06. Intellectual Property Recognises & Encourages Innovation

Medicines Australia

Better health through research and innovation

Intellectual Property

Australia has a generally strong intellectual property (IP) system, however, maintaining a stable and reliable IP regime is critical.

Australia's patent system, administered through IP Australia, aims to encourage future research and development that delivers value to the economy and the community. In addition, it is the well-accepted right of the IP holder to defend and protect their intellectual property, as the discoverer and/or inventor of the innovation. The promotion and protection of IP spurs further economic growth; creates new jobs and industries; and enhances quality of life.

Summary

Intellectual property rights, particularly patents, are a universally accepted mechanism for the recognition of the value of innovation. A patent is a right that is granted for any substance, device, method or process that is new, inventive and useful and proffers a legally enforceable right to commercially exploit the invention for the life of the patent. Patents are recognised as a significant contributor to the success of new inventions and in turn encourage research and development of new, innovative products, promote technology transfer, and incentivise trading partners to provide similar rights.[1]

IP rights and responsibilities allow an appropriate period of exclusivity to market an invention and recoup the costs of upfront investment and risks taken to discover, invent and develop the innovation. As medicines, vaccines and biotherapeutics have extensive regulatory requirements leading to extended pre-market development timeframes and additional regulatory delays to market access, pharmaceutical patents can apply for a patent term extension of up to five years. This is to ensure there is sufficient opportunity to recoup investment and encourages continued research and further innovation.

Medicines Australia strongly supports the Australian Government in the implementation of IP measures that enforce these objectives and recommends attention is placed on building commercialisation capability by encouraging investment in, and innovation by, the pharmaceutical industry.

Challenge	Solution
Australia is lagging behind comparable countries with regard to Regulatory Data Protection that creates a disincentive for innovative IP to be retained in Australia.	Increase data exclusivity provisions to align with our international trading partners and comparable jurisdictions.

Challenge	Solution
Australia adds a further disincentive for legitimate patent holders to defend their IP through the lack of adequate patent notification and the subsequent pursuit of market sized damages.	Implement an effective patent notification system as intended under the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the Australia/US Free Trade Agreement (AUSFTA) and; Reverse the policy of seeking Commonwealth market sized damages as a party to patent disputes between innovator and generic companies.

Challenge	Solution
Australia's Productivity Commission's report and Intellectual Property Amendment Legislation further erodes a stable and predictable IP system through the proposal to introduce Crown Use and Compulsory Licensing provisions that are disproportionate to the desired outcome.	Maintain a strong and stable IP environment that meets Australia's International obligations and maintains Australia's competitiveness as an innovative country.

Background

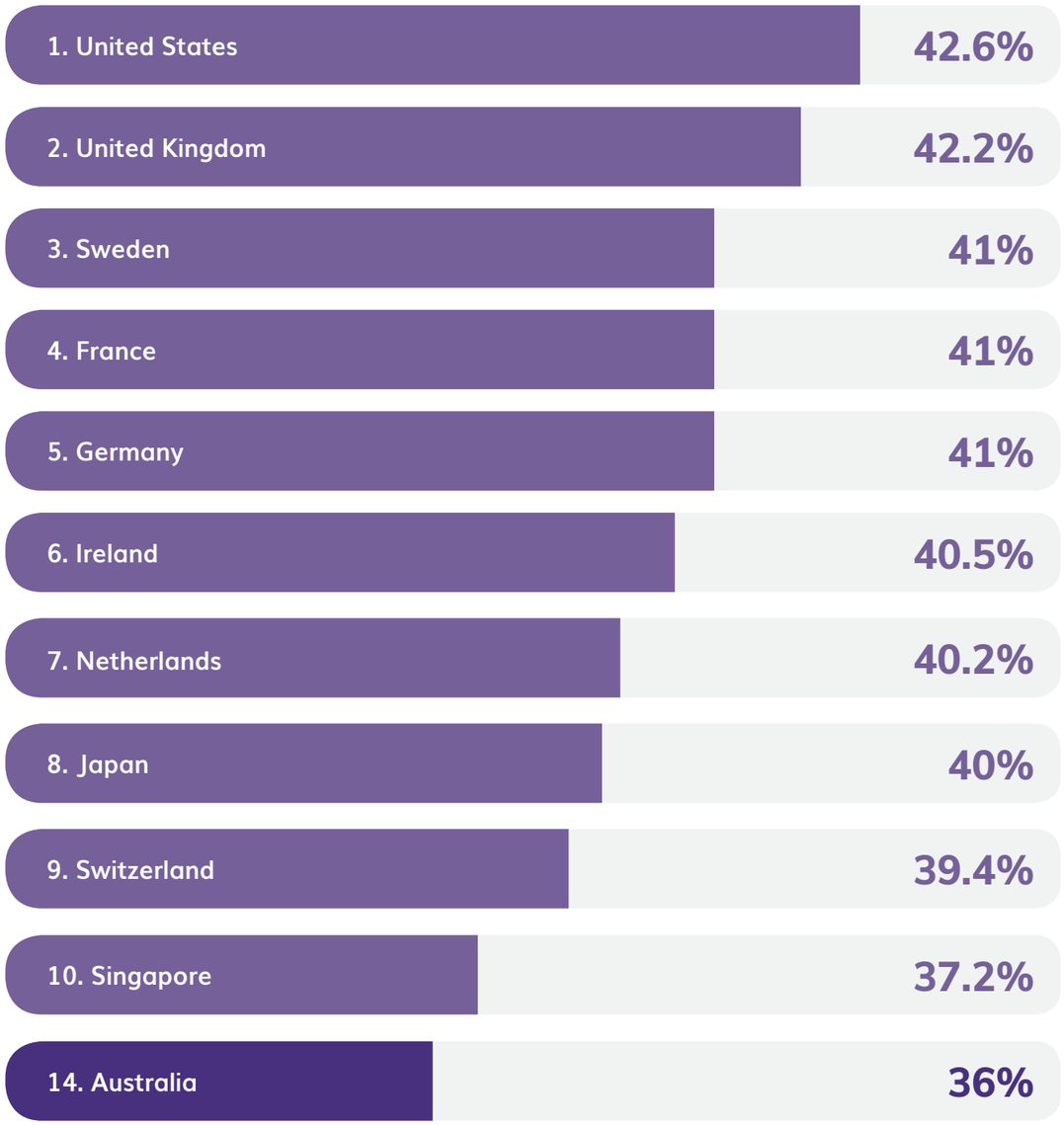
Australia Claims To Have An Emphasis On Innovation

Australia claims to have an emphasis on innovation. We rest on the knowledge that Australia has a strong academic and scientific culture and enviable education and research reputation. Coupled with advanced rules of law and stable global alliances, Australia has weathered global financial downturns and boasts over 20 years of economic success and growth. We are well positioned to be a leader in innovation.

Accordingly, the Global Innovation Index informs us that countries with robust IP regimes;[2]

- are **53% more** likely to experience increased R&D activity
- have **19 times** more early phase clinical trials
- are **33% more** likely to receive private-sector investment in R&D activities
- are **39% more** likely to attract foreign investment
- are **30% more** likely to attract venture capital and private equity funds
- are **53% more** likely to employ high-skilled and high paid workers
- are **26% more** competitive
- are **twice as likely** to produce and export complex, knowledge-intensive products
- are **55% more** likely to adapt to sophisticated, state-of-the-art technology
- have **over 500 more** high-value inventions per million population
- have **over 4 times more** online and mobile content generated

Key Fact: Australia ranks 14th out of 50 on the Global Innovation Policy Centre's IP Index.[3]



> **Australia has a generally strong and stable intellectual property system, making it largely comparable to intellectual property systems in Europe, the United Kingdom, and Japan.**

However, there are a few key areas where Australia has fallen behind. This has led to Australia's innovation ranking falling from 20th in 2018 to 22nd in 2019 on the World Intellectual Property Organization's (WIPO) Global Innovation Index.[4]

The main laws and regulations that provide the basis for Australia's IP system are:

- *Patents Act 1990 and Patents Regulations 1991*
- *Trade Marks Act 1995 and Trade Marks Regulations 1995*
- *Designs Act 2003 and Designs Regulations 2004*
- *The Therapeutic Goods Act 1989*

IP Australia is the public authority that administers the legislation within the Australian Government's portfolio of Industry.

The Patents Act 1990 provides an incentive for the cost and risk of research by providing a time-limited exclusive right to market a product.

In 1999 the Australian Government introduced the right for pharmaceutical companies to seek "patent term restoration" – that is, the right to apply for up to five years of extension of patent term to restore time lost to regulatory requirements.

The reasons for granting the opportunity for patent term extension were:

- to compensate pharmaceutical patent holders for the time taken to comply with the regulatory requirements for drug development including, but not limited to, the time taken by the regulator, the TGA,[5] to grant regulatory approval for new products
- to provide incentives for pharmaceutical companies to continue to invest in drug development R&D in Australia

Patent term extension is aimed at providing an effective patent term that is consistent with other international jurisdictions from the date of first entry of a product on the Australian Register of Therapeutic Goods. For technology industries, 15 years is considered a reasonable period to recoup the significant costs of investment and compensate for the high upfront risks. However, in Australia, recent reporting shows that the average effective patent life for a new medicine is commonly only 12 years.[6]

Challenge	Solution
Australia is lagging behind comparable countries with regard to Regulatory Data Protection that creates a disincentive for innovative IP to be retained in Australia.	**Increase data exclusivity provisions to align with our international trading partners and comparable jurisdictions.**

Operating in parallel to any patent term is a five-year period of data exclusivity that commences at the time a new pharmaceutical product is entered on the ARTG. This period of Regulatory Data Protection (RDP) prohibits other companies from using or relying on the data generated by the innovative research company's clinical development programme, without having conducted any clinical research or borne any of the risks. RDP is particularly important for products where patent protection is not available or has expired. Data exclusivity usually expires several years before the patent.

> **Key Fact:** Animal and Agricultural data protection is 10 years compared to 5 years for Human pharmaceuticals. Therefore, in Australia, animal and plant IP is valued higher than IP that improves human lives.[7]

As part of the early iterations of the Trans Pacific Partnership Agreement, the Australian Government acknowledged that Australia had fallen behind comparable countries and included provisions to extend RDP to 8 years for Biologics. This provision was suspended when the US withdrew from the TPP, but the case for improved data exclusivity remains. Canada, Japan and the EU have a minimum of 8 years Data Exclusivity while the United States has up to 12 years for Biologics.[8]

The more Australia is aligned with other countries, the more we will compete effectively in the global race for investments in research, biotechnology and commercialisation of innovative medicines. Our current system of five years' data exclusivity and an average 12 years of effective patent life are less attractive than comparable innovation and investment driven systems in other OECD countries with whom we compete.

> **Key Fact:** It takes an investment of US $1.59-2.6 billion[10] to support a medicine in its 10-15 year journey from discovery until it can be made available to the Australian public.[11]

Challenge	Solution
Australia adds a further disincentive for legitimate patent holders to defend their IP through the lack of adequate patent notification and the subsequent pursuit of market sized damages.	Implement an effective patent notification system as intended under the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the Australia/US Free Trade Agreement (AUSFTA) and; Reverse the policy of seeking Commonwealth market sized damages as a party to patent disputes between innovator and generic companies.

Medicines investment is high-risk with only 12% of drugs that enter clinical trials reaching approval for use by patients.[12] The research-based innovative pharmaceutical industry, like all research-based technology industries, relies on a robust patent system. Without intellectual property (IP) protection there would be no incentive to invest in the high-risk R&D required to discover and develop new medicines.

Generic medicines only exist because of innovative medicines. A generic medicine can be offered at a substantially lower price only because its manufacturer did not bear any risk, nor incur any of the costs of expensive discovery, research and development. A generic medicine cannot enter the Australian market if the originator medicine has not firstly been assessed as safe and effective for marketing in Australia by the Australian regulator. It is appropriate that the IP system remains strong and stable to both create incentives for innovators to develop new medicines and to support Australian access to these new medicines as the generics of the future.

A strong, stable and reliable IP system is essential in supporting investment in new research for some of our most challenging diseases. Reliability of the IP system depends upon fundamentally supporting the right and ability for a patent holder to defend their IP when it is potentially being infringed. Patent protection provides an incentive for companies to incur the cost and risk of research by providing a time-limited exclusive right to market a product. However, concurrent Australian policies are counter intuitively disincentivising innovators from defending their IP, which creates imbalance and signals a lack of support for innovation in Australia.

An innovator company (patent holder) is commonly alerted to the marketing intention of a generic medicine registered on the Australian Register of Therapeutic Goods (ARTG) when the Department of Health (DOH) notifies the innovator of a mandatory, statutory price reduction due to the listing of the generic on the Pharmaceutical Benefits Schedule (PBS).

If the patent holder believes the generic product infringes its patent, it has no option but to seek an interlocutory injunction against the generic company and provide an undertaking to the Court to prevent marketing of the generic product in Australia, pending resolution of the patent dispute.

Similarly, if the patent holder identifies the generic manufacturer's intention to market a generic product at the time of registration of the product on the ARTG (prior to PBS listing), they are also compelled to take out an interlocutory injunction, as there is very limited time from registration on the ARTG to the application of the statutory price reduction. The lack of adequate notification of the intended marketing of a generic forces the patent holder to act to defend their IP in a way that may result in delaying the market entry of a generic product. Adequate patent notification would enable time for reasonable due diligence on the status of patents held by the patent holder and allow reasonable due process to avoid unnecessary patent litigation.

Once a generic medicine lists on the PBS, the innovative medicine immediately takes a 25 percent statutory price reduction. If a generic product is launched into the market due to the Court's denial of the interlocutory injunction, there is no mechanism to allow for the price reduction to be reversed even if the patentee is ultimately successful after a full hearing on the merits.

Furthermore, since 2011, the Government has intervened in these cases under the undertakings provided by the patentees claiming that the Commonwealth has been damaged due to the interlocutory injunction. The Government is requesting substantial, 'market-sized damages', in some cases amounting to hundreds of millions of dollars, from patent holding companies. These damages are claimed to compensate the PBS for any higher price paid for a patented medicine during the period of the interlocutory injunction.

The Government's approach makes it very difficult for innovative medicines companies to defend their patent. Companies have little or no time to make a considered decision regarding a patent defence once the generic has listed. This serves as a significant disincentive for innovator pharmaceutical companies to invest in Australia. Allowing governments or other non-parties to a patent dispute to collect market-size damages undermines legal certainty, predictability and the incentives patents provide for investment in new treatments and cures.

By pursuing market-size damages, the Australian Government is unfairly tipping the scales in pharmaceutical patent disputes; favouring generic manufacturers – and discouraging innovators from enforcing their granted patents. This policy creates an inappropriate conflict of interest for the Australian Government, by permitting the same government that examined and granted a patent to seek damages if that patent is later held to be invalid or not infringed. It exposes innovators to significant additional compensation claims that may be difficult to quantify and were not agreed to or contemplated at the time the preliminary injunction was granted. The punitive size of these additional claims effectively equates legitimate patent enforcement (in circumstances where the market effects of the infringing generic entry are difficult to quantify), with patent abuse.

Medicines Australia contends that the Government should alter its policy of intervening under the undertakings to these cases and cease the pursuit of market sized damages. The current approach is damaging to Australia's international investment reputation and undermines Australia's otherwise robust patent laws.

Medicines Australia was encouraged by a recent TGA consultation paper, *Whether the TGA should publish that a prescription medicine is under evaluation*, one option of which was to list all applications accepted for evaluation.

This would have the effect of allowing greater time for the patent holders to assess the status of their patent and the risks of defending their patent. Additionally, this option would also provide a potentially effective means for Australia to meet its obligations under the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the US/Australia Free Trade Agreement (AUSFTA) which require Australia to implement a system by which patent holders receive advance notice of third party applications for marketing approval.

Medicines Australia calls on the Government to use any and all means available to encourage the TGA to implement this option.

Challenge	Solution
Australia's Productivity Commission's report and Intellectual Property Amendment Legislation further erodes a stable and predictable IP system through the proposal to introduce Crown Use and Compulsory Licensing provisions that are disproportionate to the desired outcome.	Maintain a strong and stable IP environment that meets Australia's International obligations and maintains Australia's competitiveness as an innovative country.

Medicines Australia welcomes the Australian Government's support for reliable, transparent and fair intellectual property provisions that support patient access to new medicines, and its commitment to ensure Australia's IP provisions continue to encourage investment in clinical trials in Australia and early patient access to medicines through the PBS.

Over recent years, a number of reviews, reports and consultation processes were commenced by Government which relate to IP. One of the leading reviews into Australia's IP infrastructure was the Productivity Commission's Inquiry looking at whether current arrangements provide an appropriate balance between access to ideas and products, and encouraging innovation, investment and the production of goods.

While there may be a need for the Australian Government to review IP laws from time to time, any future changes must involve extensive consultation to ensure they are well targeted. The changes to intellectual property laws made in the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 are still being implemented and their impact are yet to be fully realised or evaluated.

The Joint Committee for Trade and Investment's parliamentary inquiry into Australia's future in research and innovation report provides a useful starting point for further dialogue. Medicines Australia has welcomed a number of recommendations suggested in the Joint Committee for Trade and Investment report that relate to IP. These recommendations build on those from the McKeon.

Review in 2013 which called for strengthening Australia's IP system to ensure that it appropriately encourages investment in health and medical research and development.[15]

Finally, IP Australia has outlined the actions to be taken over the next four years to deliver on their vision of creating a world leading Intellectual Property system that fosters prosperity for Australia. In the context of IP Australia's Strategic Roadmap to 2030, their Plan sees a multi-year program of legislative change designed to ensure a more effective and balanced IP system. Focussing on the implementation of the Government's response to the recent Productivity Commission review of IP, Medicines Australia acknowledges the government is legislating in this area. However, areas of ongoing concern are:

1. Introduction of an: 'Objects' clause to the Patents Act 1990

2. Compulsory licensing of Patents

1. Introduction Of An 'Objects' Clause To The Patents Act 1990

Medicines Australia has maintained that introducing an objects clause is unnecessary and unhelpful to innovation. This objects clause, like the Productivity Commission's recommendation that preceded it, lacks clarity and could create uncertainty and unpredictability to patent applications and protections.

Should such a clause be retained, Medicines Australia maintains it should provide clarity and not include words that can create confusion and scope for dispute, which may have the potential to bring down or undermine a valid patent. For example, the proposed inclusion of the term 'technological' innovation is unclear and arguments could arise claiming that certain therapies are not of a 'technological' nature. Given the ever-evolving nature of innovation, it is preferable to keep language broad so as to accommodate, not restrict, future product, processes or service innovations.

2. Compulsory Licensing Of Patents

Compulsory licensing is rarely the best policy option to promote access to medicines and, as with Crown Use, should be used only very sparingly as they override and interfere with the private property law rights of the patentee.

Medicines Australia has stated that the proposed changes to compulsory licensing, including Crown Use, are unnecessary, weaken patent protection, discourage investment and limit the potential benefits of innovation for Australians. Changes that would encourage or make it easier for third parties to acquire innovative technologies without authorisation could have significant unintended consequences.

Medicines Australia contended that the proposed amendments are inconsistent with Australia's obligations under the Australia – U.S. Free Trade Agreement (AUSFTA). In particular, Medicines Australia is concerned that proposed amendments could permit compulsory licensing on grounds that are potentially broader than the circumstances outlined in AUSFTA Article 17.9.7.

1 Australian Government, IP Australia, 2019, https://www.ipaustralia.gov.au/patents

2 Global Innovation Policy Centre 2019, Inspiring Tomorrow, U.S. Chamber International IP Index, 7th Edition, accessed 10 May 2019, <https://www.theglobalipcenter.com/wp-content/uploads/2019/03/023593_GIPC_IP_Index_2019_Full_04.pdf>

3 Global Innovation Policy Centre. "Inspiring Tomorrow: US Chamber International IP Index, 7th edition, February 2019

4 See WIPO website: https://www.wipo.int

5 Therapeutic Goods Administration (TGA)

6 The Impact of Australia's Data Exclusivity Regime on Australia's Healthcare System, 2013.

7 Agricultural & Veterinary Chemicals Legislation Amendment Act 2013 introduced 10-year term for agricultural & veterinary chemicals from July 2014

8 Medicines Australia submission to the Productivity Commission Review of Intellectual Property Arrangements in Australia https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20151130-sub-PC-Review-IP-Arranagements-FINAL.pdf

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14 Productivity Commission, Inquiry Report, Intellectual Property Arrangements, No. 78, 23 September 2016, https://www.pc.gov.au/inquiries/completed/intellectual-property/report/ intellectual-property.pdf

15 McKeon, S. et al 2013. Strategic Review of Health and Medical Research.

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