

25 September 2015

David Simmons
IP Australia
47 Bowles Street
WODEN ACT 2606

Via email: consultation@ipaaustralia.gov.au

Dear Mr Simmons

Thank you for the opportunity to contribute to the consultation on Advisory Council on Intellectual Property's (ACIP) Recommendation on the Innovation Patent System. Medicines Australia is supportive of the review of Innovative Patents, and hopes to see that this important mechanism for encouraging innovation is continued. Although the economic analysis conducted by IP Australia recommends ceasing offering innovation patents as they were not found to be effective, there are a number of limitations that were acknowledged in this analysis that warrant further study before taking irreversible action by ceasing an important incentive for innovation and investment in intellectual property.

Previous submissions by Medicines Australia have called for the continuation of Innovation Patents, highlighting that they play an important role in encouraging investment in Research and Development (R&D) in Australia for the innovative pharmaceutical sector. Medicines Australia is pleased to make the following recommendations to this consultation:

Recommendation 1: That the Innovative Patent system be retained.

Recommendation 2: The changes proposed by the ACIP in their 2014 final report are examined further to strengthen the Innovation Patents system.

Recommendation 3: Further data collection and analysis is required to better understand company experience, and the economic benefits of, using Innovation Patents.

Introduction

Medicines Australia represents the research-based innovative medicines industry in Australia. Today, over 50 pharmaceutical companies and around 400 locally-owned medical biotechnology firms, operate in Australia. Together, they employ approximately 40,000¹ highly-skilled Australians (with at least 14,000 jobs² largely from within our member companies), invest more than a combined \$1 billion per year in R&D³ and generate nearly \$2.9 billion in exports each year⁴. 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 continue to produce through incentives such as innovation patents.

¹ 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

² IBIS World, Melbourne, 2014, Pharmaceutical Product Manufacturing in Australia: Market Research Report

³ Australian Bureau of Statistics 2012, 'Business Expenditure Report on R&D'

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

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 Agenda⁵. The next decade will provide enormous opportunities, with the Asia Pacific region set to drive huge demand for medicines. This growth is driven by a growing middle class and expanding health systems⁶. 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 second⁷. 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 2007⁸. It is imperative to limit further divestment by innovative pharmaceutical companies in Australia through communicating an intention to retain 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.

Innovation Patents and the Australian Innovative Medicines Industry

As stated in the ACIP's final report in 2014, "*The objective of the innovation patent system is to stimulate innovation in Australian SMEs. This is currently achieved by providing Australian businesses with intellectual property rights for their lower level inventions to prevent competitors from copying them. Innovation patents are also intended to reduce the compliance burden on users of the patent system by providing easier, cheaper and quicker rights for inventions.*"⁹ This report made a number of recommendations on how the innovative patent system could be changed to better support the policy objectives:

- ACIP recommends amending the Patents Act 1990 (Cth) to raise the level of innovation to a level above the current innovative step level, but below the inventive step level that applies to standard patents.
- ACIP recommends amending the Patents Act 1990 (Cth) so that substantive examination must be requested before the third anniversary of the lodgement of an innovation patent.
- ACIP recommends amending the Patents Act 1990 (Cth) so that the term 'patent' is only used for innovation patents that have been examined and certified.

⁵ Australian Government 2014. Industry Innovation and Competitiveness Agenda.

⁶ Australian Government 2012. Australia in the Asian Century.

⁷ Ibid.

⁸ Ibid.

⁹ Advisory Council on Intellectual Property. 2014. Review of the Innovation Patent System Final Report. http://www.acip.gov.au/pdfs/ACIP_Final_Report_-_Review_of_the_Innovation_Patent_System.pdf

- ACIP recommends amending the Patents Act 1990 (Cth) to exclude all methods, all processes and all systems from being patentable inventions for the purposes of an innovation patent.
- ACIP recommends that, subject to the preceding recommendations being accepted, the remedies for infringement of an innovation patent remain unchanged.

Medicines Australia supports these recommendations that propose changing and strengthening the system rather than completely abolishing innovation patents.

Recommendation 1: That the Innovative Patent system be retained.

Recommendation 2: The changes proposed by the ACIP in their 2014 final report are examined further to strengthen the Innovation Patents system.

Benefits of Innovation Patents

It is critical that pharmaceutical inventions and innovations remain eligible for standard and innovation 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 exclusivity) act to mitigate the commercial risks of bringing new medicines to market, making it significantly more likely for private enterprises to continue to invest in R&D for new medicines.

Accordingly, there is a strong and enduring rationale for making sure that no changes are implemented that would, in any way, undermine the ability to access innovation patents 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.

IP Australia's Economic Analysis

IP Australia's economic analysis is cited by ACIP as justifying cessation of the innovation patent system. Medicines Australia is concerned that whilst this economic analysis explores an area that has not been explored in detail before, there are a number of limitations in the approach and analysis 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 innovative 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. The economic analysis focuses on SME's and does not consider the costs and benefits to larger firms who may also be using innovative patents, and how removing the system would impact on their investment in R&D, or change their decision to invest in Australia.

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.

Recommendation 3: Further data collection and analysis is required to better understand company experience, and the economic benefits of, using Innovation Patents.

The conclusion that there is little benefit of innovation patents in increased investment in R&D needs to be explored further. As mentioned in section 2.2 *“It was not possible to estimate the effect on firms that only file innovation patents as the sample size was too small for making proper conclusions, so we instead look at firms that have filed at least one innovation patent and may have standard patent applications as well.”*¹⁰ This method may not capture the effect of innovation patents only, and relies on firms that have multiple patent types.

Despite this limitation, the analysis found that firms that file patent applications undertook more R&D on average than similar firms that did not file. This link between innovation patents and increased R&D indicates that the purpose of incentivising more R&D was being achieved. As a result, there is a need for further investigation of this to see if holds true for firms that file innovation patents.

Investment in Research & Development

The pharmaceutical industry is an integral component of Australia’s innovative industries¹¹. 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 upheld¹². This high level of investment has myriad important benefits for the country, including enhancing the physical health and welfare of Australians and helping to reduce health costs. It has been estimated that a dollar invested in Australian health R&D will return an average health benefit of \$2.17¹³.

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 ceasing innovation patents, 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, 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.

¹⁰ Johnson et al. 2015. The economic impact of innovation patents. IP Australia Economic Research Paper 05. <https://www.ipaustralia.gov.au/about-us/what-we-do/economic/>

¹¹ Department of Industry, Canberra, 2014, Australian Industry Report

¹² Australian Bureau of Statistics 2012, ‘Business Expenditure Report on R&D’

¹³ Access Economics 2008. Exceptional Returns: The Value of Investing in Health R&D in Australia II

Conclusion

Thank you for your consideration of our submission. We would be pleased to clarify or amplify these statements and recommendations, and would be happy to meet to discuss further.

Yours sincerely

A handwritten signature in black ink that reads "Tim James". The signature is written in a cursive, slightly slanted style.

Tim James
CEO
Medicines Australia