

**MEDICINES**

*Australia*

**Better Health through Research and Innovation**

**Submission to the Consultation on the Issues paper  
by the Productivity Commission on Intellectual  
Property (IP) Arrangements in Australia**

**30 November 2015**

## Executive Summary

Medicines Australia notes the Productivity Commission's review of Intellectual Property (IP) Arrangements in Australia (the review), and hopes to see that the review is used to strengthen Australia's IP system to further encourage innovation and support investment in new medicines. Currently in Australia, Pharmaceutical patents are granted for up to 20 years, with a potential for up to 5 years extension to reflect the additional and lengthy regulatory burden for approval of a new medicine through the Therapeutic Goods Administration (TGA) and listing on the PBS. Separately, there is a data protection period of 5 years through the Therapeutic Goods Act. Data protection runs concurrent with (in parallel), and not in addition to, a patent term, and usually expires well before the patent.

Previous submissions by Medicines Australia (most notably to the McKeon Review in 2013) have called for the continued strengthening of Australia's IP system to better support investment in new breakthrough medicines, which leads to better health for Australians. We note that the current review focuses 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."

With strong themes of innovation, investment and competition emerging, Medicines Australia calls on the Government to reflect further on how strengthening IP in Australia will help support innovation and growth in the innovative pharmaceutical sector. Without a strong IP system, innovative pharmaceutical companies will have a reduced incentive to invest in new medicines, delaying or denying access that would improve Australians' health and wellbeing.

**Recommendation 1:** Medicines Australia urges the Commission to undertake a high-level and holistic consideration of Australia's innovation and IP arrangements.

**Recommendation 2:** Government should ensure that any proposed changes to intellectual property legislation do not weaken provisions in Australia's current pharmaceutical patent framework.

**Recommendation 3:** Government should maintain the current patent terms and patent term extensions, to ensure that the widening gap between intended and effective patent life for pharmaceutical products does not continue to be eroded thus further diminishing incentives for innovation.

**Recommendation 4:** Government should increase the term of data protection in Australia to align with other jurisdictions.

**Recommendation 5:** Government should reverse its policy of pursuing damages against innovative pharmaceutical companies and introduce instead a clearer notification system.

**Recommendation 6:** Government should implement an effective patent notification system, so that patent holders are able to defend their intellectual property in a timely manner.

## Introduction

Medicines Australia represents the research-based innovative medicines industry in Australia. Over 50 pharmaceutical companies and around 400 locally-owned medical biotechnology firms, operate in Australia. Together, they employ approximately 40,000<sup>1</sup> highly-skilled Australians (with at least 14,000 jobs<sup>2</sup> largely from within our member companies), invest more than a combined \$1 billion per year in R&D<sup>3</sup> and generate nearly \$2.9 billion in exports each year<sup>4</sup>. Our member companies supply up to 86% (by value) of the therapies available on the Pharmaceutical Benefits Scheme (PBS) – medicines and vaccines that help millions of Australians live healthier, longer, more productive lives.

As the Asia Pacific region is poised for growth, there are a number of economic and regulatory opportunities for the Australian pharmaceutical industry. Some of these opportunities may be facilitated through continuing to encourage innovative pharmaceutical manufacturers to produce breakthrough medicines through incentives such as patents. A key issue for pharmaceutical companies continuing investment in Australia is how internationally competitive the intellectual property system is here compared to other jurisdictions.

For decades, the pharmaceutical industry has been a crucial component of Australia's innovation system. Underpinning this has been the strong use of Australia's intellectual property system, especially of patents, by pharmaceutical companies. By investing in research and development partnerships, clinical development and high-tech manufacturing, the industry has not only facilitated and enabled the development and commercialisation of important Australian discoveries, such as the human papillomavirus vaccine for cervical cancer, but also brought high quality medicines and vaccines to Australian consumers. Today, patients in more than 30 countries rely on pharmaceutical products manufactured in Australia to maintain and improve their health.

Currently in Australia, Pharmaceutical patents are granted for up to 20 years, with a potential for up to 5 years extension to reflect additional regulatory burden. This is separate from the provision of data protection afforded through the Therapeutic Goods Act for a period of five years from the date of initial entry on the ARTG, which runs concurrent with (in parallel), and not in addition to, a patent term, and usually expires well before a patent. Nevertheless, both of these IP components have been developed to recognise the additional regulation, time and investment that innovative pharmaceutical companies face in discovering, developing and bringing new medicines to market.

### **Innovation and Investment in Australia is underpinned by a strong IP system**

Continued innovation is fundamental to Australia's economic well-being and industries which rely on IP play a central role in driving economic growth, jobs, and competitiveness. As the 2015 Intergenerational Report (IGR) noted, Australia is poised for growth through "harnessing future opportunities to support innovation, adopt new technologies, facilitate

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<sup>1</sup> Comprises bio-medical research, biotechnology firms, originator and generic medicines companies and service related segments including wholesaling and distribution: Department of Innovation, Industry, Science and Research, Pharmaceutical Industry Fact Sheet, available at:

[www.innovation.gov.au/Industry/Pharmaceuticals/Pages/AustralianPharmaceuticalsIndustryFactSheet.aspx](http://www.innovation.gov.au/Industry/Pharmaceuticals/Pages/AustralianPharmaceuticalsIndustryFactSheet.aspx)

<sup>2</sup> IBIS World, Melbourne, 2014, Pharmaceutical Product Manufacturing in Australia: Market Research Report

<sup>3</sup> Australian Bureau of Statistics 2012, 'Business Expenditure Report on R&D'

<sup>4</sup> Australian Bureau of Statistics 2015, 'International Trade in Goods and Services': March 2015

foreign trade and investment and foster competition [which] can boost future productivity growth and living standards.” Strong intellectual property systems foster an innovative culture and provide incentives for increases in technology transfer, foreign direct investment and local R&D capacity<sup>5</sup>. The right policy settings for IP are therefore important; ensuring that Australia has a globally competitive intellectual property system is the key to our future health and economic wealth. Such a system will help:

- increase the return on inventions and developments made possible by the significant level of public support for medical research in Australia
- provide greater incentives and certainty for the commercialisation of local Australian health technology inventions and developments – supporting Australia’s rapidly developing biotechnology sector
- attract additional global investment in Australia’s research and development efforts and
- increase access to new medicines and vaccines for Australian patients (including early access via increased clinical trial activity)

Over the past decade, a number of empirical studies have been published on the positive and cumulative economic effects of IP rights. In particular, a growing body of evidence suggests a positive link between the strengthening of IP rights and economic development, job creation, technology transfer, and increased investment and innovation<sup>6</sup>.

For example, the importance of IP has been highlighted in a study by the US Patent and Trademark Office whose findings would be of similar relevance to the Australian economy. This study found that the entire US economy relies on some form of IP, because virtually every industry either produces or uses it. IP intensive industries (of which pharmaceutical and medicines fall within the top 10 in terms of patent intensity) contributed almost 35% of US Gross Domestic product in 2010 and every two jobs in IP-intensive industries support an additional job elsewhere in the economy, with a third of all jobs being directly or indirectly attributable to the most IP-intensive industries. IP intensive industries also supported higher wages and a higher level of education than non IP intensive industries.<sup>7</sup>

Research by the Centre for International Economics (CIE) (2013) for IP Australia highlights that innovation is often solely contingent on patents and other forms of IP. The risks associated with R&D for pharmaceuticals is multifaceted – in long development times, high investment costs, multiple failure points through the concept, non-clinical and clinical trial phases and lengthy periods until reimbursement. As noted by CIE, there are success stories, but overall the sector’s R&D story is characterised by sunk costs and high failure rates. It is

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<sup>5</sup> For example, in an Organisation for Economic Cooperation and Development (OECD) study (Park, WG and Lippoldt, D (2003). “The impact of trade-related intellectual property rights on trade and foreign direct investment,” OECD publishing), Park and Lippoldt compared World Trade Organization (WTO) members (ie signatories to the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)) and non-members, and found that, overall, IP rights tend to have a positive impact on foreign direct investment (FDI). With the exception of least developed countries, which may not yet have implemented the TRIPS Agreement due to transition period allowances, WTO members have higher levels of FDI than non-members.

The OECD’s Cavazos et al. (Cavazos, R et al (2010) “Policy complements to the strengthening of IPRs in developing countries,” OECD Trade Policy working papers, No.104, OECD publishing) looked at research and development (R&D) expenditure and technology transfer as well as FDI and found that a 1% change in the strength of a national IP environment (based on a statistical index) is associated with a 2.8% increase in FDI inflows, a 2% increase in service imports, and a 0.7% increase in domestic R&D.

<sup>6</sup> Ibid.

<sup>7</sup> Economics and Statistics Administration and the United States Patent and Trademark Office. “Intellectual Property and the US economy: Industries in Focus”, March 2012

estimated that up to 46% of sunk costs in R&D on new molecular entities are incurred in the innovation phase, rather than the development phase. This high proportion of cost in the initial stages of development is a significant barrier to more innovative research being undertaken, and is an opportunity for policy frameworks to address by providing greater incentives to undertake R&D.

### **The Australian Innovative Medicines Industry and Intellectual Property**

The pharmaceutical industry in Australia is complex and involves a number of complicated, government-administered systems, schemes and processes, including R&D incentives, the patent system, the regulatory approval process and the PBS listing and pricing processes. Medicines Australia is concerned that the review's scope may not capture some of this complexity with the Commission tasked to: "consider whether IP arrangements strike the right balance between incentives for innovation and investment and the interests of both individual businesses in accessing ideas and products."

**Recommendation 1:** Medicines Australia urges the Commission to undertake a high-level and holistic consideration of Australia's innovation and IP arrangements.

### IP and Access to new Medicines through the PBS

The PBS underpins the Australian Government National Medicines Policy which aims to improve positive health outcomes for all Australia through access to and quality use of medicines. Subsidising patients' prescription charges, enables affordable access to cost-effective medicines for all Australians. A decade of reform mechanisms has led to a strong and sustainable PBS that is one of the most cost effective government policies. There is a strong link between pharmaceutical companies' investment decisions to undertake research and development in new innovative medicines and the likely cost effective reimbursement of that medicine through the PBS. Further, changes to the IP system will have flow on effects to relative cost effectiveness and return on investment from new innovative medicines. This in turn will influence investment in R&D decisions by innovative pharmaceutical companies, which may impact on early access to new medicines for Australians.

Previous studies have shown that it takes between 10 and 15 years to develop a new medicine, at an average cost of US\$2.6 billion<sup>8</sup>. Given this long development phase and high level of risk (up to 93% of potential therapeutic molecules do not make it beyond clinical stage<sup>9</sup>), there needs to be a system that provides an appropriate incentive to continue investment in providing innovative pharmaceuticals. Once the new medicine is found to be effective, Australia's reimbursement system is designed to ensure that the most cost effective treatment is made available through the PBS. The average time to secure a new cost-effective molecule on the PBS is 22 months, which impacts the return on investment and may impede companies progressing new products to seek reimbursement and therefore limiting access to affordable medicines for Australians.

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<sup>8</sup> International Federal of Pharmaceutical Manufacturers and Associations, Geneva. 2013. Incremental Innovation: Adapting to Patient Needs; Tufts Centre for the Study of Drug Development, Boston, 2014. Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 billion.

<sup>9</sup> Previous studies have shown that for every 10,000 promising chemical entities, on average, only one will become a profitable new medicine (Tufts 2014).

Without a strong IP system that supports a period of market exclusivity, there is little incentive for a new medicine to be brought to market, limiting or denying access to life altering innovative pharmaceuticals.

### **Australia's IP system needs to be internationally competitive**

Australia's IP system does not operate in isolation. As reported by IP Australia<sup>10</sup>, a large proportion of patent applications are submitted from offshore. Given the international dispersion of our industry, a pharmaceutical product is generally the result of R&D that is undertaken in a number of countries. As a result of this globalisation of R&D, there is a need to ensure that Australia's IP system is aligned with international systems so as to not inadvertently discourage new research being brought to Australia.

A number of international organisations<sup>11</sup> have been progressive in promoting strengthened IP systems. Australian needs to maintain a world class IP system that encourages and supports local R&D, through a policy environment and framework that is competitive.

**Consultation Question:** *Are there other factors relating to efficiency, effectiveness, adaptability and accountability that the Commission should consider as part of the inquiry?*

Medicines Australia believes that there are opportunities to improve the efficiency and effectiveness of Australia's IP system. Research by Cornell University and the World Intellectual Property Organisation (WIPO) shows that Australia compared to other countries has a middle of the road system, with some improvements possible. As noted by the Global Innovation Index produced by Cornell University and WIPO<sup>12</sup>, Australia ranked 17th out of 141 countries, behind countries such as New Zealand, Ireland, Luxembourg and Singapore. This ranking indicates that there is room for potential improvements to be made at the systems level to further support innovation. It was noted that areas for improvement for Australia's system were in human capital and research as well as knowledge and technology outputs.

Medicines Australia believes that there is scope for improvement in our current IP system that would further support innovative pharmaceutical companies to invest and continue innovating. Two key policy mechanisms to use are patents and data protection.

### **Benefits of Patents**

It is critical that pharmaceutical inventions and innovations remain eligible for patents. A strong, stable and predictable intellectual property system is essential to Australia's ability to attract investment in R&D and high-tech manufacturing. It is also a cornerstone to the ability of Australian patients to receive the latest treatments as quickly as possible; and the Australian medicines industry remains committed to constantly improving access to new health technologies for Australian patients. This is, in part, why Medicines Australia publicly welcomed the passing of the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* legislation in March 2012. By guaranteeing a clearly defined period of market exclusivity, patents (and other forms of intellectual property rights such as data protection) act to mitigate the commercial risks of bringing new medicines to market, making it

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<sup>10</sup> IP Australia 2015. Australian Intellectual Property Report 2015. [http://www.ipaustralia.gov.au/about-us/what-we-do/reports/ip\\_report\\_2015/](http://www.ipaustralia.gov.au/about-us/what-we-do/reports/ip_report_2015/)

<sup>11</sup> Please see Pharma, World Intellectual Property Organisation and the International Alliance of Patients Organisation for further detail.

<sup>12</sup> WIPO 2015. The Global Innovation Index 2015 [http://www.wipo.int/edocs/pubdocs/en/wipo\\_gii\\_2015.pdf](http://www.wipo.int/edocs/pubdocs/en/wipo_gii_2015.pdf)

significantly more likely for private enterprises to continue to invest in R&D for new medicines.

**Recommendation 2:** Government should ensure that any proposed changes to intellectual property legislation do not weaken provisions in Australia’s current pharmaceutical patent framework.

**Consultation Question:** *What evidence is there that patents have facilitated innovations that would not have otherwise occurred or have imposed costs on the community, including by impeding follow-on innovations? Do patents provide rewards that are proportional to the effort to generate IP?*

It is widely recognised that there is a need for a market based incentives to encourage risky R&D. This is particularly important for ensuring that research is translated into downstream innovations<sup>13</sup>. Patents are one instrument used to achieve market exclusivity that mitigate the extraordinary risks that companies take when they invest in bringing new products to patients. Previous research has shown that patented drugs are an important revenue stream for pharmaceutical companies that allow them to continue to invest in new research and development. Without this level of market exclusivity, the costs of investing in new innovative pharmaceuticals would be prohibitive.

Whilst having a patent and period of market exclusivity is an important incentive to invest in research and development, there is a continued decline in the effective patent period. Whilst patents are an important part of the system, the effective period is being eroded by increased regulatory requirements, scientific testing procedures becoming more complex and the operation of competition in which competitors are ready to launch at risk when the market exclusivity period may not have expired. The fact that almost all biopharmaceutical innovation has occurred in countries with strong IP (like the US and most of Europe) but not in countries with weak IP (like India) is evidence of this. Although other factors are clearly relevant to creating an innovative biopharmaceutical ecosystem, strong but balanced IP is an indispensable part of this ecosystem.

As Medicines Australia has previously commented<sup>14</sup>, there is, in fact, a strong case for granting longer patent term extensions. The average effective patent life for pharmaceutical products in Australia is between 11 and 12 years, including any extensions of term. This is significantly less than the maximum effective patent life of 15 years intended through patent term extension for pharmaceutical products, and far less than the 20 or 25 years of protection that Australian patents provide “on paper”. Given most medicines have to be on the market for several years, sometimes decades, before they breakeven<sup>15</sup> – that is, cover the cost of their development and begin delivering revenues to their manufacturers (which can then be reinvested in R&D) – the case for further reducing patent terms would have a detrimental effect on investment in developing new medicines.

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<sup>13</sup> Centre for International Economics 2013. Economic Analysis of Human Gene Patents. [http://www.thecie.com.au/?page\\_id=358](http://www.thecie.com.au/?page_id=358)

<sup>14</sup> Medicines Australia 2013. Submission to the Pharmaceutical Patents Review <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20121218-sub-Pharmaceutical-Patents-Review.pdf>

<sup>15</sup> Henry Grabowski, 2008, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, Nature Reviews Drug Discovery.

**Recommendation 3:** Government should maintain the current patent terms and patent term extensions, to ensure that the widening gap between intended and effective patent life for pharmaceutical products does not continue to be eroded thus further diminishing incentives for innovation.

Accordingly, there is a strong and enduring rationale for making sure that no changes are implemented that would, in any way, undermine the ability for patent holders to defend their intellectual property. 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 the initial risk, are permitted to profit from new and improved products. As discussed in the Commission's issues paper, previous research has shown that innovation is likely to be increased due to patents in the pharmaceuticals, biotechnology and medical instruments sectors<sup>16</sup>.

As noted in the Commission's issues paper, there is contention on the impact of patents and IP on competition for pharmaceutical products. As noted on page 6 "The balance is particularly contentious in pharmaceuticals. Cases exist where patents have allowed pharmaceutical companies to charge what some consider to be unconscionable high prices for life-saving medicines. New compounds and biologic drugs, and their safety and efficacy are no doubt expensive to develop and test and consumers are often willing pay almost anything to access them."

Medicines Australia is concerned that this portrayal suggests that the prices paid for innovative pharmaceuticals is unfair and not reflective of the required investment. Nor does it reflect the rigorous health technology assessment (HTA) system which operates in Australia. The HTA system requires every medicine to demonstrate that it is value for money (cost effective) prior to their reimbursement. Additionally there are multiple mechanisms within the system whereby this value-for-money assessment is managed and/or reviewed. There is a risk that unsubstantiated reductions in prices may lead to further declines in investment in Australia. This was one of the reasons for industry disinvestment in the 1980s, with a similar environment of suppressed prices paid for pharmaceuticals coupled with the rising costs of R&D<sup>17</sup>.

The issues paper also raises the concept of ever-greening. Medicines Australia in previous submissions<sup>18</sup> has highlighted that this concept should not be confused with patenting of incremental technological or other innovative advances. Regardless of whether subsequent patents are applied for or granted, no later granted patent can extend the term of an earlier one. It is just not possible. By definition, a second patent cannot be issued for the same invention. When patents on the original inventions expire, then imitators are free to copy the original from a patent system perspective. Subsequent patent applications will be for other innovations which build on the prior original invention and will usually be progressively narrower in scope. Importantly, subsequent patent applications do not stop the original patent for an older technology from expiring.

### **Data Protection (Data Exclusivity)**

<sup>16</sup> Hall, B. and Harhoff, D. 2012. *Recent Research on the Economics of Patents*. Working paper, 17773, NBER Working Paper Series.

<sup>17</sup> Industry Commission 1996. *The Pharmaceutical Industry*. Volume 1: The Report. Report No.51. available: <http://www.pc.gov.au/inquiries/completed/pharmaceutical/51drugsv1.pdf>

<sup>18</sup> Medicines Australia 2013. Submission to the Pharmaceutical Patents Review. <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20121218-sub-Pharmaceutical-Patents-Review.pdf>

Data protection (also called data exclusivity) is a form of intellectual property which is not globally competitive in either its length or scope in Australia and is separate to patent protection. The data required by the TGA before a new medicine is registered for sale in Australia is extensive and is derived from years of basic research, pre-clinical research and numerous clinical trials. Without data protection, generic companies can seek to rely on original data which they played no part in generating to bring competing products to market. This is relevant where the patent provides insufficient protection or there is no existing patent and so, in the large majority of cases, will have expired well before a generic application is made. It is nonetheless increasingly important as biological medicines become more complex and uncertain in their patentability. As noted in the issues paper, Australia's data exclusivity term is currently 5 years from the date of initial registration on the ARTG. It does not allow for the lengthy period between ARTG entry and subsequent reimbursement on the PBS and does not preclude the ability for generic companies to 'springboard'. 5 years is among the shortest in the Organisation for Economic Cooperation and Development (OECD), and Medicines Australia contends that it is inadequate.

Previous evidence<sup>19</sup> shows that a shorter term may reduce the originator's return on investment, in turn reducing research and development (R&D) by companies and the economic and health benefits that flow from R&D. Among other reports, the 2013 "Strategic Review of Health and Medical Research in Australia" (the McKeon Review) called on the Government to extend the term of data protection to harmonise with global best practice. We note that there is a disconnect between innovative pharmaceutical products and that of veterinary medicines for data protection, with veterinary medicines having a 10 year data protection period – double that of pharmaceuticals for humans. Additionally the recently released text of the Trans Pacific Partnership Agreement (TPPA) also increases agricultural data protection provisions to 10 years.

Previous submissions by Medicines Australia has called for an extension of data protection<sup>20</sup>. Extending the term of data protection in Australia is important as:

- There is a demonstrable link between extending data protection and achieving better health outcomes for Australian patients. Many innovative pharmaceutical companies include the data protection system in their decision on whether and when to bring a new medicine to Australia;
- Aligning Australia's system with the leading OECD nations would send a powerful signal to the international business community that Australia values innovation; and
- It would foster quality research programs on new medicines by encouraging researchers to commercialise their innovations regardless of the patent status, or concerns about future patent challenges.

**Recommendation 4:** Government should increase the term of data protection in Australia to align with other jurisdictions.

**Consultation Question:** *Do data protection arrangements limit the ability of parties to understand breakthroughs and build on innovation? Could Australia's arrangements for the protection of test data be improved?*

<sup>19</sup> Frost and Sullivan 2014. *The Impact of Australia's Data Exclusivity Regime on Australia's Healthcare System*.

<sup>20</sup> Medicines Australia 2013. *Submission to the Pharmaceutical Patents Review*. <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20121218-sub-Pharmaceutical-Patents-Review.pdf>

We are aware of some instances already in which biological medicines were not brought to the Australian market due to Australia's short data protection period. Increasing data exclusivity would not have a significant impact on Australian's access to the latest medicines and would not increase the prices which patients pay through the PBS.

In fact, aligning Australia's data protection system with globally competitive benchmarks would:

- Increase access to new medicines and vaccines for Australian patients (including early access to medicines via increased clinical trial activity),
- Attract additional global investment in Australia's research and development efforts,
- Increase the return on inventions and developments made possible by the significant level of public support for medical research in Australia, and
- Provide greater incentive and certainty for the commercialisation of local Australian health technology inventions and developments – supporting Australia's rapidly developing biotechnology sector.

Medicines Australia has consistently presented modelling<sup>21</sup> to government which shows that any modest, short-term increase in the amount government spends on pharmaceuticals is well and truly offset by the savings being delivered through recent amendments to the PBS.

The increased data protection would support the economic potential of the Australian biotechnology sector, and could help create new investment opportunities in our best research centres, scientists and doctors as well as encourage earlier access to new, breakthrough medical treatments for Australians.

Australia's current five-year data exclusivity provision lags behind our global competitors and collaborators such as the United States (up to twelve years for biologics), Canada (eight years), the EU (up to eleven years), and Japan (eight years)<sup>22</sup>. This puts potential investment in Australian innovation at risk and is one reason why our scientists look overseas to get their inventions turned into widely available products for consumers. That means Australia misses out on the economic benefits of the innovation, including jobs and the tax streams from these medical breakthroughs.

***Consultation Question:*** *The Commission seeks input on the impact of Australia's international IP obligations on domestic innovation, production, trade and consumption. Has a move towards stronger IP rights served Australia's economic interests? Is there a case for Australia to pursue stronger IP rights in excess of minimum standards for particular types of rights or specific technologies? What are the main constraints imposed on IP Policy imposed by the TRIPS agreement and other international agreements?*

Medicines Australia notes that recent international trade agreements have focused on pharmaceutical IP. Under the recently agreed Trans Pacific Partnership Agreement, the proposed wording includes "provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party". We are hopeful that the Government will expedite the implementation of this component of the agreement and ensure that it has a tangible effect.

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<sup>21</sup> Examples include Frost and Sullivan 2014. *The Impact of Australia's Data Exclusivity Regime on Australia's Healthcare System*. And Access Economics 2010. *Evaluating the economic impact of extending data exclusivity in Australia*.

<sup>22</sup> Medicines Australia 2015. Open Letter to Parliament on TPP & IP. <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20150304-ltr-Open-Letter-to-Parliament-on-TPP-and-IP.pdf>

## **Current Opportunities and Challenges**

With supportive policy settings, our industry has the potential to be one of the key innovative industries for Australia's future, as identified by the Government in their Industry Competitiveness Agenda<sup>23</sup>. The next decade will provide enormous opportunities, with the Asia Pacific region set to drive huge demand for medicines. This growth will be driven by a growing middle class and expanding health systems<sup>24</sup>. We are strategically located, with a highly-skilled workforce and a long-standing reputation for manufacturing safe, high-quality medicines and vaccines. To maintain this reputation, it is important to ensure that a strong intellectual property framework is retained.

Despite this opportunity, there are several challenges facing the industry that are making it more difficult to achieve this aforementioned potential growth. In fact, the local industry has been in decline now for a number of years. Historically, medicines had been Australia's leading manufactured exports, but recently have fallen and are now ranked second<sup>25</sup>. In fact, Australian pharmaceutical exports plummeted by nearly a third from \$4.3 billion to \$2.9 billion between 2012 and 2014. As a result of this decline in exports, eight pharmaceutical manufacturing plants have either closed or been significantly downsized since 2007<sup>26</sup>. It is imperative to limit further divestment by innovative pharmaceutical companies in Australia through communicating an intention to retain and enhance a strong intellectual property system.

Another challenge in the industry has been that since 2007, as many as 2,500 jobs have been lost across the Australian pharmaceutical industry. Ongoing contraction of the sector will undoubtedly apply even more pressure on jobs due to the difficult fiscal settings: downward pressure on prices for pharmaceuticals and limited investment incentives for R&D, intellectual property or direct foreign investment. In this context, the innovative medicines industry is sensitive to any further policy changes that would alter the current business environment.

### Compensatory Claims

The innovative pharmaceutical industry relies on strong intellectual property protection in order to invest heavily in R&D, and to bring new and essential medicines to the Australian market. However, the Commonwealth Government has recently taken steps that threaten to undermine the strength and stability of IP law in Australia.

The Commonwealth has commenced damages claims against innovative companies through the courts as a party to pharmaceutical patent disputes following an interlocutory injunction. The damages sought by the Commonwealth relate to the PBS savings the Government may have achieved through the mandatory (or statutory) price reduction and price disclosure process if a generic product had been allowed to enter the market, but for the interlocutory injunction.

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<sup>23</sup> Australian Government 2014. Industry Innovation and Competitiveness Agenda.

<sup>24</sup> Australian Government 2012. Australia in the Asian Century.

<sup>25</sup> Ibid.

<sup>26</sup> Ibid.

**Recommendation 5:** Government should reverse its policy of pursuing damages against innovative pharmaceutical companies and introduce instead a clearer notification system.

The Commonwealth's claims could have irreversible and detrimental effects on R&D, foreign direct investment and international trade in Australia through the erosion of intellectual property rights and the destabilisation of the pharmaceutical industry as a whole.

Australia is the one of the only countries in the world pursuing such claims. Inward investment is affected by negative international perceptions regarding Australia's IP regime and this unique claim sets Australia apart from other investment locations. The Commonwealth should instead consider engaging in a constructive dialogue with both generic and innovative companies to strengthen the Therapeutic Goods Act and IP law in Australia to facilitate an earlier resolution of disputes.

Rather than take the industry to court, the Government should work with the industry to create business certainty and improve efficiency in the interests of Australians, the Government, and the pharmaceutical industry to create a policy environment that fosters innovation and manufacturing of new medicines.

The unintended consequences of this policy will potentially:

- Negatively impact trade, as foreign companies will reconsider investing in or trading with Australia;
- Stagnate innovation, as the value of Australian pharmaceutical patents (which are property rights) will be significantly diminished, acting as a disincentive to invest in R&D;
- Reduce access to innovation, as fewer innovative medicines will be developed for the Australian market; and
- May lead to fewer products launched into the Australian market, reducing access to new medicines.

If the Government wishes to address purported issues of delays to price disclosure related savings from generic uptake arising from interlocutory measures, this could be better achieved through strengthening the patent notification system. In accordance with the intent of the AUSFTA, timely and direct notification to innovator companies of generic applicants would enable earlier resolution of patent disputes. A stronger patent enforcement system would avoid the need for the claim for damages and would leave the government, taxpayers and the industry better off.

**Recommendation 6:** Government should implement an effective patent notification system, so that patent holders are able to defend their intellectual property in a timely manner.

Earlier court determination of the validity of a patent would avoid the need to consider the validity during an 'at risk' period. This would avoid the need for the Commonwealth's legal claims and would provide more certainty to industry. It would also be a good outcome for government due to a reduced drain on court resources.

## **Investment in Research & Development**

The pharmaceutical industry is an integral component of Australia's innovative industries<sup>27</sup>. Our industry already undertakes more than a combined \$1 billion of R&D annually in Australia. To ensure that this continues, a strong intellectual property system should be upheld<sup>28</sup>. This high level of investment has numerous important benefits for the country, including enhancing the physical health and wellbeing of Australians and helping to contain health costs. It has been estimated that a dollar invested in Australian health R&D will return an average health benefit of \$2.17<sup>29</sup>.

Additional investments in R&D generates new intellectual property, enhanced local infrastructure and production capacity, and new jobs in advanced manufacturing and other highly-skilled fields in Australia. There is significant scope for further expansion of our industry's medical R&D activity in the short to medium term. This expansion will by no means be automatic – it will only happen if Australia distinguishes itself as a desirable and genuinely competitive location in which to perform such research, especially as competition for R&D investment increases. If there is a signal that Australia is weakening the intellectual property system through reducing the patent term or the ability to secure patent restoration, international investment could decline.

Furthermore, diminution of Australia's intellectual property regime is misaligned with the Government's broader agenda to grow investment. An example of this is the recent Austrade Clinical Trials Capability Report<sup>30</sup>, which emphasises Australia's strong intellectual property system. This misalignment between encouraging further investment in Australia by highlighting the strong and supportive intellectual property system on one hand, but removing an important component on the other, sends mixed signals, creating uncertainty around whether Australia has a supportive environment that encourages investment by pharmaceutical companies.

## **Conclusion**

With strong themes of innovation, investment and competition emerging, Medicines Australia calls on the Government to reflect further on strengthening IP in Australia to support innovation and growth in the innovative pharmaceutical sector. Without a strong IP system, innovative pharmaceutical companies will have a reduced incentive to invest in new medicines, delaying access that would improve Australians' health. Medicines Australia also appreciates the opportunity to provide a further supplementary submission closer to the release of the draft report by the Productivity Commission.

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<sup>27</sup> Department of Industry, Canberra, 2014, Australian Industry Report

<sup>28</sup> Australian Bureau of Statistics 2012, 'Business Expenditure Report on R&D'

<sup>29</sup> Access Economics 2008. Exceptional Returns: The Value of Investing in Health R&D in Australia II

<sup>30</sup> Austrade 2015. Health and Wellbeing Industry Capability Reports <http://www.austrade.gov.au/ArticleDocuments/2814/Clinical-Trials-Capability-Report.pdf.aspx>