MEDICINES Australia

Better Health through Research and Innovation

Submission to the Productivity Commission's *Draft Report* on Intellectual Property (IP) Arrangements in Australia 2016

June 2016

Contents

Executive Summary

Medicines Australia appreciates the opportunity to provide comments and raise concerns on the Productivity Commission's Draft Inquiry Report into Intellectual Property (IP) Arrangements in Australia.

For many years and in many submissions to the Australian Government, its institutions and the Parliament, Medicines Australia has put the case for Australia's IP system to be improved and strengthened. Medicines Australia has described the reasons why strengthening the current IP laws and regulations in Australia would better support the economy through encouraging investment in, amongst other things, better and new 'breakthrough medicines and vaccines'. Such medicines will help foster the achievement of better health outcomes for Australians, one of the fundamental policy objectives across the whole-of-government.

The current Productivity Commission's Inquiry has stated a focus on ensuring "that the intellectual property system provides appropriate incentives for innovation, investment and the production of creative works while ensuring it does not unreasonably impede further innovation, competition, investment and access to goods and services."[1] However, Medicines Australia does not consider that the Productivity Commission's draft recommendations adequately meet this objective.

Medicines Australia would encourage the Productivity Commission to re-consider its draft recommendations taking the following considerations into account (many of which are contained in our earlier submission):

- Strong IP systems have been shown to drive innovation and investment. They do this by providing a framework for innovators to share their discoveries and creations with the community, in exchange for a period of exclusivity. Such systems recognise the balance between risk and reward, particularly in highly novel areas. IP systems that do not have this balance undermine investment and economic growth.
- Intellectual Property systems across the world play an important role in stimulating innovation. Together with other policy tools and levers, strong IP systems encourage medical research leading to diseases being treated. Recommendations that stand to undermine the incentives to research cures for disease will impact on the economy. In this context the Productivity Commission has ignored the shared benefits that come from a strong IP system.
- The Australian Government aspires to make Australia a more innovative country with an economy driven by inventive, research-driven, knowledge-based industries; in this context, we would suggest that the Productivity Commission draft recommendations be re-examined taking these aims into account to avoid taking a retrograde step for Australia.
- If the Government is to fulfil its agenda for Australian-based science and innovation, it must ensure that, at the very least, it maintains the current patent and data exclusivity provisions and should further explore improvements to the IP system.
- Medicines Australia members contribute to the Government's National Innovation & Science Agenda (NISA) through significant investment in Australia's world-class scientists, research collaborations, and local biotechnology and advanced manufacturing

[1] *Draft Report*, Page IV

capabilities. Medicines Australia members are leading employers of Science Technology, Engineering and Mathematics (STEM) graduates.

- The Productivity Commission *Draft Report* relies on information that is incorrect and Medicines Australia notes that this has resulted in misunderstandings about the complexity, nature and role of intellectual property in the pharmaceutical sector. 'Evergreening', which by definition in the legislation, cannot occur, is one particularly concerning example. Another is that there is no evidence of pay for delay activities and the existing mechanisms enable sufficient monitoring of competitive relationships to detect misconduct.
- Medicines Australia is concerned that there has been inadequate consultation or consideration of the flow-on impacts that measures recommended by the Productivity Commission would have on our sector and on the wider economy.

Medicines Australia urges the Commission to reconsider draft recommendations 6.1, 6.2, 6.3, 7.1, 9.1, 9.2, 9.3, 9.4 and 9.5. Further response to specific recommendations are summarised in the recommendations section.

Introduction

The purpose of this further submission, to the latest in the series of reviews of Australia's Intellectual Property (IP) system, is to reassert certain facts around IP provisions, correct errors, misconceptions and omissions in the *Productivity Commission Draft Report on Intellectual Property Arrangements* (*the Draft Report*) and to provide proper balance for an informed discussion on IP.

Medicines Australia recognises that IP laws must strike a balance between ensuring access to inventions and new products at competitive prices, and ensuring that product originators are sufficiently compensated for the resources they dedicate to research and invention, whilst being incentivised to disclose their inventions. The existing IP system in Australia achieves this to some degree without need for amendment.

Intellectual property rights, especially patents, are a universally accepted mechanism to recognise the value of innovation and to encourage future research and development that delivers value to the community. In the case of pharmaceuticals, patents enable the translation of a promising discovery into new and often better, medicines for patients who need them.

> *"Patents provide incentives by recognising creativity and offering the possibility of material reward for marketable inventions. These incentives encourage innovation, which in turn spurs economic growth and enhances the quality of human life."*
>
> - **World Intellectual Property Organisation**[2]

There are several compelling reasons why IP must be promoted and protected, but they are largely overlooked in this *Draft Report*. Firstly, the progress and well-being of humanity rests on its capacity to create and invent new works in the areas of technology and culture. Secondly, the legal protection of new creations encourages the commitment of additional resources for further innovation. Thirdly, the promotion and protection of IP spurs economic growth, creates new jobs and industries, and enhances quality of life.[3]

Governments around the world want to create an environment that harnesses innovation, embraces growth and maps the path to further progress. Critical to the creation of this path is a strong IP environment.

For a modern, knowledge-based economy like Australia's, IP is a particularly valuable commodity. The total value of Australian IP is estimated to be around $250 billion, or nearly a fifth of the nation's Gross Domestic Product (GDP).[4] Copyright industries alone employ around one million Australians and generate more than $90 billion in economic value.[5] As Australia transitions away from a resources dominated economy to an innovation and knowledge based one, maintaining and protecting our strong IP system is a critical pillar for economic growth.

The pharmaceutical industry is an integral part of Australia's "knowledge-economy". Currently, around fifty global research-based pharmaceutical companies and more than 400 locally-owned medical biotechnology firms operate in Australia. Together, they employ in excess of 40,000 highly-skilled Australians (many of whom work in STEM occupations), generate around $2.9 billion in exports each year, invest over $1 billion in Research and

[2] World Intellectual Property Organisation, Geneva, 2013. What is Intellectual Property? Available: http://www.wipo.int/about-ip/en/

[3] Adapted from: World Intellectual Property Organisation, Geneva, 2013. What is Intellectual Property? Available: http://www.wipo.int/about-ip/en/

[4] Griffith Hack, Melbourne, 2013. The Value of Australian Intellectual Property.

[5] PricewaterhouseCoopers, Sydney, 2012. The Economic Contribution of Australia's Copyright Industries.

Development (R&D) – much of it on clinical trials – and deliver medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives[6].

It is estimated that Australians gain approximately $2.17 in health benefits in return for each dollar invested in medical research in Australia. [7] Moreover, a 2011 report found that by maintaining even current levels of investment in medical research, Australians could gain up to $150 billion in health benefits over the next 10 years.[8] In short, it makes clear economic sense for Australian policy makers to ensure that in terms of the IP regime, Australia remains a competitive location for foreign and domestic investment in medical research.

To translate promising discoveries into meaningful medicines that meet the required standards of quality, safety and efficacy, requires significant high risk investment. [9,10] The total costs attributed to medicines development also account for many failures, with less than 12% of clinically tested discoveries making it to market.[11]

These financial and scientifically speculative risks are only taken when there is an incentive, such as certainty in the framework, through which the enormous outlays can be recouped and a reasonable return can be made on success. Patent protection is one way to provide an incentive, by offering a defined period of certainty for biopharmaceutical innovators. This certainty adds to the justifications for substantial investment of significant resources over many years to translate inventions into new medicines that are safe and effective.

It would be unreasonable to expect significant investment in high-risk development activities, aimed at translating promising research discoveries into tangible commercialised products, without providing reasonable opportunity to recoup investment and receive a return for the risk. The question, which has not been adequately explained in this *Draft Report* is, how long is considered a reasonable opportunity to achieve a reasonable return on investment? It is widely canvassed and accepted across this and other industries that 15 years of effective patent life provides a reasonable opportunity for return on investment. Australia's IP system has evolved over the past three decades to provide such opportunities to recoup investment.

Intellectual property rights are the backbone of the research-based pharmaceutical industry. Measures that inhibit manufacturers' ability to recoup costs, such as those recommended in the *Draft Report*, may have the unintended consequence of also hindering Australians access to new life saving medicines in a timely and affordable way.

Whilst the Commission states that recommendations to Government should be based on evidence and analysis, Medicines Australia does not consider that the case has been made to amend the Intellectual Property provisions in Australia.

Medicines Australia contends that the recommendations of the *Draft Report* would also have the negative effect of inadvertently diminishing Australia's standing as a globally competitive investment destination.

---

[6] Please see IFPMA submission to the Draft Report 2016. Available on the Productivity Commission website http://www.pc.gov.au/inquiries/current/intellectual-property/submissions#post-draft

[7] Deloitte Access Economics, Canberra, 2008. Exceptional Returns II: The Value of Investment in Health R&D in Australia. Available: http://www.asmr.org.au/ExceptII08.pdf

[8] Lateral Economics, Melbourne, 2010. The Economic Value of Australia's Investment in Medical Research. Available: http://apo.org.au/resource/economic-value-australias-investment-health-and-medical-research-reinforcing-evidence

[9] DiMasi JA, Grabowski HG, Hansen RW. 2016. Innovation in the pharmaceutical industry: new estimates of R&D costs. J Health Economics. 47:20-33. (US$2.6 Billion)

[10] Messtre-Ferrandiz, J., Sussex, J. and Towse, A. 2012. Office of Health Economics. The R&D Cost of a New Medicine. Available: https://www.ohe.org/publications/rd-cost-new-medicine

[11] DiMasi JA, Grabowski HG, Hansen RW. 2016. Innovation in the pharmaceutical industry: new estimates of R&D costs. J Health Economics. 47:20-33. (US$1.5Billion)

The Australian Government aspires to make Australia a more innovative country with an economy driven by inventive, research-driven, knowledge-based industries and care should be taken that changes to IP do not have a retrograde effect.

Intellectual Property in a Broader Economy context

Our IP system is a cornerstone of economic development in Australia, and has wider, flow-on effects to many sectors. Medicines Australia acknowledges the Commission's use of an economic framework, but agrees with other submissions that this framework could be further expanded[12]. This expansion of the framework aligns with our recommendation that the Productivity Commission should undertake a high-level and holistic consideration of Australia's innovation and IP arrangements. Previously, we took the opportunity to reaffirm the importance of IP in attracting investment; described how innovation fosters a successful medicines industry; explained that strong and effective IP systems promote access to new medicines through the Pharmaceutical Benefits Scheme (PBS); and emphasised the need for Australia to be internationally competitive. In addition, we highlighted the significant contribution that medicines make to the economic health and wealth of the nation.

The Terms of Reference for the current Inquiry (provided by the then Treasurer, Joe Hockey), directed the Productivity Commission to:

> *'ensure that the intellectual property system provides appropriate incentives for innovation, investment and the production of creative works while ensuring it does not unreasonably impede further innovation, competition, investment and access to goods and services'*

Unfortunately, evidence indicating that IP is critical to stimulating medical research and delivering medical innovation to Australians does not seem to have been properly considered in the *Draft Report*.

As we have explained, intellectual property provisions drive investment in innovation by providing a framework for innovators to share their discoveries and creations with the community in exchange for a period of exclusivity. This exclusivity arrangement is designed to provide a reasonable compensation for the substantial risks taken during the process of development and commercialisation. Thus, IP, along with other policy levers, such as the taxation system, the reimbursement system, market size and the overall operating environment, is central to stimulating medical research and ensuring timely access to innovative medicines and vaccines. Other policy and legislative levers are introduced following expiry of valid exclusivity periods to generate ongoing value from medicines provided to the community post patent protection.

The challenges in the current IP regime as it applies to the highly complex world of pharmaceutical innovation, and how it operates in Australia, appear poorly understood in the *Draft Report*. For example steps to apply for regulatory approval and then reimbursement, which are crucial milestones in the availability of new medicines for Australians, often have highly unpredictable timeframes that erode certainty in the duration of patent protection. Another challenge is how our IP system relates to other international systems, with trade agreements and notification provisions often having substantial influence over the effective patent life.

The contributions made by Medicines Australia members and the broader industry to support Australia's world-class scientists, research collaborations, local biotechnology companies and

[12] *Draft Report*, page 57 "Some stakeholders have raised concerns that an economic approach may not account for all the effects on welfare that could stem from changes to the IP system." Also, CSIRO, submission 126, page 3.

advanced manufacturing capabilities, as well as its role as leading employers of STEM graduates, are largely disregarded in the *Draft Report*. Recognition of the thousands of jobs created, economic value generated, as well as health and productivity benefits to the broader society arising as a direct result of pharmaceutical industry investment in Australia is notably absent from the *Draft Report*. [13] When considering the net benefits from IP, Medicines Australia would recommend that the scope should be broader than just social benefits as framed by the Commission to include economic impacts as well. Taking these broader factors into account is also consistent with the *Productivity Commission Act 1998*.

Further, the *Draft Report* does not reflect bipartisan Government policy, including the Government's National Innovation & Science Agenda, which as previously stated, aspires to make Australia a more innovative country with an economy driven by inventive, knowledge-based industries. The current IP regime needs to be strengthened, not wound back, to align with this policy.

Medicines Australia members contribute to the Government's National Innovation & Science Agenda (NISA) through significant investment in Australia's world-class scientists, research collaborations, and local Biotechnology and Advanced Manufacturing capabilities. Medicines Australia members are also amongst the leading employers of Science Technology, Engineering and Mathematics (STEM) graduates.

The Productivity Commission has instead chosen to evaluate the IP regime in a siloed context; the rights of innovators against the rights of the community, rather than exploring the shared benefits that come from a strong IP system.

It is well established that the pharmaceutical industry reasonably relies on effective IP to generate revenues that are then reinvested in research and development of new medicines. Higher than average per-capita income countries, in general have stronger IP protections, relative to lower than average per-capita income countries.[14] The greater share of the costs of investing in the creation of new IP, (such as new medicines), is borne therefore, by wealthier countries yet the benefits are made available to all countries. From a global equity perspective this outcome is appropriate. Australia however has a very high per capita income but does not keep pace in terms of supporting stronger IP.[15]

A recent independent international study of 56 countries' policies on scientific research, drug pricing and IP found that Australian policies are amongst those that do the least to support the global life-sciences ecosystem.[16] Australia ranked 52 out of 56 countries on a contribution to global life-sciences innovation scale. As stated by the authors:

> *"Some countries do not invest adequately in life sciences research. Some seek to pay less than their fair share for drugs by failing to protect intellectual property or forcing drug companies to sell drugs at artificially low prices. These policies make it harder for life sciences innovators to capture returns from one generation of biomedical innovation to fund investment in the next, weakening the virtuous cycle of life sciences innovation."* (Wu and Ezell, 2016:2)[17]

[13] For further detail on these benefits, please see the Medicines Australia's Facts Book 4. Available: https://medicinesaustralia.com.au/policy/publications/facts-book/

[14] For example, data exclusivity - Countries with data exclusivity (per. IFPMA, *Data Exclusivity: Encouraging Development of New Medicines*, *2011)* mapped against gross national income per capita: https://data.oecd.org/natincome/gross-national-income.htm

[15] Ibid.

[16] John Wu and Stephen Ezell. 2016 "How National Policies Impact Global Biopharma Innovation: A worldwide ranking" Information Technology and Innovation Foundation. Available: http://www2.itif.org/2016-national-policies-global-biopharma.pdf?_ga=1.245513159.237796607.1460389121

[17] Ibid.

The same study found that this type of underinvestment by countries necessarily results in fewer innovative medicines being developed globally, and made available to all patients, including those in Australia.

The approach taken in the *Draft Report* does not achieve the right balance. In particular with respect to the observations and recommendations relevant to the pharmaceutical industry, the *Draft Report* seeks to introduce further regulatory burden, without due justification, on one of the most highly regulated industries in the world.

There have been several IP reviews in Australia in recent years and as noted by the Commission: '…some participants have questioned the need for yet another.'[18] Medicines Australia agrees with the view that there is no existing rationale to repeatedly review pharmaceutical patents.

In addition to these reviews, reforms to patent law have been ongoing, most recently through the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* which Medicines Australia publicly welcomed. These reforms highlighted the importance of a strong IP system.

Accordingly, there is a strong and enduring rationale for making sure that no changes are implemented that would, in any way, undermine companies' ability to access patents and/or to defend their IP. Patents allow companies to invest in R&D, with the expectation that they will have a fair opportunity to recoup this investment before others, who did not bear any of the initial risks are permitted to profit from these new and improved products making it significantly more likely for private enterprises to continue to invest in R&D for new medicines. Pharmaceutical inventions and innovations must remain eligible candidates for strong patent protection.

The Productivity Commission makes an incorrect and misinformed claim that "EOTs [Extension of [Patent] Terms] have been ineffectual in attracting pharmaceutical investment in Australia"[19] and that "settings in the larger markets of the EU and US are far more determinative in firm's investment decisions"[20]. Patent rights are *one* of a number of critical factors which influence companies' investment decision making. Whilst it is true that Australia makes up only around 1% of the global pharmaceutical market, and therefore does not carry enormous weight from a global perspective, it is in fact even more important that Australia has globally competitive strengths in such areas as IP, medical research and high regulatory standards to continue to attract pharmaceutical investment and incentivise greater future investment in Australian's overall health outcomes.

Overall, the *Draft Report* presents a case that patents should only be granted where there is *material net benefits to society*, with a particular focus on consumer benefits. It is entirely unclear how limiting and devaluing the discovery, development, translation and commercialisation of medicines will in any way provide greater net benefit to society. It is also extremely difficult (and premature) in current research settings to model, quantify and adequately value the resultant net societal benefits from potential innovations in treatments at the time of seeking a patent for a potential medicine. Neither of these measures are adequately captured or valued in subsequent assessments or procurement processes. The Productivity Commission also fails to provide an alternative measure or indicator of when or how 'material social benefit' could be defined or measured.

[18] *Draft Report*, Page 4.
[19] *Draft Report*, Page 263.
[20] *Draft Report*, Page 264.

A strong IP system drives innovation and investment by providing a framework for innovators to share their discoveries and creations with the community in exchange for a period of exclusivity. This makes the IP system, along with such other policy levers as the taxation system, the reimbursement system, market size and the overall operating environment, an important factor in stimulating medical research and in ensuring timely access to innovative medicines and vaccines.

Extension of Patent Term

Patent term extensions were implemented in Australia, in part to provide pharmaceutical inventions with an *effective patent life* that is more in line with that available to inventions in other fields of technology.[21] Despite this, analysis of publicly available data shows that the average effective patent life for pharmaceutical products in Australia is between 11 and 12 years[22], and in some instances as short as 2 years. This effective patent life is significantly less than the 15 years of effective patent life that is intended through granting of patent term extensions for pharmaceutical products in Australia, and far less than the 20 to 25 years of protection that Australian patents provide 'on paper' (Appendix B).

Effective patent life is significantly shortened by the lengthy pre-clinical and clinical research required during a medicine's development. As technologies advance and complex biological or other new molecules are developed to treat targeted patient populations, these development timeframes are unlikely to reduce significantly in the foreseeable future. Nevertheless, the global industry continues to explore ways to improve the efficiency in clinical development and speed up development timeframes to ensure patients can access new medicines in the timeliest way.

Proposals to wind back patent term extensions in Australia should be set aside until there is clear and compelling evidence that medicines development timeframes have accelerated, costs have reduced and that average effective patent life exceeds the anticipated 15 years. This will enable due consideration for any need to rationalise periods of exclusivity and still allow a reasonable opportunity to recoup a return on the risk and investment made.

The recommendations[23] in the *Draft Report*, in relation to patent term extension would essentially remove patent term extension from the IP regime, limit decisions to only domestic factors, reduce the scope and availability and in so doing, would contravene Australia's international trade obligations such as those agreed in the Australia-US Free Trade Agreement (AUSFTA) and the more recent Trans Pacific Partnership (TPP) Agreement. Diluting the existing Australian IP regime clearly signals to international investors that Australia does not seek to be globally competitive. This is in conflict with the Government's desire to pursue an innovation and science agenda and discuss new international trade agreements.

Furthermore, it is evident that nearly half of the products granted a patent term extension will not achieve an effective patent life of 15 years (Appendix B for examples), despite receiving the full five year patent extension permitted under the current legislation. If the time taken to

---

[21] Parliament of the Commonwealth of Australia, House of Representatives, *Intellectual Property Laws Amendment Bill 1997*, Explanatory Memorandum, section 3.

[22] Data was derived from the Australian Register of Therapeutic Goods (ARTG) and AusPat.

[23] The specific Productivity Commission recommendations are as follows:

- Patent term extension should only be granted for eligible pharmaceutical patents in circumstances where the Therapeutic Goods Administration (TGA) takes more than one year to approve the product.
- Patent term extension should only be granted through a tailored system which explicitly allows for manufacture for export in the extension period- as tailored rights specific to the domestic market rather than extension of existing patents
- Section 76A of *the Patents Act 1990* (Cth) (Act) should be amended to improve data collection and ensure patent term extension are only granted once satisfactory data is received, with a view to using this data to undertake a review of the costs and benefits of the patent term extension scheme in five years.

list these medicines on the PBS were taken into account, the effective patent life for these products would be even less.

On average, it takes between 12 and 15 years to bring new medicines to market, including the time taken to complete basic, pre-clinical and clinical research. This means that typically up to two-thirds of a standard 20 year patent term is spent in the development phase required to bring a new medicine to market. Companies routinely require several additional years to obtain reimbursement in Australia (through the Pharmaceutical Benefits Scheme) which further delays market entry for most medicines available in Australia.

In recognition of these lengthy delays, the Australian Government in 1999 granted pharmaceutical companies the right to seek "patent term extension" – that is, the right to apply for up to five years of patent term extension, in order to achieve an effective patent life of up to 15 years from the date of first entry of the product on the Australian Register of Therapeutic Goods.

The reasons for granting this right are stated in the second reading of the *Intellectual Property Laws Amendment Bill 1997*:

- to compensate pharmaceutical patent holders for delays in obtaining regulatory approval for new products;
- to provide incentives for pharmaceutical companies to continue to invest in R&D in Australia;
- to provide an effective patent life more in line with that available to inventions in other fields of technology; and
- to create a patent regime for pharmaceuticals which is in line with Australia's competitors.

These reasons are clearly stated in the second reading speech for the Bill:

> *"However, considerable research and testing is still required before the product can enter the market. This long development time, combined with the considerable regulatory process to register and market a new product, means that companies usually have considerably fewer years under patent in which to gain a return on their investment.….The objective of this part of the bill is to provide an `effective patent life' more in line with that available to inventions in other fields of technology. It will also create a patent regime for pharmaceuticals which is in line with our competitors."*[24]

It was clearly not the intent of the 1997 amendment to the patents legislation to limit or reduce the rights of patent holders in Australia. On the contrary, the intent was clearly to ensure these rights were fair and reasonable and provide an incentive for ongoing investment in research and development (R&D) for the continued availability of innovative medicines in Australia. In this, the Australian Government followed the actions taken by governments of most other advanced economies around the world, including Japan, South Korea, Israel, the United States, the United Kingdom and most countries in Europe, which also provide extended patent terms for pharmaceuticals.

It was also not the intent of the amendment to limit the scope of the rights which are conferred on patent owners during the terms of an extension. For example, the Productivity Commission's proposal to allow generic companies to manufacture patented medicines for export during the period of patent extension. Implementing this proposal would, as successive Australian Governments have already determined, contravene Australia's international obligations under:

---

[24] Intellectual Property Laws Amendment Bill 1997. Second Reading Speech, The Hon Warren Truss MP, Minister for Customs and Consumer Affairs.

- Article 28 of TRIPS (reflected in section 13 of the *Patents Act 1990*) which gives patentees the exclusive right to make, use and offer for sale (including for export or import) any product related to the patented invention for the entire term of the patent;
- Article 33 of TRIPS (reflected in section 67 of the *Patents Act 1990*) which requires WTO members to grant patentees at least 20 years of [effective] patent protection; and
- Article 17.9.8(b) of the AUSFTA, which reinforces the concept of patent term extension and expressly refers to an adjustment of patent term, while making no suggestion that the rights conferred during the adjusted patent term should be less than the full patent rights as defined in TRIPS. In fact, a side letter to the AUSFTA clearly states the agreed understanding of both Australia and the United States that Australia may permit export during the adjusted term "only for the purposes of meeting the marketing approval requirements of Australia or another territory."[25]

The Productivity Commission's recommendation that the calculation of an extension of patent term should be based solely on the actions of the regulator, and their assertion that regulatory delay of one year should be considered acceptable and thus excluded from the calculation, is an insupportable suggestion. Such an approach would have significant unintended consequences for both patient access, future economic growth and investment in ongoing R&D, not to mention the potential negative impact on the viability of the industry in Australia.

Whilst the average time for the TGA to approve a medicine is reported as approximately one year, this does not include regulated or mutual 'stop clock' periods or other internal TGA or sponsor initiated delays. Furthermore, whilst inclusion on the Australian Register of Therapeutic Goods (ARTG), provides market authorisation, Australia operates in a publicly supported, universal health care system whereby medicines are additionally assessed for cost effectiveness before they are subsidised on the Pharmaceutical Benefits Scheme (PBS). Medicines are not widely available to patients until they are listed on the PBS. The evaluation and assessment process for listing on the PBS is complex and costly and frequently delays medicines' availability by another year and sometimes several years.[26]

Reducing the effective patent term by substantively eliminating patent term extensions would severely compromise the existing balance between the incentive to innovate and delivering affordable healthcare to Australian patients. This balance has served Australia and the world well; Australia punches above its weight in terms of its contribution to global medical research efforts; has a growing and vibrant home-grown biotechnology sector; and, each year, the pharmaceuticals industry in Australia generates up to $2.9 billion in exports and invests more than $1 billion in R&D.

The Commission claims part of the rationale for changes to patent term extensions is the "considerable costs on consumers, government and ultimately taxpayers through the Pharmaceutical Benefits Scheme"[27]. However data included in the *Draft Report* also indicates that the annual cost of extensions to patent terms to the government, which contributes 80% of the cost of all PBS medicines, is only 2.7% of the government expenditure on the PBS.[28] Therefore as noted by others[29], as far as a savings mechanism for taxpayers is concerned, the recommendations are misplaced.

---

[25] Letter from Mark Vaile, Australian Minister for Trade, to Ambassador Robert Zoellick, US Trade Representative (May 18, 2004) and corresponding reciprocal letter from Ambassador Zoellick to Minister Vaile.
[26] Medicines Australia. 2015. COMPARE: Comparison of Access and Reimbursement Environments. Available: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2015/03/20150331-pub-Compare_Edition1_March2015-FINAL.pdf
[27] *Draft Report*, page 253
[28] "Calculations undertaken for the recent Pharmaceutical patents review indicated that patent term extensions cost the Australian Government and consumers over a quarter of a billion dollars each year", p.13, and also p.264
[29] Spruson and Ferguson 2016 Available: http://www.spruson.com/productivity-commission-draft-report-on-ip-arrangements-pharmaceutical-patents/

If the Government is to fulfil its agenda for Australian-based science and innovation, it must ensure that, at the very least, it maintains the current patent and data exclusivity provisions. Any further changes should in fact be aimed at improving and not diminishing the strengths of our current IP system.

The Inventive Step and Allegations of 'Evergreening'

The inventive step is an important concept that has been reviewed and changed recently. The *Raising the Bar Act 2012* increased the first three elements required in granting patents. This legislation took what was already internationally a high level of inventiveness required for a patent, and increased the threshold even further. Medicines Australia supports further analysis and reporting of how the *Raising the Bar Act 2012* has been implemented as a condition precedent to any further amendments in this area.

The 'Scintilla of invention'

The *Draft Report* quotes a number of cases that have interpreted the scintilla of invention test element of the validity of a patent. These cases[30] indicate that if the advancement made is not obvious by a person skilled in the craft, then, along with the other three elements of the inventive step for a valid patent[31], the invention is considered to *not be obvious*. However, the Commission argues that this threshold of innovation is not sufficiently high enough to grant a valid patent, and that greater levels of innovation must be required to justify granting a valid patent.

The *Draft Report* incorrectly suggests that under Australian law all that is required for a patent is a scintilla of invention. The *Draft Report* asserts that there needs to be an assessment of how much above the inventive threshold an invention is to further justify a patent. With the passing of the *Raising the Bar Act 2012*, the level of inventive step required is commensurate with the level of inventive step required for Australia's major trading partners. Therefore, the Commission's recommendation would put Australia out of step internationally and undermines the advancement of Australian's wellbeing by discouraging innovation and the knowledge spill-overs from them.

Evergreening

The *Draft Report* makes reference to the concept of 'Evergreening'. The Productivity Commission puts the view that a more stringent inventive step test should be introduced to prevent the granting of follow-on patents and further claims that some follow-on patents are applied to technical changes that do not provide discernible consumer benefit.[32]

The term 'Evergreening' is pejorative and refers to allegations that 'Evergreening strategies' are employed by research-based pharmaceutical companies to "extend patents". However the notion of Evergreening' demonstrates a fundamental lack of understanding of how the patent system works, because it is not possible for a *later* patent to *extend* the term of an *earlier* one. As such, a *second or subsequent* patent cannot, by definition, be issued for the *same* invention and must cover a *new* invention in order to be granted. Moreover, once the patent on the original invention expires, imitators are free to copy the invention if they choose.

[30] *Draft Report* pages 179-182.

[31] Would the person skilled in the art, in light of the prior art and common general knowledge, have found the invention obvious?

[32] *Draft Report* page 284.

There is a fundamental misunderstanding of the notion of 'Evergreening', which by definition in the legislation, cannot occur.

The Commission even notes that "…courts have found, a follow-on patent can in many cases represent genuine cumulative innovation"[33]. Supplementary or incremental innovation during the period of exclusivity commonly occurs as a result of new data emerging from ongoing clinical trials and research, or collection of data from the on-market use of existing products. These data and clinical findings may inform a previously unforeseen clinical need, such as improvements that resolve clinically identified issues or deliver better safety profiles for certain patients.

The substantial increases in requirements for patentability introduced with the *Raising the Bar Act 2012*, actually increased the scope for IP Australia to reject patent applications that it believes do not meet the new requirements, including applications for follow-on or incremental innovations. Much of the Commission's discussions on 'Evergreening' are therefore made redundant.

Manufacture for Export

Medicines Australia opposes the adoption of proposals which would substantially weaken the IP rights/incentive balance in Australia. The Commission discusses two possible reform options that build on their previous report completed over 13 years ago[34] i) Manufacturing for export during the patent extension period and ii) Reliance on *sui generis* rights. However, the issues previously raised with these proposals remain unresolved.

Contemporary examination of the potential for a manufacture for export system that does not infringe on existing patent rights and is consistent with obligations under all trade agreements in place may be warranted. Medicines Australia concurs that it would not, however be in accordance the principle of Article 30 of TRIIPS:

> *"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." (WTO 1995)*

The second reform option proposed by the Commission refers to *sui generis rights*, noting the Supplementary Protection Certification (SPC) system as an example. The SPC system used in the European Union was intended to support innovation.[35] This system was not designed to become an instrument of promoting manufacturing localization.

The global research-based pharmaceutical industry believes it would be difficult and burdensome, if not impossible, to enforce such a measure to ensure that products manufactured under this exemption are only exported to, and remain in, countries without patent protection[36]. For example, it would be problematic to distinguish whether manufacturing activities are being carried out for:

- export to countries without IP protection;
- in support of export to countries where there is still IP protection; and/or
- to stockpile products for launch in the domestic market immediately upon patent expiry.

[33] *Draft Report*, page 284.
[34] Productivity Commission. 2003. Evaluation of the Pharmaceuticals Industry Investment Program. Available: http://www.pc.gov.au/inquiries/completed/pharmaceutical-investment/report
[35] European Commission 2016. Supplementary protection certificates for pharmaceutical and plant protection products Available: http://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates/index_en.htm
[36] Joint Submission by IFPMA, PhRMA, Interpat, JPMA and EFPIA to the Productivity Commission's *Draft Report* on Intellectual Property Arrangements 2016.

Proof of infringement will be more difficult to provide, making the enforcement of IP rights more burdensome.

Medicines Australia is concerned by the Productivity Commission's claim that "disconnecting the extended period from the standard patent system, and bringing it within a carefully tailored domestic system, *sui generis* protection preserves policy flexibility and adaptability in the future."[37]

It would seem that the explicit requirement for policy flexibility and adaptability in this area is intended to create greater instability for innovators and would further impair predictability in the already high risk medicines research environment. It is unclear from the evidence provided in the *Draft Report* that such a system would protect patent term extension provisions. Furthermore, when recommendations 9.1 and 9.2 of the *Draft Report* are read together, it becomes clear that the unstated intention is to erode and functionally eliminate, patent term extensions.

In addition, such products could be exported to countries where patent grants are delayed due to significant backlogs. In this case, innovative companies may face the threat of potentially infringing imported products despite the presence of duly filed patent applications that have not yet been granted. It would be difficult to enforce against exports to such countries, and litigation costs and associated regulatory burdens would likely rise.

It has been suggested that such proposals would strengthen incentives for domestic generic manufacturing, thereby contributing to creating jobs and enhancing growth. However, there is a lack of evidence resulting in high uncertainty that the expected benefits would materialise. It should be acknowledged that generic manufacturers rely on innovative companies to invest and develop new medicines and launch them in the market in the first place. It is questionable whether the perceived lack of competitiveness derives from the alleged late market entry or from other factors.

Therefore, whether such proposals would create a comparative advantage for the domestic generic manufacturers in Australia as claimed is highly challengeable, especially in a scenario in which such policies would be rapidly replicated by other countries.

The research-based pharmaceutical industry is a strategic, knowledge-based, IP-intensive industry, which delivers new medicines for today and the future. It creates a significant number of highly skilled research, clinical and manufacturing jobs in Australia and fosters growth both locally and internationally. Such proposals to weaken the current IP framework risks jeopardizing innovation and thus reduce patients' ability to access new treatments.

Medicines Australia is disappointed that the Productivity Commission has ignored the shared benefits that come from a strong IP system.

Data Protection

The Productivity Commission makes recommendations[38] in relation to Australia's provision of data protection for pharmaceuticals (being therapeutic goods consisting of or containing an active ingredient) with limited arguments to justify these recommendations.

The data required by the TGA before a new medicine is registered as meeting the required standards of quality, safety and efficacy for marketing in Australia, is extensive. This data, is generated through years of basic laboratory investigation, pre-clinical research and numerous

[37] *Draft Report*, page 273.

[38] The specific Productivity Commission recommendations are as follows:

1. There should be no extension of the period of data protection, including that applicable to biologics.
2. Further, in the context of international negotiations, the Australian Government should work with other nations towards a system of eventual publication of clinical trial data in exchange for statutory data protection.

clinical trials. Data protection, which applies only to the data submitted to the TGA and lasts for 5 years from the date of registration, is most relevant where a patent provides insufficient protection or where there is no existing patent. In those instances, without data protection, generic companies could seek to rely on the original data, which they played no part in generating and took no risk, nor made any investment in, to immediately bring competing products to market. Data protection runs in parallel to, and is a separate mechanism to, a patent and therefore, in the large majority of cases, data protection will have already expired well before a generic application is made at the expiry of the patent.

If Australia's data protection rights are not maintained, the potential unintended consequences would be manifold, including:

- decreased access to new medicines for Australian patients;
- a negative message to potential investors in Australian research with a reduction in the development of that research; and
- would send a local and global signal of indifference to the advancement of translational research opportunities in Australia despite public assertions to the contrary.

Recommendation of no extension of data protection

An analysis of the Productivity Commission's statements in support of not extending data protection follows.

"data protection (which is not subject to the same technological neutrality requirements as patents) has been used as an arm of industry policy."[39]

Data protection was developed to address the fact that there are significant inadequacies in the patents system as it applies specifically to pharmaceuticals – patents fail to cover a range of circumstances appropriately warranting IP protection (to support additional investment where: a patent has expired, never existed or is not adequate).[40] To argue that such a measure is an arm of industry policy is to wholly ignore the rationale that these issues are highly complex. It also ignores that data protection is not a barrier based on point of origin. For example Swiss pharmaceuticals enjoy the same data protection provisions as those of American pharmaceuticals in America and vice versa. There is no significant industry protection provided given that the pharmaceutical industry is widely dispersed across the World and rapidly growing.

"potential future evolution of regulatory exclusivities also poses significant policy issues."[41] It is difficult to address concerns regarding things that have never happened. We do note that the American Bill referred to appears to be an effort to promote collaboration to better target patients for pharmaceutical treatments.[42] If successful, this would increase efficiencies in the health system and potentially reduce the costs associated with excess usage – seemingly a worthwhile object given the Commission's concern for the taxpayer. We also note that this Bill was originally introduced into the United States Congress in 2011 and it remains one of 9,693 bills and resolutions currently before the Congress[43] that have yet to be passed and may well never be. Further, it is difficult to understand how this type of speculative query is included in the Commission's commentary with other, more substantive considerations being left unaddressed.

---

[39] *Draft Report*, Page 276.

[40] Eli Lilly, *Submission 164,* Senate Standing Committee on Economics Inquiry - Australian Innovation System 2014, p4.

[41] *Draft Report*, page 277.

[42] http://www.biocentury.com/biotech-pharma-news/regulation/2011-05-30/patient-groups-propose-moddern-cures-act-to-promote-personalized-medicine-a16

[43] https://www.govtrack.us/congress/bills/#bystatus at 25 May 2016

"in some cases pharmaceutical companies simply prefer the automatic protection afforded by data protection."[44]

This statement misrepresents a quote from a pharmaceutical company submission to a separate inquiry. The quote is a statement of fact about difficulties associated with patents in relation to small biotechnology companies, with no preference cited either way for a patent or data protection in the submission.

To reiterate the more accurate explanation on this matter; data protection is completely separate from patent protection, with the two systems running in parallel. The Commission further quotes the Department of Health[45] on suggested drawbacks as regards data protection, however omits to balance these claims with analysis of the benefits – including the absence of the complex, time-consuming, expensive litigation associated with patents. This benefit is stated in the same pharmaceutical company submission and, indeed, is stated on the same page as the extract quoted by the Commission. This lack of analysis is difficult to reconcile with the Commission's own expressions of concern regarding the civil justice system:

> *"There are widespread concerns that Australia's civil justice system is too slow, too expensive and too adversarial."*[46]

A study conducted by Frost and Sullivan in 2013[47] examined the costs and benefits associated with extending data protection from the current 5 years, to 12 years. This study found that providing a 12 year period of data exclusivity would:

- provide an additional $43 million p.a. worth of health benefits;
- drive significant productivity benefits via a healthier workforce; and
- generate up to $52 million in benefits driven via additional activity in research and development.

Increasing Australia's data exclusivity period would have only a modest impact on the Pharmaceutical Benefits Scheme costs. The best industry estimate of cost would be of the order of $43 million p.a. However, this should be considered with the backdrop of decades of reform to ensure the sustainability of the PBS and the recognition that government manages PBS expenditure through a raft of rigorous assessment, legislative and policy levers.

"there is little evidence that a problem has manifested." We note repeated reference by the Commission to the Pharmaceutical Patents Review (PPR), however, when it comes to data protection the Commission omits at least four examples of inadequate data protection which were acknowledged in the PPR[48]. One example is in relation to Lucrin, with the PPR stating: '*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.'*[49]

Recommendation of Publication of Clinical Trial Data

The Commission argues that clinical trial data submitted to the TGA should be made publicly available. They also argue that data protection should not be extended due to the confidentiality surrounding the clinical trial data also being extended.

This is somewhat inaccurate in its rationale. The innovative medicines industry is wholly committed to publishing clinical trial data. There are a number of avenues through which clinical trial data is published, and Medicines Australia's members comply with a range of

[44] *Draft Report*, Page 277.
[45] *Draft Report*, Page 279.
[46] Productivity Commission, Access to Justice Arrangements, 2014, page 2
[47] Frost and Sullivan. 2013. The Impact of Australia's Data Exclusivity Regime on Australia's Healthcare System.
[48] Harris, Nicole & Gruen. 2013. *Pharmaceutical Patents Review*, page 162-165
[49] Harris, Nicole & Gruen. 2013 *Pharmaceutical Patents Review*, page 165.

industry codes and guides for sharing this data. Two such examples are the principles for responsible clinical trial data sharing[50], and the Yale Open Data Access project[51].

Clinical trial data may be published in the medical press and is made available to doctors. Whilst clinical trial data is submitted to the TGA as part of the regulatory approval process, it is important that this data, as submitted, be kept commercial in confidence. It should be explained that even after the data protection period has expired, the clinical trial data as submitted to the TGA is not made public by the TGA. Neither are generic manufacturers provided with copies of this data. However, once the data protection period has finished, generic manufacturers are able to rely upon this data when making their submissions for an equivalent medicine where they meet the required regulatory standards to demonstrate equivalence and/or comparability.

Data Protection and Trade Agreements

A statement is made in the *Draft Report* in relation to Article 18.51: Biologics of the Trans Pacific Partnership (TPP), that: "*it is clear on the face of the provisions that Australia is not required to provide more than five years of exclusivity"*. This statement is supported in the *Draft Report* by a statement made by the Department of Foreign Affairs and Trade which broadly asserts that Australia meets the requirements of Article 18.51. It is a matter of public record[52] that this assertion is contested and that the Department has, to date, failed to set out any basis for its conclusion. Without any such credible basis it would appear difficult to conclude that Australia is not required to provide additional data exclusivity on the face of the provisions which are explicit.

The Productivity Commission concludes that Australia is not required to change its current provisions for data protection, given the recent publicity surrounding Australia's implementation of Articles 18.50 and 18.51 of the Trans Pacific Partnership. In particular, the Commission states that Australia is not required to provide more than five years of exclusivity for data submitted for regulatory approval of a biologic, noting that the relevant TPP provision acknowledges that "biologics manufacturers rely on a suite of legal and market-based mechanisms to maintain a competitive advantage"[53]. Medicines Australia asserts that data protection should be extended to eight years as stipulated in the TPP and it should be made clear how this will be implemented.

Alleged Pay-for-delay

Pay-for-delay allegations, as noted in the *Draft Report*, raise a complex issue. Medicines Australia supports a transparent reporting and monitoring system, provided that there are no *unnecessary* additional compliance or reporting burdens on companies. The recent implementation of the Government's multinational anti-tax-avoidance law, provides Government with sufficient data capture to detect any competition limiting behaviour between originator and generic pharmaceuticals.

The *Draft Report* states that pay-for-delay arrangements limit competition (and thereby limit price reductions), and also postpone regulatory price drops. The *Draft Report* refers to the ACCC's proceedings against Pfizer in 2014 for what it describes as an example of 'concerning, but unproven, anticompetitive behaviour'. This characterisation is unfounded. Firstly, the Federal Court did not find Pfizer's conduct 'concerning' and secondly, the proceedings are irrelevant to a discussion on pay-for-delay agreements. The ACCC's case against Pfizer did

[50] For the Principles of Clinical Trial Data Sharing, please see http://www.phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf
[51] For further information on the Yale Open Data Access project, please see http://yoda.yale.edu/
[52] The US Chamber of Commerce has publicly reiterated the importance within the TPP of adhering to the data protection requirements.
[53] *Draft Report,* page 280.

not involve any allegations of pay-for-delay agreements.[54] Not only was there no evidence of such conduct having taken place, a relevant fact of the case was that Pfizer had a settlement agreement with generic company Ranbaxy which permitted Ranbaxy to sell the patented product before patent expiry.[55] Further, there was no allegation or finding of anti-competitive effect and the Court found there was no evidence that Pfizer had an anti-competitive purpose.[56] In fact, the Court found that competition from generic suppliers was inevitable.[57] The case does not support the *Draft Report*'s recommended regulatory changes and is potentially misleading.

There is already an existing regulatory structure which is equipped to detect anti-competitive behaviour including pay-for-delay agreements. As noted in the *Draft Report*, the *Competition and Consumer Act 2010* prohibits anti-competitive agreements. It also makes it a criminal offence for a person to agree with a competitor to withhold or restrict supply. The ACCC has the power to detect this type of anti-competitive behaviour by issuing statutory notices which compel a person to furnish information, produce documents or give evidence relating to a matter that constitutes, or may constitute, a contravention of the *Competition and Consumer Act 2010*.[58] The introduction of an additional mandatory reporting regime is therefore not only superfluous, it would constitute significant regulatory overreach. It would effectively give the ACCC the investigative powers that are normally reserved for instances where there is reason to believe there was a contravention of the *Competition and Consumer Act 2010*.

If implemented, this recommendation would impose an additional regulatory burden on pharmaceutical companies which already bear the compliance costs of numerous and complex regulations and codes.[59] The *Draft Report* states that while the Commission 'is interested in exploring alternative methods to reduce the compliance costs involved, at this stage, the Commission considers there is merit in adopting [this] system'.[60] Medicines Australia is concerned that the *Draft Report* seems to suggest that it is not necessary to conduct a preliminary assessment of whether or not the costs of introducing this reporting system will outweigh the claimed benefits. The *Draft Report* only appears to give perfunctory consideration to potential compliance costs and does not appear to consider other costs involved in introducing further regulation.

Innovation Patents

In their review of the innovation patent system in 2015, the Advisory Council on IP made a number of recommendations. In addition to Medicines Australia's submission to the ACIP review, we believe that the recommendation in the *Draft Report* to abolish the innovation patent system is ill-informed and has not taken relevant factors into account.

Innovation Patents and Social Value

A core argument in the *Draft Report* that innovation patents do not provide sufficient net social value is ill-informed and misplaced. The Commission argue that unless innovation provides knowledge spill overs, then the value of the innovation is diminished and not worthy of receiving systematic support. This position undervalues the impact and net social benefit of

[54] *Draft Report* page 287.
[55] *Australian Competition and Consumer Commission v Pfizer Australia Pty Ltd* [2015] FCA 113 at [157].
[56] *Australian Competition and Consumer Commission v Pfizer Australia Pty Ltd* [2015] FCA 113 at [344].
[57] *Australian Competition and Consumer Commission v Pfizer Australia Pty Ltd* [2015] FCA 113 at [342].
[58] Section 155 of the *Competition and Consumer Act 2010*.
[59] For example, the *Therapeutics Goods Act 1989*, the Therapeutics Goods Advertising Code, the Medicines Australia Code of Conduct, the *National Health Act 1953* including legislative instruments made under that Act such as the Pharmaceutical Benefits Scheme, the *Competition and Consumer Act 2010* and the *Patents Act 1990*.
[60] *Draft Report*, page 288.

medicines and is in direct contradiction to the bipartisan support for Science and Innovation, and extends well beyond the provisions of the *Patent Act 1990*.

As noted on page 218 of the *Draft Report*, an argument is posited that low value patents can impose substantial costs on the community, and that the patent system should only support 'high value' patents. This argument is contradictory when the innovation patent and pharmaceutical patent recommendations are considered together.

The recommendation to abolish the innovative patent system on one hand indicates that the Commission does not consider innovation patents as providing sufficient benefits, and that only 'high value' patents provide social benefits. The similar recommendation to abolish extensions of patent term (for patents that are clearly considered high value) contradicts this argument and would impair and erode Australia's strong and effective patents system and diminish incentives for research driven innovation and investment. Additionally, in the absence of clear direction on how net social benefit will be captured, measured and valued at the time of seeking a patent, is it unclear how the issues can be resolved.

Previous IP Australia's Economic Analysis

IP Australia's economic analysis is cited by the Advisory Council on IP's review[61] as justifying cessation of the innovation patent system. Medicines Australia is concerned that whilst this economic analysis explores an area that has not been analysed in detail before, there are a number of limitations in the approach and analysis used to support the recommendation to cease innovation patents.

As acknowledged in the economic analysis, there are a number of benefits for second-tier patent systems (of which innovation patents are one), which are used in 59 countries. Although the innovation patent system as a policy is targeted towards small to medium enterprises, the fact that many larger companies have been using this system should not be discounted, or discouraged.

As acknowledged in the economic analysis, there was limited data available to be able to test the direct relationship between innovation patents and increased R&D in Australia. This highlights that further data collection and analysis is required to better understand how innovation patents are being used, and the benefits that are being derived from them. Once this data and analysis have been collected and completed, then a more informed recommendation can be made on whether there is merit in retaining the innovation patent system.

As noted by in the *Draft Report*[62], there are concerns over the robustness of the analysis conducted to date by IP Australia on the value of innovation patents. Medicines Australia would encourage the Productivity Commission to consider undertaking further consultation, in depth analysis and data collection on the benefits and uses of innovation patents, prior to recommending further changes.

Limitations in the Draft Report

There are a number of limitations of the *Draft Report* that Medicines Australia seeks to highlight, address and correct where appropriate. A summary of these limitations have been compiled in Appendix A. The *Draft Report* has not directly addressed recommendations and issues raised in our other submissions and Medicines Australia would welcome the opportunity to discuss these further. We would like to reiterate the recommendation that the Productivity Commission undertake a holistic and high-level consideration of the IP environment that captures the impacts, interactions and consequences on all stakeholders.

[61] Draft *Report*, Page 211.
[62] *Draft Report* Page 217 "IPTA and FICPI (2015) argued that IP Australia's direct estimates underestimated the private value of innovation patents."

Recommendations

Medicines Australia urges the Productivity Commission to reconsider the following draft recommendations 6.1, 6.2, 6.3, 7.1, 9.1, 9.2, 9.3, 9.4 and 9.5 until there has been further consultation and consideration of the flow on impacts and unintended consequences of these measures. The section below provides targeted comments on the specific recommendations that would have significant unintended consequences.

DRAFT RECOMMENDATION 6.1

The Australian Government should amend ss. 7(2) and 7(3) of the *Patents Act 1990* (Cth) such that an invention is taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art.

The Australian Government should state the following in the associated Explanatory Memorandum:

• the intent of this change is to better target socially valuable inventions

• the test should be applied by asking whether a course of action required to arrive at the invention or solution to the problem would have been obvious for a person skilled in the art to try with a reasonable expectation of success.

The Australian Government should explore opportunities to further raise the overall threshold for inventive step in collaboration with other countries in international forums.

Response: Medicines Australia opposes this recommendation. This recommendation seeks to change the inventive step required for a patent. The Productivity Commission has failed to incorporate the previous reforms that were implemented as part of the *Raising the Bar Act 2012*. This legislative change, which came into effect in 2013 is still being implemented, and given that the threshold for an inventive step is sufficiently high, there is no evidence based justification for increasing it.

DRAFT RECOMMENDATION 6.2

The Australian Government should incorporate an objects clause into the *Patents Act 1990* (Cth) (Patents Act). The objects clause should describe the purposes of the legislation as being to enhance the wellbeing of Australians by providing patent protection to socially valuable innovations that would not have otherwise occurred and by promoting the dissemination of technology. In doing so, the patent system should balance the interests of patent applicants and patent owners, the users of technology — including follow–on innovators and researchers — and Australian society as a whole.

The Australian Government should amend the Patents Act such that, when making a decision in relation to a patent application or an existing patent, the Commissioner of Patents and the Courts must have regard to the objects of the Patents Act.

Response: Medicines Australia opposes this recommendation. This recommendation lacks clarity and insertion of a new objects clause is unnecessary. It is difficult to see how patent examiners can be expected to assess whether the patent application balances the interests of the patent applicant, the users of technology and Australian society as a whole. This would seem to be subjective criteria, have substantial evidence requirements and would be difficult to apply.

DRAFT RECOMMENDATION 6.3

The Australian Government, with input from IP Australia, should explore the costs and benefits of using higher and more pronounced renewal fees later in the life of a standard patent, and making greater use of claim fees to limit the breadth of patent protection and to reduce strategic use of patents.

The Australian Government should seek international cooperation on making greater use of patent fees to help ensure that patent holders are not overcompensated and to limit the costs of patent protection on the community.

Response: Medicines Australia does not support changes to the fee structure for patents. The current fee structure provides stability in the decision making process for companies when submitting an application to patent a medicine in Australia. These proposed changes will make Australia's system less competitive internationally. In turn this could have a serious flow-on effect to the amount of investment in Research and Development in Australia, as an element of the decision making incorporates the costs of applying for, and managing IP.

This recommendation also seems not to be aligned with the current Government's deregulation agenda, and will make it less attractive for businesses to seek to protect their inventions.

DRAFT RECOMMENDATION 7.1

The Australian Government should abolish the innovation patent system.

Response: Consistent with our earlier submission, Medicines Australia would challenge the premise on which the Productivity Commission supports the abolition of the innovation patent system.

DRAFT RECOMMENDATION 9.1

The Australian Government should reform extensions of patent term for pharmaceuticals such that they are calculated based only on the time taken for regulatory approval by the Therapeutic Goods Administration over and above one year.

Response: As noted earlier, Medicines Australia refutes the premise for this recommendation and provides further information on the need for patent term extension specifically in pharmaceuticals to enable a reasonable incentive to share innovations with the community. There is a reasonable expectation that innovative medicine manufacturers should be compensated for the investment and risk undertaken, whilst enabling the benefits of the innovation to be shared with the community and most particularly patients. This principle does not support changes to the patent term extension as this will unnecessarily erode (and substantively eliminate) the intent of the extension to ensure an effective patent life comparable to other technology industries.

DRAFT RECOMMENDATION 9.2

Regardless of the method of calculating their duration (draft recommendation 9.1), extensions of term in Australia should only be granted through a tailored system which explicitly allows for manufacture for export in the extension period.

Response: Medicines Australia objects to changes to the extension of term enabling manufacture for export that would undermine Australia's commitments to international trade agreements and which create an environment where the risk of entry to the domestic market prior to expiration of a patent is increased. Medicines Australia further challenges the unsupported assumption that this change would cement incentives for domestic manufacture localisation.

DRAFT RECOMMENDATION 9.3

There should be no extension of the period of data protection, including that applicable to biologics.

Further, in the context of international negotiations, the Australian Government should work with other nations towards a system of eventual publication of clinical trial data in exchange for statutory data protection.

Response: Medicines Australia has previously provided submissions that note that Australia's current data protection provision lags behind those of our international competitors.[63] A further consideration is that Australia's commitments to international trade agreements with regards to data protection should be complied with.

It is misleading to suggest that data protection will extend exclusivity beyond the effective patent term. Data protection is separate from the patent, largely runs in parallel and expires before the patent. The only exception to this is where there is inadequate patent coverage or no existing patent, in which case data protection provides the innovator with a short period of time to recoup investments made in the development of clinical data where the patent does not offer protection. By not increasing the level of data protection, there is a risk that medicines will not be available to Australian patients where there are no standard patent protections available.

[63] For example, AusBiotech, Research Australia and Medicines Australia, 2015. An Open Letter to the Australian Parliament, available: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20150304-ltr-Open-Letter-to-Parliament-on-TPP-and-IP.pdf and also Medicines Australia's first submission to the Productivity Commission's Review of IP Arrangements in Australia 2015.

DRAFT RECOMMENDATION 9.4

The Australian Government should introduce a transparent reporting and monitoring system to detect any pay-for-delay settlements between originator and generic pharmaceutical companies. This system should be administered by the Australian Competition and Consumer Commission.

The monitoring should operate for a period of five years. Following this period, the Australian Government should institute a review of the regulation of pay-for-delay agreements (and other potentially anticompetitive arrangements specific to the pharmaceutical sector).

Response: Medicines Australia strongly disagrees with this recommendation given that the recent implementation of the Government's multinational anti-tax-avoidance law provides sufficient data capture to detect any competition limiting behaviour between originator and generic pharmaceuticals. Whilst Medicines Australia supports in principal, transparent reporting and monitoring, the introduction of onerous and unnecessary additional compliance or reporting burdens onto companies should always be avoided.

DRAFT RECOMMENDATION 9.5

The Australian Government should reform s. 76A of the *Patents Act 1990* (Cth) to improve data collection requirements. Thereafter, extensions of term should not be granted until data is received in a satisfactory form.

After five years of data has been collected, it should be used as part of a review to consider the ongoing costs and benefits of maintaining the extension of term system.

Response: Medicines Australia urges the Productivity Commission to reconsider this recommendation. Other submissions from a range of stakeholders on this issue[64] have highlighted that unnecessary changes to data collection requirements will impose further regulatory burden on pharmaceutical companies. The rationale for seeking to improve data collection requirements does not seem to be adequately supported, and would undermine the value of a patent term extension.

[64] IPTA. 2016. Submission to the Productivity Commission *Draft Report*; IFPMA 2016. Submission to the Productivity Commission's *Draft Report* on IP.

Appendix A: Limitations in the *Draft Report*

Limitation	Page	Response
The Terms of Reference for the Inquiry ask the Productivity Commission to: "recommend changes to the current system that would improve the overall wellbeing of Australian society, which take account of Australia's international trade obligations, including changes that would: a. encourage creativity, investment and new innovation by individuals, businesses and through collaboration while not unduly restricting access to technologies and creative works… c. provide greater certainty to individuals and businesses as to whether they are likely to infringe the IP rights of others"	Terms of Reference of the Inquiry	Medicines Australia considers that the recommendations put forward in Chapter 9 of the *Draft Report* will not result in the encouragement of investment and new innovation, and do not provide greater certainty as to whether IP rights of others are likely to be infringed.
At present not only are follow on manufacturers prevented from relying on clinical data for a period of 5 years, the data is kept confidential indefinitely	14	Whilst the clinical data that is submitted to the TGA is kept confidential, there are no restrictions on generic manufacturers relying on this data when making their own submissions following the end of the data exclusivity period.
In Australia market entry of the first generic competitor triggers an automatic statutory price reduction of 16 per cent under the PBS, and, generally, additional savings in the order of 23%	260	The assertion of 23% additional savings is incorrect. It is a matter of public record that price disclosure has delivered substantially higher savings than originally anticipated, with price reductions often over 60%. Analysis produced by the Centre for Strategic Economic Studies (Sweeney, 2013) notes that there is high variability in the average price cuts, with some molecules having cuts of up to 92%[65]. More recent analysis of 2016 PBS data shows that the average price cut across all medicines is approximately 45%.
More than half of all patents extended have received the maximum 15 years of effective patent life	261	This statement from the Harris review does not capture the range and average effective patent life for pharmaceuticals. Analysis produced by Medicines Australia shows that on average the effective patent life is around 11-12 years, with some molecules having as little as 2 years effective patent life.

[65] Sweeney, K. 2013 Centre for Strategic Economic Studies. The Impact of Further PBS Reforms. Report to Medicines Australia. Available: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20130515-rep-The-Impact-of-Further-PBS-Reforms-Final-report-from-CSES.pdf

Limitation	Page	Response
Patent term extensions have limited the opportunities for Australian based generic firms from servicing third markets, by precluding manufacture for export	264	Medicines Australia's contends that a more likely reason is that Australian generic producers are experiencing increasingly competitive challenges due to the commoditisation of the international generic export market, which is driven by cost considerations and therefore favours suppliers based in developing nations.
They [the Harris Review] assumed that the drug earns $2.5 billion in revenues over its patent lifetime and that 70 per cent of this revenue is earned during the extension period (PPR analysed PBS expenditure data for 2007-12 and *found that 9 per cent of drugs fit this revenue profile*)	265	Medicines Australia strongly disagrees that this data should be relied on, and would encourage the Commission to consider the profile of the other 91% of the F1 PBS listed molecules to gain a more accurate picture of extension of patent term.
These arrangements represent a poor basis for measuring regulatory delay. They favour patent term extension since a patent holder can choose to delay filing for regulatory approval, such that — regardless of the efficiency of the regulator or the standards they apply — a pharmaceutical product will be eligible for an patent term extension.	266	Medicines Australia strongly objects to this unfounded claim that patent holders are deliberately delaying medicines availability and delaying business opportunity to access revenue. This theory is inconsistent with the lengthy argument made earlier that discounting over such a long period means the NPV of a patent term extension is not meaningful – yet it is claimed to be effecting behaviour.
It consider[ed] the average time elapsed from dossier submission in the US until dossier submission in Australia, by reference to products in respect of which an application for an patent term extension was submitted in Australia. … These results show that on average sponsors do submit dossiers to the TGA later than equivalent submissions to the FDA, the median delay being 297 days in 2012, 236 days in 2011 and 549 days in 2010.	267	This draft finding misrepresents the reasons for time lags between regulatory filings in the US and EU compared to Australia (outside of Period D). The reasons are varied and multi-factorial and include 1). Initial registration dossier addressed FDA requirements and guidelines, but a dossier meeting EU guidelines and formatting was not available, and work had to be done to meet Australian specific and TGA regulatory requirements. 2) Pharmaceutical products can be owned by a company with no existing commercial relationship to an Australian sponsor company – delays can be due to the need for commercial negotiations and relationships to be developed before regulatory submissions can be progressed.

Limitation	Page	Response
Provides evidence of a possible $2.2billion of foregone export revenue based on a projection made in 2003 for the period of 2001 to 2009.	272	There are clear examples where, with the right policy settings, research based innovative pharmaceutical manufacturing has expanded in Australia and provided valuable investment leading to jobs and growth. One example is the Factor F policy that assisted AstraZeneca to invest in a manufacturing plant in Sydney. The plant now exports to over 30 countries. AstraZeneca has since continued to invest in the plant which now employs 431 Australians, with $90m invested to support export growth, automate processes and new technology. Over the past five years, pharmaceutical manufacturing in Australia that has been exported has been declining, but with appropriate and well-designed IP and industry polices, there is an opportunity to make advanced pharmaceutical manufacturing an industry for Australia's economic growth.

Appendix B: Pharmaceutical Substances with Effective Patent Terms Less than 15 Years

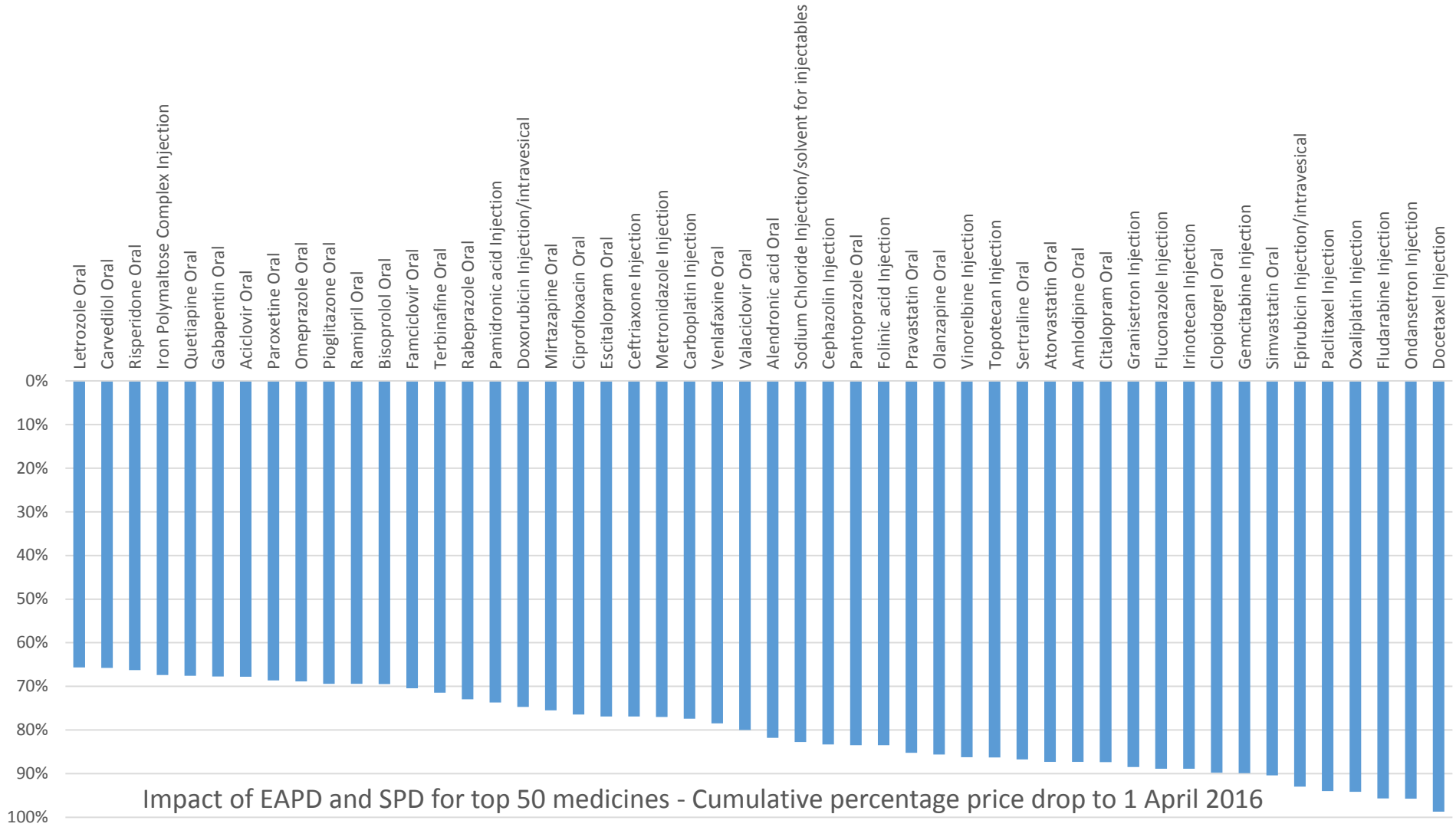
Molecule	Patent	Filing Date	Earliest First Regulatory Approval Date	Final Patent Expiry Date	PTE (years)	Technical Eligibility (years)[66]	Effective Patent Term (years)
Tocilizumab	668349	24/4/1992	21/5/2009	24/4/2017	5	12	8
Ibandronate	598279	7/7/1987	12/1/2000	7/7/2012	5	8	12
Orlistat	572851	18/6/1984	11/4/2000	18/6/2009	5	11	9
Aprepitant	701862	28/6/1993	13/4/2004	28/6/2018	5	6	14
Corifollitropin	736339	14/1/1998	30/7/2010	14/1/2023	5	7	13
Etonogestrel	603475	4/8/1988	18/1/2000	4/8/2013	5	7	13
Posaconazole	681753	20/12/1994	15/3/2006	20/12/2019	5	7	13
Olmesartan	647887	21/2/1992	6/9/2004	21/2/2017	5	7	13
Ganirelix	614275	4/2/1988	19/3/2001	4/2/2013	5	8	12
Tipranavir	701965	4/5/1995	8/6/2006	4/5/2020	5	6	14
Dipyridamole Asp	603146	12/8/1987	3/12/1999	12/8/2012	5	7	13
Pramipexole	583874	20/12/1985	30/3/1999	20/12/2010	5	9	11
Dipyridamole	539618	12/1/1981	25/11/1998	12/1/2006	5	12	8
Abatacept	661854	16/6/1992	27/9/2007	16/6/2017	5	10	10
Aciclovir	547391	17/7/1981	2/11/1993	17/7/2006	5	7	13
Adefovir Dipivoxil	586860	22/4/1986	16/9/2003	22/4/2011	5	12	8
Alefacept	660981	12/3/1992	7/5/2004	12/3/2017	5	7	13
Alemtuzumab	618989	10/2/1989	10/5/2006	10/2/2014	5	12	8
Aliskiren	699616	12/4/1995	23/6/2008	12/4/2020	5	8	12
Ambrisentan	688611	7/10/1995	24/11/2008	7/10/2020	5	8	12
Anakinara	633831	25/5/1989	17/6/2003	25/5/2014	5	9	11
Anidulafungin	689931	19/3/1993	3/4/2009	13/3/2018	5	11	9
Artemether	642747	5/6/1991	24/7/2002	5/6/2016	5	6	14
Atovaquone	574353	13/4/1984	9/5/1995	13/4/2009	5	6	14
Azelastine HCL	613107	11/11/1988	22/5/2000	11/11/2013	5	7	13
Baxter PDS	584603	12/2/1985	16/12/1999	12/2/2010	5	9	11
Beractant	520543	22/5/1980	18/3/1994	22/5/2005	5	9	11
Bicalutamide	556328	18/7/1983	1/7/1996	18/7/2008	5	8	12
rhBMP	613314	30/6/1987	5/8/2005	30/6/2012	5	13	7
Bortezomib	710564	27/10/1995	14/2/2006	27/10/2020	5	6	14
Cabergoline	540621	31/3/1981	21/4/1995	31/3/2006	5	9	11
Cefepime	532776	10/2/1983	19/7/1995	10/2/2008	5	7	13
Cefpirome	559727	11/5/1982	21/4/1994	11/5/2007	5	7	13
Cefpodoxime	547984	30/9/1981	22/2/1994	30/9/2006	5	8	12
Cetirizine HCL	544066	5/2/1982	2/7/1993	5/2/2007	5	6	14
Ciclesonide	649472	6/9/1991	24/2/2004	6/9/2016	5	8	12
Cidofovir	600002	17/7/1987	31/7/1998	17/7/2012	5	6	14
Cinacalcet	673500	21/8/1992	25/1/2005	21/8/2017	5	8	12
Desirudin	578050	21/11/1984	11/11/1996	21/11/2009	5	7	13
Desloratadine	570306	8/2/1985	28/5/2003	8/2/2010	5	13	7
Dexmedetomidine	600839	11/7/1988	20/8/2001	11/7/2013	5	8	12
Dihydroergotamine	565613	28/1/1983	15/5/1998	28/1/2008	5	10	10
Diclofenac	545006	19/2/1981	21/4/1994	19/2/2006	5	8	12
Gadoxetate Na2	637111	29/6/1990	1/7/2004	29/6/2015	5	9	11
Dofetilide	578557	30/4/1987	26/4/2000	30/4/2012	5	8	12
Drotrecogin Alfa	638796	22/2/1991	11/4/2002	22/2/2016	5	6	14
Duloxetine	591007	17/12/1987	14/3/2007	17/12/2012	5	15	5
Eculizumab	735596	1/5/1995	20/3/2009	1/5/2020	5	9	11
Emtricitabine	665187	20/2/1992	21/12/2004	20/2/2017	5	7	13
Enoxaparin	535791	13/5/1981	12/2/1993	13/5/2006	5	7	13
Entacapone	621036	27/11/1987	12/5/1999	27/11/2012	5	7	13
Entecavir	634423	4/10/1991	12/4/2006	4/10/2016	5	10	10
Eptacog Alfa	603983	16/4/1986	8/1/1999	16/4/2011	5	8	12
Exemestane	578840	7/7/1986	30/11/2000	7/7/2011	5	9	11
Fentanyl	565177	3/7/1985	24/10/1997	3/7/2010	5	7	13
Fexofenadine HCL	531146	29/1/1980	10/1/1997	29/1/2005	5	12	8
Fluticasone	544517	13/2/1981	7/1/1994	13/2/2006	5	8	12
Fondaparinux	563351	14/1/1983	25/3/2002	14/1/2008	5	14	6
Fosaprepitant	700611	28/2/1995	28/8/2007	28/2/2020	5	7	13
Gadobenate DM	591225	13/1/1987	7/7/2003	13/1/2012	5	11	9
Ganirelix Acetate	614275	4/2/1988	19/3/2001	4/2/2013	5	8	12
Gatifloxacin	610491	19/2/1987	15/2/2001	19/1/2012	5	9	11
Gemcitabine	565856	7/3/1984	2/8/1995	7/3/2009	5	6	14
Glimepiride	538129	18/12/1980	24/9/1996	18/12/2005	5	11	9
Clinoleic	609845	22/7/1988	19/2/2004	22/7/2013	5	11	9

[66] "Technical Eligibility" = "Earliest First Regulatory Approval Date" minus "Filing Date"; see, Section 77 of the *Patents Act 1990*. This effectively shows the time taken to develop a medicine from the filing date of a patent application to the date it is approved by the regulatory authority.

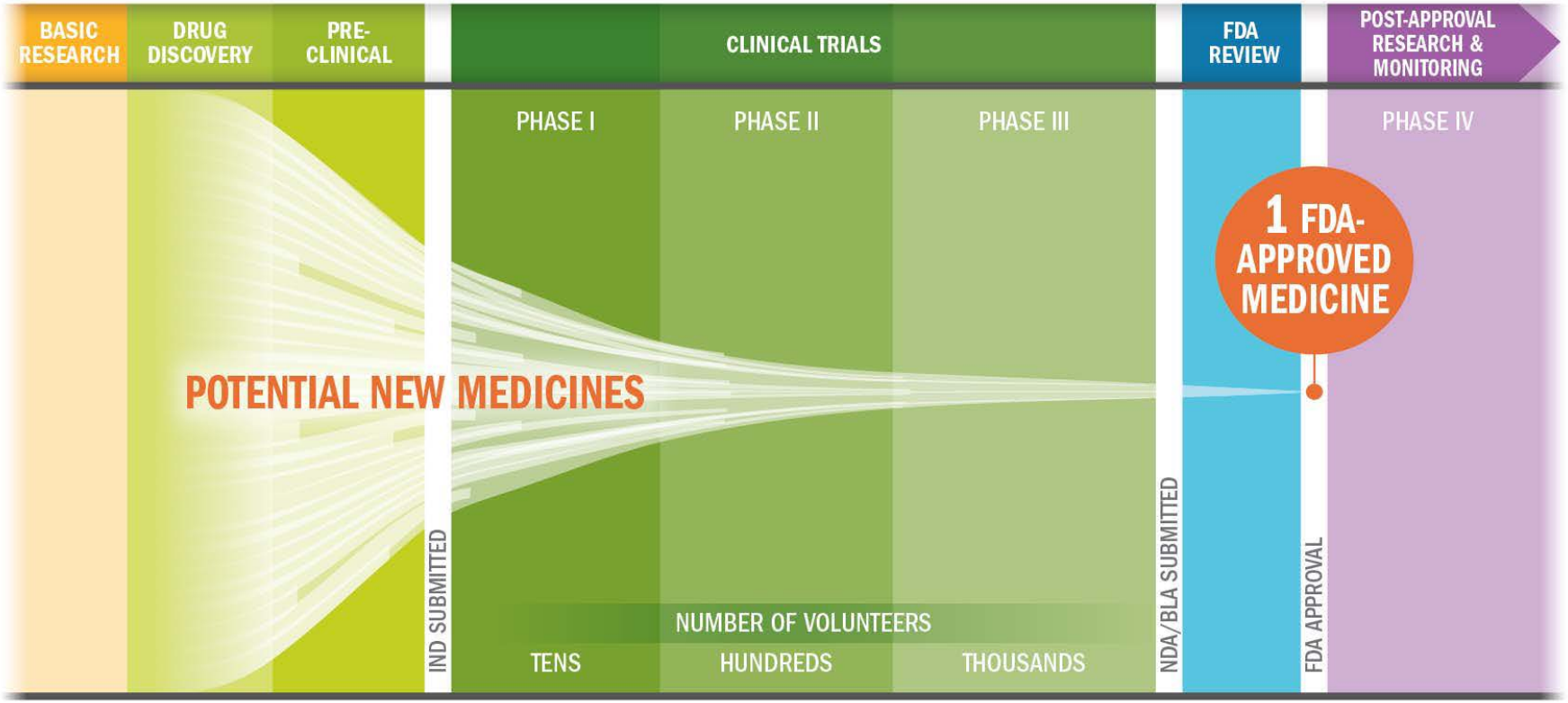
Apixaban	759711	17/12/1999	21/7/2011	17/12/2024	5	7	13
Abiraterone	668144	15/3/1993	1/3/2012	15/3/2018	5	14	6
Belatacept	263466	23/5/2001	15/3/2012	23/5/2026	5	6	14
Ciclesonide	757772	21/4/1999	16/12/2011	21/4/2024	5	7	13
Ciclesonide	776587	20/10/2000	16/12/2011	20/10/2025	5	6	14
Clevidipine	678650	3/11/1994	30/4/2010	3/11/2019	5	11	9
Clevidipine	685532	3/12/1994	30/4/2010	3/11/2019	5	11	9
Corifollitropin	736339	14/1/1998	30/7/2010	14/1/2023	5	7	13
Degarelix	728642	13/4/1998	16/2/2010	13/4/2023	5	7	13
Denosumab	713471	22/12/1997	7/6/2010	22/12/2022	5	8	12
Dronedarone	648569	30/7/1991	2/8/2010	30/7/2016	5	14	6
Dronedarone	728287	16/6/1998	2/8/2010	19/6/2023	5	7	13
Famipridine	657706	1/11/1991	24/5/2011	1/11/2016	5	15	5
HPV Types 16&18	235191	9/10/1995	18/5/2007	9/10/2020	5	7	13
HPV Types 16&18	705739	14/3/1994	18/5/2007	14/3/2019	5	8	12
Hydromorphone	693910	23/6/1995	29/7/2008	23/6/2020	5	8	12
Ibandronic Acid	598270	7/7/1987	12/1/2000	7/7/2012	5	8	12
Imiquimod	581190	14/12/1984	18/8/1997	14/11/2009	5	8	12
Osteogenic Protein	648997	15/10/1990	3/5/2001	15/10/2015	5	6	14
Insulin Aspart	593274	29/8/1986	13/6/2000	29/8/2011	5	9	11
Interferon	561343	14/10/1982	8/4/1994	14/10/2007	5	7	13
Interferon Beta-1B	563962	12/10/1983	5/7/1995	12/10/2008	5	7	13
Iopromide	529565	7/3/1980	12/9/1991	7/3/2005	5	6	14
Ipilimumab	784012	24/8/2000	4/7/2011	24/8/2025	5	6	14
Ipilimumab	201520	24/8/2000	4/7/2011	24/8/2025	5	6	14
Isradipine	536069	17/12/1979	10/1/1994	17/12/2004	5	10	10
Ivabradine	649164	24/9/1992	31/10/2006	24/9/2017	5	9	11
Jap. Encephalitis Vac	740961	2/3/1998	23/8/2010	2/3/2023	5	7	13
Ketorolac	568072	21/3/1983	23/6/1998	21/3/2008	5	10	10
Lacosamide	718577	17/3/1997	20/7/2009	17/3/2022	5	7	13
Lamotrigine	530999	30/5/1980	2/12/1993	30/5/2005	5	8	12
Leflunomide	529341	14/12/1979	11/10/1999	14/12/2004	5	15	5
Lepirudin	604925	23/6/1988	3/4/2000	23/6/2013	5	7	13
Leuprorelin	644581	27/9/1989	26/11/2003	27/9/2014	5	9	11
Pregabalin	677008	18/5/1993	13/4/2005	18/5/2018	5	7	13

For a full list, please contact Medicines Australia. Data in this table has been extracted from publicly available sources, including the ARTG and AusPat.

Appendix C: Impact of EAPD for top 50 medicines - Percentage Price Drop – April 2016



Appendix D: The Research and Development Process for Biopharmaceutical Products



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on DiMasi JA, et al.; Tufts CSDD; FDA Available: http://chartpack.phrma.org/