Pharmaceutical Patents Review

Copyright Notice
© Commonwealth of Australia 2013
Except for third party work attributed in the paper and the Coat of Arms, this copyright work is licensed under a Creative Commons Attribution 3.0 Australia licence. This licence can be viewed at http://creativecommons.org/licenses/by/3.0/au/.

General inquiries (02) 6283 2632
Website http://pharmapatentsreview.govspace.gov.au

An appropriate citation for this paper is:
The Hon Greg Combet AM MP  
Minister for Climate Change, Industry and Innovation  
Parliament House  
Canberra ACT  

Dear Minister,  

On behalf of the Panel, Dr Nicholas Gruen, Professor Dianne Nicol and me, I present the report of the Pharmaceutical Patents Review which was established by the then Parliamentary Secretary for Innovation, the Hon Mark Dreyfus QC MP.  

Yours Sincerely,  

Tony Harris  
Chairman
Foreword

The members of the Review Panel would like to acknowledge and thank IP Australia for the professional team which it seconded to the Panel for the Pharmaceutical Patents Review. Led by the ever-patient and able Ms Terry Moore, the team provided invaluable help to the preparation of this Report.

The Panel also wishes to thank those members of the pharmaceutical and biotechnology industries, researchers, academics and others who participated in the review process. The Panel appreciates that many participants do not agree with the Panel’s findings and recommendations. But those disagreeing with the Report’s conclusions hopefully realise that the Report is aimed at improving Australia’s welfare by providing affordable access to best available medicines; by encouraging research and development into innovative new medicines; and by promoting the long term sustainability of the Australian pharmaceutical industry.
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 Appendix B.

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, in November 2012, and a draft report in April 2013. The Panel invited submissions to both reports and held hearings in February and May 2013. Fifty one parties provided submissions, and twelve parties provided further evidence in hearings. In addition, several Commonwealth departments provided oral advice to the Review Panel and its Secretariat.

The Panel has drawn on information in submissions to the issues paper and draft report and oral evidence in preparing this final report, which was presented to the Minister for Climate Change, Industry and Innovation, the Hon Greg Combet AM MP on 30 May 2013.
Overview

The pharmaceutical industry relies on patents more than most: successful pharmaceuticals require significant prior investment in research and development (R&D), yet competitors can cheaply copy them once they are on the market. The patent system restricts such free riding giving patentees a period of market exclusivity. It allows a reward for past investments and, more importantly, provides incentives for continued innovation.

Patents also have negative effects. They may increase prices – and so restrict supply – by more than the amount required to provide the necessary incentives to innovate. These negative features are important because they impact on human health. And though innovators seeking to patent must disclose considerable information about their inventions - thus providing a platform to others for further innovation - patents can also restrict further innovation by increasing legal risks and constraining competition in follow-on innovation.

Thus 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. They can also constrain follow on innovation: too weak a 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 environment. Some critical features of Australia’s patent system have been set by international agreements.

Larger developed countries that are major net IP exporters 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 but impose significant costs on users of patented technologies.

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 thus binding ourselves to this policy for the future was in our own economic interest.

In negotiating such agreements in the future, 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 that are 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 which are not well rewarded in markets.

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 3 offers recommendations about Australia’s stance in international forums where patent systems feature and it considers two pressing issues that have materially limited Australia’s welfare whilst providing little or no offsetting benefits to patentees. 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, for the drugs will be produced for the export market, but it prevents Australian business and its workers from producing them.

Secondly, for so long as a patent runs in Australia, current patent law prevents a generic manufacturer from stockpiling generic pharmaceuticals for future export or for future sale in Australia upon expiry of the Australian patent. This is an
important issue, because the firm that first enters any generic market here or offshore enjoys 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 patent regimes or shorter patent lives.

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. Yet little has been done to advance their cause in international negotiations. In Chapter 3, the Panel recommends that Government act on these matters

Most of the major pharmaceutical companies participating in this Review have opposed most of the Panel’s recommendations, including that they voluntarily not assert their rights to prevent Australian manufacture for export to markets where there is no relevant patent. The Panel believes that its suggestion is not just consistent with companies’ corporate social responsibilities: it would relieve them of the embarrassment of Australia lose pharmaceutical investment, employment and exports as a result of their enforcing IP rights which have little value.

**Extensions of Term**

An important part of the terms of reference of this inquiry is to evaluate the extension of term (EOT) 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 current scheme dates from 1998. It 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. The scheme currently provides an effective patent term of up to 15 years.

At the time that the EOT was introduced, the annual cost to the Pharmaceutical Benefit Scheme (PBS) was estimated to grow from $6 million in 2001-02 to $160 million in 2005-06. This cost arises because there is a delayed entry to the PBS
of cheaper generic drugs. The estimate for 2012-13 is around $240 million in the medium term and, in today’s dollars, around $480 million in the longer term. The total cost of the EOT to Australia is actually about 20 per cent more than this, because the PBS is only one source of revenue for the industry.

Using the patent scheme to preferentially support one industry is inconsistent with the TRIPS rationale that patent schemes be technologically neutral. More importantly, particularly where there is already substantial patent protection and where the EOT comes into effect after the patent term has already run 20 years, patents are unlikely to be as effective as direct funding as a policy instrument for increasing pharmaceutical investment.

In 1984, the Government’s Intellectual Property Advisory Committee found it difficult to accept 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 gathers additional force in light of the post-TRIPS extension of the standard patent term to 20 years and the further five year EOT for pharmaceuticals.

It is difficult to see why a pharmaceutical firm would choose to conduct R&D in Australia merely because the Government decided to offer an EOT here, for it can qualify for the EOT whether or not its R&D was done here. More fundamental issues such as relative costs of R&D and skill availability are likely to drive the location of R&D spending. And indeed, the Review finds that the increased patent protection afforded by increasing patent life and establishing an EOT has not led to an increase in investment in Australian pharmaceutical R&D that is commensurate with the costs of the EOT to Australia.

The introduction of the EOT in 1998 provided a wind-fall to pharmaceutical companies: they were rewarded with an incentive for work they had already undertaken. And regarding R&D yet to be undertaken it would have been more efficient for the Government to provide a direct subsidy to support Australian-based pharmaceutical R&D, rather than the EOT. This reflects several factors including: the difference in discount rates applicable to Government and commercial firms; the effect of subsidising activity at the beginning and throughout product development, instead of during its period of marketing; and
the ability of a subsidy to be linked to spending on pharmaceutical R&D in Australia.

An additional benefit of a direct subsidy is that it can target research for which patents provide inadequate incentives. Such areas include new antibiotics which, once developed, must be used sparingly to prevent the development of drug resistance, and pharmaceuticals to address rare diseases, paediatric illnesses and endemic health issues in low income countries.

The Panel considered several options to reform patent extensions. Australia is required by AUSFTA to provide some form of pharmaceutical EOT but its scope and length are not specified. Actual savings obtained from reducing the term of the extension 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. But there are timing issues in reducing the EOT provisions immediately without compensation. Savings from the options considered in this report, including the recommendation to reduce the effective life of extended Australian pharmaceutical patents, would take several years to reach full effect.

Chapter 5 of the report canvasses some technical issues concerning EOTs. The class of pharmaceuticals that is eligible for EOT in Australia is narrower than that in some other developed countries (on the other hand, there are countries, such as Canada and New Zealand that do not provide for EOT). 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 it was justified by national interests.

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 EOT. 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 or are useful. Complying with the requirement is costly and the Panel sees little reason for its continuation.

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 EOT available to a patent. The Panel recommends an amendment to this provision to address this.

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.

**Patent Standards and Evergreening**

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 large costs 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 a pejorative, relevant literature has dubbed such actions ‘evergreening’: steps taken to maintain the market place of a drug whose patent is about to expire. Chapter 6 discusses these and associated matters.

The Panel has little doubt that pharmaceutical manufacturers act to preserve the profitability of their products as they are legally required to do on behalf of their 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 *Intellectual Property Amendments (Raising the*
Bar) Act 2012 (Cth) (Raising the Bar) was intended to moderate this problem somewhat, though the extent to which it will do so is unclear. The Panel sees a need for an external body, the Patent Oversight Committee, to audit the patent grant processes to help ensure these new standards are achieved, and to monitor whether they inhibit the patenting of follow-on pharmaceuticals which promote evergreening with no material therapeutic benefit. The Government should also review the effectiveness of the patent scheme when the impact of Raising the Bar Act has become clear.

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 7 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 partly because they lack finality (administrative decisions of the Patent Office can always be appealed to the courts).

As in other matters heard by Australian courts, patent challenges and patent infringement cases are very expensive and time consuming. 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 – and diminishing - margins from generic drugs make a challenge worthwhile. In addition, although the Government does not contribute to a challenger’s costs, it will typically be the major single beneficiary from a finding of patent invalidity. The benefits come from reduced drug prices for the PBS. On the other hand, the Government 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 Government 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. It recommends 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 listing was established, the Panel further recommends that the Therapeutic Good Administration (TGA) notify the owners of listed patents when a generic equivalent of the ARTG listed drug received regulatory approval.

**Data Protection**

When an originator seeks regulatory approval for a drug, it must provide data to the TGA demonstrating the drug’s safety and efficacy. Although these data remain confidential to the TGA, it 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 8 - 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 poorly targeted response to issues affecting a small number of pharmaceuticals. A policy of subsidising drug development discussed above seems more appropriate.

Chapter 8 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.

**Biologics**
Chapter 9 discusses the emerging challenge of biologics and biosimilars – the generic versions of biologics. Currently biologics have the same data protection period as small molecule drugs in Australia, although a longer period is provided for biologics in some other countries. Originators call for a longer data protection period for these types of drugs. However, given that standardised regulatory processes for registration of biosimilars are still under development in Australia and elsewhere, the Panel does not recommend changes at present.

**Better Integration and attention to detail in governing the Pharmaceutical System**
In concluding, Chapter 10 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 means that isolated consideration of particular features would likely not give optimum results.
Agencies need to consider how their own issues impact on the responsibilities of other agencies. 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 and attention to the fine details of the system to identify the best options to promote the national interest.

The Report shows that the Australian patent system has worked against Australia’s best interests. Patents are clearly necessary and important for the development of and access to needed drugs. But Australia’s patent system has allowed and will continue for some time to allow patents to be granted which would not be granted elsewhere; it has awarded a longer effective patent life than is provided in the United States or than seems necessary to underpin drug development in Australia; it has allowed patents to expire later in Australia than in its major trading partners. All of this has limited the generic manufacturing base, employment and exports and it has increased Australia’s pharmaceutical costs. The Raising the Bar Act which recently came into force may moderate this, but its efficacy will not be evident for some years, and there is the prospect that, even with the changes introduced by Raising the Bar, patent standards are still insufficient to moderate evergreening in the pharmaceutical industry. The Panel’s recommendations, if adopted, would only start the next phase of the repair work.
Recommendations

**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.

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.

**Recommendation 3.2:**
The Government should ensure that future trade negotiations 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 IP rights – which are likely to reduce world economic and social welfare and it should lead other countries in opposing such measures as a matter of principle.

**Recommendation 3.3:**
Given the current constraints placed on Australia by its international obligations, as an interim measure the Government should actively seek the cooperation of the owners of Australian pharmaceutical patents to voluntarily agree to enter into non-assertion covenants with manufacturers of generic pharmaceuticals seeking to manufacture patented drugs for export. This would help them avoid the embarrassment of Australia’s trade and investment performance being penalised by its previous agreement to strengthen IP rights.

**Recommendation 4.1:**
The Government should change the current EOT to reduce the maximum effective patent life provided from 15 years.

Harris and Gruen support reducing the effective life to 10 years, whereas Nicol supports reducing the effective life to 12 years.
The length of the extension should be calculated as being equal the number of days between the patent date and the date of first inclusion on the Australian Register of Therapeutic Goods minus 20 years less the maximum effect patent life.

The current 5 year cap on extensions should remain, providing a maximum of 25 years patent term for extended patents.

**Recommendation 4.2:**
The Government should use part of the associated savings from recommendation 4.1 to fund R&D directly. Some of this funding could be targeted to socially beneficial research where patent incentives may be inadequate. 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 effective patent life with some share of those savings used to fund replacement R&D subsidies.

**Recommendation 4.3:**
Section 76A of the Patents Act should be deleted. The Pharmaceutical System Coordinating Committee recommended in 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 Canadian Patent Medicine Prices Review Board (PMPRB) and superior to s.76A, can and should be developed.

**Recommendation 5.1:**
The Government should maintain the current approach that allows extensions for drugs and formulations but not for methods of use and manufacture. This 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.
**Recommendation 5.2:**
Section 70(3) should be amended to clarify that the ARTG registration on which an EOT is based is that of the relevant product, the use of which would infringe the claim.

**Recommendation 6.1:**
The Government should establish an external patent oversight committee (eg. as part of the ACIP) that is tasked with reviewing grants issued by IP Australia and auditing the decisions involved in making such grants, to ensure that IP Australia’s decisions are consistent with the relevant Australian law as well as being aligned with Australia’s major trading partners and with Australia’s interests.

**Recommendation 6.2:**
The Government should request the Productivity Commission to undertake a broad review of the patent system, including of the effectiveness of Raising the Bar Act no later than five years from the commencement of the Act.

**Recommendation 6.3:**
The Government should implement strategies for minimising the extent to which PBS policies permit evergreening practices, where these practices provide no net benefit to Australia. An overarching body, such as the PSCC (see recommendation 10.1) should be tasked with overseeing such strategies.

**Recommendation 7.1:**
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 should involve the Government sharing with the successful challenger of a patent the savings to the PBS from earlier generic entry or recovered costs to the PBS through compensation or repayment of damages from the patentee or manufacturer of the PBS-listed drug.

The quantum of savings should be formula driven rather than negotiated on a case-by-case basis, with savings estimates based on the price reductions
following first listing of a competitor brand on the PBS (currently 16 per cent) and price disclosure arrangements.

**Recommendation 7.2:**
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. It may be presumed that “reasonable steps” have been taken where the product has been labelled with indications which do not include any infringing indications.

**Recommendation 7.3:**
The Government should introduce a transparency register linking therapeutic goods included on the ARTG with related patents.

The register should include the numbers of all patents owned by, or licensed to, the sponsor of the therapeutic good and relevant to the therapeutic good.

Patent numbers should be supplied to IP Australia when the sponsor receives notification of the ARTG inclusion, or when the patent is granted, if grant is subsequent to ARTG listing.

A sponsor should only be able to commence infringement proceedings in respect of a patent that is on the register.

Upon inclusion of a generic product on the ARTG that relies on information provided earlier in relation to another product, the TGA should directly notify the owner(s) of the patent(s) listed on the transparency register in relation to that earlier product about the inclusion.

**Recommendation 8.1:**
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.
**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).

**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 social and economic welfare of Australians; and
- provide strong, targeted IP protection - but only up to the point at which the costs (to consumers and through impediments of ‘follow on innovation’) are no greater than the benefits of incentivising innovation.
Findings

Finding 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.

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 does not appear to be being followed.

Finding 9.1
There is insufficient evidence to support an increase in data protection beyond the current five year period for biologics at the present time. However, the Panel acknowledges that the regulatory environment and market for biologic and biosimilar medicines is still developing and that the situation should be revisited when further market experience gives us a better understanding of the relevant issues.

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 in their deliberations. Each agency needs to be the eyes and ears of the system from various perspectives, aware of inter-actions of several factors – 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 influencing pharmaceutical pricing particularly have both the need and the resources to obtain a detailed appreciation of the pharmaceutical patent system and its impact on a range of health issues.
Contents

1. Introduction ........................................................................................................... 25
   1.1. Focus of the inquiry .......................................................................................... 25
   1.2. What is a pharmaceutical patent? ................................................................. 25
   1.3. Report structure .............................................................................................. 26

2. The pharmaceutical patent system - setting the scene ..................... 27
   2.1. Introduction to the patent system ................................................................. 27
   2.2. Pharmaceutical patents ............................................................................... 29
   2.3. The pharmaceutical lifecycle ...................................................................... 32
   2.4. Generic pharmaceuticals ............................................................................ 34
   2.5. Challenges for the pharmaceutical system .............................................. 36
   2.6. Optimisation .................................................................................................. 39
   2.7. The extending scope and length of patents .............................................. 40
   2.8. Regulatory complexity ................................................................................ 41

3. International context ......................................................................................... 43
   3.1. Background ................................................................................................... 43
   3.2. Australia’s approach to international agreements .................................... 45
   3.3. Manufacturing for export and stockpiling ............................................... 49
       3.3.1. Current law ........................................................................................... 49
       3.3.2. Implications of international agreements ............................................ 51
   3.4. A more strategic engagement with international agreements ............ 55
       3.4.1. Interim approach to MFE ................................................................... 58

4. Extension of term – length of extension .................................................. 60
   4.1. How the scheme works ............................................................................... 60
   4.2. History of pharmaceutical patent extension of term provisions .......... 61
       4.3. The stated policy objective ....................................................................... 63
   4.4. Incentivising R&D in a global market ....................................................... 64
   4.5. The value of extensions in incentivising R&D .......................................... 67
   4.6. Cost of extension of term provisions to the PBS .................................... 72
       4.6.1. Figures used in calculations ................................................................. 73
       4.6.2. Calculations – reduction in maximum length of extension of term .............. 75
       4.6.3. Calculations – reduction in maximum effective patent life offered by extension of term ............................................................... 76
       4.6.4. Findings from Duckett et al ................................................................. 79
7.4.1. Current law ................................................................. 137
7.4.2. Carve outs ................................................................. 138
7.4.3. Staple commercial product ........................................... 140
7.5. Patent certificates .......................................................... 140
7.5.1. Current law ................................................................. 141
7.5.1.1. Section 26B ............................................................. 141
7.5.1.2. Sections 26C and 26D .............................................. 142
7.5.2. Notification ................................................................. 143
7.5.3. Transparency .............................................................. 146
7.5.4. Certificate standards .................................................... 146
7.5.5. Penalties .................................................................... 147
7.6. Transparency register ...................................................... 149
7.6.1. The orange book system .............................................. 150
7.6.2. A transparency and notification system for Australia .... 151

8. Data protection ................................................................. 155
8.1. Data as public good .......................................................... 155
8.2. Data protection in Australia ............................................ 155
8.3. Comparison internationally ............................................. 157
8.4. Data protection and the patent system ................................ 159
8.5. Period of data protection .................................................. 159
8.6. New indications ............................................................... 164
8.7. Listed medicines ............................................................. 166
8.8. Orphan drugs and paediatric indications ......................... 166
8.9. Confidentiality ............................................................... 167

9. Biologics ................................................................. 170
9.1. What are biologics? .......................................................... 170
9.2. Why are biosimilars important? ....................................... 171
9.3. Market profile ............................................................... 172
9.4. Patent perspective .......................................................... 173
9.5. The generic industry and biosimilars ................................ 174
9.6. Regulatory environment .................................................. 175
9.7. Biosimilars and the PBS .................................................. 177
9.8. Data protection and biologics .......................................... 178

10. Better integration and governance of detail in the pharmaceutical system .................................................. 182
10.1. Current situation ............................................................ 182
10.2. Improved coordination and policy understanding of detail ... 184
Appendices........................................................................................................... 189
Appendix A: Terms of reference ................................................................. 189
Appendix B: Relevant provisions from international agreements ...... 190
Appendix C: Extension of term – length of extension ......................... 203
Appendix D: Net Present Value Calculations ............................................ 223
Appendix E: Simvastatin ........................................................................ 225
Appendix F: List of submissions ............................................................... 228
Appendix G: Government agencies consulted ...................................... 231
Appendix H: Abbreviations .................................................................. 231
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?
A pharmaceutical patent is taken to be a patent for a medicine or a patent that directly relates to a medicine. Pharmaceutical patents include (but are not limited to) 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. (chapter 3)

• Extensions of term – the rationale for having an EOT 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 4 and 5)

• 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 6 and 7)

• Data exclusivity – the term of data protection in Australia; interactions between data protection and patents. (chapter 8)

• Biologics - 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)
2. The pharmaceutical patent system - setting the scene

2.1. Introduction to the patent system

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 broader objective of the statute was to prohibit monopolies and curb abuses of monopoly power: monopolies were only to be granted for inventions in exchange for communicating the invention to the public and were for a finite period of time.¹

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* (Cth) (Patents Act) 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.

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. These extensions, available only to pharmaceuticals, might be more or less generous than is required to promote inventiveness.

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)

3 Submission to the Pharmaceutical Patents Review
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 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%

5 Data obtained from IP Australia records on 30 September 2012. Pharmaceutical applications are those classified in IPC A61K.
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
from business ($1,220 million). A significant proportion of this funding, both Government and industry is expected to be spent on pharmaceutical research.

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):

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

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

---


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.

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.

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.

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.13 A significant proportion of this, on average $700 million per medicine, is typically spent on clinical trials.14 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

13 Medicines Australia submission to the PPR, pg 1, made in January 2013.
14 Medicines Australia submission to the PPR, pg 14, made in January 2013.
companies between 1988 and 2009.\textsuperscript{15} Similarly, a 2006 Congress Budget Office report found that using standard accounting principles the industry’s return on assets had consistently been 2 to 3 times higher than the median for \textit{Fortune} 500 firms.\textsuperscript{16}

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.\textsuperscript{17}

The medicines industry is the largest high-technology exporter from Australia, with exports totalling over $4$ billion in 2011-12. This figure includes both exports (66\%) and re-exports (44\%), with exports from originator companies accounting for 65\% of exports and generic companies the remainder.\textsuperscript{18}

### 2.4. Generic pharmaceuticals

The generic sector is an important element of the pharmaceutical industry, with generic pharmaceuticals accounting for 35\% 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


\textsuperscript{17} Datamonitor. 2012. \textit{Industry Profile – Pharmaceuticals in Australia}.

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 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. The Government estimates that the price disclosure program will deliver a further $2 billion in savings through price reductions occurring in 2012 and across the next four years.

---

20 GMiA submission to the PPR, pg 4, made in February 2013.
21 GMiA submission to the PPR, pg 5, made in February 2013.
22 DoHA, PBS Portfolio Budget Statement 2013-14, p.73.
A recent report published by the Grattan Institute suggested that at least another $550 million could be saved every year if the PBS paid similar prices to those negotiated in New Zealand or in agreements with Australian public hospitals.\textsuperscript{23}

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. The Panel notes that generics account for 80\% of the pharmaceutical market in the US and 60\% in Canada, which is substantially more than the 30\% share of the market in Australia.\textsuperscript{24}

2.5. \textbf{Challenges for the pharmaceutical system}

The pharmaceutical system currently faces a number of challenges. A first challenge arises 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.\textsuperscript{25}

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 Government through the PBS. These were Atorvastatin ($593.3 million),

\begin{itemize}
\item \textsuperscript{23} Duckett S. 2013 \textit{Australia’s bad drug deal: High pharmaceutical prices} <accessed at http://grattan.edu.au/static/files/assets/5a6efeca/Australias_Bad_Drug_Deal_FINAL.pdf on 20 May 2013>
\end{itemize}
Rosuvastatin ($359.2 million) and Ranibizumab ($307.8 million).\textsuperscript{26} Each of these drugs is patented, with the key patent on Atorvastatin expiring in 2012, patents on Rosuvastatin\textsuperscript{27} due to expire in 2020 and the key patent on Ranibizumab due to expire in 2020.\textsuperscript{28}

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%.\textsuperscript{29}

A second challenge comes from 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.\textsuperscript{30}


\textsuperscript{27} 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).

\textsuperscript{28} Patent expiry data obtained from AusPat.


\textsuperscript{30} UK Office of Health Economics The R&D cost of a new medicine, December 2012, accessed at \url{http://www.ohe.org/publications/article/the-rd-cost-of-a-new-medicine-124.cfm}. (This work was partly funded by a research grant from AstraZeneca)
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.\(^{31}\)

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 and increased reliance on out-sourced research done by institutes and universities.\(^{32}\)\(^{33}\)

This presents opportunities for a country such as Australia to capitalise on its strong medical and biotechnology research sectors to attract investment from originator pharmaceutical companies searching for new drug leads and new research and clinical partners.

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 put this investment at risk and increase the chances of Australians missing out on new medicines.

A strong Australian IP system plays some part in encouraging investment in pharmaceutical R&D. However, 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. Factors such as relative costs of conducting R&D, access to skilled researchers and the presence of strong

\(^{31}\) Ibid.


\(^{33}\) Pfizer’s oral submission to the PPR, Sydney Hearings, 12 February 2013.
medical infrastructure to support laboratory research and clinical trials are far more likely to be key to R&D investment decisions.

Similarly, it is difficult to see how features of Australia’s patent system would have a strong 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 a major factor in deciding whether or not to bring a drug to Australia.

2.6. Optimisation

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 interests.

Firstly, the Australian originator industry represents a small part of what is a global industry. Even a large increase in pharmaceutical industry revenues in Australia would not materially lift the global industry’s total revenue flows. Moreover, there is no evidence that any increase in revenues provided to the Australian industry through extensions of term has been directed to additional R&D in Australia. These decisions tend to be made internationally and are subject to many factors most of which would be expected to relate to costs and quality of R&D as is discussed further in chapter 4.

Evidence also supports the view that the generic industry and the total costs of the PBS are facing challenges arising from the ways in which originators are able to maintain their market advantage. In a technology where the costs and failure rates of bringing a drug to market are high it is no surprise that an originator would make every reasonable effort to extend the period and scope of market protection for an existing drug.

One practice available to originators is to file subsequent patents for improvements and modifications to an original drug. This is a legitimate practice
and these subsequent patents can produce substantial benefits in improved bioavailability or efficacy, new indications or 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 6.

2.7. The extending scope and length of patents

Further challenges to optimising the patent system arise from the increases over recent times in term and scope of patent protection. For instance, although patents were primarily granted for mechanical inventions and industrial processes, over the last few decades the scope of patenting has extended to areas like business methods, software and biological materials.

Likewise, the term of patent protection for pharmaceuticals was extended in 1999 from the standard 20 years up to 25 years for eligible pharmaceutical substances. Extensions are discussed in chapters 4 and 5.

There has also been a gradual lowering of patent thresholds in the past few decades. Although there has been some movement to readjust these thresholds, Australia has been slower to respond than some other jurisdictions. Addressing this divergence has been the focus of reforms introduced by the Raising the Bar Act 2012. Patent thresholds are discussed in chapter 6.

IP provisions in trade agreements have also played a role in expanding patent scope and term domestically. 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 chapter 3.

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 regulated directly and indirectly 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 regulated through the market regulatory approval process administered by TGA and through the PBS which provides a further layer of indirect market intervention. 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. 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 be unwilling or unable to pay the drug’s prices. In this respect, the Australian market is very different to the US market. This is an extremely complex system which cannot be governed effectively unless different arms of Government are well coordinated and each has a strong grasp of the detail from their own perspective. As discussed in Chapter 10, the Panel concluded that agencies have been falling well short of this benchmark and has made recommendations to remedy matters.
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
To speak generally, the IP policy task is twofold. The first imperative is to ensure that investors in worthwhile R&D can capture sufficient returns to ensure that they have the incentives to invest in IP. Secondly, providing the incentives to produce new knowledge are secure, we should give IP users (both consumers and follow on innovators) as good access to IP as is consistent with the first imperative, so as to maximise IP’s social value. Thus the logic of IP creation justifies robust IP protection whilst the logic of maximising IP’s social value requires that IP protection be limited in time and in scope.

These policy dilemmas are posed by IP within national economies but they also arise between countries. For similar incentives to free ride take place between countries as they do between firms. This has led some countries – particularly those who are exporters of large values of IP – to seek agreement from other countries to secure minimum standards of IP protection within their markets.

But while this can be seen as a healthy response to any costs imposed on the global economy by free riding, the political economy of such international negotiations also carries with it two risks:

- first, that the need to optimise user access to IP is under-represented in such negotiations, or in other words negotiators pay more attention to constraining damaging free riding than they do to optimally constraining the scope and duration of IP rights; and
- secondly that innovation in IP policy itself is constrained by international agreements. Innovations in IP policy will typically occur in one country first, but if such innovations are ruled out by international agreement, this can easily constrain the scope for countries to experiment and/or become ‘pacesetters’ in refining IP policy to optimise the felicity of the balance it strikes between IP creators and users (both consumers and follow on innovators).

The evidence suggests mounting problems in both regards. Not only have IP rights been extended by international negotiation without strong evidence of this being in the global economic interest, but they have involved retrospective...
extensions to IP rights which are even harder to justify. The most striking illustration of both problems is probably the treatment of manufacturing for export as discussed later in this chapter. Tightly defining patent rights to allow others the right to sell into a foreign market would have negligible impact on incentives to invest whilst lowering the user costs. Yet such innovation is now difficult because the minimum rights guaranteed by patents – including an exclusive right to export into markets even where patent protection has expired – has now been entrenched by international agreements.

Evidently, in practical thought about how a country should regulate its IP rights, it is important to appreciate the often subtle relationship between a country’s interest in crafting its IP regime considering its circumstances unilaterally, and its interests in negotiating global agreements which, if implemented would impose constraints not just on Australia but on other countries. In this inquiry, the Panel has made recommendations regarding Australia’s interests acting unilaterally and its interests in multilateral negotiations.

Where the Panel has made recommendations regarding pharmaceutical patent extensions it has not recommended action that might be in the global interest if all countries took it, unless it is also in Australia’s interests unilaterally. However, this is not to deprecate the significance of multilateral perspectives. To the contrary they are of great significance. But if the global interest is to be properly serviced it will not come as a result of countries like Australia – that is smaller countries that are IP importers – simply forswearing their own interests by acquiescing to the entreaties of larger, more powerful countries with stronger IP exports. One of the Panel’s concerns about the past conduct of international IP negotiations is that Australia has been too passive in articulating its broader interests.

It is conceivable that there are exceptional circumstances in which retrospective extensions to IP property could help bring pharmaceutical products to market (See IPTA, Response to the Draft Final Report, pp.2-3, 10) because incentives are required to progress drugs that have had lengthy development periods through the final stages of development. However these would be exceptional circumstances far better dealt with through exceptional, rather than general measures.
strategic interests in these negotiations. As this chapter argues, Australia is most likely to advance the global interest by representing its own strategic interests more clearly in international IP negotiations, and thereby counter the weight of interests which have hitherto focused their energies largely on extending IP protections, rather than balancing this imperative against the need also to constrain them.

3.2. Australia’s approach to international agreements

Australia is a signatory to several international agreements that have IP aspects to them, with the TRIPS Agreement and the AUSFTA having most relevance to this Review. AUSFTA’s IP provisions are what is called “TRIPS-Plus”. That is, they set higher minimum IP standards than those in TRIPS.

### Differences between international agreements and domestic law

Domestic law is the law of a sovereign. Thus subjects breaching domestic law risk sanctions that the law may contemplate.

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 signatory countries. Rather, it obliges the states to each make domestic arrangements realising 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 and delivered. 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.

For a matter to be dealt with under an international agreement any individual party must persuade a state that its case should be raised and pursued. Where a remedy is sought by one state for breach of an international agreement by another, if conciliation proves ineffective the matter may be referred to a panel. If the panel finds that there has been a breach, the matter returns to the states

---

36 Relevant provisions of these agreements are in Appendix B.
for resolution. Where resolution cannot be reached and it is contemplated within the agreement a state may impose sanctions on another.\textsuperscript{37}

Thus, rather than the agreement being regarded as “the law”, 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.

None of this suggests that Australia should be cavalier about its obligations under international agreements. Australia’s 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 that might ultimately be disciplined by resolution under an international agreement. For those firms will be establishing investments and trade patterns that could ultimately be disrupted by adverse action from another state under an international agreement.

Given the significance of international agreements as both potential constraints and enablers of Australian economic prosperity, Australia’s Government representatives – at both the official and political level – require a broad strategic economic understanding of Australia’s national interest when negotiating international agreements containing substantial IP content. Making a similar point,\textsuperscript{38} the Productivity Commission (PC) has previously indicated that it was not convinced that the approach adopted by Australia in negotiating IP within trade agreements has always been in Australia’s or of (most of) its trading partners’ interest. The PC noted that there appears to have been no economic analysis of the specific provisions in AUSFTA prior to its finalisation, despite clear net costs to Australia and other countries on some issues.

\textsuperscript{37} 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. Andrew T. Guzman, \textit{The Design of International Agreements}, \url{http://ejil.oxfordjournals.org/content/16/4/579.full}

In the past Australia has taken a leading role in the shaping of international trade agreements, most notably with the Cairns Group of countries.\textsuperscript{39} We initiated and played a leading role within this group to better reflect our own and the global interest in lowering trade barriers for agricultural products. We have also taken an active role in some aspects of international patent law.

However, no evidence presented to the Panel has suggested that there are clear strategic goals for Australia in IP negotiations other than to minimise changes to its own IP system.\textsuperscript{40} To be effective in international IP negotiations, those representing Australian interests need an understanding of those aspects of the existing international IP system that require improvement, particularly where Australian and global interests coincide. As the Panel outlines below, there are plenty of opportunities for improvement.

\textsuperscript{39} \url{www.cairnsgroup.org}.

\textsuperscript{40} Anna George, Response to the Draft Final Report, pp.1-2. Ms George submits that, in her experience working in DFAT on the TRIPS Agreement, AUSFTA negotiations and as a former Australian Ambassador, there was a lack of knowledge about the significance and consequences of IP in policy dialogue. Ms George submits that DFAT plays a significant role but it operates in an environment where positions are traded against other perceived economic gains.
Trans-Pacific Partnership Agreement (TPP)

The TPP is currently under negotiation 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. Although TPP negotiations are confidential, documents leaked in 2011 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 protection. 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;
- 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.

The generic pharmaceutical sector\footnote{GMiA Briefing Paper – Trans Pacific Partnership Agreement, GMiA, September 2012, available at \url{http://gmia.com.au/wp-content/uploads/2013/01/GMiA-Briefing-TPPA.pdf}; Alphapharm submission to DFAT on TPPA, 14 March 2011.} and others\footnote{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; Medecins Sans Frontiers, How the Trans-Pacific Partnership Agreement Threatens Access to Medicines, September 2011, \url{http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf}.} have raised concerns that the adoption of US laws by smaller economies reduces the flexibility for these Governments to adopt laws appropriate to their own circumstances and compromises affordable health care. For example, some have argued that various measures in AUSFTA when it was implemented delayed competition from generic manufacturers, thus increasing costs for consumers, with little benefit from added incentives for originators to invest in Australia. Similar concerns are expressed in submissions to this Review.\footnote{Alphapharm, Submission to the Pharmaceutical Patents Review, p.3; AFTINET et al., Response to the Draft Report, pp.3-4.} GMiA argues that the trend to include pro-patentee provisions in international trade agreements will upset the balance between patentee interests and public interests. In contrast, other submissions\footnote{Submissions to the Pharmaceutical Patents Review, Abbvie, AIPPI Australia, Ausbiotech, FICPI Australia, IPTA, Lundbeck, Medicines Australia, MSD, Novartis, Roche, Walter and Eliza Hall Institute.} support TRIPS-Plus measures like AUSFTA as necessary to support pharmaceutical investment in Australia.

3.3. Manufacturing for export and stockpiling

3.3.1. Current law

International agreements constrain Australia’s freedom to adapt its IP law to permit manufacturing for export to destinations where patents have expired and stockpiling during the patent period. TRIPS requires that patentees enjoy exclusive rights to make, use, import or export patented products.\footnote{Article 28(1).} TRIPS and
AUSFTA do allow certain exceptions to these rights, provided that they do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patentee, taking account of third parties’ legitimate interests.47

### Manufacture for export and stockpiling

Under current Australian law, manufacturing a patented product or using a patented process solely for export to another country where there has been no patent or it has expired (MFE) is most likely a breach of patent without the authorisation of the patentee. MFE would involve one or more of the exclusive rights of the patentee listed above. Likewise stockpiling a patented product without the patentee’s permission, for sale upon expiry of the patent also currently constitutes patent infringement.48

The significance of this situation should not be underestimated, particularly for small countries. As there are typically strong ‘first mover advantages’ in newly generic markets, obstructing producers in countries where patents are still running from servicing generic markets, whether they are offshore or domestic, severely disadvantages local suppliers with little apparent benefit to local patentees which cannot avoid competition at the end of the patent term. In this regard those countries adopting stronger IP rights will lose out on investment to countries with weaker IP rights, a perverse result from the perspective of those arguing that strong IP rights attract investment.

MFE has been raised as an issue in Australia several times since TRIPS commenced in 1995.49 The PC considered MFE in 2003.50 In its submission to the

---

47 TRIPS Agreement Article 30 and AUSFTA Article 17.9.3.
48 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.
49 For example, 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.
PC inquiry, the then Department of Industry, Tourism and Resources (DITR) estimated that up to 70% of pharmaceutical patents expire later in Australian than in other countries. DITR also estimated that, without MFE, export revenue of $2.2 billion would be lost from 2001–2009. Arguing that MFE would have little impact on patentee rights the PC made a compelling economic case to allow MFE during the patent extension period.\(^{51}\)

As the figures quoted above indicate, allowing MFE in Australia could be of significant benefit to the domestic generic industry. Yet constraining it is of negligible value to Australian patentees, for they cannot stop the supply of generics to countries where the equivalent patent has expired, they can only stop their supply from Australia. Despite these apparent national benefits, there is no evidence of Australian officials raising the issue in international forums or in their discussions with the US either in their negotiations for AUSFTA or subsequently or giving the matter a high priority in the TPP negotiations.

A perverse consequence of the law on stockpiling is 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. In public hearings GMiA submitted 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 allow competition on an even playing field with foreign generic industries.

### 3.3.2. Implications of international agreements
The WTO dispute in 2000 regarding Canada’s exceptions for the regulatory approval and stockpiling of pharmaceutical patents provides some guidance on

---


the way in which the exceptions to patent infringement provided under the TRIPS Agreement may be interpreted.\textsuperscript{52} The WTO dispute resolution panel found that Canada’s stockpiling exception curtailed the exclusive rights provided to the patentee sufficiently that it could not be construed to be a limited exception within the meaning of the exception in Article 30. The WTO panel explored the words in the agreement rather than focusing on their economic effect:

\begin{quote}
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.
\end{quote}

The reasoning in this case – which led Canada to repeal its stockpiling exception – also suggests that a broad MFE exception applying during the original patent term would not be held permissible under TRIPS, but TRIPS is silent as to patent extensions.\textsuperscript{53}

Little guidance is available on the intent and interpretation of AUSFTA regarding MFE and stockpiling. In its submission GMiA argues that MFE can be introduced consistently with TRIPS and AUSFTA.\textsuperscript{54} Israel is cited as an example of a country

\begin{flushleft}
\textsuperscript{52} Canada – Patent Protection of Pharmaceutical Products, Complaint by the European Communities and their Member State, WT/DS114/R, 17 March 2000. \textsuperscript{53} The Panel is unaware of any jurisdiction that is a WTO member and allows general MFE or stockpiling during the standard 20 year patent term. A number of countries allow limited MFE in accordance with \textit{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. \textsuperscript{54} GMiA, Submission to the Pharmaceutical Patents Review, p.20.
\end{flushleft}
that has designed its patent extension system to remove barriers to trade.\textsuperscript{55} However, the Panel agrees with the Law Council of Australia,\textsuperscript{56} Medicines Australia and others that, if it came to resolution by an independent panel a general exception for MFE would likely be held to contravene these agreements.\textsuperscript{57} Similarly, a general exception for stockpiling is unlikely to be consistent with AUSFTA as it contains the same limits on exceptions as TRIPS.

A more parsimonious definition of IP rights to permit MFE and stockpiling (See box below) should have been relatively straightforward to negotiate as a \textit{quid pro quo} for the extensions of IP rights sought and negotiated in recent years. Unfortunately such considerations have not been advanced with any force by the parties.

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

\textsuperscript{55} Israeli Patents Law, 5727 – 1967, s.64A – 64Q. 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.


\textsuperscript{57} Medicines Australia, Submission to the Pharmaceutical Patents Review, p.10.
Parsimony in defining intellectual property rights

There is typically a penumbra of rights existing around any property right. Until the twentieth century real property rights in many jurisdictions extended above and below the land an approach which became progressively more impracticable as miners sought to mine beneath the surface and planes began flying overhead. Efficiency was restored in real property with more parsimonious definition of the core property rights. Similar obsolescence has emerged in IP law and it should be tackled similarly, with more parsimoniously defined IP.

In earlier centuries the penumbra of rights to ‘work’ and ‘import’ around the monopoly of sale in a market assisted in enforcing that central right. That is no longer true today and if it were it could be finessed with ‘carve outs’ for MFE and stockpiling. Moreover the costs of such prohibitions rise as industry grows progressively more complex.

Over-specified rights contribute to unnecessary cascades of permissions, to costly ‘border disputes’ and strategic behaviour around disputed legal boundaries. This encourages costly strategic behaviour in which competitors focus on obstructing each other at the expense of competing through improved efficiencies.

Thus precluding stockpiling gives domestic originators another month or so of exclusivity. If policy makers had really intended to do this, they could have done so explicitly by extending the patent term thus keeping the law from making unnecessary and expansively litigated distinctions and qualifications on the extent of production permitted before patent expiry.

The case of MFE is even more perverse 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 little positive benefit to them. The constraints to which both AUSFTA parties have bound themselves will obstruct the growth of generic exports in both countries with negligible gains for originators – effectively the opposite of the stated aim of trade agreements.
3.4. A more strategic engagement with international agreements

The gains available from MFE and its lack of costs identifies an agenda which should unite countries wishing to expand trade 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 we led with the Cairns Group, which built a global coalition in favour of freer agricultural trade, Australia could pursue important advances in the international patent system.

It is routine for IP chapters to be included in trade agreements. Australia should actively oppose such chapters unless independent analysis suggests that their inclusion would improve the economic welfare of signatory countries and the world. The Government does not appear to have done this to date, 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 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 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.58

Of greater concern, 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 PC, Australia is well placed to take a leadership role in negotiations such as TPP and should seize such opportunities as they arise.

58 Joint Standing Committee on Treaties, Report 126, June 2012, page 12 and recommendations 1-2, 8.
Finding 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 patentees. The Government does not appear to have a positive agenda regarding the IP chapters of the TPP Agreement.

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 does not appear to be being 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. There is a wide range of fronts on which international IP law and practice could be improved in the global interest and the national interests of individual countries. The Australian Government should take a leadership role in seeking consensus with other jurisdictions to identify such improvements in international IP disciplines embodied in international agreements. Examples include:

- examining the breadth of exclusive rights provided by a patent, and the length of protection, to see whether independent expertise concludes that they are appropriate or whether they should be rationalised, reduced or expanded;\(^{59}\)
- ensuring that the disclosure requirements for patent specifications are sufficient, particularly in fields like biologics (see Chapter 9);

\(^{59}\) 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.
• enabling MFE during the patent term and extension period;
• enabling stockpiling of patented pharmaceuticals before the expiry of the patent for sale after the expiry of the patent;
• enabling data provided in support of regulatory approval to be published upon the expiry of the data protection period,\textsuperscript{60} noting the European proposal (see Chapter 8);
• 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 will not pursue IP changes where such analysis indicates that this was clearly contrary to global economic interests; and
• 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.

Australia has pioneered the provision of domestic economic transparency delivered by bodies such as the PC 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 should also champion the cause of transparent deliberative processes involving appropriate expertise into the negotiation of international economic agreements.

\textsuperscript{60} Depending on how this could be implemented, it appears to be consistent with TRIPS Article 39(3) and AUSFTA Article 14.10.1(e).
**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.

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.

**Recommendation 3.2:**
The Government should ensure that future trade negotiations 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 IP rights – which are likely to reduce world economic and social welfare and it should lead other countries in opposing such measures as a matter of principle.

### 3.4.1. Interim approach to MFE

It is likely to take the Government some time to achieve changes to IP treaties that are in its national interest. For MFE, an interim approach is to introduce an exception that is likely to be consistent with international agreements, as discussed above. Such an exception would be too limited to be of significant value.

Another option is that the Government actively encourage 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. A number of submissions argue that voluntary agreements would not be workable.\(^\text{61}\) Nevertheless, patentees may be encouraged to agree not to enforce their patents in respect of MFE.

---

encouraged to agree through a sense of corporate social responsibility and in order to avoid the embarrassment of effectively penalising countries for the strength of their IP regimes. Such outcomes are not in their interests, and most assuredly not in the interests of those countries which have responded to their entreaties.

**Recommendation 3.3:**

Given the current constraints placed on Australia by its international obligations, as an interim measure the Government should actively seek the cooperation of the owners of Australian pharmaceutical patents to voluntarily agree to enter into non-assertion covenants with manufacturers of generic pharmaceuticals seeking to manufacture patented drugs for export. This would help them avoid the embarrassment of Australia’s trade and investment performance being penalised by its previous agreement to strengthen IP rights.
4. Extension of term – length of extension

4.1. How the scheme works

The provisions for extensions of term are set out in chapter 6, part 3 of the Patents Act. 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 EOT 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 EOT 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 (up to a maximum of 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.

From the commencement of the current EOT scheme in 1999 through to October 2012 there were 599 applications for extensions and 560 (94%) of these were accepted. An effective patent life of 15 years was provided for 53% of extended patents. More information on the operation of the EOT scheme and the extensions granted is provided in Appendix C.
For the period 2003-2010 inclusive, an estimated 58% of new chemical entities approved by the TGA had a pharmaceutical patent term extension. Hence, of the 188 new chemical entities approved during this period, an estimated 108 will receive, or have received an extension. The remaining approvals for new chemical entities include medicines that took less than 5 years to get TGA approval (and therefore had more than 15 years effective patent life), medicines with patents not eligible for extension and medicines without patent protection. New chemical entities only account for a proportion of all TGA approvals. Of the 446 remaining medicinal approvals during that time, it is estimated that only 5-10% are the subject of patent extensions. Therefore, of all the new medicines approved by the TGA for the period 2003-2010 (some of which would be expected to be eligible for an extensions and others which would not) an estimated 21-24% would have received an EOT.

4.2. History of pharmaceutical patent extension of term provisions

Prior to the current EOT provisions for pharmaceutical patents introduced in 1998, there were other provisions for extensions. For example, the Patents Act 1903 and Patents Act 1952 allowed for an extension to the patent term 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

62 Based on a sample of 160 new chemical entities recommended for TGA approval in this period, 92 of which were associated with a patent having an extension of term.

63 There were a total of 634 approvals for new medicines between 2003-2010. In addition to new chemical entities, these include new indications, which are not eligible for patent extensions, as well as new formulations and combinations.
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.64

The Government accepted the recommendation and repealed the general EOT 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:

> 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.65

These EOT 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 to meet the requirements of the TRIPS Agreement. 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.’66

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”.67

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.68 Australia is obliged to retain a system of extensions for pharmaceutical patents under the AUSFTA.69 However, the Agreement does not specify a particular length for the extensions.

At that time, the cost to the Pharmaceutical Benefit Scheme of this concession was estimated to increase from $6 million in 2001-02 to $160 million in 2005-06. Because not all pharmaceutical revenues are sourced through the PBS, additional costs to Australia, would have added around another 20 per cent to those costs.

4.3. The stated policy objective

The explanatory memorandum of the bill introducing the current EOT 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

---

69 Article 17.9.8(b) requires Australia to “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.” See Appendix C for more details.
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.

4.4. Incentivising R&D in a global market

The pharmaceutical research industry claims that pharmaceutical investment is attracted to countries which offer strong patent protection and that countries with weaker patent protection will attract less investment. According to this logic, both the decision to extend general patent protection from 16 to 20 years and introduction of the current EOT provisions – and the associated significantly increased contributions to the industry’s gross profits - might have been expected to lead to a marked increase in pharmaceutical investment in Australia.

However data for investment in R&D suggest that this has not occurred and that the extension of patent term is not meeting the stated objective of attracting investment in pharmaceutical R&D in Australia. As illustrated by Figure 4.1 below, there has been only a gradual increase in investment in R&D over the period between 1992-93 and 2010-11, and no notable increase in investment post introduction of the 20 year term in 1994 or introduction of the current pharmaceutical EOT in 1999, let alone a commensurate increase.
Figure 4.1: Business Expenditure on Pharmaceutical R&D in Australia and Government PBS Expenditure

Figure 4.2: Global Pharmaceutical Revenues, 2011

More tellingly still, although the Australia market represents 2% of the estimated market for global pharmaceuticals, the $1 billion a year spent on pharmaceutical R&D in Australia represents less than 0.3% of global pharmaceutical R&D.\(^71\) In comparison, business expenditure on pharmaceutical R&D in the US makes up 53% of the total globally with Japan the next largest with 14% and the UK 8%. If pharmaceutical industry funding of R&D were more closely aligned to Australia’s contribution to the industry’s revenue or to its provision of strong IP protection, Australia could expect many times greater funding by industry than is currently the case.

Not only does the pharmaceutical industry invest less in Australia than the country’s strong patent arrangements suggest, Medicines Australia, the body representing originators, warns that pharmaceutical research is growing faster in cost-competitive countries than in Australia. Australian R&D actually fell in real terms in the two financial years to June 2011.

We should not be surprised that the outcomes expected by Government have not materialised. Pharmaceutical companies endeavouring to maximize shareholder benefits could be expected to make decisions about where to locate pharmaceutical R&D on the basis of countries’ relative costs (after taxes and subsidies) and skills, although other influences, such as the location of company headquarters also play an important role in those decisions.

4.5. The value of extensions in incentivising R&D

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 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 to market.

In this section, and in the context of issues discussed in the previous section, the value of the EOT is considered from the perspective of expenditure by the Government through the PBS and the incentive effect it has on R&D. This is done through the lens of Net Present Value (NPV) analysis.

NPV analysis is used to evaluate the respective attractiveness of investment projects which builds into the analysis the idea that revenue earned in the future is worth less than revenue in the present. The basic reason for this is that the funds used to generate a new drug could instead have been invested with the expectation that they would be worth more in the future. NPV takes this into account by applying a discount rate to the future streams of money.

Standard commercial discount rates of 9, 13 and 15 per cent are widely used in NPV analyses with the former representing relatively risk tolerant investors and the latter reflecting risk-averse investors, who discount heavily because of the riskiness of the project. Appendix D presents the full set of results of NPV
analysis for the pharmaceutical EOT, but the 13% is used below for simplicity of exposition.

If it were presumed that firms earned a steady stream of revenue each year, then at the 13% discount rate, a drug with a five year EOT would earn only 4.1% of its revenue during the final five years. However, revenues for pharmaceuticals do not arrive regularly each year, so to make the NPV model more representative, actual revenue profiles of Australian pharmaceutical firms have been considered.

To do so, PBS expenditure data is used based on pharmaceuticals that have received an EOT which expired between 2007 and 2012. Using this, the PBS expenditure on each drug can be tracked through its life. This shows three different revenue profiles:

- Type 1: Drugs that earn 70% of their returns during the extension
- Type 2: Drugs that earn between 15% and 70% during the extension
- Type 3: Drugs that earn less than 15% during the extension

72 The range was established by taking the median and mean, and then testing to see what observations would lie one standard deviation away, and rounding to split the sample.
For each type of drug, the net present value of the extension will be quite different. From the PBS data 63% of drugs are type 2, while type 3 drugs make up 21% of the population and type 1 the remaining 15%.

Further, a number of drugs on the PBS do not receive or qualify for extensions, and the data on new chemical entities suggests that approximately 40% of TGA approved drugs which are patented receive no extension. We call these ‘Type 0’ drugs that make no money from the extension itself. Therefore, 60% of new chemical entities have historically received extensions, and when this is
controlled for, an estimate can be made for the approximate value of the extension to each type of firm.

If NPV is only taken from the first year, when the patent is filed and the firm is presumably making decisions about basic research, it would ignore the repeated decision making to invest as drugs go through multiple stages. The decision to continue investing occurs at different times, usually in connection with clinical trials, and for illustrative purposes the NPV is calculated at the fifth year and the tenth year.

Table 4.1 reports the returns to each type of drug from the five years of extension. This is in NPVs and, for the purposes of this illustration, it is assumed that a drug earns $2.5bn over its patented lifetime. What this suggests is that a firm deciding whether to invest in a drug in the tenth year, will expect to earn $372m in NPV during the EOT, while in year 1 that same return is only worth $112m to the firm.

<table>
<thead>
<tr>
<th>Type</th>
<th>Revenue Profile</th>
<th>NPV of 5 year extension at year 1</th>
<th>NPV of 5 year extension at year 5</th>
<th>NPV of 5 year extension at year 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 0</td>
<td>(40%)</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Type 1</td>
<td>(9%)</td>
<td>$124,006,669</td>
<td>$202,189,602</td>
<td>$372,521,235</td>
</tr>
<tr>
<td>Type 2</td>
<td>(38%)</td>
<td>$71,837,388</td>
<td>$117,128,966</td>
<td>$215,802,527</td>
</tr>
<tr>
<td>Type 3</td>
<td>(13%)</td>
<td>$10,542,046</td>
<td>$17,188,527</td>
<td>$31,668,747</td>
</tr>
</tbody>
</table>

73 The proportion of each type of drug is distributed across the 60%. So the 63% of type 2 drugs becomes 38% of the total number of drugs.

The amount of additional investment in pharmaceutical R&D the EOT might generate in Australia will now be considered. To illustrate, an ‘additionality’ of 50 per cent is assumed - 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.

If Australia’s pharmaceutical industry is around 2 per cent of the global industry, and it is assumed 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. Given these figures, the effect on the incentive to conduct R&D in Australia would be 2% of the value of the NPV. Therefore, if a firm thought it was developing a ‘type 1 drug’ i.e. one of the 9% of drugs where the value of the extension is greatest because most of the revenue is earned during that period, the incentive effect of the extension would be $7.5 million. Therefore, while the incentive effect for conducting R&D in Australia in the tenth year of the patent would be $7.5 million, the net present cost to the Australian Government at the same time would be approximately $1.4 billion.

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 something that the Panel has observed is not evident in the data from past extensions to Australian IP rights. For the purposes of illustration, instead of attracting 2 per cent of the investment promoted by the additional assistance Australia provides with patent extensions, assume that the firm directs 25 per cent of the additional assistance produced by Australia’s patent extension to Australia. Under this, the highest expected incentive effect would be $93 million.

Note: this assumption is very favourable for investment because as stated earlier, Australia’s share of pharmaceutical R&D investment (as opposed to its share of pharmaceutical consumption) is around 0.29% of the global total.

i.e. $372,521,235 × 0.02 = $7,450,424

Assuming a social discount rate of 3.0%. See Appendix D for calculations.
for a type 1 drug in the tenth year\textsuperscript{78} (against $1.4 billion in net present cost), which would still be less than half a per cent of the R&D undertaken by the three largest pharmaceutical earners in the Australian market. On this generous assumption of a very direct link between market value and R&D location, the majority of drugs would still not realise much of an incentive effect under the extension.

4.6. Cost of extension of term provisions to the PBS

At the time that the EOT 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.\textsuperscript{79} 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 following generic entry through the Price Disclosure system, discussed in chapter 2.

An overview of the effect on PBS expenditure of generic products entering the market is provided in Appendix C. Generally, the average subsidy paid by the Government per script is lower after the EOT expires and a generic medicine enters the market compared to the date it is first listed on the PBS.

The following section considers the current cost extensions of term to the PBS and the potential savings from either a reduction to the maximum available length of extensions of term or a reduction to the maximum effective patent life provided. 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 indicative estimates rather than actual projected savings to the PBS from a change in the EOT.

\textsuperscript{78} i.e. $372,512,235 \times 0.25 = $93,128,058

\textsuperscript{79} Revised Explanatory Memorandum to the Intellectual Property Laws Amendment Bill 1998, pg 2.
4.6.1. Figures used in calculations

The total expenditure by the PBS in 2012 was $9.25 billion.\textsuperscript{80} In any given year, an estimated 2.6\% of the total PBS expenditure is on drugs having an EOT which will expire within the next year.\textsuperscript{81} This is based on an average across 2008 to 2011.

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 expected to be the case for costly drugs where there is high PBS expenditure and therefore greater incentive for generic competitors to enter the market; 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 EOT 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 conservative as it represents the minimum average saving across the PBS agreed to in the MOU between the Australian Government and Medicines Australia.


\textsuperscript{81} 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 length of an EOT can be up to 5 years. Table 4.1 shows the distribution of the length of extensions of term for all extensions granted since the current scheme commenced in 1999 (approximately 560).

Table 4.2: Distribution of extended patents by length of extension of term

<table>
<thead>
<tr>
<th>Length (years)</th>
<th>5</th>
<th>4-5</th>
<th>3-4</th>
<th>2-3</th>
<th>1-2</th>
<th>0-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of all extended patents</td>
<td>47%</td>
<td>11%</td>
<td>11%</td>
<td>11%</td>
<td>12%</td>
<td>7%</td>
</tr>
</tbody>
</table>

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.
4.6.2. Calculations – reduction in maximum length of extension of term

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

\[
\text{\$9.25 bn PBS expenditures 2011-12} \\
\times 2.6\% \text{ (share of PBS expenditures on drugs with extension expiring in any given year)} \\
= \text{\$241 mln PBS expenditures on drugs with EOT expiring in any given year}
\]

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

For patents with the maximum 5-year extension:

\[
\text{\$241 mln PBS expenditures 2011-12} \\
\times 47\% \text{ (share of patent extensions affected)} \\
\times 1 \text{ (average length of reduction in years)} \\
\times 35\% \text{ (long run price reduction)} \\
= \text{\$40.2 mln estimated savings}
\]

\[
+ \text{ estimated savings}
\]

For patents with an extension greater than 4 years and less than 5:

\[
\text{\$241 mln PBS expenditures 2011-12} \\
\times 11\% \text{ (share of patent extensions affected)} \\
\times 0.5 \text{ (average length of reduction in years)} \\
\times 35\% \text{ (long run price reduction)} \\
= \text{\$4.8 mln estimated savings}
\]

\[
\text{= \$45.0 mln}
\]

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

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 EOT. The summary of estimates is presented below.
Table 4.3: Estimated potential savings from reductions in extension lengths

<table>
<thead>
<tr>
<th>Reduction in extension length</th>
<th>Estimated Savings ($m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 years to 4 years</td>
<td>45</td>
</tr>
<tr>
<td>5 years to 3 years</td>
<td>95</td>
</tr>
<tr>
<td>5 years to 2 years</td>
<td>145</td>
</tr>
<tr>
<td>5 years to 1 year</td>
<td>194</td>
</tr>
<tr>
<td>5 years to 0 years</td>
<td>244</td>
</tr>
</tbody>
</table>

4.6.3. Calculations – reduction in maximum effective patent life offered by extension of term

An alternative to reducing the maximum length of extensions is to modify the extension calculation such that the effective patent life achieved is reduced, while still maintaining a possible extension length of five years. Table 4.4 shows the relative distribution of extended patents by effective patent life and the length of the extension.

Table 4.4: Distribution of extended patents by Effective Patent Life

<table>
<thead>
<tr>
<th>Effective patent life (and extension length)</th>
<th>Percentage of all extended patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 (0-0.99)</td>
<td>7%</td>
</tr>
<tr>
<td>15 (1-1.99)</td>
<td>12%</td>
</tr>
<tr>
<td>15 (2-2.99)</td>
<td>11%</td>
</tr>
<tr>
<td>15 (3-3.99)</td>
<td>12%</td>
</tr>
<tr>
<td>15 (4-5.00)</td>
<td>11%</td>
</tr>
<tr>
<td>14-15 (5)</td>
<td>9%</td>
</tr>
<tr>
<td>13-14 (5)</td>
<td>9%</td>
</tr>
<tr>
<td>12-13 (5)</td>
<td>8%</td>
</tr>
<tr>
<td>11-12 (5)</td>
<td>6%</td>
</tr>
<tr>
<td>10-11 (5)</td>
<td>5%</td>
</tr>
<tr>
<td>5-10 (5)</td>
<td>11%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100%</td>
</tr>
</tbody>
</table>

Source: PBS data and IP Australia calculations.

82 Source: PBS data and IP Australia calculations.
The average value of PBS expenditures on drugs with EOT expiring in any given year:

\[
\text{\$9.25 bn PBS expenditures 2011-12} \\
\times 2.6\% \text{ (share of PBS expenditures on drugs with extension expiring in any given year)} \\
= \\
\text{\$241 mln PBS expenditures on drugs with EOT expiring in any given year}
\]

Potential savings from decreasing the maximum effective patent life from 15 to 14 years:

For patents provided with the maximum 15 year effective patent life and an extension longer than 1 year:

\[
\text{\$241 mln PBS expenditures 2011-12} \\
\times 46\% \text{ (share of patent extensions affected)} \\
\times 1 \text{ (average length of reduction in years)} \\
\times 35\% \text{ (long run price reduction)} \\
= \\
\text{\$38.9 mln estimated savings}
\]

+ 

For patents provided with the maximum 15 year effective patent life and an extension less than 1 year:

\[
\text{\$241 mln PBS expenditures 2011-12} \\
\times 7\% \text{ (share of patent extensions affected)} \\
\times 0.5 \text{ (average length of reduction in years)} \\
\times 35\% \text{ (long run price reduction)} \\
= \\
\text{\$3.0 mln estimated savings}
\]

+ 

For patents provided with between 14 and 15 years effective patent life:

\[
\text{\$241 mln PBS expenditures 2011-12} \\
\times 9\% \text{ (share of patent extensions affected)} \\
\times 0.5 \text{ (average length of reduction in years)} \\
\times 35\% \text{ (long run price reduction)} \\
= 
\]
The above methodology was applied to calculate potential savings from a reduction in the maximum effective patent life offered by an EOT. A summary is presented below.

Table 4.5: Estimated potential savings from reducing the maximum effective patent life offered by an extension of term

<table>
<thead>
<tr>
<th>Reduction in Maximum Effective Patent Life</th>
<th>Estimated Savings ($m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 years to 14 years</td>
<td>46</td>
</tr>
<tr>
<td>15 years to 13 years</td>
<td>91</td>
</tr>
<tr>
<td>15 years to 12 years</td>
<td>134</td>
</tr>
<tr>
<td>15 years to 11 years</td>
<td>172</td>
</tr>
<tr>
<td>15 years to 10 years</td>
<td>206</td>
</tr>
</tbody>
</table>

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 as being indicative rather than definitive. These data suggest that there may be substantial savings from even a small reduction in either the length of EOT or the maximum effective patent life achieved by the extension.

When considered in light of the inefficiency of the EOT in encouraging additional R&D investment in Australia owing to the small value to originators of a longer extension in Australia, because of the small size of Australia’s market compared with the global market, the diminishment in incentive to invest owing to the impact of discounting, there is an argument for reducing extensions. The

—

83 Source: PBS data and IP Australia calculations.
argument gains greater force if the Government uses some of the resulting savings to bolster pharmaceutical R&D in Australia.

4.6.4. Findings from Duckett et al

The Panel notes Duckett et. al’s recent finding in a report from the Grattan Institute on pharmaceutical prices in Australia that Australia’s drug prices are ‘high by international standards’.\(^\text{84}\) Duckett et. al. stated that:

> ... 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.\(^\text{85}\)

Figure 4.5, shows that prices set by the PBS for pharmaceuticals have risen significantly in recent years compared to those paid in comparable markets. The report argues that this results mainly from the higher prices paid by PBS for generic drugs although a later submission to this Review notes that the Australian Government is also paying more for patented drugs. Australia’s higher exchange rates over the period have also contributed to these higher prices.


Duckett recommends changes to Australian pricing policies and actions to encourage the use of cheaper pharmaceutical products where possible. The estimated savings shown in Tables 4.3 and 4.5 from reducing 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 EOT would be substantially increased.

4.7. Reducing extensions of term

However important pharmaceutical R&D is to Australia’s economy and to Australian’s health, there is no evidence or convincing argument to demonstrate that the EOT scheme is contributing to the development of the Australian industry or to Australian R&D in a way that is commensurate with its very substantial costs.

Given this, the Panel proposes that the extent of the EOT be reduced. There are two main ways in which this could be achieved. The first is to reduce the maximum length of extensions. The effect of this would be to continue granting extensions to patents that would have received an extension under the current

---

86 Ibid p.5.
scheme. However, in most cases the extension would be shorter. The second option is to reduce the maximum effective patent life. This change would grant extensions to fewer patents. However, extensions of up to five years would still be provided where patents would not otherwise achieve the maximum effective patent life.

Tables illustrating the effect of each option are provided in Appendix C. Each option has advantages and disadvantages. The second option, reducing effective patent life, is the preferred option of the Panel for the reasons discussed below.

4.7.1. Reducing the maximum effective patent life

Reducing the maximum effective patent life offered by an EOT has the effect of providing savings to Government while still providing up to five years extension for those patents where there has been the greatest delay, and hence would otherwise have the shortest effective patent life remaining.

Continuing to provide a five year extension in cases where delays are greatest recognises that there may be a need for an incentive to bring a product to the Australian market where the effective patent life would otherwise have been very small. There are a number of costs associated with bringing a new pharmaceutical to the Australian market, including regulatory approval and PBS listing fees. It is possible that there are some cases, in which it is only marginally profitable to provide the product to the Australian market.

Reducing the effective patent life, while still providing up to a five-year extension, is the mechanism least likely to affect these pharmaceutical products. Notwithstanding this, a reduction to the effective patent life may still make it unfeasible to bring some products to the Australian market in the future. However, the Panel is unaware of any examples and if there are, the Government could make arrangements on a case-by-case basis to ensure Australian access to such drugs.\textsuperscript{87} To some extent the PBS is already targeted in this way offering its

\textsuperscript{87} Note, in such circumstances it would be more efficient to tailor solutions to specific problems rather than to provide incentives to all drugs to address exceptional casts. Moreover the solutions adopted might not necessarily involve
Pharmaceutical Patents Review

A reduction of extension length to, for example, one year would result in the same number of patents being granted an extension as under the current scheme (albeit with shorter extensions). Under such a change, drugs that take longer to get to market enjoy benefits that are no more than drugs subject to much shorter delays. On the other hand, a reduction in the maximum effective patent life would result in fewer extensions being granted, but with those being granted being for drugs taking the longest to get to market. Given that delays in getting to market are a prime risk for those investing in pharmaceutical innovation, the latter approach which focuses additional patent protection on the drugs which take longest to get to market is a better-targeted means for Government to share risk with pharmaceutical innovators than shortened EOT lengths.

A comparison of the pharmaceutical EOT provided in Australia with those provided in the United States and United Kingdom is provided in Appendix C. At the median, the extension length and effective patent life provided in Australia is similar to those provided for equivalent patents in the UK. However, compared with the US, extensions are 18 months longer in Australia and the effective patent life provided is 12 months longer in Australia.

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 freely to do so from Australia if the patent is still in force in Australia. Also, if the patents expire later in Australia, then Australian generic 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

greater subsidy from Australians via the PBS but rather (for instance) streamlined TGA approval.
markets beforehand and the prohibition on Australian generic stockpiling whilst the Australian patent remains in force.

The effective patent life in the United States (14 years) is less than that currently provided in Australia (15 years). Delays in seeking regulatory approval in one jurisdiction and different methods of calculating the length of extensions also contribute to differences in expiry dates. Reducing the effective patent life provided in Australia will result in fewer patents expiring later here than the equivalent patents in the US.

Highly innovative drugs are more valuable to society than me-too drugs, but from the originator perspective they are likely to carry far more risks. It seems possible that highly innovative drugs take longer to develop than me-too drugs, because safety and efficacy requirements may be more difficult to satisfy. As a consequence, highly innovative drugs are more likely to require the full five-year EOT than me-too drugs. Reducing the effective patent life allows the remaining EOT required to be consistent with AUSFTA to be targeted towards those cases where it is most needed.

4.7.2. Determining a new maximum effective patent life

There is no clear rationale for the selection of 15 years effective patent life as a benchmark. The origin of this figure is uncertain and does not appear to be supported by any economic analysis. Further, no evidence has been provided to the Panel to suggest that 15 years is an appropriate figure which optimises the costs and benefits of the EOT. Given the unrepresentatively low percentage of global pharmaceutical R&D undertaken in Australia, compared with our percentage of global pharmaceutical purchases, it seems inappropriate that Australia should provide one of the longest periods of effective patent life.

The powerhouses for the development of drugs originating from Australian R&D are small biotechnology firms. There is a common view that the Australian patent system has minimal impact on their business, since they are looking to overseas markets, particularly the US and Europe, and hence have to secure patent rights in those jurisdictions. In theory then, significantly reducing the EOT scheme will not have a significant detrimental impact on them. However, other factors need to be considered.
The vast majority of small biotechnology firms in Australia lack the capacity to take drugs to market. Rather, they need to find development partners, usually at the end of phase 2 clinical trials. Any minor impediment in the drug development pipeline can lead to project abandonment. Radical changes to the Australian patent system may have a detrimental impact on the willingness of large pharmaceutical firms to partner with small Australian biotechnology firms. Although it is difficult to put a measure on this risk, a number of submissions suggest that it is real enough not to be trivialised. While Australia should not be held to ransom by big pharmaceutical firms, nor should we be capricious about changes patent law if there is a risk that they could directly or indirectly adversely affect Australian industry.

In determining the extent to which the maximum effective patent life should be reduced, the Panel members have reached different conclusions.

Mr Harris and Dr Gruen recommend reducing the effective patent life from 15 to 10 years. Over time this would save the PBS approximately $200 million a year.\(^88\) in today’s dollars, based on current pricing arrangements (that the entry of generics will lead to price falls of 35 per cent) which the Government has agreed with Medicines Australia. The savings would grow in line with PBS costs which are growing at 4.5% per annum, substantially faster than real GDP. If the Government secured all of the pricing benefits allowed by the entry of generics, annual savings in today’s dollars could amount to around $400 million which would similarly be expected to grow with PBS costs. This is calculated on data that generics have led to a 70% price reduction in the United States. This is consistent with recent findings by the Grattan Institute that the price of generics paid by the PBS is several times the price secured by relevant Australasian Governments. The report also explains that the Canadian province of Ontario requires a 75% price reduction for all new generic drugs.

Professor Nicol supports a recommendation to reduce the effective patent life from 15 years to 12 years. The estimated savings resulting from this reduction

\(^88\) See Table 4.5 Estimated potential savings from reductions in extension lengths
would be approximately $130 million a year. If a 70% price reduction from generic entry was achieved as discussed above, the savings would be approximately $260 million a year. The additional savings provided by reducing the effective patent life diminish with each year’s reduction. Professor Nicol considers 12 years to be an appropriate reduction which reduces current inefficiencies funding system without posing a risk to future investment in R&D. One rationale for choosing 12 years of effective patent life is that this is at the lower end of the estimated time taken to bring new drugs to the market, as provided in Medicines Australia’s submission.

Recommendation 4.1:
The Government should change the current EOT provisions to reduce the maximum effective patent life provided from 15 years.

Harris and Gruen support reducing the effective life to 10 years, whereas Nicol supports reducing the effective life to 12 years.

The length of the extension should be calculated as being equal the number of days between the patent date and the date of first inclusion on the Australian Register of Therapeutic Goods minus 20 years less the maximum effect patent life.

The current 5 year cap on extensions should remain, providing a maximum of 25 years patent term for extended patents.

4.8. **Subsidising pharmaceutical R&D directly**

As discussed above, extensions of patent term are a costly and ineffective means of expanding pharmaceutical R&D in Australia. Thus it is not surprising that increasing extensions for those categories of pharmaceuticals where the existing system is inadequate is unlikely to achieve the desired outcomes.

---

89 See Table 4.5 Estimated potential savings from reductions in extension lengths
90 Medicines Australia submission to the PPR, pg 1, made in January 2013.
It follows that, if the Government has selected pharmaceutical R&D as a desirable activity for Australia and wishes to promote it, the most efficient and effective means of doing so would be to establish a scheme which links Government subsidies directly with pharmaceutical R&D, rather than employing a patent extension arrangement which, though it is something the pharmaceutical industry wishes to see, has no causal link between its cost to Australians in higher drug prices and the location of pharmaceutical R&D.

The direct subsidy would be funded using some portion of the savings identified from the reduction to effective patent life (See section 4.6). As the Productivity Commission (2007, 108) has observed, in the case of simple subsidies “it is likely that every dollar of public support generates somewhat less than a dollar of new business R&D because it substitutes for R&D that businesses would otherwise undertake”.\(^9\) However to maximise ‘additionality’ or the extent to which subsidies increase R&D rather than simply subsidise R&D that would have taken place in any event, it is likely to be better to design such schemes to subsidise increases in R&D within firms. The PC observes that additionality “may well rise above one dollar for well-designed incremental schemes”.

Funding could be directed to a general scheme to subsidise pharmaceutical R&D according to the Government’s priorities, such as basic research on biologics. Another portion of savings could be directed towards developing pharmaceuticals, such as for malaria and drug-resistant conditions, where research has not been adequately funded by the private sector because of inadequate expected returns, particularly because of their applicability to low income countries. Australia could initiate such action unilaterally, but also invite other countries to join us in building what would in effect be global public goods.

Some might argue that a Government R&D subsidy program of, say, $100 million a year is insignificant, insufficient even to fund the development of one new drug. But that argument cuts both ways: it also allows the conclusion that the $200 million indicative savings obtainable from reducing effective patent life to ten

years or $130 million for a reduction to 12 years would have little impact on the global industry’s investment in drug development. The savings represents less than 5 per cent of Australia’s patent drug market and it is a miniscule part of the global pharmaceutical market of US$782.1 billion.

The design of a subsidy scheme, as described above, would need to account for a number of complexities.

The Government may be unable to commit in the long term to transfer of PBS savings to Australian-based biomedical R&D. The drug development business is inherently risky and certainty around funding is of considerable importance. In order to increase the transparency regarding this transfer of savings, an independent assessment of the savings delivered to Government from a reduction in effective patent life should be made and published each year.

Any change to effective patent life would be expected to apply after the date specified in the new proclaimed legislation. Following this change, pharmaceuticals with an effective patent life of 15 years granted under the current scheme would remain in the system for some time and could take up to 15 years before they expire. As a result, while some savings will be seen soon after the change to effective patent life, the full savings benefits would not be realised for many years. The Government should be aware that the presence of pharmaceutical companies in Australia is an important asset for Australian research organisations which do not have the capacity to develop products themselves. This means that the subsidy fund should be designed to maintain R&D in Australia before the full savings are realised.

The pharmaceutical industry is best placed to make commercial decisions on investments in pharmaceutical R&D. Any Government subsidy program should therefore involve the private sector in determining where Government funding is best directed.
4.9. Extension for drugs needing greater incentives – paediatric, orphan, antibiotics

Australia does not currently provide an additional EOT for the development of paediatric treatment indications, orphan drugs, or for antibiotics. The US and the EU provide an additional six month extension for paediatric medicines where additional paediatric clinical studies are conducted.92

Some submissions argue that providing additional extensions of patent term for medicines for paediatric indications, antibiotics and “orphan” drugs would provide an additional incentive for the development of these drugs.93 The development of paediatric medicines, it is argued, presents further challenges for the industry that should be acknowledged through appropriate policies. Evidence is given in submissions to the Review of a decline in the development of antibiotics over the last 30 years and it is suggested that patent term extensions could be provided to signal to innovators that they will be given adequate opportunity to recoup their investment.

However, it is questionable whether extensions of patent term in Australia are an appropriate, or even sufficient, mechanism for addressing this issue. First, as discussed elsewhere the Australian market is very small in comparison to the global market. 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 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

92 In Europe Supplementary Protection Certificate (SPC) can be extended by six months if the patented product is approved for paediatric indications (Regulation (EC) No 1901/2006, Article 36). In the US a patentee can receive an additional six months patent protection for agreeing to conduct paediatric trials in relation to the patentee’s already FDA-approved drug, whether or not this results in approval for paediatrics (Best Pharmaceuticals for Children Act).

93 Pfizer, Dr David Lim and Merck Sharp and Dohme submissions to the Pharmaceutical Patents Review.
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.

A more efficient approach to encouraging investment in R&D for these categories of pharmaceuticals would be to provide assistance in the form of additional grant funding to 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.

**Recommendation 4.2:**
The Government should use part of the associated savings from recommendation 4.1 to fund R&D directly. Some of this funding could be targeted to socially beneficial research where patent incentives may be inadequate. 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 effective patent life with some share of those savings used to fund replacement R&D subsidies.

**4.9.1. Section 76A of the Patents Act**

**4.9.1.1. 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 EOT 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. The EOT provision was intended as a further measure to encourage investment in R&D in the pharmaceutical industry. The reporting requirements in s.76A were meant to assist the Government to evaluate whether extensions of term were in fact achieving this objective.

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. To its knowledge, the Panel is the first to obtain such collective information.

4.9.1.2. Effectiveness of section 76A
DoHA has provided the Panel with a summary of the information provided to it under s.76A. DOHA has denied permission for its publication. 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 information provided under s.76A appears to be of little value. The data only relates to a small sample – those pharmaceutical patents that have been extended - and is inconsistently provided. Providing the return places a burden on patentees that is not balanced by any usefulness to Government or the public.

---

in terms of better understanding or evaluation of the effectiveness of the EOT scheme.

IPTA argues in its submission that the purpose of the provision is unclear and, as it served no useful purpose, it should be deleted.\(^7\) 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 its usefulness could be determined.\(^8\)

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. The Australian Bureau of Statistics (ABS) reports that around $1 billion is spent on R&D in pharmaceuticals in Australia each year.\(^9\)

However, a breakdown of this figure by source of funding is not available.\(^10\) 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 all pharmaceutical patentees must provide information about revenue, licensing and R&D expenditure to the Patent Medicine Prices Review Board (PMPRB).\(^11\) Each year, the PMPRB must report on the percentage of R&D expenditure undertaken by

\(^7\) IPTA, Submission to the Pharmaceutical Patents Review, p.13.
\(^8\) Dr C. Lawson, Submission to the Pharmaceutical Patents Review, p.1.
pharmaceutical patentees. It should be noted that Canada does not have EOT 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.

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. The PSCC should assess whether the s.76A requirements can and should be replaced with a useful reporting mechanism.

**Recommendation 4.3:**

Section 76A of the Patents Act should be deleted. The Pharmaceutical System Coordinating Committee recommended in 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 Canadian Patent Medicine Prices Review Board (PMPRB) and superior to s.76A, can and should be developed.

---

5. Extension of term – scope

5.1. Broadening or narrowing the scope

Under Australian law patents with claims to active ingredients or new formulations of a known active ingredient are eligible for an extension. Extensions are available for these pharmaceutical inventions in the US, Europe, UK and Japan. However, these jurisdictions also provide extensions for uses and methods of manufacture of pharmaceuticals, whereas Australia does not.

The explanatory memorandum accompanying the legislation that introduced the current EOT provisions states that:

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

GMiA argues that this was intended to limit eligibility to patents claiming new active ingredients. Conversely, originator companies argue that new formulations containing known active ingredients can and should be considered to be new and inventive substances 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.

The current approach of allowing extensions of patents claiming active ingredients and new formulations appears reasonable on the basis that products based on these inventions are desirable, require considerable R&D and may not enter the market until regulatory approval is obtained. This is supported by data demonstrating that the time taken to obtain regulatory approval is similar for

104 Article 1(c) European Community Regulation 469/2009; 35 USC 156(a).
106 Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [15].
new actives, new formulations, new compositions and biologics (see Figure 5.1 below).

**Figure 5.1: Average Effective Patent Life for Extended Patents by (Equivalent FDA) Pharmaceutical Classification**

Data from IP Australia indicate that new active ingredients make up the vast majority of extended patents (Figure 5.2 below). Limiting extensions to patents on new active ingredients, as proposed by some in the generics industry, would therefore have little effect in reducing the overall cost of pharmaceuticals or barriers to competition. GMiA disputes this figure and argues that it is not sufficient reason for such patents to continue to be eligible for an extension, given that the proportion may significantly increase in the future. The Panel is not aware of evidence that patents for new formulations and compositions are likely to increase. GMiA argues that new formulations do not warrant extensions because they require significantly less R&D compared with the active ingredient.108

---

107 IP Australia Data.
The proportion of new formulations and compositions is not significant and a case has not been made to make them ineligible for extensions. Further, if the majority of these are minor innovations as argued, they will not take as long to gain market approval and so will not qualify for an EOT.

**Figure 5.2: Number of Extended Patents by (Equivalent FDA) Pharmaceutical Classification**

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

- subsequent medical uses require significant capital investment and risk to bring a product to market; \(^{110}\)
- allowing extensions for such patents would more closely match the EOT schemes in the US, Europe and Japan; \(^{111}\)

---

\(^{109}\) IP Australia Data. Note: this is based on a reduced set of 473 extended patents where it was possible to match each to the equivalent FDA pharmaceutical classification.

\(^{110}\) Responses to the Draft Final Report, FICPI Australia at [4], IPTA at [12], Sanofi at [12-13].
• ‘[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 and new therapeutic uses may be comparable to that involved in developing the original active ingredient;’\textsuperscript{112}

• 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 EOT provisions were introduced. IPTA argues ‘… it would seem appropriate to expand the types of patents which may be eligible for a patent term extension accordingly.’\textsuperscript{113}

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.

Sanofi-Aventis provides an example of the development process for a new method of treatment. Sanofi produces the product Arava, which is used to treat rheumatoid arthritis. In order to obtain regulatory approval to market Arava for the treatment of psoriatic arthritis, Sanofi was required to conduct human clinical trials to demonstrate the safety and efficacy of the product for the new treatment indication.\textsuperscript{114}

As discussed previously in this report, clinical trials involve a significant investment of resources and carry some risk. Sanofi argues that the absence of extensions for new methods will mean that Australians are at risk of losing access to new and innovative medicines, when extensions are granted for the same drug

\textsuperscript{111} Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [14].
\textsuperscript{112} Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [16].
\textsuperscript{113} IPTA, Submission to the Pharmaceutical Patents Review, p.8.
\textsuperscript{114} Sanofi-Aventis, Response to the Draft Report, p. 13.
in other jurisdictions. However, no evidence has been provided to the Panel of a new treatment indication that was not brought to Australia due to the lack of an EOT.

The guiding principle for any change to the intended scope of pharmaceutical patents eligible for an EOT is that changes should only be made if it is clearly in the national interest to do so. Consistency with other jurisdictions for its own sake is not a sufficient reason to match Australian laws with those of other countries. The current policy of providing extensions for new and inventive substances and not for new methods of treatment or processes of manufacture is appropriate.

**Recommendation 5.1:**
The Government should maintain the current approach that allows extensions for drugs and formulations but not for methods of use and manufacture. This 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.

5.2. **Clarity of the provisions**

5.2.1. **Section 70(3) and ’consists or contains’**
The period of the EOT 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.\(^{115}\)

A number of submissions raise concerns that goods “containing” the patented substance have been interpreted by the courts to include products in which the substance is present as only an impurity or minor contaminant. This results in 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

---

\(^{115}\) *Patents Act 1990* (Cth), s.70(5).
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.\textsuperscript{116} Australia’s approach is different to the approach taken in other jurisdictions. For example, in the US and EU, an extension is based on the first regulatory approval date of the product.\textsuperscript{117}

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

In \textit{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 EOT was the date of listing of Cipramil: Cipramil being a product ‘containing’ escitalopram. \textit{Lundbeck} sought leave to the High Court to appeal this decision. However, the request was denied: the High Court considered that the approach taken by the Federal Court was not attended with sufficient doubt to warrant grant of special leave to appeal.\textsuperscript{118}

In \textit{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:

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{116} IPTA, Submission to the Pharmaceutical Patents Review, p.10.
\item \textsuperscript{117} 35 USC 156(a)(5)(A), European Community Regulation 469/2009, Article 3(d).
\item \textsuperscript{118} \textit{Lundbeck v Alphapharm} [2009] HCA Trans 324 at [955].
\end{itemize}
\end{footnotesize}
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.  

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 EOT. 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.

As noted above, 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. 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.

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. The exact wording of any change would be critical and should be subject to the usual public consultation by IP Australia for such amendments.

---

119 *Law Council of Australia*, Submission to the Pharmaceutical Patents Review at [15].
121 H. Lundbeck A/S, Submission to the Pharmaceutical Patents Review p.3.
Recommendation 5.2:
Section 70(3) should be amended to clarify that the ARTG registration on which an EOT is based is that of the relevant product, the use of which would infringe the claim.

5.3. The stated policy objective
5.3.1. Pharmaceutical substance per se
Concerns have also been raised 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.122 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.123

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.

122 Law Council of Australia, Submission to the Pharmaceutical Patents Review at [2]–[8].
123 GMiA, Submission to the Pharmaceutical Patents Review, p.17.
As discussed above, the purpose of this was to limit extensions to pharmaceutical substances and not delivery systems, new uses of known pharmaceutical substances, or methods of制造 pharmaceutical substances.124

5.3.1.1. Judicial interpretation of pharmaceutical 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.125 The single judge’s decision was the first time the courts had considered the construction of s.70(2)(a).126

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 EOT would only be available for new and inventive substances where the claim is for a pharmaceutical substance as such, 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).

5.3.1.2. Judicial interpretation of method and process claims
In Prejay Holdings & Anor v Commissioner of Patents,127 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.

5.3.1.3. Inconsistency in judicial decisions
The decisions in Boehringer and Prejay appear consistent with the original policy intent, which was to provide extensions for substances but not for delivery systems or methods of administering or using substances. These decisions have been affirmed many times and have not been overturned.

GMiA argue that the IP Australia decisions of Sanofi and NV Organon are inconsistent with the principles established in Boehringer and Prejay, leading to a broadening in scope of the extensions.  

In these decisions IP Australia hearing officers respectively considered that a thermoplastic ring adapted to deliver a slow-release steroidal composition (N.V. Organon) and a biphasic table (Sanofi Aventis) fell within the definition of pharmaceutical substance per se. Both of these decisions have been the subject of criticism. In a separate case, the AAT expressly disapproved of the decision in Organon, finding it inconsistent with previous judicial reasoning on the issue. However, neither case has been considered by a higher court.

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.

128 GMiA, Submission to the Pharmaceutical Patents Review, p.16.
130 [2007] APO 35.
5.4. Multiple extensions based on one ARTG listing

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 5.1, there have been 77 instances identified (covering 179 patents, which is 32% of all extended patents) where this has occurred.

<table>
<thead>
<tr>
<th>No. of Patents per ARTG Registration</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Instances</td>
<td>381</td>
<td>60</td>
<td>11</td>
<td>5</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Necessarily, where there is more than one patent receiving an EOT 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.

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. Alphapharm made similar comments in its submission. 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 regulatory approval.

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.

---

131 IP Australia data.
132 Alphapharm, Submission to the Pharmaceutical Patents Review, p.11
133 35 USC 156(c)(4).
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. Patent standards and evergreening

The term ‘evergreening’ is sometimes used to describe strategic utilisation of patent law and regulations to maximise or extend the IP protection surrounding particular products. It is most commonly used in relation to the pharmaceutical industry to describe strategies employed by pharmaceutical companies to increase market advantage and extend patent protection for high-earning drugs.134 The term ‘evergreening’ is not used in this report in a pejorative way but rather to describe the lawful 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. One strategy is to seek multiple patents surrounding a single pharmaceutical product. These “follow-on” patents are 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 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.

In addition to the accumulation of multiple related patents, 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). Prescription switching occurs when prescribers are invited to switch prescriptions from an older variety of a drug, for which the patent is due to expire, to a new –

patent protected – variety, the intention being to maximise the extent to which patients received patented rather than off-patent drugs.

Views on the extent and validity of such practices in the pharmaceutical industry are polarised. One 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.136

On the other hand patents exist not just to provide incentives for firms to develop wholly new drugs, but also to provide incentives to improve drugs and to exploring additional indications for which they can be used. As a matter of law, follow-on patents are distinct IP rights and are incapable of extending the life of an original patent.137

This chapter refers to original (i.e. first), and later patents filed in relation to the same pharmaceutical substance. For the sake of conciseness, the terms ‘original patent’ and ‘follow-on patent’ are used. The term “original patent” refers to the first patent application disclosing the active pharmaceutical ingredient (API). “Follow-on patent” refers to any subsequently filed patent directed towards that API and is not intended to imply any pejorative tone.

6.1. 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 via delays in PBS subsidy price reductions and loss of a competitive market.

135 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
136 These views are reflected in submissions to the Pharmaceutical Patents Review by received by Alphapharm, GMiA, Dr. Hazel Moir, AFTINET
137 Views reflected in submissions from originator pharmaceutical companies and IP professionals
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.\textsuperscript{138}

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” patents\textsuperscript{139} 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.

Each of the points summarised above has been raised as a concern in submissions received by the Panel.\textsuperscript{140}

GMiA submits that follow-on patents are being used to delay the entry of generic medicines following the expiration of the original patent. Furthermore, they state that the density of follow-on patents 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.\textsuperscript{141}

\textsuperscript{139} Referred to as follow-on patents in this report
\textsuperscript{140} Submissions to the Pharmaceutical Patents Review provided by GMiA, Alphapharm, Dr. Hazel Moir and AFTINET each express concern about the purported use of evergreening tactics by originator pharmaceutical companies
\textsuperscript{141} GMiA public submission, pages 44-46
Alphapharm has provided a number of examples where pharmaceutical companies have been granted multiple follow-on patents for modifications to an original pharmaceutical compound.\textsuperscript{142}

6.2. Follow-on patenting
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 claim variations of the originally filed invention that provide improvements or solve problems not envisaged at the original time of filing. Similarly, improvements to a marketed medicine may be made (and patented) following feedback and further research once a medicine is on the market.

Bristol-Myers Squibb summarises this type of cumulative innovation in their submission:

\begin{quote}
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
\end{quote}

\textsuperscript{142} Some 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. 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)”.

108
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 ongoing research and development results in new patentable inventions, new patents are applied for.\(^{143}\)

Further examples of the types of improvements that may be protected by follow-on patents include enhanced bioavailability, reduction of harmful side effects, improved safety, efficacy or stability and improved dosing options.\(^{144}\)

Follow-on patenting is allowable under Australian patent law. Furthermore, the facilitation of cumulative innovation is an important role of the patent system. This chapter later considers whether this aspect of the system is serving Australia well.

### 6.2.1. 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.

\(^{143}\) Bristol-Myers Squibb submission, paragraph 30

\(^{144}\) Responses to Draft Report by Novartis, Abbvie, IFPMA, AIPPI.
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 EOT 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. 145

Follow-on patent 2002250058, directed towards desvenlafaxine, was filed in 2002, granted146 in 2008 and will expire in 2023, having gained an EOT 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.147

145 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
146 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
147 Alphapharm, Submission to the Pharmaceutical Patents Review, p. 14
The Panel has seen no evidence to suggest that the EFEXOR-XR (extended release) and PRISTIQ (desvenlafaxine) patents restricted generic versions of Efexor (venlafaxine) from entering the market once the original Efexor patent expired. Rather, it appears 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.\textsuperscript{148} This issue, however, has already been addressed by the TGA and such practices are no longer possible.\textsuperscript{149}

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 to 39 years of market exclusivity are somewhat overstated.\textsuperscript{150}

The Panel accepts, however, that certain life-cycle management strategies do appear to have been 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 submit that a shift in prescriptions has occurred as a result of marketing campaigns directed towards physicians.\textsuperscript{151}

\textsuperscript{148} Such practices were referred to in Dr. Hazel Moir’s Submission to the Pharmaceutical Patents Review, p. 11. Bioequivalency is discussed further in Chapter 8.

\textsuperscript{149} 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 - \textit{Therapeutic Goods Amendment Regulation 2012 (No. 3) - Schedule 9, Part 1, subitem 1(1)}

\textsuperscript{150} However, the Panel notes that the entry of these generics was only made possible following the successful challenge of the 2003259586 patent. This patent 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.

\textsuperscript{151} Alphapharm, Submission to the Pharmaceutical Patents Review, p. 7
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.\(^\text{152}\)

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 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.

\(^\text{152}\) The patent was extended based on Nexium (Esomeprazole magnesium trihydrate) though the patent did not disclose any specific enantiomer of omeprazole.
Ranbaxy has applied to the Court for revocation of the 676337 and 695966 patents. AstraZeneca cross-claimed for infringement and was granted interlocutory injunction. The matter is yet to be decided in the Court.

The combination drug marketed as Vimovo, comprising esomeprazole and naproxen, is the subject of three patents and is listed on the PBS. 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 and PBS, presumably under a co-licensing agreement.

IPTA addresses this case study in their submission. Referring to the omeprazole formulation patent, they state:

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.

---

153 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

154 601974

155 IPTA Submission to the Pharmaceutical Patents Review, p. 20
The omeprazole formulation patent (601974) was challenged and found to be valid in the High Court.\textsuperscript{156} 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,\textsuperscript{157} 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 prolong the patent life of the original omeprazole pharmaceutical.\textsuperscript{158} 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, as claims have been made that esomeprazole provides no therapeutic benefits over omeprazole.\textsuperscript{159}

Enantiomer patents for atorvastatin and clopidogrel have been found invalid, and revoked in recent years.\textsuperscript{160} The pending decision\textsuperscript{161} regarding the omeprazole enantiomer may provide guidance as to whether this type of follow-on innovation meets patentability standards.

\textsuperscript{156} Aktiebolaget Hassle v Alphapharm [2002] HCA 59
\textsuperscript{157} 676337
\textsuperscript{158} The entry of generic omeprazole pharmaceuticals to the market is evidence of this
\textsuperscript{159} Summarised in Esomeprazole (Nexium) - What is Esomeprazole? (http://www.news-medical.net/health/Esomeprazole-%28Nexium%29-What-is-Esomeprazole.aspx)
\textsuperscript{160} Albeit on different grounds – Clopidogrel patent 597784 revoked on grounds of novelty and inventive step, Atorvastatin patent revoked on grounds of false suggestion
\textsuperscript{161} Federal Court – VID 1008/2011
A key consideration in the concerns raised about evergreening and follow-on patents is the standards set for grant of patents and the quality of the grant process. Low patent standards allow the grant of patents for minor modifications of existing drug products which provide little advance over the existing product.\textsuperscript{162} The ability to gain such patents may permit originator pharmaceutical companies to accrue large numbers of follow-on patents which they can then use to frustrate generic entry. Substantial costs to the PBS also accrue where the subsequent drugs are listed in separate F1 formularies, thereby attracting the highest level of PBS subsidisation, even though they provide no substantial advantage over existing drugs.

\subsection*{6.2.2. Patent thickets}

A number of submissions that raise concerns about evergreening express similar concerns about patent thickets.

The European Patent Office recently published a report from a workshop focussing on patent thickets.\textsuperscript{163} In their definition of a patent thicket, the authors included the criteria that multiple patents for similar technology need to be held by multiple parties.\textsuperscript{164} Furthermore, they suggested that it is the blocking effects of these multiple overlapping patents, held by multiple parties, which contribute

\begin{flushleft}
\textsuperscript{162} Submissions to the Pharmaceutical Patents Review by Alphapharm, GMiA, Dr. Hazel Moir, AFTINET
\textsuperscript{164} 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.
\end{flushleft}
to a patent thicket. Pharmaceuticals were classified as a discrete technology\textsuperscript{165} in which “thickets were thought to be less prevalent and less problematic”.\textsuperscript{166}

The “patent thickets” described in submissions to the Panel generally refer 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.

There is, however, some evidence that thickets of multiple patents held by multiple parties exist in the pharmaceutical sector. A recent study by Christie et al of the fifteen costliest drugs in Australia over the last 20 years demonstrates that for each of these drugs there is a mean of 49 associated patents. Three quarters of these surrounding patents are owned by third parties (i.e. not the originator pharmaceutical company).\textsuperscript{167} Appendix E provides further analysis of two of the drugs, omeprazole/esomeprazole and simvastatin, demonstrating that the majority of the patents filed later in the life of original patent are filed by third parties, rather than the original patent owner.\textsuperscript{168} A similar finding has also been published in regard to formulation patents surrounding atorvastatin (Lipitor).\textsuperscript{169}

\textsuperscript{165} A discrete technology is explained in terms of the patentable product (or process) requiring few ‘patentable elements’, compared to a complex technology which requires many such elements

\textsuperscript{166} Ibid - In comparison to complex technologies such as electronics semi-conductors. Page 8, Annex 1 – Figure 3

\textsuperscript{167} Christie, A.F. et al. Patents associated with high-cost drugs in Australia, PLoS ONE (2013)Vol. 8, No. 4, e60812; and Response to the draft report by Andrew Christie et al.

\textsuperscript{168} Whereas filings before market entry appear to be exclusively by originators

\textsuperscript{169} Howard, L. ‘Formulation patents in pharmaceutical development’, The Journal of Generic Medicines, 2008, Vol. 5, No. 4, pages 365-370 (see Figure 1)
This level of patenting may be far less than the levels observed in software and electronics technologies. However, the presence of this number of patents around high value drugs adds to the complexity of what is already a contested environment, increasing the costs and uncertainty for generics and others seeking to innovate or enter the market.

Regardless of whether, or to what extent, patent thickets exist, patent standards are a key safeguard against strategies that result in a web of overlapping patents, frustrating competitors’ effort to enter the market. Furthermore, as suggested by Christie et al in their conclusion, targeting policy to address the patenting practices of originator pharmaceutical companies alone is unlikely to improve matters.

6.2.3. Patentability standards
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 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.
6.2.4. Raising the bar

In 2009 IP Australia commenced consultation on reforms to Australia’s IP system. Central to these reforms was concern that Australia’s patent standards were set at lower levels than standards elsewhere.

The Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth) (Raising the Bar), which was enacted in April 2012, is the result of that consultation. It makes significant amendments to the Patents Act to raise the thresholds for the grant of patents in Australia and to better align Australian standards with standards elsewhere (refer to Appendix C).

These amendments apply across all technologies, including pharmaceuticals, with the higher thresholds generally applying to patent applications for which a request for examination was made after April 2013.

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.

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.170 Similarly, generic companies acknowledge attempts to achieve the right balance between strong IP

170 Submissions to the Pharmaceutical Patents Review by Amgen, Medicines Australia, Bristol-Myers Squibb, Merck Sharpe & Dohme, Novartis
rights, the encouragement of innovation and the interests of both patentees and society as a whole.\textsuperscript{171}

\textbf{6.2.5. Means for assuring patent quality}

Assuming the Raising the Bar amendments effectively meet their goal, they will make it harder for applicants to obtain patents for trivial advances or obvious variations, thereby limiting the opportunities for patent portfolio-type evergreening.

But has been criticism, that the Raising the Bar amendments do not go far enough. Submissions argue that the amendments do not raise the inventive step threshold high enough to sufficiently align the level of inventive step with that of our major trading partners (specifically, the United States and Europe)\textsuperscript{172}. This would have the effect of Australia continuing to grant patents which are not valid in other jurisdictions, leading to the patent protection of pharmaceuticals which are open to generic competition in other countries.

Submissions from GMiA and Alphapharm suggest that quality issues in the patent examination process may be contributing to the grant of low quality patents. There are quality systems in place within IP Australia which are specifically aimed at improving the quality of the examination process.\textsuperscript{173} However, other than the review of office decisions provided by the 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 help in this matter. The grant of poor quality pharmaceutical patents can cost the Government

\textsuperscript{171} GMiA, Submission to the Pharmaceutical Patents Review, p. 22
\textsuperscript{172} Response to the Draft Report by AFTINET, Alphapharm, Dr. Hazel Moir
\textsuperscript{173} In 2009–10, IP Australia established a Quality Improvement Section. This section will provide independent quality review of the work of each examiner who exercises a delegation to accept IP rights and whose decisions have the potential to affect the future of applicants’ rights, the marketplace and the reputation of IP Australia – Department of Innovation, Industry, Science and Research Annual Report 2009-10
significant money in PBS subsidies. The cost of establishing an external auditing
c委员会 would be small in comparison to the potential savings that could occur
through the associated improvement in, and maintenance of, patent quality.

Such a committee may be run by the Advisory Council on Intellectual Property
(ACIP). It is envisaged that the committee would review patents granted by IP
Australia. This would include monitoring the outcome of examination and grant of
equivalent patents in jurisdictions of Australia’s major trading partners. Instances
in which patents are granted in Australia but refused or invalidated in other
jurisdictions\textsuperscript{174} could indicate that the Raising the Bar legislation has not met its
policy objective of aligning Australia’s IP law with its major trading partners. The
audit committee would recommend action be taken if this was found to be the
case.

The external audit process could also examine whether Australia’s patent
standards, even where they equate with those applied by our major trading
standards, are too low to prevent minor pharmaceutical enhancements from
obtaining patent protection.

**Recommendation 6.1:**
The Government should establish an external patent oversight committee (eg. as
part of ACIP) that is tasked with reviewing grants issued by IP Australia and
auditing the decisions involved in making such grants, to ensure that IP
Australia’s decisions are consistent with the relevant Australian law as well as
being aligned with Australia’s major trading partners and with Australia’s
interests.

Given the concerns regarding the Raising the Bar amendments, as well as the
substantial negative impacts that low patentability standards have not only on
the pharmaceutical system, but also on the broader IP system, it would be

\textsuperscript{174} A recent example is the Federal Court decision to uphold a patent protecting
the contraceptive pharmaceutical – Yaz (Bayer Pharma Aktiengesellschaft v
Generic Health Pty Ltd (No 2) [2013] FCA 279). Corresponding patents in the
United States were invalidated on grounds of lack of inventive step.
prudent to review the effectiveness of the Raising the Bar amendments (and inventive step requirements more generally) at the earliest date feasible.

A Productivity Commission review could consider the effectiveness of the amendments from policy, legal and economic points of view and could assess whether the amendments are meeting their policy objectives and serving Australia’s best interest. The Panel considers that five years, following the commencement of the Raising the Bar Act, should allow sufficient time to gather evidence for a review.

**Recommendation 6.2**
The Government should request the Productivity Commission to undertake a broad review of the patent system, including of the effectiveness of Raising the Bar Act no later than five years from the commencement of the Act.

**6.2.6. Factors external to the patent system**
Patentability standards and, in particular, the threshold for inventive step, are a key issue in the efficiency of the patent system. Thresholds that were too lax 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. Thus, the discussion and recommendations presented in the previous section are considered by the Panel to be the best course of action at the present time.

However, 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, as changes to the patent system alone will do little to affect the marketing strategies utilised by pharmaceutical companies.

It is worth reiterating at this point that these 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.
The pharmaceutical market in Australia, gives end users little incentive 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.\textsuperscript{175} It is evident that PBS policies play a role in permitting evergreening practices. It follows that there is potential for the PBS to play a role in minimising these practices.

As an example, 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.\textsuperscript{176} 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 1.2.1 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 outcome\textsuperscript{177}. 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.

\textsuperscript{175} Although it is acknowledged that intermediaries such as physicians and pharmacists also have a strong influence on the choice of drugs for patients, from those within the PBS range

\textsuperscript{176} This role need not be performed by the PBAC alone. See section 10 of this report discussing inter-authority co-operation

\textsuperscript{177} Submissions to the Pharmaceutical Patents Review by Alphapharm, Dr. Hazel Moir
Pharmaceutical Patents Review

or therapeutic outcomes.\textsuperscript{178} Alphapharm estimates that the cost of the prescription shift to desvenlafaxine will amount to $257 million by the end of the desvenlafaxine patent in 2023\textsuperscript{179}.

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.

\textsuperscript{178} 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)

\textsuperscript{179} Alphapharm Submission to the Pharmaceutical Patents Review, p. 7

123
Recommendation 6.3
The Government should implement strategies for minimising the extent to which PBS policies permit evergreening practices, where these practices provide no net benefit to Australia. An overarching body, such as the PSCC (see recommendation 10.1) should be tasked with oversighting such strategies.
Efficient and effective mechanisms for enforcing and challenging patents are important elements in maintaining a robust and appropriately balanced intellectual property system. Once a patent has been granted, the patentee has the right to enforce it and can pursue infringement proceedings in the courts. 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, including actions for patent infringement and revocation. It is often the case that revocation is raised as a counterclaim in infringement proceedings as well as an action in its own right.

In addition to seeking revocation in the courts, parties who wish to challenge the granting or validity of a patent can utilise a number of processes involving the Commissioner of Patents: third party notifications, opposing the grant of the patent and requesting re-examination of the patent. Parties may also settle disputes without recourse to the Commissioner or the courts, such as through licensing agreements.

Patent litigation in Australia is a slow and expensive process. Submissions provide estimates of legal costs ranging from $750,000 to $2 million for general litigation\textsuperscript{180} up to $7 million for patent challenges.\textsuperscript{181} These costs are disproportionately large in relation to the size of the Australian pharmaceutical market, making use of the court system difficult to justify for many parties. In recent years, various Governments have had a number of reviews and measures to address this.\textsuperscript{182} However, more needs to be done to reduce litigation costs, particularly those associated with discovery and expert witnesses.

\textsuperscript{180} Novartis Submission to the Pharmaceutical Patents Review, page 4.
\textsuperscript{181} Alphapharm Submission to the Pharmaceutical Patents Review, page 8.
7.1. **Non-judicial third party challenges**
Third party notification, opposition and re-examination aim to provide rapid, inexpensive alternatives to litigation. 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 grant.

The Raising the Bar Act has recently made a number of changes to some of these processes. There is a general consensus in submissions that any further reform would be premature before the consequences of these changes have been assessed. GMiA submits that non-judicial systems of examination overall provide a relatively rapid and inexpensive means for challenging the validity of a patent claim. However, it appears that the attractiveness of these mechanisms is limited because decisions may be appealed to the courts and consequently do not provide an acceptable degree of certainty to either the patentee or other party. Where decisions are appealed, lengthy delays may result and prolong the period of uncertainty. GMiA submits:

> 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.183

This is not an issue that can be easily addressed. It is appropriate that IP Australia decisions are appealable to the courts, where they can be subjected to the scrutiny of an independent judiciary and formal evidentiary requirements apply.

**7.1.1. Third party notification**
Section 27 of the Patents Act provides for a person to submit information to IP Australia showing that the claimed invention is not novel or does not involve an inventive step. This information can only be provided after publication of the

---

application and not more than three months after the publication of a notice of acceptance of the application.\textsuperscript{184}

This provision ensures that examiners have access to all relevant prior art during the examination process and 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.\textsuperscript{185} 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-technology, traditional knowledge patents, rather than small molecular entity or biologic type pharmaceutical patents. Apart from this exception, the number of s.27 filings has remained low and fairly constant.

\textbf{7.1.2. 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 any interested party can file a notice of opposition challenging the grounds on which the patent was accepted.\textsuperscript{186} An opposed patent cannot be granted until the opposition process is complete.\textsuperscript{187} Opposition is intended to provide a faster and less expensive process for settling disputes between patent applicants and third parties than the courts. However, it can take two to three years before an opposition progresses to hearing by a delegate of the Commissioner.\textsuperscript{188}

\textsuperscript{184} 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.

\textsuperscript{185} In comparison to an average of 35 per annum in all technologies. IP Australia data, March 2013.

\textsuperscript{186} \textit{Patents Act 1990} (Cth), Chapter 5.

\textsuperscript{187} Similar provisions apply to innovation patents under s.101M.

\textsuperscript{188} IP Australia data, March 2013.
Pre-grant opposition systems like Australia’s enable issues to be resolved before the patent is granted, thereby increasing certainty in the validity of granted patents. 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. An office decision on an opposition can be appealed to the Federal Court by the patent applicant or opponent.

Only a very small proportion of accepted applications - less than 1 per cent - are opposed. From 2003 to 2012, there have been, on average, 88 oppositions filed per year and approximately 17 per cent are in relation to pharmaceutical patents.189

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 extensions of time and filing of further evidence to prevent delays in resolution of opposition and thereby, reduce public uncertainty.

A limitation of the opposition process is that it is undertaken early in the life of a patented pharmaceutical product. At this stage competitors may not yet know whether it is worthwhile opposing the grant of the patent. Post-grant opposition systems in other countries do not solve this problem because they require oppositions to be filed within a limited period after grant in order to prevent opposition processes becoming involved in related court proceedings. The European and US post-grant opposition processes provide a period of nine months after grant.

The Advisory Council on Intellectual Property (ACIP) briefly considered the introduction of a post-grant opposition system in 2010. ACIP found little justification for Australia to move to a post-grant system and recommended that the situation be monitored.190 The Government accepted this recommendation.191

---

189 IP Australia data, March 2013.
ACIP found that the European opposition system has a higher rate of use (5 per cent of all granted patents) than the Australian system and there appears to be quite a high revocation rate in some technologies.\textsuperscript{192} There may be other elements of the European system that could be adopted in Australia to make our opposition process more effective.

7.1.3. Re-examination
Section 97\textsuperscript{193} 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. Re-examination can also be directed by a court where the validity of a patent has been challenged in court proceedings. The patentee can appeal an adverse re-examination finding, and any party can oppose an amendment to the patent arising from re-examination.

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. The changes introduced by the Raising the Bar Act expand the grounds for re-examination to all substantive grounds considered during examination, opposition and in court revocation proceedings. The changes also require the Commissioner to be convinced to a higher standard of proof than was previously the case.

In the pharmaceutical area, about 49 per cent of the third party re-examination requests resulted in successful narrowing of the scope of the granted patent,


\textsuperscript{192} Moir, Response to the Draft Report, pp.8-9.

\textsuperscript{193} Similar provisions apply to innovation patents under s.101G.
while 28 per cent of challenges were unsuccessful to the extent that the scope of the claimed monopoly remained unchanged.194

Third party re-examination is little used. Since 2001, there have been 117 re-examination requests filed by third parties. Thirty three of these requests (28 per cent) were in relation to pharmaceutical technologies. The average time taken to issue a first re-examination report was 13 weeks. The average time for resolution of the re-examination proceedings was 48 weeks.195 The usefulness of re-examination may be increased by the Raising the Bar changes and if IP Australia’s average of 13 weeks to issue a first re-examination report is reduced.

7.2. 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 a serious question to be tried and that the balance of convenience favours the grant of such relief.196

The applicant 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 respondent may be ordered to keep an account of profits.

The statutory price reduction and ongoing price disclosure systems of the PBS are important factors in determining whether interlocutory injunctions are granted in pharmaceutical cases. The most recent guidance on the matters that the courts consider when granting interlocutory injunctions in patent cases is the Novartis

194 The remaining 23% of re-examinations have related court proceedings.
195 IP Australia data, March 2013.
196 For example, Samsung Electronics Co Ltd v Apple Inc (2011) 286 ALR 257 at [52] – [74].
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 per cent statutory reduction in the subsidy for the F1 (original) pharmaceutical. The statutory reduction is discussed in Chapters 2 and 4.

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”. By “irreversible effects”, Medicines Australia is referring to the 16 per cent statutory price reduction and further price reductions resulting from generic competition in the market. Although the 16 per cent 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.

GMiA submits that the balance of convenience persistently falls against generic companies and that the damages payable to a generic sponsor if the patentee is unsuccessful at trial do not dissuade originators from seeking interlocutory injunctions. Injunctions prevent generic manufacturers from selling their product and so limit the funds available for their legal defence. GMiA claims that in the last eight years, 22 interlocutory injunctions concerning pharmaceuticals and medical devices have been sought, with injunctions granted in 18 of these cases.

Medicines Australia’s submission similarly states that since 2007, at least 20 interlocutory injunctions have been granted by the Federal Court in view of the

---

198 Medicines Australia Submission to the Pharmaceutical Patents Review, page 12.
199 Bristol-Myers Squibb, Medicines Australia submissions to the Pharmaceutical Patents Review.
16 per cent 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.\textsuperscript{201}

A number of submissions raise concerns regarding timing issues for interlocutory injunction applications. BMS states that due to a lack of any early notification process for listing of drugs on the ARTG, interlocutory injunctions are required to be pursued urgently in order to prevent generic PBS listing.\textsuperscript{202} The issue of early notification is considered in more detail in the discussion of Patent Certificates below.

The Panel considers that interlocutory injunctions have a role in protecting rights owners from irreparable damage. But, as discussed below, patentees in the future may take more care when assessing whether to seek interlocutory injunctions, given that the Government is currently seeking damages in relation to two cases where interlocutory injunctions were granted and the patentees were unsuccessful at trial.

\textbf{7.3. Costs of invalid patents and incentives to challenge}

A patentee that has commenced infringement action against another party may undertake to pay damages as a condition of obtaining an interlocutory injunction. If, in response, the patent is challenged and found invalid, the patentee may be liable to pay damages to the Government as well as the respondent to the action. Government damages would involve the foregone savings to the PBS budget resulting from delay in generic entry into the market and reduction in the

\textsuperscript{201} Medicines Australia, Submission to the Pharmaceutical Patents Review, page 12.

\textsuperscript{202} Bristol-Myers Squibb Submission to the Pharmaceutical Patents Review.
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 above, there have been two recent cases of injunctions being granted for PBS-listed products and the patents subsequently being revoked – Sanofi-Aventis’ patent for clopidogrel (Plavix)\(^{203}\) and Wyeth’s patent for venlafaxine (EFEXOR XR).\(^{204}\) In both cases the Department of Health and Ageing is currently seeking compensation from the patentees.\(^{205}\) On these, 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 and will, therefore, result in fewer pharmaceutical products coming to market in Australia.\(^{206}\)

The Panel considers that it is appropriate that the Government continue to seek damages from the owners of invalid patents that have resulted in higher costs to the PBS due to delayed entry of generic versions resulting from the grant of interlocutory injunctions. 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, no evidence has been provided to support these arguments.

\(^{203}\) Apotex Pty Ltd v Sanofi-Aventis [2009] FCAFC 134.

\(^{204}\) Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2011] FCAFC 132.

\(^{205}\) Government seeks millions for drug delay, Sydney Morning Herald, 19 April 2013.

However, the Panel considers that the recovery of damages in failed infringement actions is insufficient. The PBS is the party that ‘internalises’ many of the benefits of a successful challenge to a patent through reduced prices and thus 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. This includes independent invalidity proceedings as well as infringement proceedings where the defendant has counterclaimed for revocation.

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 to the cost of litigation. Moreover, the profit margins of generic manufacturers are lower than originators, thus allowing originators a greater capacity to contest litigation. Also, originators generally have the benefit of an income stream from the drug during the litigation process, whereas a generic will not yet have entered the market. This is exacerbated by the lack of special reward or period of market exclusivity for a successful generic challenger: a generic manufacturer which succeeds in a court challenge opens the market for all relevant generic manufacturers and thus might be able to ‘internalise’ only a small proportion of the benefits. Therefore it is often in a competitor’s interest to wait and hope that another competitor incurs the cost and risk of a challenge.

Many of these points are made in submissions to the Review. GMiA submits that the patent litigation “investment” in Australia is not capable of reaping comparable commercial returns for suppliers of generic medicines as it does elsewhere. Alphapharm states that a reward to risk ratio of 10:1 must be demonstrated before patent litigation is initiated. Alphapharm also submits that, due to recent PBS price reforms, it cannot be assumed that the generics industry will be able to bring patent challenges at the same rate as in the past, and that a clear incentive to challenge is needed.\(^{207}\)

A number of submissions argue that the Government should not provide incentives to challenge patents, as they are not required and it is inappropriate for the Government to encourage challenges to patents it has granted. PhARMA and the US Chamber of Commerce note that there is no equivalent undertaking to compensate an originator where the price is reduced due to the entry of a generic product and the product is subsequently found to be infringing. Submissions argue that the Government and generic companies should make better use of the re-examination process to determine the validity of patents.

The Panel considers that there is a significant imbalance of power between originator and generic pharmaceutical litigants in Australia and there is a need to reduce the disincentives for generic manufacturers to challenge potentially invalid patents. This must be done without removing all the risk for challengers and thereby creating inefficiencies and a litigation industry. There are a number of possible mechanisms to achieve this. These include:

- providing the first generic manufacturer to successfully challenge a relevant patent with six months of market exclusivity, as per the US Orange Book system (discussed further below);
- making it a mandatory condition of being granted an interlocutory injunction in pharmaceutical cases that the patentee undertakes to repay any damages to the Government;
- providing a successful 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 when a successful challenge is made to patent validity; or
- requiring the patentee to pay a portion of its profits for the product during the injunction period to a successful challenger.

The Panel considers that the most effective mechanism is for the Government to share with a successful challenger of a patent the estimated savings to the PBS from earlier entry of generics on the market. For example, the share of savings provided to the successful challenger could comprise the drug price and estimated volume for a period of six months multiplied by the 16 per cent statutory price reduction plus the minimum 23 per cent reduction for on-going price disclosure. The main benefits of such a mechanism are that:

- frivolous litigation is minimised because the challenger still carries significant risk and the reward relates directly to the value of the pharmaceutical in question;
- other generics are free to immediately enter the market, providing competition and further price reductions; and
- reasonable certainty and efficiency is provided because the share to the challenger is based on a formula rather than case-by-case negotiation. A potential challenger would be able to estimate the quantum of reward and use this in calculating the reward to risk ratio for challenging particular patents.

**Recommendation 7.1:**
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 should involve the Government sharing with the successful challenger of a patent the savings to the PBS from earlier generic entry or recovered costs to the PBS through compensation or repayment of damages from the patentee or manufacturer of the PBS-listed drug.

The quantum of savings should be formula driven rather than negotiated on a case-by-case basis, with savings estimates based on the price reductions following first listing of a competitor brand on the PBS (currently 16 per cent) and price disclosure arrangements.
7.4. **Contributory infringement**

7.4.1. **Current law**

Contributory infringement is a form of indirect infringement and, like interlocutory injunctions, is a mechanism that enables patentees to enforce their rights effectively. 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”\(^{210}\) 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 Committee\(^ {211}\) and the equivalent US provisions.\(^ {212}\)


\(^{212}\) 35 USC 271(c).
7.4.2. **Carve outs**

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. As IPTA submits, 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.\(^{213}\) 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, in some respects the current contributory infringement provisions are unclear and lead to uncertainty for both patentees and generic manufacturers. Where a product has patented and unpatented indications, a supplier should be able to supply the product for the unpatented indications in good faith without fear of infringing. Supplying a product for a non-patented indication is commonly referred to as a “carve out”. The use of a carve out is currently sufficient to avoid liability for patent infringement in the EU\(^ {214}\) and the US,\(^ {215}\) but not yet in Australia. 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 the infringement of a patent covering another indication for the drug.

GMiA submits that s.117 needs to be amended to provide a clear and certain carve out.\(^ {216}\) Novartis also supports the use of carve outs, submitting 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 should not, however, preclude the patentee from arguing that there was in fact

\(^{213}\) IPTA, Submission to the Pharmaceutical Patents Review, p.18.

\(^{214}\) European Community Directive 2001/83/EC, Article 11.

\(^{215}\) 21 USC 355(j). This was recently confirmed in the case of *AstraZeneca Pharm LP v Apotex Corp.* 669 F.3d 1370 (Fed.Cir.2012).

\(^{216}\) GMiA, Submission to the Pharmaceutical Patents Review, p.35.
an infringing use of the product, irrespective of any carve out.\textsuperscript{217} Other submissions argue that the current provisions work well and do not need changing.\textsuperscript{218}

The Panel supports the use of carve outs to provide greater certainty for originators and generic manufacturers. Preventing a generic manufacturer from supplying a drug for a non-patented indication would effectively broaden the scope of the claims of the original patent, and extend patent rights to a method of treatment which was not claimed in the patent. This would reduce consumer access to competitively priced medicines.

The Panel considers that where a generic manufacturer supplies a patented drug for an indication which falls outside the scope of the claims of that patent, and takes reasonable steps to ensure that the product is only used for the non-patented use, that generic manufacturer should not be held liable for contributory infringement. What constitutes a reasonable step may include the supply of product information specifying that the product should only be used for the non-patented indication. 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” would be a matter for the court to determine in the circumstances. The exact form of the amendment to s.117 is a matter to be considered by the drafters of the legislation.

\textsuperscript{217} Novartis, Submission to the Pharmaceutical Patents Review, p. 4, Response to the Draft Report, p.10.

\textsuperscript{218} For example, responses received from FICPI, Eli Lilly, and the Biotechnology Industry Organisation.
Recommendation 7.2:
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. The law should establish a presumption that “reasonable steps” have been taken where the product has been labelled with indications which do not include any infringing indications.

7.4.3. Staple commercial product
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.

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

7.5. 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. 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.
7.5.1. Current law

7.5.1.1. Section 26B

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.\(^{219}\) 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. Data protection is further discussed in Chapter 8.

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.\(^{220}\) 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 certificates\(^{221}\) and does not provide them to the originator.

\(^{219}\) *Therapeutic Goods Act 1989 (Cth)*, s.25A.

\(^{220}\) *Therapeutic Goods Act 1989 (Cth)*, s.22A(4), s.26B(2).

\(^{221}\) Ibid, s.25(4).
Patent certificates 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.\textsuperscript{222}

7.5.1.2. Sections 26C and 26D

Where a generic applicant has provided a certificate under s.26B(1), and the patentee seeks to commence patent infringement proceedings, under s.26C the patentee must provide a certificate to the TGA and to the generic applicant. The certificate must state that proceedings are to be commenced in good faith, have reasonable prospects of success, and will be conducted without unreasonable delay.\textsuperscript{223}

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.\textsuperscript{224} The Panel is unaware of any instances where an originator company has been subject to a penalty under s.26C.

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 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

\textsuperscript{222} AUSFTA Article 17.10.4(b).
\textsuperscript{223} Therapeutic Goods Act 1989 (Cth), s.26C.
\textsuperscript{224} Therapeutic Goods Act 1989 (Cth), s.26C (5A).
applicant, the Commonwealth and/or a State or Territory - for losses sustained as a result of the injunction. The Panel is unaware of any action being taken in relation to s.26D.

Sections 26C and 26D of the *Therapeutic Goods Act* are not required under AUSFTA. However, they were introduced at the same time as other provisions implementing AUSFTA with the intention of limiting the potential for patentees to use the court system to extend their patents and delay generic entry.

### 7.5.2. Notification

The current provisions do not appear to work well for originators or generic manufacturers because of complex relationships between the patent, drug regulatory and pharmaceutical benefit systems. One of the issues which originators raise is the short prior notice patentees get of a generic entering the market, and the potential consequences of this.

It appears that generic companies rarely notify an originator of their intention to enter the market by filing a certificate under 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. 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 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.

---

225 *Therapeutic Goods Act 1989* (Cth), s.26D(4), s26D(5).


The Panel is aware of some cases where generic companies have chosen to notify the patentee of their intention to enter the market in an attempt to reduce the likelihood of an interlocutory injunction being granted. However, it appears that these were not always successful.\(^\text{228}\)

Consequently, the first notification received by an originator pharmaceutical company of another company’s intention to enter the market is often when the 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.

Originators argue that without early notification they have no way of ascertaining whether a generic applicant is engaged in activities which could be considered infringing. This can leave insufficient time to conduct proper due diligence in order to file a s.26C certificate, if court proceedings are considered necessary.\(^\text{229}\)

It can also lead to the originator seeking an interlocutory injunction and the commencement of infringement proceedings in order to prevent the irreversible reduction in the PBS listing price.\(^\text{230,231}\)

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.\(^\text{232}\) 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.\(^\text{233}\) Some submissions favour the

\[^{228}\text{For example, see Novartis AG v Hospira Pty Limited [2012] FCA 1055.}\]
\[^{229}\text{Medicines Australia, Submission to the Pharmaceutical Patents Review, p.18.}\]
\[^{230}\text{Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review, p.22.}\]
\[^{231}\text{Pfizer, Submission to the Pharmaceutical Patents Review, p.5.}\]
\[^{232}\text{Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review, p.38.}\]
\[^{233}\text{Law Council of Australia, Submission to the Pharmaceutical Patents Review, pp.51–53.}\]
implementation of a system similar to that of the “Orange Book” used in the US (discussed below) to achieve early notification.\textsuperscript{234}

Early notification would not significantly reduce the number of interlocutory injunctions sought. In most cases originators currently have two to four months notice of a generic entering the market, this being the typical time between inclusion of the ARTG and listing on the PBS.\textsuperscript{235} Earlier notification may provide more time for negotiation between the parties and alternative methods of dispute resolution to be attempted. However, even if notification was required 6 months prior to market entry, this would not provide sufficient time to commence and resolve infringement and invalidity proceedings before the court. A period of 12 to 18 months from institution of proceedings to trial is typical. It would also not provide enough time to resolve any re-examination proceedings before IP Australia, because any decision would likely be appealed to the court.

This view is shared by generic manufacturers, which also argue that early notification would disclose their business plans and so place them at a significant disadvantage to their competitors. They claim this would enable originators to take steps to retain market share.\textsuperscript{236} Such steps might include the originator introducing its own generic version, licensing out to other generics and/or marketing an equivalent but patented formulation of the pharmaceutical.

However, it appears that improvements to the current notification system could be made without significantly disadvantaging generic manufacturers. At present, patent owners have to monitor the ARTG and PBS to become aware of generic products entering the market that may relate to their patents. To improve transparency and minimise costs, patent owners should be notified directly when a generic that relates to one or more of their patents is included on the ARTG. Such a system is discussed below in relation to a transparency register.

\textsuperscript{234} Merck Sharp & Dohme, Law Council of Australia, AIPPI Australia Submissions to the Pharmaceutical Patents Review.

\textsuperscript{235} Information provided by DoHA, May 2013.

\textsuperscript{236} GMiA, Response to the Draft Report, pp.10-11.
7.5.3. Transparency

Another major issue related to the s.26B system is the absence of clear public information on which patents relate to a particular pharmaceutical product. Although patents are listed on IP Australia’s patent register, identifying those that are relevant to a particular pharmaceutical product is complex and requires significant expertise.

The generic sector argues that they unfairly bear the burden of determining which patents apply to the relevant drug in order to file a s.26B certificate. GMiA submits that it is difficult to ensure that all relevant patents are identified and argues for a system with greater transparency. The Panel notes that there are various databases and professional search services for identifying patents relevant to particular therapeutic goods. 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 activities, and committing to costs, necessary to bring a generic drug to market. 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 lack of clear information on pharmaceutical patents is a significant issue for industry and Government. Problems with notification and transparency can be partly addressed by directly notifying patent owners when a relevant generic is to enter the market and by introducing a patent transparency register. This proposal is discussed in more detail in 7.6 below.

7.5.4. 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.\textsuperscript{238} 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.\textsuperscript{239}

Bristol-Myers Squibb argues that s.26B(1)(a) as currently drafted effectively allows generic manufacturers to self-assess whether the generic goods would infringe a valid patent claim. (However, such self-assessment is the practice in every other technology. There is no general requirement for competitors to alert patent holders that they are entering the market.) Bristol-Myers Squibb submits that the drafting of s.26B(1)(a) is so broad and open to interpretation that generics can almost always file a s.26B(1)(a) certificate, 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.\textsuperscript{240}

Again, these concerns would be partly addressed by the introduction of a transparency register and direct notification of patent owners, as discussed below.

\textbf{7.5.5. Penalties}

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

\textsuperscript{238} A copy of the required TGA patent certificate can be viewed at: http://www.tga.gov.au/pdf/forms/international-forms-usfta-certificate26b.pdf

\textsuperscript{239} 21 CFR 314.95(c)(6).

\textsuperscript{240} Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at [36] to [39].
manufacturers for providing a false or misleading s.26B certificate.\textsuperscript{241} \textsuperscript{242} 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 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.\textsuperscript{243}

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.\textsuperscript{244} 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.\textsuperscript{245}

The Panel is not persuaded that any changes should be made to s.26C and s.26D of the \textit{Therapeutic Goods Act}. 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. It would also 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.

\textsuperscript{241} Medicines Australia, Submission to the Pharmaceutical Patents Review, p.18.
\textsuperscript{242} Pfizer, Submission to the Pharmaceutical Patents Review, p.5.
\textsuperscript{243} Medicines Australia, Submission to the Pharmaceutical Patents Review, p.19.
\textsuperscript{244} GMiA, Submission to the Pharmaceutical Patents Review, p.53.
\textsuperscript{245} GMiA, Submission to the Pharmaceutical Patents Review, p.53.
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. 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 similar penalties apply for providing false or misleading statements in other areas of law.

7.6. Transparency register

There would be significant 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. A system which requires the listing of relevant patents against a therapeutic good would promote greater transparency and efficiency in the pharmaceutical patent system.

Due to the complexity of pharmaceuticals and the patent system, there are significant costs involved in determining the patents that relate to particular products on the market. This is a cost to industry and to policy makers in Government. Although patents are publicly available on the Patents Register, this complexity means that the patent system is not adequately enabling competitors to determine the boundaries of IP rights and their freedom to operate. The great majority of originators would be very aware which of their patents relate to products approved by the TGA. Therefore the cost to patent owners of identifying and listing relevant patents on a public register would be minimal, while the overall benefits would be significant.

---

246 Explanatory Memorandum to the AUSFTA Implementation Bill 2004 (Cth), at [225].

247 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.
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;\(^{248}\)
- the Patents Register should include information about therapeutic goods based on that patent;\(^{249}\) and
- Australia should introduce a system similar to the US publication known as the “Orange Book”.\(^{250}\)

### 7.6.1. The 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 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. Applicants for new drug approvals are required to provide information about any granted or pending patents relating to the product at the time of filing the application. Only patents related to the drug itself, or a method of use of the drug are required – patents which claim a process to produce a substance or a method of manufacture are excluded. If a patent is granted following regulatory approval, the applicant has thirty days in which to file this information with the FDA. Once regulatory approval is granted, the drug name, trade (brand) name, patent information, and the identity of the applicant are published in the Orange Book.

---

\(^{248}\) Bristol-Myers Squibb, Submission to the Pharmaceutical Patents Review at \[39\].

\(^{249}\) GMiA, Submission to the Pharmaceutical Patents Review, p.51.

\(^{250}\) Merck Sharpe & Dohme, Submission to the Pharmaceutical Patents Review, p.5.
A generic applicant can then rely on the clinical and safety data provided to the FDA when seeking regulatory approval for a reference drug product listed in the Orange Book. This process is known as the abbreviated new drug application process (ANDA). ANDA applicants 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. 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. 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.

Several submissions received by the Panel advocate the introduction of a similar system in Australia to provide greater transparency and certainty in relation to freedom to operate. The Panel also notes that the US Government is seeking to introduce elements of the Orange Book system as part of the new Trans-Pacific Partnership Agreement (discussed in Chapter 3 of this report). 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 would not be of benefit in Australia.

7.6.2. A transparency and notification system for Australia

A transparency and notification system with the following features would be beneficial for Australia:

- a company that has obtained regulatory approval for a pharmaceutical product (the drug owner or sponsor) would be required to identify on a public register the details of all patent applications and granted patents

owned by, or licensed to that company and its subsidiaries that relate to that product within a certain period of the product being included on the ARTG. Patents which are granted subsequent to regulatory approval must be listed within a set time frame following the grant of the patent. Pharmaceutical products that require their own inclusion on the ARTG would require a separate listing on the register;

- patents that are directly related to the listed product would be required to be listed by the sponsor/patentee. A directly related patent is one which claims the drug for which the patentee/sponsor submitted the application for regulatory approval or which claims a method of using that drug;

- the patentee would be precluded from commencing infringement action in relation to a patent which is not listed on that register. A sponsor may request that additional patents be added to the register at a later date, but cannot sue for infringement for the period between notification of ARTG inclusion and the sponsor requesting addition of the patent to the register (if the patent as granted prior to ARTG inclusion), or between grant of the patent and the sponsor requesting addition of the patent to the register (if the patent was granted after ARTG inclusion);

- generic manufacturers would continue to provide s.26B certificates to the TGA. Upon the inclusion of a generic product on the ARTG, the TGA would immediately and directly notify the owner of the patent(s) to which the generic product relates of the inclusion;

- incentives would be provided for the first generic manufacturer to successfully challenge a patent, such as a share of the savings to the PBS from the entry of generics to the market (as discussed at 7.3).

Such a system would increase transparency and certainty for both originator and generic pharmaceutical manufacturers, thereby increasing efficiency, with minimal additional costs to industry or the Government.

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’. Evidence suggests that patent linkage promotes litigation rather than reducing it.

The originator sector generally supports a transparency register that lists the patents related to an approved product, but only if early notification is provided to patent owners of generic manufacturers’ intentions to enter the market.\textsuperscript{254} Conversely, the generics sector only supports a transparency register if early notification is not required.\textsuperscript{255} Alphapharm argues that such a register should list all patents relating to a drug, even those not owned by or licensed to the sponsor for the original, to provide certainty for generic manufacturers.\textsuperscript{256} However, this would place an unreasonable burden on such parties.

\textsuperscript{254} Medicines Australia, Response to the Draft Report, p. 6; AIPPI, p. 10; Sanofi-Aventis, p. 15.

\textsuperscript{255} GMiA, Response to the Draft Report, p. 10.

\textsuperscript{256} Alphapharm, Response to the Draft Report, p. 8.
Recommendation 7.3:
The Government should introduce a transparency register linking therapeutic goods included on the ARTG with related patents.

The register should include the numbers of all patents owned by, or licensed to, the sponsor of the therapeutic good and relevant to the therapeutic good.

Patent numbers should be supplied to IP Australia when the sponsor receives notification of the ARTG inclusion, or when the patent is granted, if grant is subsequent to ARTG listing.

A sponsor should only be able to commence infringement proceedings in respect of a patent that is on the register.

Upon inclusion of a generic product on the ARTG that relies on information provided earlier in relation to another product, the TGA should directly notify the owner(s) of the patent(s) listed on the transparency register in relation to that earlier product about the inclusion.
8. Data protection

8.1. 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. 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.

8.2. 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 simply be listed on the ARTG.257

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 used internally by the 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 restrict 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, a generic is not prevented from conducting its own clinical trials and presenting its results in a full application for regulatory approval, or from making a literature-based submission.

Data protection is governed by s.25A of the Therapeutic Goods Act 1989 (Cth). It was introduced through amending legislation in 1998.\textsuperscript{258} 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.

\textsuperscript{258} Therapeutic Goods Legislation Amendment Act 1998 (Cth).
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. 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.

8.3. 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 five year term available for new APIs. A variety of approaches are taken by other countries, as described in Table 8.1 below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Length</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>5 years</td>
<td>New API</td>
</tr>
<tr>
<td></td>
<td>4 years</td>
<td>Where a paragraph IV certification is made.261</td>
</tr>
<tr>
<td></td>
<td>4 years</td>
<td>Biologics (a further eight year period of marketing exclusivity applies).262</td>
</tr>
</tbody>
</table>

260 International Federation of Pharmaceutical Manufacturers & Associations. 2011. Data Exclusivity: Encouraging Development of New Medicines. Available online:
261 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).
<table>
<thead>
<tr>
<th>Country</th>
<th>Duration</th>
<th>Protection Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 years</td>
<td>'Orphan drugs' (those intended to treat diseases and conditions that affect 200,000 or fewer people in the United States)</td>
<td></td>
</tr>
<tr>
<td>12 years</td>
<td>New biological molecules</td>
<td></td>
</tr>
<tr>
<td>+ 6 months</td>
<td>Paediatric clinical trial completed</td>
<td></td>
</tr>
<tr>
<td>European Union</td>
<td>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).</td>
<td></td>
</tr>
<tr>
<td>10 years</td>
<td>'Orphan drugs' (regulator cannot accept applications during this period)</td>
<td></td>
</tr>
<tr>
<td>Japan(^{263})</td>
<td>8 years New API</td>
<td></td>
</tr>
<tr>
<td>10 years</td>
<td>'Orphan drugs'</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>8 years New API</td>
<td></td>
</tr>
<tr>
<td>+ 6 months</td>
<td>Paediatric indication approved</td>
<td></td>
</tr>
<tr>
<td>Israel</td>
<td>6 years New API approved in Israel, or 6 years and 6 months from the date of approval in a 'recognised country', whichever is earlier.</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>6 years New API</td>
<td></td>
</tr>
</tbody>
</table>

Note: Many other countries also provide data protection.

Australia’s data protection provisions comply with our international obligations. TRIPS requires World Trade Organisation (WTO) Members to “protect test data against unfair commercial use” and disclosure,\(^{264}\) while the AUSFTA requires Australia to provide at least five years data protection for undisclosed data.\(^{265}\)

\(^{262}\) 42 USC 262(k)(A) and (B).


\(^{264}\) TRIPS, Article 39.

\(^{265}\) AUSFTA, Article 17.10.
8.4. 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 expire before the patent period.

For patents that have received an EOT in Australia under the current provisions, the effective patent life has been greater than five years (that is, greater than the length of data protection) in all cases. In 98 per cent of cases, these patents had an effective patent life exceeding data protection by two years or more.²⁶⁶

This data set does not include patents which did not receive an EOT. However, using the 20 year expiry date for patents in the data set reveals that, if no EOT had been available, 89 per cent would still have had an effective patent life longer than the five year data protection period and that in 78 per cent of cases the effective patent life would have exceeded data protection by two years or more.²⁶⁷

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 does not require 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.

8.5. Period of data protection

Data protection provides an incentive for originators to make the investments necessary to obtain regulatory approval of medicines, particularly where there is no patent protection either because a patent was never obtained or because it has already expired, or where it is easy to work around existing patents.

²⁶⁶ Source: IP Australia Data.
²⁶⁷ Source: IP Australia Data.
Amgen submits that data protection is important for biologics, where patents can be “designed around” because of the complicated size and structure of biologic medicine. Amgen 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.268

Issues relating to biologics are discussed in more detail in Chapter 9. A number of submissions argue that the current scope and five year data protection period should be extended to increase the incentive to bring new drugs and therapies to market in Australia and to match the length offered in other jurisdictions such as the US, EU and Japan.269 McKeon et al also recommended extending the term of data exclusivity to harmonise Australian data protection with international best practice and strengthen Australia’s IP system.270

However, extending data protection provides only limited benefits for originators and data protection appears to have little impact on the levels of pharmaceutical investment in a country. For example, research has shown that where longer periods of data protection are available, very few high-selling drugs gain further marketing monopoly from data protection, particularly where the patent term had been extended.271 Recent research also shows that there is no relationship

268 Amgen, Submission to the Pharmaceutical Patents Review, p.8
269 IPTA, FICPI, AusBiotech, Medicines Australia, INTERPAT, Abbvie, MSD, CSL, AIPPI, Novartis, Amgen, Roche, Amcham.
270 Department of Health and Ageing, Strategic Review of Health and Medical Research, 2013 at p.228.
271 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.
between whether or not a country has data protection and the amount of investment in the country in the pharmaceutical industry.\footnote{Palmedo, M. \textit{Do pharmaceutical firms invest more heavily in countries with data exclusivity?} CURRENTS International Trade Law Journal, Summer 2013 <accessed at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2259797 on 16 May 2013>}

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.\footnote{Medicines Australia, Submission to the Pharmaceutical Patents Review, p.15.}

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 EOT 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 EOT 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 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 to the composition of the drug was filed in 1999, granted in 2003 and will expire in 2020 after it received a 6 month EOT 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 EOT. 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 substances 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 or where patent protection is not available, a longer period of data protection could make supplying the Australian market commercially viable. However, the above examples do not demonstrate clearly that this has been the case. Furthermore, if and when circumstances arise where some form of assistance is necessary to make supply of a therapeutically valuable drug in Australia commercially viable, these are better addressed through specific targeted assistance, such as by waiving or reducing TGA application fees and/or negotiating appropriate PBS subsidies, rather than by providing across-the-board increases in data protection period.
8.6. New indications

A number of submissions also argue that the scope of data protection should be extended to include new indications. Amgen explain that data protection plays a particularly valuable role in encouraging R&D of new therapies using existing drugs, especially in the oncology area.\(^{274}\) These subsequent developments are not covered by data protection.

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.\(^ {275}\)

Such an approach would do nothing to stifle generic competition, post an innovator company being allowed to recoup the investment required to make a medicine available to treat each disease that it is registered for.\(^ {276}\)

AbbVie 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.

---


\(^{275}\) AbbVie, Submission to the Pharmaceutical Patents Review, p.7.

\(^{276}\) AbbVie, Response to the Draft Final Report, p.4.
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.277

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.’278

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. However, as discussed in the previous section, the efficient solution in such circumstances is to provide case-by-case assistance where it is necessary to ensure that a particular treatment is available in Australia, rather than to expand data protection to all new indications.

277 Therapeutic Goods Act 1989 (Cth), s.25A.
278 AbbVie, Submission to the Pharmaceutical Patents Review, p.6.
8.7. Listed medicines

The Australian Group of the International Association for the Protection of Intellectual Property (AIPPI) argues that data protection should also be available for medicines listed on the ARTG, not just for those registered:

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.279

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.

8.8. Orphan drugs and paediatric indications

‘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.

A number of submissions argue for extending data protection in the case of ‘orphan’ drugs and paediatric indications, similar to that provided in some other jurisdictions.280 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 uneconomical to do so. Such an incentive would likely provide a benefit to vulnerable populations such as children and those suffering from rare diseases.

279 AIPPI, Submission to the Pharmaceutical Patents Review, p.10.
280 For example, submissions received from JIPO, IPTA, FICPI, Abbvie, CSL.
However, as discussed in Chapter 4 in relation to 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.

8.9. 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 provide a 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 ...’.  

---

BIO argues that making data protection contingent upon the disclosure of clinical or other test data would not be consistent with Australia’s international obligations to protect trade secret information under Article 39.3 of TRIPS, which provides that:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

BIO submits that the dossier submitted for regulatory approval contains details of manufacturing and bio-analytical methods, details of specific formulations, information relating to experimental design, methodologies and patient disease records. BIO’s view is that such information is not required to protect the public and is therefore entitled to protection under Article 39.3.

The Panel considers that publication of clinical trial data, once the data protection period has ended, would enhance transparency and efficiency for researchers, medical practitioners, the public, and provide a social benefit for society. It appears that this could be done in a manner consistent with Australia’s international obligations. Clinical trial data relates to the safety and effectiveness of medical products and, providing it can be done whilst leaving adequate incentive for R&D investment, it is in the public interest to disclose it.

There is growing international interest in making these data publicly available. In 2012, the European Medicines Agency (EMA) ‘committed to proactive publication

\[282 \text{ BIO, Response to the Draft Report, p.7.}\]
of the data from clinical trials supporting the authorisation of medicines.\textsuperscript{283} 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.\textsuperscript{284} The policy takes into account the need to protect commercial confidential information when considering whether to release a document.\textsuperscript{285} It is envisaged that the final policy will be published in November 2013 and commence operation from 1 January 2014. The Panel notes that an injunction has been issued against the EMA to prevent the release of clinical trial data belonging to InterMune and Abbvie and given to the EMA as part of the marketing approval process.\textsuperscript{286}

The Panel believes it would be in Australia’s interest to engage with the EMA 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.

\textbf{Recommendation 8.1:}
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.

\textsuperscript{284} Ibid.
\textsuperscript{286} http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/04/news_detail_001779.jsp&mid=WC0b01ac058004d5c1
9. Biologics

9.1. 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 entities, such as cells and tissues.\(^{287}\) 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, what might loosely be called generic versions of biologics are referred to as ‘Similar Biological Medicinal Products (SBMPs)’, but they may also be referred to as ‘biosimilars’ or ‘biogenerics’.\(^{288}\) A biosimilar is a biological product that can demonstrate an acceptable 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.

\(^{287}\) US Food and Drug Administration

\(^{288}\) DoHA Annual Report 2011-12
The introduction of biosimilars into the Australian market brings significant challenges for both policy makers and originator and generic manufacturers.

9.2. Why are biosimilars 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.\(^{289}\)

The smallpox vaccine was probably the first biologic to be developed, in the late 18th century. However, commercial development 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,\(^{290}\) which is now protected by a family of patents.


9.3. Market profile
The US Pharmaceutical Industry Association estimates that there are 400 biologic drugs on the market and 900 others in the pipeline.\textsuperscript{291} In Australia, there are currently 64 biologics listed on the PBS.\textsuperscript{292} 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. Many high value biologic drugs are due to lose patent protection in the next five years,\textsuperscript{293} 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%.\textsuperscript{294} IMS Health estimates that biosimilars will constitute 50% of the off-patent biological medicines market by 2020.\textsuperscript{295}

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.\textsuperscript{296}

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

\textsuperscript{292} Source data: Department of Health and Ageing, March 2013.
\textsuperscript{293} \textit{Shaping the Biosimilars Opportunity}, IMS Health, December 2011, p.6.
\textsuperscript{295} \textit{Shaping the Biosimilars Opportunity}, IMS Health, December 2011, p.6.
contrast, manufacture of biologics is more complex and expensive.\textsuperscript{297} 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.

\subsection*{9.4. Patent perspective}
Reliable statistics on the patenting of biologic drugs are not currently 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.\textsuperscript{298} The study found that of the 44 FDA approved biologics examined, a total of 151 relevant patents existed. 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.\textsuperscript{299} 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 for other drugs. There is also no clear evidence that the pace of development has in fact been slowed by early-stage patents.\textsuperscript{300}

\begin{thebibliography}{99}
\item 299 M. Heller and R. S. Eisenberg, \textit{Can patents deter innovation? The anticommons in biomedical research}. Science Vol.280, 1998 p.698
\item 300 J. P. Walsh, A. Arora and W. M. Cohen, \textit{Effects of research tool patenting and licensing on biomedical innovation}. In W. M. Cohen and S. A. Merrill (eds),
\end{thebibliography}
9.5. 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 difficult. At present only 13 biosimilars have received regulatory approval around the world.\textsuperscript{301}

The clinical performance of biologics is highly dependent on the method of production and purification. Even minor differences in the atmosphere or manufacturing process can compromise activity. Another concern is that of immunogenicity. Immunogenicity refers to the ability of the human body to identify a biological medicine as foreign and generate an immune response to it such as by producing neutralising antibodies.\textsuperscript{302}

Due to the complex nature of biologics, obtaining regulatory approval for biosimilars is more complicated than for 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 data to ensure that a biosimilar can be used in the same manner as the reference product.

Alphapharm provided evidence in public hearings which outlined these difficulties, noting that manufacturing of biosimilars would require a specialised facility and it would be difficult to manufacture on a large scale in comparison to small molecule drugs. Alphapharm further stated that manufacturing was complicated

\begin{footnotesize}


\textsuperscript{302} R. McKinnon, \textit{Biosimilars are not (bio)generics}, Australian Prescriber, Vol.32, No.9, December 2009, p.146.
\end{footnotesize}
by the highly sensitive nature of biologics and the high risk of contamination. As noted above, generic companies would also incur additional costs by having to undertake clinical trials to demonstrate safety and efficacy.

Despite these difficulties, Hospira has been successful in obtaining regulatory approval and PBS listing for its biosimilar of the drug filgrastim, marketed as Nivestim.

9.6. 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.303 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.304

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.\textsuperscript{305}

The TGA has adopted the European Medicines Agency (EMA) Guidelines for assessing biosimilars.\textsuperscript{306} These guidelines require that applicants submit 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.\textsuperscript{307} Although a generic manufacturer of a biosimilar cannot rely on the entire data of the reference product to establish similarity, it may be able to rely on the data of the reference product in part. Similar to the process for generic small molecule drugs, a product claiming to be similar to a biological product already registered in Australia may seek registration on the basis that:

- the quality attributes of the new product are such that it is substantially similar to the reference product; and
- comparability studies can demonstrate similar safety and efficacy in at least one registered indication.

in which case the product will be evaluated and may be approvable on the basis of a reduced clinical dataset.\textsuperscript{308}

\textsuperscript{305} Australian Regulatory Guidelines for Biologics, June 2011, available at &lt;http://www.tga.gov.au/industry/biologicals-argb.htm&gt;
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. 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 the statutory price reduction and moved to the F2 formulary on the PBS.

9.7. Biosimilars and the PBS

Currently the PBS pricing of biosimilars 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. Hospira’s Nivestim is an example of this. 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.

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 incur. In addition, the difficulties in obtaining regulatory approval may delay biosimilar market entry.

9.8. Data protection and biologics

As discussed in Chapter 8, Australia currently provides a period of five years data protection for new drugs, including biologics. In the EU, data protection for drugs, including biologics, 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 four years for biologics.\textsuperscript{311} A further period of eight years marketing exclusivity applies to biologics, 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.\textsuperscript{312} 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.\textsuperscript{313}

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.\textsuperscript{314} Grabowski et al estimated that an originator biologic drug could be expected to break even after a period of 12.9 to 16.2 years.\textsuperscript{315} 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

\textsuperscript{311} 42 USC 262(k)(7)(B).
\textsuperscript{312} 42 USC 262(k)7(A).
\textsuperscript{314} Grabowski et al, Data exclusivity for biologics, Nature Reviews, Vol 10, January 2011, p.16.
\textsuperscript{315} Grabowski et al, Data exclusivity for biologics, Nature Reviews, Vol 10, January 2011, p.15.
provided through patents and market-based pricing. In contrast, industry representatives argued that 14 years should be provided due to the complexity and expense involved in developing biologics.\(^{316}\)

Most recently, President Obama’s proposed 2014 budget includes a proposal to shorten the data exclusivity period for biologics to 7 years. This is similar to proposals put forward in the 2012 and 2013 US budgets. These proposals were not implemented.

A number of submissions argue for increased data protection for biologics.\(^{317}\) Amgen submits that data protection should be increased because of the substantial investment required to develop biologics and because patents offer less protection against biosimilars.\(^{318}\) Amgen submitted in hearings that because biologics are complex, those parts of a compound that are essential to its efficacy and those that are not may not be determined until some years after the patent is filed. This enables competitors to design a biosimilar which has a similar effect to the original but falls outside the scope of the patent claims. Yet an applicant seeking ARTG listing of a biosimilar can still partly rely on the data developed at significant financial risk and investment by the originator. Amgen argues that extended data protection may be the only means of protection available.\(^{319}\)

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.\(^{320}\) The findings of the FTC suggest that patent protection for biologics is adequate, even though


\(^{317}\) JIPA, Response to Draft Report, p.9; PhRMA, Response to Draft Report, p.3.

\(^{318}\) Amgen, Submission to the Pharmaceutical Patents Review, p.8, Response to Draft Report, p.2.

\(^{319}\) Amgen, Response to Draft Report, p.3.

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, although some in the biologics sector argue that the opposite is true, making patent protection unreliable.

Biologics are an important development in pharmaceuticals which have the potential to deliver substantial health benefits to the public. Policy settings need to optimise the incentives to invest in R&D and provide access to affordable medicines. At present, data protection only provides additional market exclusivity and an incentive to invest in cases where 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. However, biologics and biosimilars are still emerging markets. The Panel acknowledges the possibility that the current data protection systems may provide insufficient incentives to innovate and bring biologic products to market. Yet no specific examples of this occurring have been provided. Further, it may be possible for originators to develop commercial strategies to overcome these issues. For example, Roth suggests that originators might co-ordinate patent terms with the period of data exclusivity to maximise coverage. The Panel considers that at this stage the case has not been made to extend data protection for biologics in Australia.

**Finding 9.1:**
There is insufficient evidence to support an increase in data protection beyond the current five-year period for biologics at the present time. However, the Panel acknowledges that the regulatory environment and market for biologic and biosimilar medicines is still developing and that the situation should be revisited when further market experience gives us a better understanding of the relevant issues.
10. Better integration and governance of detail in the pharmaceutical system

10.1. Current situation

The pharmaceutical system involves numerous 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 new medicines or medical treatments to market, reducing reliance on Government funding;
- 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 (DIICCSRTE) 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 per se 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 per cent of major submissions considered by the PBAC took advantage of this process.\(^{325}\)

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.

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.

However no body or group informs the PIWG, AMWG or, more widely the Government as to the interaction of the patent, R&D, regulatory approval and

\(^{325}\) DoHA Annual Report 2011-12, p.99.
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. Coordination between the regulatory systems in Australia must take into account the requirements of international agreements.

10.2. Improved coordination and policy understanding of detail

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, these appear to cover a wide range of issues and do not focus on pharmaceutical policy.

Further, there are innumerable details of the system which may require close practical knowledge to ensure good governance. For instance, to the extent that it occurs excessively, the practice of ‘evergreening’ will be the product of a wide range of practices all of which are legal and to some extent legitimate. However taken together they may impose sufficient costs on generic drug sellers to substantially hamper their market growth. The extent to which systems are being abused for strategic reasons is very difficult to determine if one is not embedded within the system. For this reason the Panel expected that DoHA which has a

326 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.
strong financial interest in access to generic drugs to have a close practical interest and detailed knowledge of the practices of originator firms in seeking to maintain their market. Yet the Panel did not find that DoHA had a strong grasp of the detail from its own perspective as a user. However without that the system as a whole will be insufficiently informed to satisfactorily use the arms of policy to resist excessive ‘evergreening’.

Agencies do not appear to take a sufficient interest in areas outside their portfolios that directly affect their primary areas of responsibility. For example, despite having considerable expertise and resources, DoHA and DIICCSRTE have demonstrated a fairly narrow range of views and knowledge on the impact of patent law on access to medicines, total health costs, manufacturing and R&D. There would be great value in these agencies assessing these issues from each other’s perspective and detailed knowledge of the impacts on industry and consumers, and thereby helping to inform the Government about the pharmaceutical system.

**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 in their deliberations. Each agency needs to be the eyes and ears of the system from various perspectives, aware of inter-actions of several factors – 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 influencing pharmaceutical pricing particularly have both the need and the resources to obtain a detailed appreciation of the pharmaceutical patent system and its impact on a range of health issues.

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. As discussed in Chapter 6, the PSCC should assess whether PBS policy is supporting evergreening practices and, if so, develop a strategy to minimise these where they provide no net benefits. 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. The Panel does not envisage that the PSCC would require significant resources to conduct its responsibilities.

The Consumers Health Forum argues that such a committee should include industry and consumer representatives to ensure these views are taken into account. The Panel accepts that the views of these stakeholders should be taken into account, but considers that this can be addressed through proper consultation by the agencies on the PSCC.

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* (Cth) 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.\textsuperscript{328} The \textit{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.\textsuperscript{329} The Panel 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. The Panel considers that such a clause should be as technologically neutral as possible.\textsuperscript{330}

\begin{flushright}
\textsuperscript{328} Section 4.
\textsuperscript{329} 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”.
\textsuperscript{330} As argued by the Law Council of Australia, Response to the Draft Report, pp.7-8.
\end{flushright}
**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 social and economic welfare of Australians; and
- provide strong, targeted IP protection - but only up to the point at which the costs (to consumers and through impediments of ‘follow on innovation’) are no greater than the benefits of incentivising innovation.
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 EOT 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. 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.

331 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 importing\(^{332}\) 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.

\(^{332}\) 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 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; 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

333 17-[22] “Use” in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement.

334 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\textsuperscript{17-24}\textsuperscript{335} 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.

\textsuperscript{335} \textsuperscript{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.\textsuperscript{17-125}\textsuperscript{336}

(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);

\textsuperscript{336} 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]337

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

337 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.
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
Page Two

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

[Signature]

Mark Vaile
Minister for Trade
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."
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,

[Signature]

Robert B. Zoellick
Appendix C: Extension of term – length of extension

Use of the extension of term provisions
From the commencement of the current EOT scheme in 1999 through to October 2012:

- there were 599 applications for extensions
- 560 (94%) of these were accepted. 554 of these progressed to grant (the remaining 6 are accepted and awaiting grant)
- 3 applications remain pending at this point in time
- 35 applications were withdrawn or refused. In one instance, the patent was revoked before the EOT could be fully considered
- durations of extensions ranged from 0 months to 5 years, with an average of three years nine months
- there were 10 oppositions to an EOT filed, and subsequently five of these oppositions were withdrawn
- the time taken for an application to be granted varies considerably, depending on a number of factors. The median time is around 27 weeks.

Evidence of whether 15 year effective term is being achieved

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.
The data on patent extensions granted by IP Australia indicate that the median effective patent life provided by the EOT has remained at or close to 15 years each year since its introduction (see Figure C.2). For drugs which have been accorded an extension, this is the maximum period provided under the 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.339

338 Source data: IP Australia.
Figure C.2: Effective Patent Life Provided Under Current Provisions – Percentiles by Year

For all patents granted an extension Jan 1999 - Dec 2012; approved between 1995-2012

Efficiency of the administration of the pharmaceutical patents extension of term scheme

Figure C.3 shows the mean and median processing times by IP Australia for all accepted EOT applications under the current provisions. The median time for IP Australia to accept an EOT application was four weeks in 2011 and this is also the long-term median time for acceptance since the current provisions came into effect.
The estimated average cost of administering the EOT scheme is $809.64 per application including time taken to process applications and hearings where applicable.341

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. 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 EOT scheme since 2000 is $23,277 per year.

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

340 IP Australia data.
341 IP Australia data.
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.\(^{342}\)

While much of this expenditure can be expected to come directly from companies, some may also be provided through Government grants\(^{343}\) and/or be supported by Government through the R&D Tax Incentives.

Figure C.4 is reproduced from the recently released report by The Grattan Institute, *Australia’s bad drug deal: High pharmaceutical prices*.\(^{344}\) 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.

\(^{342}\) 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).

\(^{343}\) Australian Bureau of Statistics, *8104 – Research and Experimental Development by ANZSIC06 industry subdivision by source of funds, Businesses, Australia, 2010-11*.

Changes since 1998

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 effective patent life being provided. As shown in Figure C.5, the time taken for TGA approval has not been a significant factor in determining the effective patent life provided under the current EOT provisions.
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.\(^{346}\)

However, this is not supported by other studies or data collated on EOT pharmaceuticals. *Pretium’s Drug Tracker*\(^ {347}\) found that the time taken from 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 EOT indicate that while there was a significant spike in the median time taken for drugs listed on

---

\(^{345}\) Source data: IP Australia, Therapeutic Goods Administration.

\(^{346}\) AusBiotech, Submission to the Pharmaceutical Patents Review, p.2.

the PBS in 2006, this has decreased in recent years and is in line with the long term average.\textsuperscript{348}

**Figure C.6: 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 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.

\textsuperscript{348} Source: IP Australia, Department of Health and Ageing.
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.

**Pharmaceutical R&D Profitability**

In its response to the draft report, Sanofi suggests that “pharmaceutical R&D is on the cusp of being unprofitable, if not already unprofitable.”\(^{349}\) Referring to research from two sources, Sanofi concludes that the forecasted internal rate of return (IRR) on R&D for products in the late stages of development (7.2%)\(^{350}\) has been declining and has fallen below the cost of capital to the industry (7.49%)\(^{351}\). The Panel appreciates Sanofi’s contribution as the only submission to offer empirical evidence on the question of industry profitability.

These data suggest that profits in the pharmaceutical industry will be reduced in future years. However, the analysis of IRR is limited to showing a trend over a two year period and, as the report states, future years’ data will be needed before definitive conclusions can be drawn. Further, the calculated IRR is a forecast based on data that is not publicly available and hence cannot be reproduced.

**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 C.7: General Process for Regulatory and Patent Processing**

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Complete) application date</td>
<td>Patent grant</td>
<td>First clinical trials</td>
<td>Submission of request to regulatory</td>
<td>Marketing approval</td>
<td>20 year expiry date</td>
</tr>
</tbody>
</table>

Note: The scheme represented in Figure C.7 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 C.1: Comparison of Extension of Term Systems**

<table>
<thead>
<tr>
<th>Country</th>
<th>Max Effective Patent Life</th>
<th>Calculation of extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>AU</td>
<td>15</td>
<td>F=A+B+C+D – 5</td>
</tr>
<tr>
<td>US</td>
<td>14</td>
<td>F=C/2 +D</td>
</tr>
<tr>
<td>EP/UK</td>
<td>15</td>
<td>F=A+B+C+D – 5</td>
</tr>
<tr>
<td>JP</td>
<td>15</td>
<td>F=C+D</td>
</tr>
</tbody>
</table>

Figure C.8 and Table C.1 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 C.8: Difference in effective patent life between Australia and other jurisdictions

![Box plot showing difference in effective patent life between Australia and other jurisdictions.](image)

n=339 for US; 340 for UK; outliers not shown; positive means Australian effective life is longer

Table C.2: Difference in effective patent life between Australia and other jurisdictions

<table>
<thead>
<tr>
<th></th>
<th>United States</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>5 months</td>
<td>0.5 months</td>
</tr>
<tr>
<td>Median</td>
<td>12 months</td>
<td>0 months</td>
</tr>
</tbody>
</table>

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

---

Source data: IP Australia.
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 C.9 and Table C.3 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 C.9: Difference in patent term extensions between Australia and other jurisdictions\textsuperscript{353}

![Bar chart showing the difference in patent term extensions between Australia and other jurisdictions]

Table C.3: Difference in extension length (and hence expiry date) between Australia and other jurisdictions

<table>
<thead>
<tr>
<th></th>
<th>United States</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>18 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Median</td>
<td>18 months</td>
<td>0 months</td>
</tr>
</tbody>
</table>

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.\textsuperscript{354}

\textsuperscript{353} Source data: IP Australia.

\textsuperscript{354} Source data: IP Australia.
Effect of reducing the extension of term

Figure C.10 shows the effect of reducing the maximum length of extensions provided, from the current 5 years to 4, 3, 2, 1 and 0 years.

Figure C.11 shows the effect of reducing the maximum effective patent life of 15 years to 14, 13, 12, 11 and 10.
### Figure C.10 – Effect of reducing the maximum length of extensions

<table>
<thead>
<tr>
<th>Extension Length Calculation</th>
<th>Effective Patent Life Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>$L = T - 5$, $0 \geq L \geq 5$</td>
<td>$E = 20 - T + L$</td>
</tr>
<tr>
<td>$L = T - 5$, $0 \geq L \geq 4$</td>
<td>$E = 20 - T + L$</td>
</tr>
<tr>
<td>$L = T - 5$, $0 \geq L \geq 3$</td>
<td>$E = 20 - T + L$</td>
</tr>
<tr>
<td>$L = T - 5$, $0 \geq L \geq 2$</td>
<td>$E = 20 - T + L$</td>
</tr>
<tr>
<td>$L = T - 5$, $0 \geq L \geq 1$</td>
<td>$E = 20 - T + L$</td>
</tr>
<tr>
<td>$L = T - 5$, $0 \geq L \geq 0$</td>
<td>$E = 20 - T + L$</td>
</tr>
</tbody>
</table>

**Time to get ARTG approval (T):**

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
<th>17</th>
<th>18</th>
<th>19</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>13</td>
<td>14</td>
<td>15</td>
<td>16</td>
<td>17</td>
<td>18</td>
<td>19</td>
<td>20</td>
</tr>
</tbody>
</table>

**Effective Patent Life is the same as the current system**

**Extension provided and effective patent life is reduced**
### Changing the Effective Patent Life

<table>
<thead>
<tr>
<th>Time to get TGA approval (T)</th>
<th>Up to 15 Years Effect Patent Life, Maximum 5 Year Extension</th>
<th>Up to 14 Years Effect Patent Life, Maximum 5 Year Extension</th>
<th>Up to 13 Years Effect Patent Life, Maximum 5 Year Extension</th>
<th>Up to 12 Years Effect Patent Life, Maximum 5 Year Extension</th>
<th>Up to 11 Years Effect Patent Life, Maximum 5 Year Extension</th>
<th>Up to 10 Years Effect Patent Life, Maximum 5 Year Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extension Length Calculation</td>
<td>L = T - 5, 0 ≤ L ≤ 5</td>
<td>Extension Length Calculation</td>
<td>L = T - 6, 0 ≤ L ≤ 5</td>
<td>Extension Length Calculation</td>
<td>L = T - 7, 0 ≤ L ≤ 5</td>
<td>Extension Length Calculation</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>19</td>
<td>0</td>
<td>19</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>18</td>
<td>0</td>
<td>18</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>17</td>
<td>0</td>
<td>17</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>16</td>
<td>0</td>
<td>16</td>
<td>0</td>
<td>16</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>15</td>
<td>0</td>
<td>15</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>15</td>
<td>0</td>
<td>14</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>7</td>
<td>2</td>
<td>15</td>
<td>1</td>
<td>14</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>8</td>
<td>3</td>
<td>15</td>
<td>2</td>
<td>14</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>9</td>
<td>4</td>
<td>15</td>
<td>3</td>
<td>14</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>10</td>
<td>5</td>
<td>15</td>
<td>4</td>
<td>14</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>11</td>
<td>5</td>
<td>14</td>
<td>5</td>
<td>14</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>12</td>
<td>5</td>
<td>13</td>
<td>5</td>
<td>13</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>13</td>
<td>5</td>
<td>12</td>
<td>5</td>
<td>12</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>14</td>
<td>5</td>
<td>11</td>
<td>5</td>
<td>11</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>15</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>16</td>
<td>5</td>
<td>9</td>
<td>5</td>
<td>9</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>17</td>
<td>5</td>
<td>8</td>
<td>5</td>
<td>8</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>18</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>19</td>
<td>5</td>
<td>6</td>
<td>5</td>
<td>6</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>20</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

- Extension provided and effective patent life is the same as the current system
- Extension provided and effective patent life is reduced
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.

The sample shows that the average subsidy paid by the Government per script is lower after the EOT 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 C.12, C.13 and C.14 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. Figures C.12 and C.13 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 statutory 16% price reduction that occurs once a second brand of a drug is listed on the PBS and the further price reductions that occur with price disclosure. 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 Government subsidy per script; the actual expenditure and volume figures have been removed.

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.

**Figure C.12: PBS Expenditure for Example Drug #1**

For the drug described in Figure C.12, 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 C.13: PBS Expenditure for Example Drug #2

In Figure C.13, 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 C.14: PBS Expenditure for Example Drug #3

In Figure C.14, 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.
### Appendix D: Net Present Value Calculations

#### Firm type 1 - make 70% in EoT

<table>
<thead>
<tr>
<th>Year</th>
<th>Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>5,930,453</td>
</tr>
<tr>
<td>4</td>
<td>12,993,870</td>
</tr>
<tr>
<td>5</td>
<td>17,044,640</td>
</tr>
<tr>
<td>6</td>
<td>30,255,346</td>
</tr>
<tr>
<td>7</td>
<td>94,782,029</td>
</tr>
<tr>
<td>8</td>
<td>222,369,009</td>
</tr>
<tr>
<td>9</td>
<td>286,012,185</td>
</tr>
<tr>
<td>10</td>
<td>354,729,224</td>
</tr>
<tr>
<td>11</td>
<td>412,625,096</td>
</tr>
<tr>
<td>12</td>
<td>495,512,693</td>
</tr>
</tbody>
</table>

Starting in year 1

<table>
<thead>
<tr>
<th>Discount Rates</th>
<th>NPV no EoT</th>
<th>NPV EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>$73,365,027</td>
<td>$358,786,031</td>
</tr>
<tr>
<td>13%</td>
<td>$103,590,725</td>
<td>$506,956,760</td>
</tr>
<tr>
<td>15%</td>
<td>$159,341,008</td>
<td>$779,244,999</td>
</tr>
</tbody>
</table>

Starting in year 5

<table>
<thead>
<tr>
<th>Discount Rates</th>
<th>NPV no EoT</th>
<th>NPV EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>$60,109,309</td>
<td>$262,298,910</td>
</tr>
<tr>
<td>13%</td>
<td>$94,782,029</td>
<td>$483,368,740</td>
</tr>
<tr>
<td>15%</td>
<td>$159,341,008</td>
<td>$779,244,999</td>
</tr>
</tbody>
</table>

Starting in year 10

<table>
<thead>
<tr>
<th>Discount Rates</th>
<th>NPV no EoT</th>
<th>NPV EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>$46,161,137</td>
<td>$222,369,009</td>
</tr>
<tr>
<td>13%</td>
<td>$94,782,029</td>
<td>$483,368,740</td>
</tr>
<tr>
<td>15%</td>
<td>$159,341,008</td>
<td>$779,244,999</td>
</tr>
</tbody>
</table>

NPV, first ten years

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NPV, second ten years

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Social Discount Rate

<table>
<thead>
<tr>
<th>1.50%</th>
<th>3%</th>
<th>4.50%</th>
<th>1.50%</th>
<th>3%</th>
<th>4.50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>13%</td>
<td>15%</td>
<td>9%</td>
<td>13%</td>
<td>15%</td>
</tr>
</tbody>
</table>

NPV (no EoT)

<table>
<thead>
<tr>
<th>2-4</th>
<th>3-4</th>
<th>7/2</th>
<th>7/5</th>
</tr>
</thead>
<tbody>
<tr>
<td>$73,365,027</td>
<td>$358,786,031</td>
<td>389.0%</td>
<td>389.0%</td>
</tr>
<tr>
<td>$358,786,031</td>
<td>$1,783,661,563</td>
<td>336.4%</td>
<td>336.4%</td>
</tr>
</tbody>
</table>

NPV (EoT)

<table>
<thead>
<tr>
<th>2-4</th>
<th>3-4</th>
<th>7/2</th>
<th>7/5</th>
</tr>
</thead>
<tbody>
<tr>
<td>$358,786,031</td>
<td>$1,783,661,563</td>
<td>313.4%</td>
<td>313.4%</td>
</tr>
<tr>
<td>$1,783,661,563</td>
<td>$1,783,661,563</td>
<td>389.0%</td>
<td>389.0%</td>
</tr>
</tbody>
</table>

NPV (first ten years)

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NPC (no EoT)

<table>
<thead>
<tr>
<th>11-13</th>
<th>12-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>$287,889,783</td>
<td>$1,783,661,563</td>
</tr>
</tbody>
</table>

NPC (EoT)

<table>
<thead>
<tr>
<th>11-13</th>
<th>12-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,783,661,563</td>
<td>$1,783,661,563</td>
</tr>
</tbody>
</table>

NPC, first ten years

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NPC, second ten years

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Difference in NPC

<table>
<thead>
<tr>
<th>15-14</th>
<th>16-15</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,495,771,780</td>
<td>$1,495,771,780</td>
</tr>
</tbody>
</table>

NPC, second ten years

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NPC, third ten years

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NPC, fourth ten years

<table>
<thead>
<tr>
<th>No EoT</th>
<th>EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Reduction in NPC from 4 yr reduction

<table>
<thead>
<tr>
<th>27</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,286,554,453</td>
</tr>
</tbody>
</table>

Additionality (patent)

<table>
<thead>
<tr>
<th>19</th>
</tr>
</thead>
<tbody>
<tr>
<td>$142,710,502</td>
</tr>
</tbody>
</table>

Additionality in Aust (2%)

<table>
<thead>
<tr>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2,854,210</td>
</tr>
</tbody>
</table>

Additionality (in Aust 25%)

<table>
<thead>
<tr>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>$29,825,170</td>
</tr>
</tbody>
</table>

Additionality with patent

<table>
<thead>
<tr>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>$119,300,681</td>
</tr>
</tbody>
</table>

Additionality in Aust (2%) subsidy

<table>
<thead>
<tr>
<th>28</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2,386,014</td>
</tr>
</tbody>
</table>

Additionality (in Aust 25%) subsidy

<table>
<thead>
<tr>
<th>26</th>
</tr>
</thead>
<tbody>
<tr>
<td>$29,692,116</td>
</tr>
</tbody>
</table>

Reduction in NPC from 4 yr reduction

<table>
<thead>
<tr>
<th>23</th>
</tr>
</thead>
<tbody>
<tr>
<td>$238,601,363</td>
</tr>
</tbody>
</table>

Additionality with patent

<table>
<thead>
<tr>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>$119,300,681</td>
</tr>
</tbody>
</table>

Additionality in Aust (2%) subsidy

<table>
<thead>
<tr>
<th>28</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2,386,014</td>
</tr>
</tbody>
</table>

Additionality (in Aust 25%) subsidy

<table>
<thead>
<tr>
<th>26</th>
</tr>
</thead>
<tbody>
<tr>
<td>$29,692,116</td>
</tr>
</tbody>
</table>

Additionality (Subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$747,885,890</td>
</tr>
</tbody>
</table>

Additionality (40% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (25% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (50% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (75% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (100% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (20% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (30% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (40% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (50% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (75% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (100% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (20% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (30% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (40% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (50% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (75% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
</tbody>
</table>

Additionality (100% of subsidy)

<table>
<thead>
<tr>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td>$257,310,821</td>
</tr>
<tr>
<td>Firm type 2</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>Starting in year 1</td>
</tr>
<tr>
<td>Discount Rates</td>
</tr>
<tr>
<td>NPV no EoT</td>
</tr>
<tr>
<td>[3-4] (no EoT)</td>
</tr>
<tr>
<td>[11-13] (EoT)</td>
</tr>
<tr>
<td>[11-15] Difference in NPC</td>
</tr>
<tr>
<td>[7*50%] Additionality (patent)</td>
</tr>
<tr>
<td>[19*25%] Additionality in Aust (25%)</td>
</tr>
<tr>
<td>[24*20%] Reduction in NPC from 4 yr reduction</td>
</tr>
<tr>
<td>[29*40%] Additionality (40% of subsidy)</td>
</tr>
<tr>
<td>diff</td>
</tr>
<tr>
<td>Year</td>
</tr>
<tr>
<td>-----</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

Discount Rates

<table>
<thead>
<tr>
<th>Year</th>
<th>Discount Rates</th>
<th>NPV no EoT</th>
<th>NPV EoT</th>
<th>NPV, first ten years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9% 13% 15%</td>
<td>$844,186,902</td>
<td>$866,776,494</td>
<td>$397,461,991</td>
</tr>
<tr>
<td>5</td>
<td>9% 13% 15%</td>
<td>$741,114,581</td>
<td>$441,027,181</td>
<td>$309,587,810</td>
</tr>
<tr>
<td>9</td>
<td>9% 13% 15%</td>
<td>$309,587,810</td>
<td>$441,027,181</td>
<td>$274,859,596</td>
</tr>
</tbody>
</table>

Social Discount Rate

<table>
<thead>
<tr>
<th>Year</th>
<th>Social Discount Rate</th>
<th>NPC no EoT</th>
<th>NPC EoT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.50% 3% 4.50%</td>
<td>$1,954,337,414</td>
<td>$2,056,453,088</td>
</tr>
<tr>
<td>5</td>
<td>1.50% 3% 4.50%</td>
<td>$1,369,215,890</td>
<td>$1,424,335,540</td>
</tr>
<tr>
<td>9</td>
<td>1.50% 3% 4.50%</td>
<td>$537,207,080</td>
<td>$887,128,460</td>
</tr>
</tbody>
</table>

Additionality (patent)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (patent)</th>
<th>Additionality in Aus (2%)</th>
<th>Additionality in Aus (25%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11,294,796</td>
<td>5,271,023</td>
<td>3,637,683</td>
</tr>
<tr>
<td>5</td>
<td>8,594,264</td>
<td>4,661,727</td>
<td>3,190,598</td>
</tr>
<tr>
<td>9</td>
<td>6,362,330</td>
<td>3,664,555</td>
<td>2,307,745</td>
</tr>
</tbody>
</table>

Additionality subsidy

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality subsidy</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>51,057,837</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>42,123,898</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>32,865,604</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (20%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>225,896</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>105,420</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>72,754</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (25%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>22,945</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>10,207</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>6,883</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (20%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2,285,067</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>1,317,756</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>909,421</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (25%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>286,810</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>127,581</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>86,033</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (20%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1,998,257</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>1,073,621</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>537,207</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (25%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>51,057,837</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>37,426,538</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>27,569,825</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (20%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>225,896</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>105,420</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>72,754</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (25%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2,285,067</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>1,317,756</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>909,421</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>

Additionality (Subsidy) (20%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Additionality (Subsidy)</th>
<th>Reduction in NPC from 4 yr reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1,998,257</td>
<td>11,425,337</td>
</tr>
<tr>
<td>5</td>
<td>1,073,621</td>
<td>9,238,501</td>
</tr>
<tr>
<td>9</td>
<td>537,207</td>
<td>7,067,303</td>
</tr>
</tbody>
</table>
Appendix E: Simvastatin

Case study – Omeprazole and Simvastatin

Omeprazole is the subject of a large number of follow-on patents. It was found that more than half of these are from applicants other than the original patentee.

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.

Figure 7.3.1: Omeprazole patent timeline

---

355 In comparison to the majority of other pharmaceuticals studied by the Panel
356 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.
A similar pattern was observed for simvastatin. As seen in the previous omeprazole example, follow-on patenting following market approval was dominated by third parties.

**Figure 7.3.2 : Simvastatin patents - Originator vs. Non-Originator**

357 Ibid

358 Marketing approval was granted on 19 July 1990
Appendix F: List of submissions

Submissions to Background and Suggested Issues Paper

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 Srinvasan
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

Submissions to Draft Report
Centre for Adaptive Behaviour and Cognition – Max Planck Institute for Human Development
Professor Stephen Duckett - Grattan Institute
Dr Mary Osborn
Consumer’s Health Forum of Australia
AFTINET, PHAA, AFAO, APN+ and Palliative Care Australia
Japan Pharmaceutical Manufacturers Association (JPMA)
AbbVie
F.Hoffman La-Roche and Roche Products Pty Ltd
FICPI
FICPI Australia
Pharmaceutical Research Manufacturers of America (PhRMA)
US Chamber of Commerce
Research Australia
Anna George - Adjunct Professor, Sir Walter Murdoch School of Public Policy, Murdoch University and Associate Fellow, Centre on Global Health Security, Chatham House London
Pfizer
Amgen
Consumers’ Federation of Australia
Dr Hazel VJ Moir – Adjunct Associate Professor, Research School of Social Sciences, College of Arts and Social Sciences, The Australian National University
Pharmaceutical Client of Davies Collison Cave
AusBiotech
Eli Lilly Australia
Bristol-Myers Squibb
IPTA
Japan Intellectual Property Association (JIPA)
Sanofi
GlaxoSmithKline
International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
American Chamber of Commerce in Australia
Medicines Australia
Starpharma
Professor Andrew Christie et al – Melbourne Law School
Biotechnology Industry Organisation (BIO)
Monash University
Novartis
Janssen-Cilag
Alphapharm
Law Council of Australia
Merck Sharp and Dohme
Generic Medicines Industry Association (GMiA)
Appendix G: Government agencies consulted

Department of Foreign Affairs and Trade
Department of Health and Ageing
Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education
The Treasury
### Appendix H: Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAT</td>
<td>Administrative Appeals Tribunal</td>
</tr>
<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
</tr>
<tr>
<td>ACIP</td>
<td>Advisory Council on Intellectual Property</td>
</tr>
<tr>
<td>ACTA</td>
<td>Anti-Counterfeiting Trade Agreement</td>
</tr>
<tr>
<td>AIPPI</td>
<td>The Australian Group of the International Association for the Protection of Intellectual Property</td>
</tr>
<tr>
<td>AMWG</td>
<td>The Access to Medicines Working Group</td>
</tr>
<tr>
<td>API</td>
<td>Active pharmaceutical ingredients</td>
</tr>
<tr>
<td>ARGB</td>
<td>Australian Regulatory Guidelines for Biologics</td>
</tr>
<tr>
<td>AUSFTA</td>
<td>Australia-United States Free Trade Agreement, entered into force 1 January 2005</td>
</tr>
<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
</tr>
<tr>
<td>DIICCSTRE</td>
<td>Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education</td>
</tr>
<tr>
<td>DITR</td>
<td>Department Tourism, Industry and Resources</td>
</tr>
<tr>
<td>DoHA</td>
<td>Department of Health and Ageing</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>FDA</td>
<td>United States Food and Drug Administration</td>
</tr>
<tr>
<td>FICPI</td>
<td>International Federation of Intellectual Property Attorneys</td>
</tr>
<tr>
<td>FTC</td>
<td>Federal Trade Commission</td>
</tr>
<tr>
<td>Generics</td>
<td>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.</td>
</tr>
<tr>
<td>GMiA</td>
<td>Generic Medicines Industry Association</td>
</tr>
<tr>
<td>IP</td>
<td>Intellectual Property</td>
</tr>
<tr>
<td>IPAC</td>
<td>Industrial Property Advisory Committee</td>
</tr>
<tr>
<td>JSCOT</td>
<td>Joint Standing Committee on Treaties</td>
</tr>
<tr>
<td>MFE</td>
<td>Manufacture for export</td>
</tr>
<tr>
<td>NIA</td>
<td>National Interest Assessment</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
<tr>
<td>---------</td>
<td>------------</td>
</tr>
<tr>
<td>NPV</td>
<td>Net Present Value</td>
</tr>
<tr>
<td>Originators</td>
<td>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&amp;D required to bring potential new drugs to market.</td>
</tr>
<tr>
<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee</td>
</tr>
<tr>
<td>PBPA</td>
<td>Pharmaceutical Benefits Pricing Authority</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
</tr>
<tr>
<td>PC</td>
<td>Productivity Commission</td>
</tr>
<tr>
<td>PI</td>
<td>Product Information</td>
</tr>
<tr>
<td>PIWG</td>
<td>The Pharmaceutical Industry Working Group</td>
</tr>
<tr>
<td>PMPRB</td>
<td>Patent Medicine Prices Review Board</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and development</td>
</tr>
<tr>
<td>RTB</td>
<td>Intellectual property laws amendment (Raising the Bar) Bill 2011 [2012]</td>
</tr>
<tr>
<td>SBMPs</td>
<td>Similar Biological Medicinal Products</td>
</tr>
<tr>
<td>SPC</td>
<td>Supplementary Protection Certificates</td>
</tr>
<tr>
<td>TRIPS</td>
<td>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</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>TPP</td>
<td>Trans-Pacific Partnership Agreement</td>
</tr>
<tr>
<td>WEHI</td>
<td>Walter and Elizabeth Hall Institute</td>
</tr>
<tr>
<td>WIPO</td>
<td>World Intellectual Property Organization</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organization</td>
</tr>
</tbody>
</table>