- making it a mandatory condition of being granted an injunction for pharmaceutical cases that the patentee undertakes to repay any damages to the Government;

²⁸¹ Helm, J. 'Comment – The patent end game: evaluation generic entry into a blockbuster pharmaceutical market in the absence of FDA incentives', 2007, Mich. Telecomm. Tech. L. Rev., Vol. 14, pages 175-196: The author provides a case study illustrating high returns to a first mover generic company following successful patent challenge.

- providing the challenger of a patent with a portion of the damages obtained by the Government from an undertaking by the patentee;
- providing a challenger with a combination of guaranteed and conditional subsidies or negotiating some other arrangement;
- requiring the patentee to repay to the Government an amount based on the lost reduction in PBS subsidy due to the delayed entry to the market of generics; or
- requiring the patentee to pay a portion of its profits for the product during the injunction period to a successful challenger.

Draft recommendation 8.1:

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

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

8.5. Patent certificates

Section 26B of the *Therapeutic Goods Act 1989* (Cth) provides that a generic manufacturer seeking to rely on data provided by an originator company for registration of the generic’s goods on the ARTG must provide a certificate to the TGA in relation to any patents that may exist for the goods.²⁸² An originator company who commences proceedings in response to a patent certificate must then comply with the requirements set out in s.26C and s.26D of the *Therapeutic Goods Act*.

²⁸² *Therapeutic Goods Act 1989* (Cth), s.26B.

8.5.1. Section 26B certificates

8.5.1.1. Current Law

A pharmaceutical company that is successful in obtaining regulatory approval for a new drug is entitled to a period of five years data protection for the clinical efficacy and safety data provided to the TGA.²⁸³ This means that for five years no other entity can rely on the data to gain approval to market a bioequivalent, or biosimilar, generic drug. Once the five year period has ended, a generic manufacturer can rely on the data for approval of its own drug.

A generic manufacturer seeking to rely on data previously provided to the TGA must provide the TGA with a certificate stating that:

- the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market the therapeutic goods in a manner or circumstances that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods (s.26B(1)(a)); or
- a patent has been granted in relation to the goods, and that the applicant proposes to market the therapeutic goods before the end of the patent, and that the applicant has notified the patentee accordingly (s.26B(1)(b)).

Penalties apply for providing false information to the TGA. Providing a false or misleading s.26B certificate is an offence which incurs a fine of \$170,000 and/or imprisonment for 12 months.²⁸⁴ The Panel is not aware of any legal actions that have been brought against an applicant for providing a false s.26B certificate.

Section 26B certificates are required before the product can be included on the ARTG but are typically provided to the TGA late in the application process. The TGA does not assess the correctness of certificates²⁸⁵ and does not provide them to the originator.

²⁸³ *Therapeutic Goods Act 1989 (Cth)*, s.25A.

²⁸⁴ *Therapeutic Goods Act 1989 (Cth)*, s.22A(4), s.26B(2).

²⁸⁵ *Ibid*, s.25(4).

These s.26B patent certificates are unique to pharmaceutical patents. They were introduced in 2005 to comply with Australia's obligations under Article 17.10.4 of AUSFTA. Under AUSFTA, Australia must provide a system whereby patentees are notified of applications for regulatory approval by another party when that application seeks to rely on data previously submitted by the patentee for a product that is the subject of a patent, and the applicant seeks regulatory approval to enter the market during the term of the patent. The patentee must be notified and the identity of the applicant disclosed to the patentee.²⁸⁶

8.5.1.2. Submissions

Submissions received about patent certificates focus primarily on the issue of notification, on the drafting of the legislation, and on whether the legislation was consistent with Australia's international obligations.

8.5.1.3. Notification

A common theme among submissions received from originator companies is that generic companies rarely notify an originator of their intention to enter the market by filing a certificate pursuant to s.26B(1)(b).

The Law Council of Australia submits that these certificates effectively require the applicant to certify that their product would infringe an existing patent.²⁸⁷ The Law Council also submits that s.26B(1)(b) certificates are not typically used because they publicise the commercial intentions of the generic manufacturer, expose the company to possible infringement proceedings and may also result in the generic manufacturer losing commercial advantage (the "first mover advantage"). A generic company is therefore much more likely to prefer to file a s.26B(1)(a) certificate, stating that it is not marketing or intending to market therapeutic goods in a manner which would infringe a valid patent claim.

Consequently, the first notification received by an originator pharmaceutical company of another company's intention to enter the market is often when the

²⁸⁶ AUSFTA Article 17.10.4(b).

²⁸⁷ Law Council of Australia, Submission to the Pharmaceutical Patents Review at [48].

other company's drug is listed on the ARTG or PBS. The TGA publishes searchable updates of new ARTG listings on its website, although it does not actively notify patentees of generic entrants. This is akin to the practices applying to other technologies where there is no requirement that a new entrant to a market must advise its intentions to the holder of a patent which the new entrant claims has expired or is invalid. Pfizer submits that in response, originator companies commonly seek an urgent interlocutory injunction to restrain the generic company from entering the market until the courts assess the originator's claims that its patent has been infringed.²⁸⁸

Bristol-Myers Squibb argues that there is a lack of appropriate notification as a result of the drafting of s.26B(1)(a).²⁸⁹ As indicated earlier, the provision requires an applicant to certify that, acting in good faith, it believes on reasonable grounds that it is not marketing the goods in a manner that would infringe a valid claim of a patent that has been granted in relation to the goods.

The required standard of belief, on reasonable grounds, effectively allows generic manufacturers to self-assess whether the generic goods would infringe a valid patent claim. Bristol-Myers Squibb submits that generics often took the view that a patent claim was not valid until tested by the courts,²⁹⁰ and that if a generic company had formed the view that a patent claim was invalid, it should be required to communicate that position to the patentee.²⁹¹ Bristol-Myers Squibb also argues that the drafting of s.26B(1)(a) was so broad and open to interpretation that generics could almost always file a s.26B(1)(a) certificate,

²⁸⁸ Pfizer, Submission to the Pharmaceutical Patents Review, p.5.

²⁸⁹ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [36].

²⁹⁰ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [36].

²⁹¹ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [38].

even where a generic product would fall within the scope of a valid patent claim, thereby avoiding notifying the patentee of its intention to enter the market.²⁹²

Originator companies argue that generics should be required to notify them of intended market entry. Bristol-Myers Squibb argues that such early notification is fair because generics are relying on the data that originators have developed after years of research and substantial financial investment.²⁹³

Medicines Australia submits that originators face serious adverse consequences when a generic drug is accepted for listing on the PBS. Under current arrangements, there is an irreversible reduction in the PBS listing price, even while the originator is contesting in the courts an alleged patent infringement by the generic manufacturer.²⁹⁴ Should the originator succeed in its claim of patent infringement, the loss of revenues up to that time is not made good by the PBS and because the price reduction is irreversible the previous price cannot be reinstated. Furthermore, notification is a requirement of AUSFTA, and Medicines Australia states that the current provisions are inconsistent with that agreement.²⁹⁵

Submissions from originators such as Merck Sharp and Dohme favour the implementation of a system similar to that of the “Orange Book” used in the US (discussed below). The introduction of an Orange Book system is also supported by organisations such as the Law Council of Australia and the Association for the Protection of Intellectual Property.

Submissions from the generic sector argue that generics unfairly bear the burden of determining which patents apply to the relevant drug in order to file a s.26B

²⁹² Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [36].

²⁹³ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [38].

²⁹⁴ Medicines Australia, Submissions to the Pharmaceutical Patents Review, p.18.

²⁹⁵ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [35].

certificate.²⁹⁶ GMIA argues that searching is complex and that it is difficult to ensure that all relevant patents are identified.²⁹⁷

Similar to submissions favouring an Orange Book-style system, submissions on behalf of the generic industry argue for a system which provides greater transparency and easier discovery of patents relating to therapeutic goods. The introduction of such a transparency system is discussed in detail at section 8.5.3.1 below.

However, in public hearings, GMiA cautioned that the US system is a complete package unique to that country and that it involves a number of measures which may not be of benefit in this jurisdiction. Accordingly, GMiA argued that Australia should design a system to suit its own needs rather than import the US system.

Dr Moir proposes that companies seeking regulatory approval for the listing of a drug should, as part of the application process, be required to submit information to the TGA about any patents in relation to the drug for which approval is being sought. This information would be published on the ARTG when approval was granted.²⁹⁸ Under this system, a generic manufacturer would be responsible for any infringement of the notified patents. GMiA suggest a slightly different proposal in which a sponsor of therapeutic goods should be required to identify each patent relevant to its therapeutic good and the name of the therapeutic good should be recorded against these patents on the Register of Patents.

8.5.2. Analysis

8.5.2.1. Notification

The Panel considers that, because of complex relationships between the patent, drug regulatory and pharmaceutical benefit systems, the current provisions do not appear to work well for originators or generic manufacturers and do not appear to be in the national interest.

²⁹⁶ GMIA, Submission to the Pharmaceutical Patents Review, p.51.

²⁹⁷ GMIA, Submission to the Pharmaceutical Patents Review, p.51.

²⁹⁸ Hazel Moir, Submission to the Pharmaceutical Patents Review, p.10

A certificate provided pursuant to s.26B(1)(a) is only required to be submitted to the TGA. There is no provision for the generic manufacturer applying for TGA approval or the TGA to notify the patentee of the application for regulatory approval. As a consequence, the patentee is unaware of the application and the identity of the applicant until the generic manufacturer obtains regulatory approval and is publicly listed on the ARTG or PBS.

Without early notification an originator has no method of ascertaining whether a generic applicant is engaged in activities which could be considered infringing. There is often insufficient time to conduct proper due diligence in order to file a s.26C certificate, if court proceedings are considered necessary.²⁹⁹

Discovery of a generic application at regulatory approval stage often leads to the originator seeking an interlocutory injunction and the commencement of infringement proceedings.³⁰⁰ Court proceedings can lead to a delay to generic entry and incur substantial financial costs for both parties. They can also result in increased costs to the Commonwealth due to the use of the court system and lost savings to the PBS if the generic is found to not be infringing the patent or the patent is invalid.

Generic entry to the market is reliant on data which has been established as a result of years of research, development, and financial investment by originator companies. The intent of the certificate provisions was to provide patentees with notification of applicants for regulatory approval where those applicants sought to rely on data provided by the patentee, in accordance with the terms of AUSFTA.³⁰¹ Because the generic applicant is able to take advantage of the data provided by the originator company, there is an arguable case that the generic applicant should disclose to the patentee/originator the application for regulatory approval. Notification would allow patentees to better determine whether there is

²⁹⁹ Medicines Australia, Submission to the Pharmaceutical Patents Review, p.18.

³⁰⁰ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review, at [22].

³⁰¹ Explanatory Memorandum to the United States Free Trade Agreement Implementation Bill 2004.

a risk of their patents being infringed, or whether a generic company is undertaking genuine activities to prepare for market entry when the patent expires.

Early notification would provide originators with more certainty about the business plans of their competitors, thereby enabling them to engage in steps which hinder generics gaining market share. Such steps might include the originator introducing its own generic version, licensing out to other generics and/or moving patients onto an equivalent but patented formulation of the pharmaceutical. However, this is balanced by early notification reducing the likelihood of the originator needing to seek an interlocutory injunction because there would be sufficient time to try other mechanisms to resolve issues before the regulatory approval was given and the generic could enter the market. Interlocutory injunctions are discussed in more detail at section 8.3 of this Chapter.

Generic manufacturers also argue that they face a substantial burden in conducting searches in order to comply with s.26B(1). However, there are various databases that can be used to identify patents relevant to particular therapeutic goods. There are professional search companies which conduct patent searches. The costs of undertaking such services are small compared to the cost of bringing a product to market. Also, it would be expected that a generic manufacturer would conduct a comprehensive search of the patent landscape to determine where they had freedom to operate before commencing the activities, and committing the costs, necessary to bring a generic drug to market. The Panel also notes that the risk of an infringement action being brought against a generic manufacturer appears to be far greater than the risk of legal action for providing a false patent certificate.

Nonetheless, the Panel considers that there would be public benefit in requiring originators seeking listing of a drug on the ARTG to disclose the patents relating to their product on a public register. This would enable competitors to more easily identify which patents are relevant to their plans. A system which requires the listing of relevant patents against a therapeutic good would be consistent with the aims of the patent system, one of which is to publish IP rights information to enable competitors to determine their freedom to operate. The

disclosure of the boundaries of IP rights should be made as clear as possible, as it is for most other important property rights.

It is not clear to the Panel that section 26B(1)(a) in its current form provides a mechanism for notification which adequately balances the reasonable needs of originators and potential generic manufacturers. The Panel is willing to consider whether s.26B(1)(a) should be amended to require notification to patentees by generic manufacturers of their intention to enter the market. This would need to be done in association with a system which provides potential generic manufacturers with increased certainty about all patents associated with a therapeutic good.

8.5.2.2. Certificate Standards

Section 26B(1)(a) requires that the certificate be provided in good faith and with belief on reasonable grounds that a valid patent claim will not be infringed by the marketing of the goods. No evidence is required to be submitted to support the certificate. The certificate requires only a description of the therapeutic goods for which approval is sought, and it is not necessary to provide patent application or registration numbers, even where an applicant declares that a patent exists.³⁰²

The situation in Australia can be contrasted with the position in the US. In the US, a generic company submitting a certification that the relevant patent is invalid, unenforceable, or will not be infringed must provide evidence in support of the application. The evidence must include a detailed statement of the factual and legal basis of the applicant's opinion.³⁰³

A mechanism for notification to a patentee that a generic manufacturer is seeking regulatory approval for a product that could infringe their patent would allow the patentee to determine whether its patent is likely to be infringed. The generic company may be undertaking genuine preparations to enter the market when the

³⁰² A copy of the required TGA patent certificate can be viewed at:
<http://www.tga.gov.au/pdf/forms/international-forms-usfta-certificate26b.pdf>

³⁰³ 21 CFR 314.95(c)(6).

patent expires, or it may be the case that the generic might enter the market with a product that would not fall within the scope of a relevant patent claim.

8.5.3. Possible policy solutions

The majority of submissions received by the Review support increased transparency and disclosure in relation to the ARTG and patent information. Several options for improvement were suggested in these submissions, and these can be summarised as follows:

- a generic applicant seeking to rely on data provided to the TGA by originators for the purposes of regulatory approval should be required to notify the originator sponsor and this should be done through the TGA;³⁰⁴
- ARTG listings should contain information about patents related to therapeutic goods;³⁰⁵
- the Patents Register should include information about therapeutic goods based on that patent;³⁰⁶ and
- Australia should introduce a system similar to the US publication known as the “Orange Book”.³⁰⁷

The Panel favours the introduction of a system that adopts some limited elements of the Orange Book.

8.5.3.1. Introduction of an Orange Book system

The Federal Drug Administration (FDA) in the US produces a publication called *Approved Drug Products with Therapeutic Equivalence Evaluations*. The publication is colloquially known as the Orange Book. The FDA is responsible for the administration of the Orange Book.

³⁰⁴ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [39].

³⁰⁵ Hazel Moir, Submission to the Pharmaceutical Patents Review, p.10.

³⁰⁶ GMIA, Submission to the Pharmaceutical Patents Review, p.51.

³⁰⁷ Merck Sharpe & Dohme, Submission to the Pharmaceutical Patents Review, p.5.

The Orange Book contains a list of approved prescription drug products and their therapeutic equivalence evaluations. An addendum to the Orange Book contains patent and data exclusivity information relating to particular drugs. The drug names and any trade (brand) names are included, as well as the name of the applicant granted regulatory approval.

A pharmaceutical company seeking regulatory approval for a new drug is required to provide information about any granted or pending patents that it has at the time of filing the application. After regulatory approval has been granted, the applicant has thirty days in which to file information about the patent. Only patents related to the drug itself, or a method of use of the drug, are published in the Orange Book. Patents which claim a process to produce a substance or a method of manufacture are excluded.

A generic company seeking to rely on data provided for regulatory approval by an originator must provide a certificate to the FDA that marketing the goods will not constitute infringement of the listed patents. The certificate must contain a detailed statement about the factual and legal basis that the patent is invalid or will not be infringed.³⁰⁸ The notice must also be supplied to the patentee and the originator. If the originator decides to institute proceedings then an automatic stay of 30 months will apply to the generic application while the matter is resolved.³⁰⁹ However, where a generic company successfully challenges a patent which has been listed in the Orange Book, it will be entitled to a period of six months market exclusivity.³¹⁰

Several submissions received by the panel advocate the introduction of a similar system in Australia. Such a system would provide greater transparency and certainty in relation to freedom to operate. The Panel also notes that the US government has pushed for elements of the Orange Book system to form part of

³⁰⁸ Food, Drug, and Cosmetic Act 505 [21 USC 355] D(ii).

³⁰⁹ 21 CFR 314.107(b)(3)(i)(A).

³¹⁰ 21 USC 355(j)(5)(B)(iv).

the new Trans-Pacific Partnership Agreement (discussed in Chapter 3 of this report).

The Panel does not recommend the adoption of the Orange Book system in its entirety, but takes the view that the following limited elements of the system would be beneficial for Australia:

- a company that has obtained regulatory approval for a pharmaceutical product (the drug owner) would be required to identify on a public register the details of all patent applications and granted patents owned, or licensed by that company and its subsidiaries that relate to that product within a certain period of the product being included on the ARTG or of the patent application being published, whichever is the later;
- patents that are directly related to the listed product would be required to be listed by the sponsor/patentee. Patents which are relevant to the product but not directly related to it, for example, a new method of use, would not be listed;
- the patentee would be precluded from commencing infringement action against generic manufacturers seeking TGA listing in regards to a patent which is not listed on that register;
- generic manufacturers would provide s.26B certificates to the TGA and to the relevant patentee within a certain period of filing an application for inclusion on the ARTG. To meet the requirements of the patent certificate, generic manufacturers would need to conduct their own search for relevant patents owned by other parties; and
- incentives would be provided for the first generic manufacturer to successfully challenge a patent, such as a period of marketing exclusivity or a share of the savings to the PBS from the entry of generics to the market.

Key advantages of such a system include:

- greater transparency and certainty for both originator and generic pharmaceutical manufacturers, increasing efficiency;
- linkage of information about patents and therapeutic goods, reducing the difficulty of searching, and increasing certainty of freedom to operate. The

Panel is of the view that all relevant patents owned by the sponsor/patentee, not just those which claim the active pharmaceutical ingredient or use of that ingredient, should be listed; and

- a likely reduction in litigation.

The Panel does not support the introduction of the features of the Orange Book that provide for an automatic stay on generic applications for regulatory approval, should an originator commence court proceedings, nor those that prevent generic manufacturers from undertaking all the steps necessary to prepare to enter the market upon expiry of the relevant patent, which includes obtaining regulatory approval. This latter feature is often referred to as 'patent linkage'.

Key challenges in the introduction of an Orange Book system include:

- a need for a detailed investigation into the mechanics of the system and how it should work in Australia would need to be undertaken;
- a requirement for significant legislative amendment;
- imposition of a significant administrative burden for the responsible agency; and
- possible imposition of an administrative burden on small businesses and individuals to identify relevant patents and keep the register updated.

Draft recommendation 8.2:

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

8.5.4. Section 26C and 26D

Patentees must comply with certain requirements set out in the TGA where they are seeking to commence proceedings after a generic applicant has provided a certificate to the TGA pursuant to s.26B.

8.5.5. Current law

8.5.5.1. Section 26C certificates

Where a generic applicant has provided a certificate under s.26B(1), and the patentee seeks to commence patent infringement proceedings, the patentee must provide a certificate to the TGA and to the generic applicant that proceedings are to be commenced in good faith, have reasonable prospects of success, and will be conducted without unreasonable delay.³¹¹

A penalty of up to \$10 million may be ordered for providing a s.26C certificate where the certificate contains false or misleading particulars, or where an undertaking given in the certificate is breached.³¹² The Panel is unaware of any instances where an originator company has been subject to a penalty under s.26C.

8.5.5.2. Section 26D requirements

Section 26D applies to circumstance where a generic applicant has provided a certificate under s.26B(1)(b) and the patentee (or its licensee) has sought and been granted an interlocutory injunction restraining the applicant from marketing their goods on the ground that the goods may infringe the patentee's patent. The section provides that, if the infringement proceedings are subsequently discontinued or dismissed, or the court finds that the patentee did not have reasonable belief that final relief would be granted, or that the proceedings had no reasonable prospect of success, the court may award compensation to the applicant, the Commonwealth and/or a State or Territory - for losses sustained as a result of the injunction.³¹³ The Panel is unaware of any action being taken in relation to s.26D.

Sections 26C and 26D of the TGA are not required under AUSFTA. However, they were introduced at the same time as other provisions implementing AUSFTA with

³¹¹ *Therapeutic Goods Act 1989* (Cth), s.26C.

³¹² *Therapeutic Goods Act 1989* (Cth), s.26C (5A).

³¹³ *Therapeutic Goods Act 1989* (Cth), s.26D(4), s26D(5).

the intention of limiting the potential for patentees to use the court system to extend their patents and delay generic entry.³¹⁴

8.5.5.3. Submissions

A number of submissions criticise the effectiveness of sections 26C and 26D. As discussed in relation to s.26B certificates, submissions from originator companies argue that they usually only became aware that a generic product is being prepared for market entry as a result of listing on the ARTG or PBS. This leaves little time for originators to prepare and conduct due diligence to ensure the accuracy of the s.26C certificate.

Bristol-Myers Squibb submits that earlier notification would enable the originator to undertake proper due diligence and determine the likelihood of infringement at an earlier stage.³¹⁵ The Law Council of Australia submits that, with earlier notice, other avenues of dispute resolution can be undertaken in preference to commencing court proceedings and seeking an interlocutory injunction, and therefore a reduction in litigation would follow.³¹⁶

A number of originators raise concerns about the substantial penalty faced by originator companies for providing a false or misleading s.26C certificate with the penalty widely considered to be disproportionate to that faced by generic manufacturers for providing a false or misleading s.26B certificate.^{317,318} For example, Medicines Australia submits that:

... An originator company, the patent holder, must be afforded sufficient time, through notification in advance of generic market entry, to enable it

³¹⁴ Senate Committee Speech of Sen.Kim Carr, *US Free Trade Implementation (Customs Tariff) Bill 2005*, 12 August 2004.

³¹⁵ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review, at [38].

³¹⁶ Law Council of Australia, Submission to the Pharmaceutical Patents Review at [51] – [53].

³¹⁷ Medicines Australia, Submission to the Pharmaceutical Patents Review, p.18.

³¹⁸ Pfizer, Submission to the Pharmaceutical Patents Review, p.5.

to undertake due diligence to ensure the accuracy of the s.26C certificate. The corresponding penalty for potential infringements by generic companies for filing a false or misleading s.26B certificate is up to \$550,000 or (up to) only 5.5 per cent of a patent holder's potential liability. Clearly there is a gross imbalance in the preventative deterrents for originator and generic medicine companies filing false and misleading claims in patent cases in Australia.³¹⁹

The Panel agrees that patent rights are an important incentive for investment in R&D in the pharmaceutical sector. The effective enforcement of patent rights is essential to protecting that investment.³²⁰

Although the penalty faced by originator companies is much higher than that faced by generic manufacturers under s.26B, GMIA submits that penalties favour originator companies because s.26B provides for an offence, rather than a civil penalty.³²¹ GMIA argues that s.26B should be amended to specify that filing a false or misleading certificate is a civil matter, because any harm likely to result from the filing of a certificate would be pecuniary in nature.³²²

8.5.5.4. Analysis

The Panel considers that the substantial penalty for providing a false or misleading s.26C certificate is an appropriate disincentive for commencing proceedings other than in genuine enforcement actions. The Panel also expects it to be rare for a patentee to be penalised under s.26D for obtaining an interlocutory injunction inappropriately. If the patentee did not have a reasonable case or was instituting litigation vexatiously, the injunction should not have been granted in the first place. The Panel found no evidence to suggest that patentees were commencing proceedings other than in circumstances where such action was genuine.

³¹⁹ Medicines Australia, Submission to the Pharmaceutical Patents Review, p.19.

³²⁰ Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review, at [42].

³²¹ GMIA, Submission to the Pharmaceutical Patents Review, p.53.

³²² GMIA, Submission to the Pharmaceutical Patents Review, p.53.

It is the view of the Panel that s.26C and s.26D of the TGA are generally appropriate. The issue to be resolved is one of notification to patentees of generic entry. As discussed above in relation to s.26B certificates, notifying patentees of applications for regulatory approval by generic applicants would lead to disputes being resolved earlier and by methods that do not involve litigation. However, litigation remains a legitimate option for patentees to enforce their rights in appropriate circumstances. Sections 26C and 26D of the TGA are therefore an appropriate safeguard.

The Panel is not persuaded that any changes should be made to s.26C and s.26D of the TGA.

The panel is also not persuaded that the penalty provided under s.26B is unduly harsh, or is an unusual penalty for providing false or misleading information. For the s.26B penalty to be applied, it would have to be shown that a generic manufacturer was “reckless” in the filing of the certificate.³²³ The Panel is unaware of any penalties being applied in relation to s.26B, and considers that the likelihood of the penalty being applied is minimal.

It should be noted that there are other provisions in the TGA which provide criminal penalties for any party found to have filed a false or misleading statement in an application for registration that results in harm from the use of the therapeutic goods.³²⁴ Similar penalties also apply for providing false or misleading statements in other areas of law.³²⁵ As such, it is not inappropriate for s.26B to impose a criminal sanction.

³²³ Explanatory Memorandum to the AUSFTA Implementation Bill 2004 (Cth), at [225].

³²⁴ Therapeutic Goods Act 1989 (Cth), s.22A.

³²⁵ For example, s.243V of the *Customs Act 1901* (Cth) provides that is an offence to file a false or misleading statement in relation to cargo reports. Part 4-25 of the *Taxation Administration Act 1953* (Cth) provides that it is an offence to provide a false or misleading statement in relation to taxation statements.

9. Non-patent TGA-related issues

9.1. Data Protection

9.1.1. Data as public good

Data, such as the kind provided from mining explorations or in the specifications of a patent application, are a public good. The information has value not only to those providing or directly requesting it, but also to others in society who can make use of and build on it. However, these data may take considerable time and investment to produce and the provider of the data expects to benefit from doing so. The usual solution has been to provide a form of exclusive rights for a time in return for the publication of the data.

Data provided in seeking regulatory approval for a pharmaceutical drug are similarly of value. Currently, under Australian law these data can be relied on by another company seeking regulatory approval for a generic 'bioequivalent' medicine. However, where the data relate to a drug that has not been previously registered by the TGA, and the data have not been publicly disclosed, the data cannot be relied on until five years after registration of the original drug. This is known as data protection and is discussed in the following section.

Currently, these data are not made public. Although the end of the data protection period means the data can be relied upon by others seeking approval for an equivalent therapeutic good, it does not result in the data being publicly available. This will be discussed in further detail later in this chapter.

9.1.2. Overview of data protection in Australia

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. This involves the TGA individually evaluating the quality, safety and efficacy of the medicine. Lower risk medicines containing

pre-approved, low-risk ingredients and medicines with limited therapeutic claims, such as over-the-counter products, can be simply listed on the ARTG.³²⁶

In seeking registration of a pharmaceutical product on the ARTG, a pharmaceutical company (the sponsor) submits a dossier of information to the TGA demonstrating the medicine's safety, efficacy and quality. Where the medicine relates to a chemical entity that has not previously been registered on the ARTG, the data contained in the dossier are often the result of substantial investment by the sponsor in clinical trials and testing. These data are not published or released; they are used internally by TGA and retain their status as confidential information unless and until they are voluntarily made public by the sponsor.

As part of an abbreviated marketing approval process, these data can be relied upon at a later date by the same or another company to obtain registration for medicines which are 'bioequivalent' to the original. This avoids unnecessary duplication of clinical trials.

However, a condition is placed on the use of the data to prevent imitators free-riding on sponsors' expenses in conducting clinical trials and tests. This condition is known as data protection, or data exclusivity.

Data protection prevents the regulator, for a limited time, from relying on the data without the permission of the sponsor for the purpose of approving generic copies of the registered product. Australia provides five years of protection for undisclosed data submitted to the TGA for the registration of products containing a new active pharmaceutical ingredient (API). Although data protection prevents unauthorised use of the sponsor's data by the TGA, another pharmaceutical company is not prevented from conducting its own clinical trials and presenting its results in a full application for regulatory approval. Alternatively, a generic applicant is not precluded from making a literature based submission.

³²⁶ 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>.

9.1.3. Australian law on data protection

Data protection is governed by s.25A of the *Therapeutic Goods Act 1989* (Cth). It was introduced through amending legislation in 1998.³²⁷

The period of five years data protection applies from the date the product is registered on the ARTG.

Data protection applies to therapeutic goods consisting, or containing, an active component not previously registered on the ARTG. An active component is defined in s.25A(3) as a substance, or one of the substances which, together, are primarily responsible for the biological or other effect identifying the goods as therapeutic goods.

Data protection applies to the first application for the active component. Therefore, new dosage forms, routes of administration, new indications, or combinations with other substances are excluded. Therapeutic devices are also excluded from data protection.

Data protection only applies to information provided for *registrations* on the ARTG.³²⁸ Products which are *listed* on the ARTG such as most complementary medicines, do not receive data protection for the information provided to the TGA. Due to their nature, many listed complementary medicines may also not be eligible for patent protection.

9.1.4. Comparison internationally

Australia is among a large number of nations providing data protection. Australia, New Zealand, Singapore and Korea have a similar approach to data protection, with a 5 year term available for new APIs. A variety of approaches are taken by other countries, as described in Table 9.1 below.

³²⁷ *Therapeutic Goods Legislation Amendment Act 1998* (Cth).

³²⁸ *Therapeutic Goods Act 1989* (Cth) s 25A(2)(a).

Table 9.1 – Data Protection Periods ³²⁹

Country	Length	Conditions
United States	5 years	New API
	4 years	Where a paragraph IV certification is made. ³³⁰
	4 years	Biologics (a further eight year period of marketing exclusivity applies). ³³¹
	7 years	'Orphan drugs' (those intended to treat diseases and conditions that affect 200,000 or fewer people in the United States)
	12 years	New biological molecules
	+ 6 months	Paediatric clinical trial completed
European Union	Up to 11 years	New API (8 years data protection plus 2 years marketing exclusivity plus 1 year further marketing exclusivity where a new indication is approved within 8 years: 8+2+1).
	10 years	'Orphan drugs' (regulator cannot accept applications during this period)
Japan ³³²	8 years	New API
	10 years	'Orphan drugs'
Canada	8 years	New API
	+ 6 months	Paediatric indication approved
Israel	6 years	New API approved in Israel, or 6 years and 6 months from the date of approval in a 'recognised

³²⁹ International Federation of Pharmaceutical Manufacturers & Associations.

2011. *Data Exclusivity: Encouraging Development of New Medicines*. Available online:

http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity_En_Web.pdf [Accessed 1 March 2013].

³³⁰ A paragraph IV certification is one where the generic applicant notifies the patentee that it intends to enter the market despite the existence of the patent, because the patent is invalid or the generic goods will not infringe the patent: see 21 USC 355(j)(2)(A)(iv).

³³¹ 42 USC 262(k)7(A) and (B).

³³² Japan Pharmaceutical Manufacturers Association. 2012. *Pharmaceutical Administration and Regulations in Japan*. Available online:

http://www.jpma.or.jp/english/parj/pdf/2012_ch04.pdf [Accessed 1 March 2013]

		country', whichever is earlier.
China	6 years	New API

Note: Many other countries also provide data protection.

Australia's data protection provisions comply with our international obligations. 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,³³³ while the AUSFTA requires Australia to provide at least five years data protection, which is limited to undisclosed data.³³⁴

9.1.5. Data protection and the patent system

Data protection operates separately but often in parallel to the patent system. Typically, the period of data protection will overlap the patent period.

For patents that have received an extension of term in Australia under the current provisions, the effective patent life has been greater than 5 years (that is, greater than the length of data protection) in all cases. In 98% of cases, these patents had an effective patent life exceeding data protection by 2 years or more.³³⁵

These data do not include patents which did not receive an extension of term. However, using the 20 year expiry date for patents in the data set reveals that, if no extension of term had been available, 89% would have had an effective patent life longer than the 5 year data protection period and that in 78% of cases the effective patent life would have exceeded data protection by 2 years or more.³³⁶

³³³ TRIPS, Article 39.

³³⁴ AUSFTA, Article 17.10.

³³⁵ Source: IP Australia Data.

³³⁶ Source: IP Australia Data.

Notwithstanding the fact that patent protection extends beyond data protection in most cases, data protection does provide additional certainty of market exclusivity for two key reasons. Firstly, the validity of the data protection provided is not expected to be challenged in the way a patent may be. Secondly, data protection is effectively enforced by the regulator and hence does not rely on the active enforcement by the originator. Hence, even where a patent is in force, the increased certainty of data protection is likely to be of value from the perspective of the originator.

9.1.5.1. Submissions

A number of submissions argue³³⁷ that the length of data protection is too short in Australia and should be increased to match the length offered in other jurisdictions such as the US, EU and Japan. As shown above, where a pharmaceutical product is the subject of patent protection and data protection, patent expiry typically determines when competitors may enter the market. In Europe where longer periods of data protection are available, studies have shown that very few high-selling drugs gain further marketing monopoly from data protection, particularly where the patent term had been extended.³³⁸

Extending the duration of data protection might, however, be valuable to sponsors in cases where there is no patent protection because a patent was never sought, was not granted or has already expired. In some circumstances, there might also be public benefit in extending the data protection period – or using another policy instrument, such as subsidies - if the product offers important therapeutic benefits and the currently available data protection period of five years provides insufficient incentive for the sponsor to recover expenses required to bring the product to market in Australia.

³³⁷ IPTA, FICPI, AusBiotech, Medicines Australia, INTERPAT, Abbvie, MSD, CSL, AIPPI, Novartis, Amgen, Roche, Amcham.

³³⁸ 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.

Medicines Australia, in making the case for longer periods of data protection refers to the results of a survey of members:

For instance, in a recent survey of pharmaceutical companies operating in Australia ... eight companies provided a total of 13 examples of medicines which they chose not to sell in Australia or whose sale was delayed or otherwise affected in Australia over the last 10 years due to what they perceived as an insufficient period of data exclusivity.³³⁹

Medicines Australia has provided the Panel with three examples of products (the remainder were said to be confidential) and suggests these demonstrate delayed or otherwise affected entrance into the Australian market due to a perception of an insufficient period of data protection. The key patent and regulatory approval details identified by IP Australia for each of these examples are discussed generally in the following box. Medicines Australia also identifies four other pharmaceuticals undergoing late-stage development which could be delayed on the basis of insufficient data protection in Australia.

Examples suggested by Medicines Australia as demonstrating insufficient data protection

Drug A

Drug A was approved for marketing in Australia in 2007, around 2.5 years after approval in the United States.

The first patent for Drug A was filed in 1987 and expired in 2012 after obtaining an extension of term resulting in an effective patent life of 5 years and 9 months. A second patent relating to the formulation of the drug was filed in 1995, granted in 1998 and will expire in 2020 after obtaining an extension of term resulting in an effective patent life of 13 years and 4 months.

If there were no additional patents after the first patent, there might be evidence that the 5 years and 9 months effective patent life for the first patent would have been insufficient time to recoup the costs of providing these products to Australia

³³⁹ Medicines Australia, Submission to the Pharmaceutical Patents Review, p.15.

and that longer data protection would have created greater incentive. However, the presence of other patents appears to provide a considerable length of protection for the drug in Australia.

Drug B

Drug B was approved for marketing in Australia in 2005, nearly 3 years after approval in the United States.

The first Australian patent for Drug B expired in 2004 while a second patent relating the composition of the drug was filed in 1999, granted in 2003 and will expire in 2020 after it received a 6 month extension of term based on the 2005 ARTG registration.

Had Drug B been approved in Australia at the same time as in the United States, the first patent would have provided an effective patent life of 7 years. This includes an extension of term. Also in this scenario, the second patent would have provided an effective patent life of around 17 years, although it was not granted until 2003, which may have been a factor in the application with the TGA not being made until 2004.

It is unclear how only having a 5 year data protection period contributed to the delay in applying for regulatory approval and entering the market in Australia because there was a follow-on patent that provided a longer effective patent life.

Drug C

Drug C is not currently approved for marketing in Australia.

The first Australian patent for Drug C expired in 2007. Patents pertaining to a method of use and a composition of Drug A have also been granted and will expire in 2020 and 2025. Other patents relating to use in combination with other substance and methods of manufacture have also been granted.

Drug C was approved for use in limited circumstances by the European Medicines Agency in 2007 and has an orphan drug designation, meaning it is used to treat a rare condition. An application for approval by the US Food and Drug Administration was withdrawn following requests for more clinical trials. It is

unknown whether an application for approval has been made with the Therapeutic Goods Administration in Australia.

It is not clear how having only a 5 year data protection period contributed to Drug C not being available in the Australian market given the regulatory issues in other jurisdictions. Furthermore, the presence of other patents could provide further patent protection for the drug in Australia.

It is conceivable that in some circumstances, where patents have expired or are close to expiring, a longer period of data protection could be needed to make supplying the Australian market commercially viable. However, the above examples do not demonstrate clearly that this has been the case.

In its submission to the review, AbbVie proposes that:

... amendments be made to our data exclusivity provisions to allow new data, generated for new indications to be provided protection. This is particularly important in orphan diseases with significant unmet need.³⁴⁰

AbbVie also identifies leuprorelin acetate (marketed in Australia as Lucrin) as an example of where data protection for additional indications of approved drugs would provide the incentive needed to undertake further studies required by the TGA for approval. This example is discussed in the box below.

³⁴⁰ AbbVie, Submission to the Pharmaceutical Patents Review, p.7.

Example suggested by AbbVie as demonstrating the need for data protection for new indication approvals

Lucrin (leuprorelin acetate)

Leuprorelin acetate is approved in Australia under the brand name Lucrin for the treatment of prostate cancer. It may also be of use in treating Central Precocious Puberty (CPP), a rare childhood disease, but it has not yet been approved for this indication in Australia.

According to AbbVie, the TGA has requested additional pharmacokinetic studies to be performed for the purpose of assessing the application to use Lucrin in treating CPP. The drug has been approved by the FDA for treating CPP since 1993.

The Australian patents relating to Lucrin have expired. Data protection will also not be available for any subsequent registrations of Lucrin as the active component is already the subject of a previous ARTG registration.³⁴¹

Therefore, if AbbVie proceeds in bringing the drug to market for the treatment of CPP, it 'faces the prospect of being required to invest in additional studies while not being afforded the protection for any data generated.'³⁴²

The Lucrin example reveals a situation where data protection is unavailable and, as such, there is a risk that a treatment for a rare condition will not be available in Australia. AbbVie's proposal to expand data protection to include data submitted in applications for treating new indications may address the issue in this case. It would also expand the five year protection to all cases where treatment of a new indication with a previously approved substance was approved by the TGA.

³⁴¹ *Therapeutic Goods Act 1989* (Cth), s.25A.

³⁴² AbbVie, Submission to the Pharmaceutical Patents Review, p.6.

Amgen submits that data protection is particularly important in the case of biologics where patent protection may be less certain and suggests that:

Without data exclusivity, innovative biologics will be at risk of imitation long before they have an opportunity to recover the cost of research and development or earn a return on the investment.³⁴³

Issues relating to biologics are discussed in more detail later in this chapter.

The Australian Group of the International Association for the Protection of Intellectual Property (AIPPI) also argue that data protection should be available for medicines listed (not just registered as is currently the case) on the ARTG:

The preparation of information for product listing takes time and incurs cost that should be rewarded by some degree of exclusivity. This is particularly so as listed products will not always be suited to patent protection.³⁴⁴

This argument suggests that there are products which are not brought to market because the returns are insufficient in relation to the costs to do so. These products do not meet the requirements for obtaining a patent and are not protected by data protection as they have gone through the lesser requirements of listing, as opposed to registration, on the ARTG. The Panel has not been provided with examples of these products and as such cannot make a judgement as to whether they are innovative products that would warrant additional protection beyond what is currently available.

A number of submissions argue for extending data protection in the case of 'orphan' drugs and paediatric indications.³⁴⁵ The argument in favour of doing so is that it would provide an increased incentive for bringing products to market where it may otherwise be insufficient.

³⁴³ Amgen, Submission to the Pharmaceutical Patents Review, p.8

³⁴⁴ AIPPI, Submission to the Pharmaceutical Patents Review, p.10.

³⁴⁵ For example, submissions received from JIPO, IPTA, FICPI, Abbvie, CSL.

‘Orphan’ drugs and drugs for paediatric indications can face particular challenges due to smaller target populations. Although clinical trials are required in each case, the target population has fewer potential participants for other trials. These smaller patient populations might also limit potential sales and returns.

However, as discussed more fully in the chapter 5 on extensions of term, it is unlikely that these challenges are best met by extending the time during which the sponsor has market exclusivity, as even a one or two year extension may provide limited benefit to a sponsor in a small market. Where there are concerns about sufficient incentive in particular problem areas, greater benefit may arise from subsidising or assisting research and development during the early and clinical trial stages.

Dr Moir argues that data protection should not apply during the last three years of the term of a patent so as not to delay generic market entry when the patent expires.³⁴⁶

While this would result in data protection being reduced in a relatively small number of instances (less than 5% of cases where patents receive an extension)³⁴⁷ the effect would be to reduce the certainty provided by data protection in general as drug development timeframes are uncertain.

9.1.6. Analysis

Data protection is of value to originators due to the increased certainty it provides in relation to market exclusivity and may provide additional value in a small number of cases where the relevant patent expires before data protection. The Panel has not seen any evidence that lengthening the period of data protection would result in pharmaceutical products being made available in Australia that otherwise would not have.

³⁴⁶ Dr Hazel Moir, Submission to the Pharmaceutical Patents Review, p.8.

³⁴⁷ Source data: IP Australia.

A case has been presented where providing data protection in the case of approvals of new indications, instead of only new active ingredients, may increase the availability of treatments in Australia. However, this appears to be a rare case and such a change would have broad implications. Therefore, the Panel is not inclined to suggest that expanding this form of protection is the most appropriate mechanism for encouraging the registration of these new indications in Australia.

The Panel invites inquiry participants to provide examples where data protection has been or would be significant in bringing an innovative medicine to Australia that would otherwise not have been available.

9.1.7. Current situation of indefinite confidentiality

Unlike other forms of intellectual property where a period of exclusivity is provided in return for public disclosure, the data protected by data protection remains confidential indefinitely. This is despite the data having value to pharmaceutical researchers involved in the development of other pharmaceuticals and research directed towards a better understanding of complex medical conditions and responses to drugs. Opening these data for further research would not commercially disadvantage the sponsor, with respect to the drug registered by TGA, and could be of substantial public health benefit. It thus makes sense, in principle, that these data should be publicly available.

However, any proposal to make data publicly available should be addressed in an internationally coordinated way because a country publishing company data unilaterally would face the risk that companies would not seek regulatory approval in that country. At present, data are only eligible for data protection if they have not previously been put in the public domain. This requirement is common to many jurisdictions. If Australia alone were to make otherwise confidential data publicly available this may make such data ineligible for protection in other jurisdictions.

Concerns about the impact of not maintaining confidentiality of data were discussed by the Industry Commission in 1996. The Commission stated that '[i]f

commercial confidentiality cannot be assured, there is a potential for new drugs to be withheld from the Australian market ...'.³⁴⁸

It appears, however, that there is growing international interest in making these data publicly available. In 2012, the European Medicines Agency (EMA) 'committed to proactive publication of the data from clinical trials supporting the authorisation of medicines.'³⁴⁹ It is currently conducting a consultation process to address practical and policy issues related to this commitment. Since 2010, the EMA has had a practice of releasing, on request, a number of documents relating to the assessment of medicinal products under its access-to-documents policy.³⁵⁰

The Panel believes it would be in Australia's interest to engage with these discussions and to contribute to the development of a protocol where these important clinical data are made publicly available, and where the protection given by data protection is provided in exchange for publication. This recommendation should be considered as part of a number of recommendations relating to international negotiations made in Chapter 3.

Draft recommendation 9.1:

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

9.2. Biologics

9.2.1. What are biologics

The term "biologics" generally refers to a class of drugs which are made using biological, as opposed to chemical processes. Biologics are complex compounds which may be comprised of proteins, sugars, or nucleic acids, or may be living

³⁴⁸ Industry Commission, 1996. *The Pharmaceutical Industry Volume 1: The Report, Report No. 51.*

³⁴⁹ European Medicines Agency. 2012. *Release of data from clinical trials.*

[website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac0580607bfa]

³⁵⁰ Ibid.

entities, such as cells and tissues.³⁵¹ There are various categories of biologics, including therapeutic proteins made using recombinant DNA technology, monoclonal antibodies and vaccines. Common examples of biologics are the drugs Enbrel and Humira, which are antibody-based recombinant proteins used to treat rheumatoid arthritis.

In Australia, generic versions of biologics are referred to as 'Similar Biological Medicinal Products (SBMPs)', but they may also be referred to as 'biosimilars' or 'biogenerics'.³⁵² A biosimilar is a biological product that can demonstrate a degree of similarity to a biologic product which has already received approval for registration on the ARTG.

Unlike generic versions of small molecule drugs, biosimilars are not considered to be bioequivalent to a reference biological product. This is due to the highly complex nature of biological medicinal products.

The EU Guideline on Similar Biological Medicinal Products (CHMP/437/04) states that by definition:

...similar biological medicinal products are not generic medicinal products, since it could be expected that there may be subtle differences between similar biological medicinal products from different manufacturers or compared with reference products, which may not be fully apparent until greater experience in their use has been established.

The introduction of biosimilars into the Australian market brings significant challenges for both policy makers and generic manufacturers.

³⁵¹ US Food and Drug Administration
<<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm>>, accessed 15 March 2013.

³⁵² DoHA Annual Report 2011-12
<<http://www.health.gov.au/internet/annrpt/publishing.nsf/Content/annual-report-1112-toc~11-12part2~11-12part2.2~11-12outcome2>> accessed 15 March 2013.

9.2.2. Why are biologics important

Biologics are an important and innovative development in pharmaceuticals. They have revolutionised the treatment of diseases such as anaemia, diabetes, cancer, hepatitis, and multiple sclerosis.³⁵³

The smallpox vaccine was probably the first biologic to be developed, in the late 18th century. However, commercial manufacture of biologics only started in earnest in the 1980s, as recombinant DNA technology became widely used and the biotechnology industry emerged. At that time, US-based companies like Genentech and Amgen first started to produce first generation therapeutic proteins such as insulin, erythropoietin and human growth hormone using recombinant DNA technology.

The Australian biotechnology industry is involved in the development of a range of new biologics, and has experienced some success. Gardasil is perhaps the best known example. Gardasil is a vaccine against the human papilloma virus, which causes cervical cancer. Professor Ian Frazer at the University of Queensland made the initial discovery of a potential target for the vaccine on the coat of the virus in 1991. Australian biotechnology company CSL, in collaboration with the multinational pharmaceutical company Merck, commercialised the technology,³⁵⁴ which is now protected by a family of patents.

³⁵³ H. Schellekens, *Biosimilar therapeutics – what do we need to consider?* NDT Plus, (2009) 2 [Suppl 1]: i27-i36.

³⁵⁴ For a brief overview of these developments see: Graeme O'Neill, 'CSL Celebrates Cervical Cancer Vaccine Success' (2002) *Australian Life Scientist*, available at: http://www.lifescientist.com.au/article/48933/csl_celebrates_cervical_cancer_vaccine_success/ (accessed 21 February 2011).

9.2.3. Market profile

The US Pharmaceutical Industry Association estimates that there are 400 biologic drugs on the market and 900 others in the pipeline.³⁵⁵ In Australia, there are currently 64 biologics listed on the PBS.³⁵⁶ The use of biological medicines is set to increase in the future, with the development of targeted therapies and personalised medicine.

IMS Health estimates that since the origins of biologics in the 1980s, the market has developed into one with a world-wide value of US\$138 billion.³⁵⁷ Many high value biologic drugs are due to lose patent protection in the next five years,³⁵⁸ providing a significant market opportunity for the production of biosimilars. The entry of biosimilars is important for consumers, as it is estimated that they provide an affordable alternative to originator medicines, with a cost reduction in the region of 20-25%.³⁵⁹ IMS Health estimates that biosimilars will constitute 50% of the off-patent biological medicines market by 2020.³⁶⁰

Despite the promise of biologics, they are more costly to develop than chemical drugs, and more prone to failure. Roth gives figures of \$802 million as the average cost of developing a chemical drug and \$1.2 billion as the average cost of developing a new biologic.³⁶¹

The market for a biologic is also typically very different to the market for a small molecule drug. Small molecule drugs can have very large patient cohorts and be relatively inexpensive to manufacture, resulting in a low price per unit. In

³⁵⁵ V. J. Roth, *Will Data Exclusivity Make Biologic Patents Passe?*, Santa Clara Computer & High Technology Law Journal, Vol 29, Issue 2, p.254.

³⁵⁶ Source data: Department of Health and Ageing, March 2013.

³⁵⁷ *Shaping the Biosimilars Opportunity*, IMS Health, December 2011.

³⁵⁸ *Shaping the Biosimilars Opportunity*, IMS Health, December 2011, p.6.

³⁵⁹ M. Narayanamoni, *Biodynamism, Insights into the Biosimilars market: An overall perspective*, Grant Thornton, 2013.

³⁶⁰ *Shaping the Biosimilars Opportunity*, IMS Health, December 2011, p.6.

³⁶¹ V. J. Roth, *Will Data Exclusivity Make Biologic Patents Passe?*, Santa Clara Computer & High Technology Law Journal, Vol 29, Issue 2, pp.259-260.

contrast, manufacture of biologics is more complex and expensive.³⁶² Although some biologics have a large patient cohort, such as patients requiring insulin therapy or treatment for rheumatoid arthritis, biologics have the potential to develop targeted solutions for small patient cohorts with particular conditions.

9.2.4. Patent perspective

At the time of writing, reliable statistics on the patenting of biologic drugs were not available. The Panel was advised by IP Australia that this was due to the difficulty in differentiating between patents for small molecule drugs and biologics without examining each individual patent.

Marimuthu et al conducted a study which examined the patent landscape for biologics based on information available from the product labels.³⁶³ The study found that of the 44 FDA approved biologics examined, a total of 151 relevant patents existed.³⁶⁴ This suggests that the patent landscape for biologics is no more complex than that for small molecule drugs.

The availability of patents for biological materials and for many of the research tools used in early stage research and development in biomedicine has raised concerns about a so-called anti-commons effect, which could slow the pace of biologic drug development.³⁶⁵ This is where a large number of intellectual property rights owned by different parties relate to a single product, making it difficult for any one party to make the product. As discussed in the previous paragraph, there is no evidence that this is occurring for biologics more so than

³⁶² V. J. Roth, *Will Data Exclusivity Make Biologic Patents Passe?*, Santa Clara Computer & High Technology Law Journal, Vol 29, Issue 2, p.258.

³⁶³ Marimuthu et al, *Maintaining patents protecting biologics or small-molecule drugs*, Nature Biotechnology, Vol 30, No. 1, January 2012.

³⁶⁴ Marimuthu et al, *Maintaining patents protecting biologics or small-molecule drugs*, Nature Biotechnology, Vol 30, No. 1, January 2012.

³⁶⁵ M. Heller and R. S. Eisenberg, *Can patents deter innovation? The anticommons in biomedical research*. Science Vol.280, 1998 p.698

for other drugs. There is also no clear evidence that the pace of development has in fact been slowed by early-stage patents.³⁶⁶

9.2.5. The generic industry and biosimilars

The development of biosimilars poses challenges for the generic manufacturing sector when compared with small molecule drugs. Biosimilars are complex and achieving therapeutic equivalence is extremely difficult.

The clinical performance of biologics is highly dependent on the method of production and purification.³⁶⁷ Even minor differences in the atmosphere or manufacturing process can compromise activity.³⁶⁸

Another concern is that of immunogenicity. Immunogenicity refers to the ability of a biological medicine to be considered foreign by the human body and generate an immune response such as neutralising antibodies.³⁶⁹

Due to the complex nature of biologics, obtaining regulatory approval for biosimilars is more complicated than that of generic small molecule drugs. A biosimilar drug is not considered to be bioequivalent to an originator reference product by the TGA. As a consequence, a generic company cannot rely wholly on the clinical and safety data of the reference product and must produce its own

³⁶⁶ J. P. Walsh, A. Arora and W. M. Cohen, *Effects of research tool patenting and licensing on biomedical innovation*. In W. M. Cohen and S. A. Merrill (eds), *Patents in the Knowledge-Based Economy*. National Academies Press, 2003; D. Nicol and J. Nielsen, *Patents and medical biotechnology: an empirical analysis of issues facing the Australian industry*. Occasional Paper No 6, Centre for Law and Genetics, 2003.

³⁶⁷ R. McKinnon, *Biosmilars are not (bio)generics*, Australian Prescriber, Vol.32, No.9, December 2009, p.146.

³⁶⁸ R. McKinnon, *Biosmilars are not (bio)generics*, Australian Prescriber, Vol.32, No.9, December 2009, p.146.

³⁶⁹ R. McKinnon, *Biosmilars are not (bio)generics*, Australian Prescriber, Vol.32, No.9, December 2009, p.146.

data to ensure that a biosimilar can be used in the same manner as the reference product.

Alphapharm provided evidence in public hearing which outlined these difficulties. Alphapharm stated that manufacturing of biosimilars would require a specialised facility and it would be difficult to manufacture on a large scale. Manufacturing was complicated by the highly sensitive nature of biologics and the high risk of contamination. The additional costs that generic companies would incur by having to undertake clinical trials to demonstrate safety and efficacy was also raised.

Despite these difficulties, Hospira has been successful in obtaining regulatory approval and PBS listing for its biosimilar of the drug filgrastim, marketed as Nivestim.

Regulatory Approval of the Biosimilar – Nivestim (filgrastim)

Filgrastim is a granulocyte colony-stimulating factor produced using gene technology. It is used to treat neutropenia, a condition in which infection-fighting white blood cells become too low. Neutropenia often occurs as a result of chemotherapy.

The reference product for filgrastim was the subject of Australian Patent No. 769969, owned by Amgen, which expired in 2006. Amgen marketed filgrastim under the brand name Neupogen. Neupogen was estimated to have sales of \$25m AUD in 2010.³⁷⁰ Hospira applied for TGA approval via the biosimilar pathway and was granted ARTG listing for Nivestim on 16 September 2010. It was listed on the PBS on 1 September 2011. As a result, filgrastim was subject to a statutory price reduction and moved to the F2 formulary on the PBS.

³⁷⁰ <<http://www.news-medical.net/news/20100927/Hospiras-Nivestim-receives-Australian-TGA-approval.aspx>> accessed at 21 March 2013.

9.2.6. Regulatory environment

The TGA introduced the Biologicals Regulatory Framework and the Australian Regulatory Guidelines for Biologicals (ARGB) in 2011. The purpose of the Framework is to regulate human cell and tissue-based products. The Framework provides a system of assessment and controls that must be completed before biological products can be marketed in Australia, as well as further controls to apply once the goods are marketed.³⁷¹ The key benefits of the Framework are designed to:

- minimise the risk of infectious disease transmission;
- ensure the level of regulation is appropriate to the level of risk posed by specific biologic products by separating them into four classes;
- provide a framework to deal with emerging technologies;
- provide a unique framework for biological medicines as current arrangements for non-biologics may not be appropriate;
- reduce ambiguity about what is included or excluded from regulation; and
- increase harmonisation of therapeutic goods regulation.³⁷²

Biological products included in the framework are human tissue therapy products, processed human tissues, human cellular therapy products, immunotherapy products containing human cells, and genetically modified human cellular products, and other products which include such biologics as combination products.³⁷³

The TGA has adopted the European Medicines Agency (EMA) Guidelines for assessing biosimilars.³⁷⁴ These guidelines require that applicants submit

³⁷¹ Australian Regulatory Guidelines for Biologicals, June 2011, available at <
<http://www.tga.gov.au/industry/biologicals-argb.htm>>

³⁷² Australian Regulatory Guidelines for Biologicals, June 2011, available at <
<http://www.tga.gov.au/industry/biologicals-argb.htm>>

³⁷³ Australian Regulatory Guidelines for Biologicals, June 2011, available at <
<http://www.tga.gov.au/industry/biologicals-argb.htm>>

³⁷⁴ <http://www.tga.gov.au/pdf/euguide/chmp043704final.pdf> accessed 18 March 2013.

comparative clinical and pharmacokinetic studies, non-clinical studies, clinical pharmacodynamic studies, toxicology studies, comparative clinical efficacy studies, and a post-marketing surveillance plan to monitor any onset of immunogenicity that may occur.³⁷⁵

9.2.7. Biosimilars and the PBS

Currently the pricing of biosimilars to be listed on the PBS is determined by the same process as for all prescription medicines. If a biosimilar enters the market, the reference product and the biosimilar will be placed in the F2 formulary and be subject to ongoing price disclosure. An example of this can be seen with Hospira's Nivestim product. DoHA continues to work with its agencies, the TGA and the PBAC, and the pharmaceutical industry to develop an agreed policy position for the pricing and reimbursement of biosimilars.³⁷⁶

The savings to consumers and the PBS when a biosimilar enters the market are likely to be less than those generated from a standard generic drug. This is primarily due to the much higher development, manufacturing, and ongoing market surveillance costs that biosimilars will incur, requiring the generic manufacturer to charge more per item than for small molecule drugs. In addition, the difficulties in obtaining regulatory approval may mean that a biosimilar will not enter the market until some time after patent expiry of the reference product. A price reduction of the reference product will not occur until the biosimilar is listed on the PBS.

³⁷⁵ P.Declerck, *Biologicals and biosimilars: a review of the science and its implications*, Generics and Biosimilars Initiative Journal, Vol.1, March 2012.

³⁷⁶ DoHA Annual Report 2011-12.

<<http://www.health.gov.au/internet/annrpt/publishing.nsf/Content/annual-report-1112-toc~11-12part2~11-12part2.2~11-12outcome2>> accessed 15 March 2013.

9.2.8. Data Protection

As discussed previously in this chapter, Australia currently provides a period of five years data protection for new drugs. In the EU data protection is eight years, with two years marketing exclusivity, and an additional one year available for a new indication.

The US has a data protection period of five years for new APIs and four years for biologics.³⁷⁷ A further period of eight years marketing exclusivity applies to biologics,³⁷⁸ which means that an application for a biosimilar cannot be made effective by the FDA for at least twelve years from the date of marketing approval of the reference product.³⁷⁹ The additional data period for biologics was provided as an incentive for innovators and to compensate for the additional time taken to enter the market and the subsequent reduction in effective patent life.³⁸⁰

In considering the period of data protection that should apply, the US Congress determined that a twelve year period for biologics appropriately balanced the potential cost savings from price competition from biosimilars with long term incentives for investment in innovative biologics.³⁸¹ Grabowski et al estimated that an originator biologic drug could be expected to break even after a period of 12.9 -16.2 years.³⁸² However, there has been much debate on the subject. In 2009 the US Federal Trade Commission (FTC) found that 12 years data protection was not necessary to spur innovation, with sufficient incentive provided through patents and market-based pricing. However, representatives

³⁷⁷ 42 USC 262(k)(7)(B).

³⁷⁸ 42 USC 262(k)7(A).

³⁷⁹ 42 USC 262(k)7(A).

³⁸⁰ John P. Hanish, *Implementation of the Biologics Price Competition and Innovation Act* <<http://www.goodwinprocter.com/Publications/Newsletters/IP-Advisor/2012/20120501.aspx?article=2>> (accessed 15 March 2013).

³⁸¹ Grabowski et al, *Data exclusivity for biologics*, Nature Reviews, Vol 10, January 2011, p.16.

³⁸² Grabowski et al, *Data exclusivity for biologics*, Nature Reviews, Vol 10, January 2011, p.15.

argued that 14 years should be provided due to the complexity and expense involved in developing biologics.³⁸³

Amgen submits that data protection is particularly important in the area of biologics, due to the scientific differences between biotechnology medicines and traditional small molecules, and argues that data protection should be increased.³⁸⁴ Data protection is perceived as a valuable instrument that protects years of financial investment and significant effort in the development of new medicines. Amgen submit that this was particularly so for biologic medicines:

Without data exclusivity, innovative biologics will be at risk of imitation long before they have an opportunity to recover the cost of research and development or earn a return on the investment. This will dramatically erode an incentive to risk the substantial sums of money and many years of effort required to develop innovative biologic medicines.³⁸⁵

Grabowski et al demonstrated that where remaining patent life is short at the time of market entry, data protection greatly enhanced investment incentives. Conversely, where the biologic patent was considered to have strong patent protection, this on its own was sufficient to maintain investment incentives.³⁸⁶

³⁸³ Federal Trade Commission, 'Emerging Health Care Issues: Follow-on Biologic Drug Competition', pg 27, June 2009.

³⁸⁴ Amgen, Submission to the Pharmaceutical Patents Review, pp.7-8.

³⁸⁵ Amgen, Submission to the Pharmaceutical Patents Review, p.8.

³⁸⁶ Grabowski et al, *Data exclusivity for biologics*, Nature Reviews, Vol 10, January 2011, p.16.

Arguments against extending data protection for biologics primarily focus on the lack of need for such an extension, as the inherent complexity of the products makes them difficult to replicate. The US FTC concluded that given the high costs of development, competition from generics would be muted.³⁸⁷ The findings of the FTC also suggest that patent protection for biologics is adequate, even though they may be based on naturally occurring substances that are not patentable subject matter. The FTC also found that biologics are difficult to design around,³⁸⁸ although some in the biologics sector argue that the opposite is true, making patent protection unreliable.³⁸⁹

Data protection provides additional market exclusivity only to the extent that a patent can be circumvented by a biosimilar, or the remaining period of patent protection after the approval of the originator biologic is shorter than the data protection period.³⁹⁰ As Amgen's submission illustrates, in this situation, data protection is considered an important factor to preserve the incentive to invest in developing biologics by originator companies.

³⁸⁷ Federal Trade Commission, 'Emerging Health Care Issues: Follow-on Biologic Drug Competition', June 2009.

³⁸⁸ Federal Trade Commission, 'Emerging Health Care Issues: Follow-on Biologic Drug Competition', June 2009.

³⁸⁹ 'PhMRA Statement on President's Budget Proposal', PhMRA, 14 February 2011, <http://www.phrma.org/media/releases/phrma-statement-ongoing-investments-domestic-innovation>.

³⁹⁰ Grabowski et al, *Data exclusivity for biologics*, Nature Reviews, Vol 10, January 2011, p.15.

Draft finding 9.1:

The Panel considered whether data protection should be increased for biologics.

The Panel is unconvinced that an extension of data protection would be beneficial. The Panel found no evidence to suggest that patents for biologics will be more difficult to obtain than patents for small molecule drugs, or that effective patent life would be substantially reduced by the complexity of biologics.

Additionally, given that the generic manufacturer of a biosimilar cannot rely solely on the clinical data of the reference product to obtain regulatory approval, there is reduced advantage to be gained from granting an additional term of data protection.

The Panel is of the view that given the substantial market opportunity that will arise in the near future for biosimilars, and the corresponding potential for cost savings to the PBS and consumers, competition in this area should be encouraged. At present the Panel does not have sufficient evidence to support an increase in data protection beyond the current five year period for biologics.

10. Integrated approach to the pharmaceutical system

10.1. Current situation

The pharmaceutical system is complex. It involves a number of complicated government-administered schemes and processes: R&D funding and assistance schemes; the patent system; regulatory approval processes; and the PBS listing and pricing process. The operation of each of these systems can have a significant effect on one or more of the others. For example:

- patent protection encourages investment in the R&D and clinical trials necessary to bring a new medicines or medical treatments to market, reducing reliance on Government funding to bring new medicines and health treatments to market;
- the time it takes to conduct clinical trials and obtain marketing approval affects the period of effective market exclusivity for a patented pharmaceutical and when an application for PBS listing is made;
- the granting of patents and patent term extensions directly affects the availability of generic products to the market, which in turn affects the level of PBS subsidies, and ultimately the cost of the PBS to the Government and taxpayers.

All of the regulatory systems affect whether a product will be made available to the public in a timely and cost effective manner.

A number of different agencies are responsible for administering these schemes and processes:

- the Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education (DIICCS RTE) and the Department of Health and Ageing (DoHA) administer government R&D funding programs;
- IP Australia administers the patent system;
- TGA administers the marketing approval system; and
- PBAC evaluates applications for PBS listing.

Each agency has its own role within the system, with limited interaction between agencies when fulfilling their separate administrative roles. For example, applications to IP Australia, the TGA and PBAC are all separate processes with their own criteria for success, with patent eligibility considered by IP Australia an entirely separate matter to safety and efficacy evaluations undertaken by the TGA, or cost-effectiveness evaluations by PBAC. Whether a patent exists for a particular drug is not a relevant consideration for the TGA or PBAC.

One example of coordination between the systems is the parallel process for TGA and PBS applications recently introduced by DoHA to assist pharmaceutical companies to reduce the time taken to obtain the required approvals. In 2011-12, 39% of major submissions considered by the PBAC took advantage of this process.³⁹¹

As far as policy development is concerned there are a number of bodies that coordinate government health policy, such as the Council of Australian Governments Standing Council on Health. The Pharmaceutical Industry Working Group (PIWG) provides a forum where Government and industry representatives can discuss key issues relevant to the development of the pharmaceutical industry. PIWG is chaired jointly by the Minister for Innovation, Industry, Science and Research and the Minister for Health and Ageing. Representatives include the CEO of the NHMRC, originator and generic pharmaceutical manufacturers, biotechnology companies, over the counter and complementary medicine companies and research institutions. The terms of reference for PIWG include the discussion of impediments and opportunities in various areas, including innovation, regulation and approvals processes and research and path to market.

³⁹¹ DoHA Annual Report 2011-12, p.99. In public hearings representatives of Pfizer and MSD said that, while the industry was broadly supportive of measures to reduce the total regulatory approval timeframe, the parallel process was unlikely to significantly reduce the total timeframe in many instances. Using the parallel process involves some risk for companies because if changes are necessary to the TGA application, this can require a new PBS application to be submitted at significant extra cost. In such circumstances a company is better off completing the TGA application before filing their PBS application.

Another relevant forum with industry is the Access to Medicines Working Group (AMWG). This group consists of representatives from DoHA and Medicines Australia. The purpose of the AMWG is to enhance co-operation between industry and government and to consider issues regarding the timely and appropriate access to new medicines for the PBS.

There is, however, no body or group to inform the PIWG, AMWG or, more widely the Government as to the interaction of the patent, R&D, regulatory approval and PBS approval processes and how well they are achieving innovation and national medicines policy objectives.

Each of the regulatory systems is subject to ongoing reform and some are aligned with international systems.³⁹² Coordination between the regulatory systems in Australia must take into account the requirements of international agreements.

10.2. Analysis

When setting government policy on the pharmaceutical sector, decision makers need to take into account the system as a whole. Pharmaceutical industry policies need to consider how the different elements of bringing a drug to market interact and influence each other, including the patent system.

Policy considerations are discussed at forums such as PIWG. However, there appears to be little coordination between IP Australia and other agencies such as DoHA and DIICCSRTE, despite the obvious and significant impacts the patent system can have on public health. The Panel understands that although regular meetings are held between senior officials of at least some of these agencies,

³⁹² The patent system complies with a number of international agreements, including the WIPO Patent Cooperation Treaty, TRIPS and AUSFTA. The clinical trial and marketing approval systems comply with a range of international systems. These include Mutual Recognition Agreements and Memoranda of Understanding with other countries, the Pharmaceutical Inspection Cooperation Scheme, Good Clinical Practice standards and requirements in AUSFTA.

these appear to cover a wide range of issues and do not focus on pharmaceutical policy.

Draft Finding 10.1:

The patent system is of obvious significance to the pharmaceutical industry, trade negotiations and health policy. However, the government agencies with policy and program responsibility in these areas are not engaging sufficiently with each other and are not taking highly relevant issues into account. Each agency needs to be actively engaging from its own perspective – end users, innovation, industry and international implications – in order to optimise policy settings for the pharmaceutical system in what is a complex regulatory and service delivery environment. The areas of government responsible for regulating pricing of pharmaceuticals particularly have the need for and the resources to obtain a well-informed appreciation of the pharmaceutical patent system and its impact on a range of health issues. However, the only area in which they appear to have a strong view is in relation to gene patents.³⁹³

It would be beneficial to the pharmaceutical sector to have greater co-operation and transparency between relevant government agencies when making decisions about pharmaceutical industry policy. The Panel considers there is a need for a non-statutory Pharmaceutical System Coordinating Committee (PSCC) with the ability to provide strategic oversight and to ensure engagement between the relevant agencies to ensure that the pharmaceutical system is meeting its objectives as efficiently and effectively as possible. The PSCC should be chaired by an agency with an economy- wide focus such as Treasury. The PSCC would respond to any issues raised by industry and report publicly to Parliament on a yearly basis and to the Government.

³⁹³ Department of Health and Ageing, *Submission to the Productivity Commission Inquiry into Compulsory Licensing*, September 2012; Submission to the Senate Community Affairs Committee Inquiry into Gene Patents, 2009; Submissions P65 and P79 to the ALRC Inquiry into Gene Patents, 2004.

Draft recommendation 10.1:

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

Some of the Government's objectives for the pharmaceutical system are defined in legislation. The Therapeutic Goods Act 1989 includes an objects clause stating that the object of the Act is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy, and timely availability of therapeutic goods which are used in Australia or exported from Australia.³⁹⁴ The *National Health Act 1953* (Cth), which governs the operation of the PBS, does not contain an objects clause. Similarly, the Patents Act does not currently have an objects clause. However, in its response to the Senate Community Affairs Gene Patents Report, the Government committed to introducing an objects clause to give effect to the intention that patents should not lead to patients being denied reasonable access to healthcare.³⁹⁵ The Panel

³⁹⁴ Section 4.

³⁹⁵ Government Response to Senate Community Affairs Committee Gene Patents Report, p.13. ACIP recommended that the objects clause should describe the purposes of the legislation as being "to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technological knowledge, and Australian society as a whole." The Government response agreed to develop legislation to give effect to this recommendation and to the Government's "intention that patents should not lead to patients being denied reasonable access to healthcare".

understands that progress on developing the clause, including public consultation, will commence later this year.

The Panel supports the Government's decision to introduce such a clause in the Patents Act.

Draft recommendation 10.2:

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

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

Appendices

Appendix A: 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: Relevant provisions from international agreements**TRIPS Agreement, Part II, Section 5***Article 27 - Patentable Subject Matter*

1. Subject to the provisions of paragraphs 2 and 3, patents shall 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.³⁹⁶ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

³⁹⁶ For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

Article 28 - Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing³⁹⁷ for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 30 - Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

³⁹⁷ This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

AUSFTA - Chapter 17

Article 17.9 – Patents

1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any new uses or methods of using a known product. For the purposes of this Article, a Party may treat the terms “inventive step” and “capable of industrial application” as synonymous with the terms “non-obvious” and “useful”, respectively.

2. Each Party may only exclude from patentability:

(a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and

(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

3. A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

4. Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.

5. Each Party shall provide that a patent may only be revoked on grounds that would have justified a refusal to grant the patent, or on the basis of fraud, misrepresentation, or inequitable conduct.

6. Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for marketing approval for the product, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.

7. A Party shall not permit the use^{17-[22]398} of the subject matter of a patent without the authorisation of the right holder except in the following circumstances:

(a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices;^{17-[23]399} or

(b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:

(i) the Party shall limit such use to use by the government or third persons authorised by the government;

(ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and

³⁹⁸ 17-[22] "Use" in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement.

³⁹⁹ 17-[23] With respect to sub-paragraph (a), the Parties recognize that a patent does not necessarily confer market power.

(iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.

8. (a) If there are unreasonable delays in a Party's issuance of patents, that Party shall provide the means to, and at the request of a patent owner, shall, adjust the term of the patent to compensate for such delays. An unreasonable delay shall at least include a delay in the issuance of a patent of more than four years from the date of filing of the application in the Party, or two years after a request for examination of the application has been made, whichever is later. For the purposes of this paragraph, any delays that occur in the issuance of a patent due to periods attributable to actions of the patent applicant or any opposing third person need not be included in the determination of such delay.

(b) With respect to a pharmaceutical product^{17-[24]400} that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

9. Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure (a) was made or authorised by, or derived from, the patent applicant, and (b) occurs within 12 months prior to the date of filing of the application in the territory of the Party.

10. Each Party shall provide patent applicants with at least one opportunity to make amendments, corrections, and observations in connection with their applications.

⁴⁰⁰ 17-[24] For Australia, the term pharmaceutical substance as used in Section 70 of the Patents Act 1990 on the date of entry into force of this Agreement may be treated as synonymous with the term pharmaceutical product as used in this sub-paragraph.

11. Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date.

12. Each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention, as of the filing date.

13. Each Party shall provide that a claimed invention is useful if it has a specific, substantial, and credible utility.

14. Each Party shall endeavour to reduce differences in law and practice between their respective systems, including in respect of differences in determining the rights to an invention, the prior art effect of applications for patents, and the division of an application containing multiple inventions. In addition, each Party shall endeavour to participate in international patent harmonisation efforts, including the WIPO fora addressing reform and development of the international patent system.

15. Each Party shall endeavour to establish a cooperative framework between their respective patent offices as a basis for progress towards the mutual exploitation of search and examination work.

17.10: Measures related to certain regulated products

1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical product, the submission of undisclosed test or other data concerning safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who provided the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for at least five years from the date of marketing approval by the Party.

(b) If a Party requires, as a condition of approving the marketing of a new agricultural chemical product, including certain new uses of the same product, the submission of undisclosed test or other data concerning safety or efficacy of

that product, the Party shall not permit third persons, without the consent of the person who provided the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for ten years from the date of the marketing approval of the new agricultural chemical product by the Party.

(c) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously submitted information concerning safety or efficacy, to market the same or a similar product on the basis of evidence of prior marketing approval in another territory, or information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory, for at least five years, and ten years for agricultural chemical products, from the date of marketing approval by the Party, or the other territory, whichever is later.^{17-[25]401}

(d) For the purposes of this Article, a **new product** is one that does not contain a chemical entity that has been previously approved for marketing in the Party.

(e) If any undisclosed information concerning the safety or efficacy of a product submitted to a government entity, or entity acting on behalf of a government, for the purposes of obtaining marketing approval is disclosed by a government entity, or entity acting on behalf of a government, each Party is required to protect such information from unfair commercial use in the manner set forth in this Article.

2. With respect to pharmaceutical products, if a Party requires the submission of (a) new clinical information (other than information related to bio equivalency);

^{401 17-[25]} The Parties acknowledge that, at the time of entry into force of this Agreement, neither Party permits third persons, not having the consent of the person that previously submitted information

or (b) evidence of prior approval of the product in another territory that requires such new information, which is essential to the approval of a pharmaceutical product, the Party shall not permit third persons not having the consent of the person providing the information to market the same or a similar pharmaceutical product on the basis of the marketing approval granted to a person submitting the information for a period of at least three years from the date of the marketing approval by the Party or the other territory, whichever is later.^{17-[26]402}

3. When a product is subject to a system of marketing approval in accordance with paragraph 1 or 2, as applicable, and is also subject to a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in paragraph 1 or 2, as applicable.

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

(a) that Party shall provide measures in its marketing approval process to prevent those other persons from:

(i) marketing a product, where that product is claimed in a patent; or

^{402 17-[26]} As an alternative to this paragraph, where a Party, on the date of entry into force of this Agreement, has in place a system for protecting information submitted in connection with the approval of a pharmaceutical product that utilizes a previously approved chemical component from unfair commercial use, the Party may retain that system, notwithstanding the obligations of this paragraph.

(ii) marketing a product for an approved use, where that approved use is claimed in a patent,

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

(b) if the Party permits a third person to request marketing approval to enter the market with:

(i) a product during the term of a patent identified as claiming the product; or

(ii) a product for an approved use, during the term of a patent identified as claiming that approved use,

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

Side Letter – Application of IPR



18 May 2004

The Honourable Robert B. Zoellick
United States Trade Representative
600 17 Street, NW
Washington, D.C. 20508

Dear Ambassador Zoellick

In connection with the signing on this date of the Australia – United States Free Trade Agreement (“the Agreement”), I have the honour to confirm the following understanding reached by the Governments of Australia and the United States in relation to Chapter Seventeen (Intellectual Property) of the Agreement:

1. Notwithstanding Article 17.9.6, if a patent for a pharmaceutical product has been granted an adjustment of its term pursuant to Article 17.9.8(b), Australia may permit the export by a third party of a pharmaceutical product covered by that patent, only for the purposes of meeting the marketing approval requirements of Australia or another territory.
2. With respect to the obligation set out in Article 17.4.10(b), if, at any time more than two years after the entry into force of this Agreement, it is the considered opinion of either Party that there has been a significant change in the reliability, robustness, implementability and practical availability of technology to effectively limit the reception of Internet retransmissions to users located in a specified geographic market area, that Party may request, and the other Party agrees to enter into, consultations to review the continued applicability of the obligation set out in Article 17.4.10(b) and whether, in light of technological and other relevant developments, it should be modified, which agreement shall not be unreasonably withheld.
3. Notwithstanding Article 17.11.6(a)(i) where, on the entry into force of this Agreement, a Party provides any one or more of the following: that only one or other of the remedies set out in sub-paragraph 17.11.6(a)(i) and (a)(ii) is available at the election of the right holder; and that only the remedy set out in sub-paragraph 17.11.6(a)(ii) is available in the case of innocent copyright infringement and in the case of a finding of non-use of a trademark that the right

The Honourable Robert B. Zoellick
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holder may not be entitled to either of the remedies set out in sub-paragraph 17.11.6(a), the Party may continue to so provide.

4. Notwithstanding Article 17.9.5, Australia may provide that a patent may be revoked on the basis that the patent is used in a manner determined to be anti-competitive in a judicial proceeding.

I have the honour to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Agreement.

Yours sincerely



Mark Vaile
Minister for Trade

EXECUTIVE OFFICE OF THE PRESIDENT
THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

May 18, 2004

The Honorable Mark Vaile MP
Minister for Trade
Parliament House
Canberra ACT 2600

Dear Minister Vaile:

I have the honor to acknowledge receipt of your letter of this date, which reads as follows:

"In connection with the signing on this date of the Australia – United States Free Trade Agreement ("the Agreement"), I have the honour to confirm the following understanding reached by the Governments of Australia and the United States in relation to Chapter Seventeen (Intellectual Property) of the Agreement:

1. Notwithstanding Article 17.9.6, if a patent for a pharmaceutical product has been granted an adjustment of its term pursuant to Article 17.9.8(b), Australia may permit the export by a third party of a pharmaceutical product covered by that patent, only for the purposes of meeting the marketing approval requirements of Australia or another territory.
2. With respect to the obligation set out in Article 17.4.10(b), if, at any time more than two years after the entry into force of this Agreement, it is the considered opinion of either Party that there has been a significant change in the reliability, robustness, implementability and practical availability of technology to effectively limit the reception of Internet retransmissions to users located in a specified geographic market area, that Party may request, and the other Party agrees to enter into, consultations to review the continued applicability of the obligation set out in Article 17.4.10(b) and whether, in light of technological and other relevant developments, it should be modified, which agreement shall not be unreasonably withheld.
3. Notwithstanding Article 17.11.6(a)(i) where, on the entry into force of this Agreement, a Party provides any one or more of the following: that only one or other of the remedies set out in sub-paragraph 17.11.6(a)(i) and (a)(ii) is available at the election of the right holder; and that only the remedy set out in sub-paragraph 17.11.6(a)(ii) is available in the case of innocent copyright infringement and in the case of a finding of non-use of a trademark that the right holder may not be entitled to either of the remedies set out in sub-paragraph 17.11.6(a), the Party may continue to so provide.

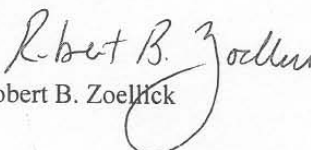
The Honorable Mark Vaile MP
Page Two

4. Notwithstanding Article 17.9.5, Australia may provide that a patent may be revoked on the basis that the patent is used in a manner determined to be anti-competitive in a judicial proceeding.

I have the honour to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Agreement."

I have the honor to confirm that my Government shares this understanding and that your letter and this reply shall constitute an integral part of the United States-Australia Free Trade Agreement.

Sincerely,


Robert B. Zoellick

Appendix C: List of submissions

Dr Hazel Moir – Innovation Perspectives & Adjunct Fellow, Centre for Policy
Innovation, ANU College of Arts and Social Sciences

Japan Intellectual Property Association

Dr David Lim & Professor V Bruce Sutherland – Curtin University

Dr Charles Lawson – Griffith Law School

AusBiotech

IPTA

FICPI Australia

INTERPAT

AbbVie

AFTINET

AIPPI

Cancer Voices Australia

Consumer Health Forum of Australia

CSL Limited

GlaxoSmithKline

Japan Pharmaceutical Manufacturers Association (JPMA)

Lundbeck

Merck Sharp and Dohme Australia

Monash University

Pfizer

Vimala Srinivasan

Pharmaceutical Society of Australia

Medicines Australia

Civil Liberties Australia

Novartis

Amgen

Roche

Law Council of Australia

American Chamber of Commerce in Australia

Bristol-Myers Squibb

Centre for Adaptive Behaviour and Cognition – Max Planck Institute for Human Development

ACIP

Janssen-Cilag

Biota

GMiA

Alphapharm

Mundipharma

Walter and Eliza Hall Institute of Medical Research

Professor Andrew Christie et al – Melbourne Law School

Appendix D: Abbreviations

AAT	Administrative Appeals Tribunal
ABS	Australian Bureau of Statistics
ACIP	Advisory Council on Intellectual Property
ACTA	Anti-Counterfeiting Trade Agreement
AIPPI	The Australian Group of the International Association for the Protection of Intellectual Property
AMWG	The Access to Medicines Working Group
API	Active pharmaceutical ingredients
ARGB	Australian Regulatory Guidelines for Biologicals
AUSFTA	Australia-United States Free Trade Agreement, entered into force 1 January 2005
ARTG	Australian Register of Therapeutic Goods
DIICSTRE	Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education
DITR	Department Tourism, Industry and Resources
DoHA	Department of Health and Ageing
EMA	European Medicines Agency
FDA	United States Food and Drug Administration
FICPI	International Federation of Intellectual Property Attorneys
FTC	Federal Trade Commission
Generics	Companies that manufacture generic brand medicines - These are both local and multi-national companies. The competition provided by generic medicines is an important contributor to keeping the prices of medicines down.
GMiA	Generic Medicines Industry Association
IP	Intellectual Property
IPAC	Industrial Property Advisory Committee
JSCOT	Joint Standing Committee on Treaties
MFE	Manufacture for export
NIA	National Interest Assessment

NPV	Net Present Value
Originators	Research pharmaceutical companies. These are generally multi-national companies that rely on the IP system to protect their brand-name medicines, drugs and medical treatments. These companies conduct the bulk of R&D required to bring potential new drugs to market.
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PC	Productivity Commission
PI	Product Information
PIWG	The Pharmaceutical Industry Working Group
PMPRB	Patent Medicine Prices Review Board
R&D	Research and development
RTB	Intellectual property laws amendment (Raising the Bar) Bill 2011 [2012]
SBMPs	Similar Biological Medicinal Products
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
TPP	Trans-Pacific Partnership Agreement
WEHI	Walter and Elizabeth Hall Institute
WIPO	World Intellectual Property Organization
WTO	World Trade Organization