

An Open Letter to the Australian Parliament

12 March 2015

Australia's Economic Prosperity Relies on Innovation and Innovation Needs Strong Intellectual Property Protections

As an alliance of Australia's medical researchers, developers and manufacturers of innovative health technologies, we write to you regarding recent media commentary on the proposed Trans Pacific Partnership (trade) Agreement. The commentary raises concerns about the possibility of changes to Australia's intellectual property system. These concerns are entirely misplaced.

Innovation – doing things better, doing things smarter – is critical to Australia's future. There are many well established sectors of the Australian economy whose success relies entirely on continued innovation, including of course the medical research and bio-pharmaceutical manufacturing sectors.

As the 2015 Intergenerational Report notes, “harnessing future opportunities to support innovation, adopt new technologies, facilitate foreign trade and investment and foster competition can boost future productivity growth and living standards. Government policy settings will be very important to helping individuals, businesses and governments take full advantage of opportunities from technological developments so that productivity growth is maintained, or even improved.”

Intellectual property is the fundamental source of protection for innovation: the new research, the new medicines, diagnostics, medical devices and methods of treatment which have been invented through sustained effort and investment. It is especially critical that local innovation is not disadvantaged in any way. Ensuring that Australia has a globally competitive intellectual property system is the key to our future health and 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 incentive 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).

From penicillin to the bionic ear to the HPV vaccine for cervical cancer, Australian innovation has helped to revolutionise healthcare here and around the world, and, in the process, brought enormous economic benefits to this nation. The value to Australia of (both publicly and privately funded) medical research and continued investment in high-tech bio-pharmaceutical manufacturing exceeds \$10 billion annually, including around \$3.5 billion in annual exports alone.

Our intellectual property system is not fixed. It is constantly evolving to address the challenges that come when dynamic scientific invention meets the legal system. For example, Australian patents provide a formal 20 years of protection to certain types of pharmaceutical inventions (or longer if an extension of term is granted). However, the average effective patent life for these products in this country is between 11 and 12 years. This is because it typically takes around 10 years, and sometimes longer, to bring new a pharmaceutical product to market, after a patent registration. As this time between patent registration and market approval lengthens (or the cost of research rises), the formal protection (and therefore the invention's value) becomes less and less.

To maintain a reasonable level of protection the system needs to be updated from time to time. Over the last 20 years, major reforms have included: changes to patent terms, enhancement of patentability standards and expansion of exemptions to patent infringement.

At the moment, this need for reform applies to Australia's provision of data exclusivity, a niche but critical component of our intellectual property system.

In some circumstances, a patent, a concept over 400 years old, does not provide adequate intellectual property protection to certain types of new medicines and vaccines, particularly “biologic” medicines. Australia’s five-year data exclusivity provision lags global competitors and collaborators such as the United States (up to 12 years), Canada (eight years), the EU (up to 11 years), Japan (eight years) and even countries like Russia and China (six years). This puts at risk investment in Australia’s rapidly growing domestic pharmaceutical and biotechnology sectors.

Among other reports, we note that the 2013 “Strategic Review of Health and Medical Research in Australia” (the McKeon Review) called upon the Federal Government to extend the term of data exclusivity to harmonise an important element of the Australian IP system with global best practice. We also note that the Australian Parliament recently granted, without controversy, data protection to veterinary medicines for companion animals, namely medicines for Australia’s dogs, cats and other pets. The level of protection went from zero to ten years. That is twice the level of intellectual property protection provided to new cancer medicines and other medicines - for humans - that rely on data exclusivity.

There were a number of claims contained in recent media articles that are inaccurate. Perhaps the most important of these include claims that:

- **“...intellectual property reforms envisaged in the TPP would lead to a rise in the cost of medicines...”**

The price of every medicine on Australia’s PBS is fixed at the time of listing; it is not even adjusted for cost of living, no matter how long it stays listed. No change to intellectual property law can increase the price that a consumer would pay for any PBS medicine. More importantly, nearly ten years ago, when Australia and the United States signed a free trade agreement, critics similarly predicted the demise of the PBS. They argued that prices for medicines in Australia would skyrocket and that Australian patients would be denied access to new and essential medicines. They were wrong. The PBS today is more sustainable than at any point in its history.

- **“...there would be provisions to prevent the grant of minor patents which would contribute to ‘evergreening’.”**

Reference to “evergreening” shows a fundamental misunderstanding about how our patent system works in reality. No later patent can extend the term of an earlier one. Moreover, a second patent cannot, by definition, be issued for the same invention and must cover a new invention in order to be granted. Once a patent on an original invention expires, imitators are free to copy the invention if they so choose.

The recent so-called “Health Impact Assessment” in relation to the TPP, which was extensively quoted in the media, was prepared by the Centre for Health Equity Training and Research and Evaluation at the University of NSW. We were not aware of any consultation with our respective sectors in relation to any of the many (largely unsubstantiated) claims contained in this “assessment”.

For decades, Australia’s intellectual property system has helped Australian patients get prompt and affordable access to the latest and most effective treatments. It has also enabled Australia to attract billions of dollars in investment in medical research and high-tech pharmaceutical and medical manufacturing, thus creating thousands of high-skill jobs and generating billions of dollars in exports every year.

Strengthening our intellectual property system will further cement Australia’s place among the world’s leading investment destinations for pharmaceutical and biotechnology companies, and ensure ongoing patient access to innovative medicines and vaccines.

Yours sincerely,



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