Dear Ms Moore,

Submission: Pharmaceutical Patents Review 2013

We welcome the opportunity to provide comment on the Pharmaceutical Patents Review. Our submission is based in part on our recent paper presented at the 2012 National Medicines Symposium held in Sydney.¹ This international Symposium was attended by over 540 delegates. The paper presented was a systematic review of case law, peer-reviewed journal articles, books, dissertations, government documents and loose-leaf services on the topic of pharmaceutical intellectual property protection. Five legal indexing databases and snowball sampling from reference lists were utilised. Our research paper was a novel attempt to integrate an established rigorous scientific approach to a humanity subject (laws). Systematic reviews have been conducted since the 1990s to integrate the rapidly accumulating wealth of scientific research findings to inform practice, create substantive and formal theory, and influence policy.² Systematic review techniques are designed to identify as many relevant studies as possible to help ensure that relevant studies are not lost in the growing body of research. Meta-synthesis techniques then permit those studies to be appraised and findings combined in a logical and useful manner. By drawing on a broad range of descriptions, systematic reviews can yield more powerful results than any one study of the same topic. Greater generalizability would also be attained as the process achieves a higher level of evidence than an individual study.³ This is especially useful on the topic of pharmaceutical


intellectual property protection as diverse and opposing descriptions can be combined to counterbalance the limitations inherent in a single descriptive and would further strengthen the resulting meta-synthesis by enhancing the richness of the analysis and provide new understanding of individual study findings.⁴

We are supportive of the need for a pharmaceutical patents review and acknowledge the excellent consultative process undertaken by the Panel. We are optimistic that a balance can be achieved in promoting innovation in pharmaceutical research and development and the need to strengthen the pharmaceutical industry in Australia, against the public health needs of equitable access to affordable pharmaceuticals. We believe that any review to further extend the current pharmaceutical patents termsbeyond the 20+5 years needs to promote genuine inventiveness. A tier system of patents extension based on prevalence of disease and public health objectives may be warranted to foster pharmaceutical investment in pharmacotherapy of rare diseases and those of national interest. We submit that rectification of article 31bis TRIPS Agreement would in our opinion provide such a national safeguard. We hold the belief that any further amendments to the Patents Act 1990 (Cth) would need to balance Australia’s international obligations (e.g. Australia-US Free Trade Agreement) against the national interest of having safe, affordable and equitable access to pharmaceuticals.

We welcome the opportunity to provide further comment on the Pharmaceutical Patents Review.

Yours sincerely,

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⁴John Wallace, Charles Byrne and Mike Clarke, 'Making evidence more wanted: a systematic review of facilitators to enhance the uptake of evidence from systematic reviews and meta-analyses' (2012) 10 International Journal of Evidence-Based Healthcare 338.
Suggested submission questions

1: Is the breadth of the pharmaceutical patents eligible for an extension of term appropriate?

As alluded to in the Background and Suggested Issues Paper, in Australia extension of patents term under section 77 Patents Act 1990 (Cth) (the “Act”) is only available to active ingredients and formulation of active ingredients. This is opposed to US and Japan which ‘also provides extensions for uses and methods of manufacture’.

The US has a protectionistic policy on pharmaceutical patents and treats pharmaceutical intellectual property as a matter of trade policy since a majority of the pharmaceutical manufacturers are based in the US. For instance, the US threatened Brazil with trade sanctions for manufacturing generic copies of anti-HIV medications.

This is in contrast to the pro-public health approach to pharmaceutical patents as campaigned for by the European Union and adopted by the United Nations Committee on Economic Social and Cultural Rights which defined intellectual property as a social product that has a social function, namely to provide incentives for inventiveness and creativity from which society benefits. Intellectual property is granted by the State according to criteria defined by legislation. Unlike natural rights, intellectual property protection only exists for a limited time and for a definite purpose. Therefore intellectual property rights are subsidiary to a natural right. Consequently pharmaceuticals with significant health effects are deemed not patentable. For example: ether, penicillin antibiotics, radium and polio vaccine. This

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5Page 7.
6Ibid.
9Morton v New York Eye Infirmary (1862) 17 F Cas 879.
appears to concur with the court’s interpretation of why intellectual property exists.\textsuperscript{11} Specifically, section 18(2) of the Act specifically carves out anything that relates to the biological human being.\textsuperscript{12} However, in recent time the breadth of what is patentable has been challenged.\textsuperscript{13} Innovation in medical research means that pharmaceutical patents no longer work in isolation. With the advancement and use of pharmacogenomics to individualise medical treatment, should the breadth of what is patentable be expanded to include gene sequences there is a real risk of an increased economic burden on Australians and the public health system, especially the Pharmaceutical Benefits Scheme (PBS). The PBS is the major buyer of pharmaceuticals in Australia and has an almost universal coverage of between 60\% to 90\% of pharmaceutical use in Australia.\textsuperscript{14} Take for instance, the chemotherapy drug trastuzumab (Herceptin\textsuperscript{TM}) used for treatment of breast cancer and stomach cancer. Each 1,000mg dose of trastuzumab costs the PBS $7,120.75.\textsuperscript{15} Before the patient is eligible to have trastuzumab dispensed under the PBS, the treating doctor would need to request for genetic testing to ensure that the cancer cells are expressing human epidermal growth factor receptor-2 (gene). Therefore if the breadth of what is patentable is to be expanded to include gene sequence, it would mean that consumers would have to pay thrice for the patents: once for the pharmaceutical, again for the genetic testing and another for having expressed that gene. This also raises the issue of whether the research subjects who contributed towards the


\textsuperscript{11} Lim et al, above1. See for example Bristol-Myers Squibb Company v F H Faulding & Co Ltd [2000] FCA 316 (Finkelstein J).

\textsuperscript{12} See also European Convention 1973 articles 52-53 which biological processes, methods for treatment of human or animal body are not patentable, and Patent Amendment (Human Genes and Biological Materials) Bills.

\textsuperscript{13} See for example the Promethus patent cases.

\textsuperscript{14} David Lim et al, 'Australian dispensing doctors' prescribing: quantitative and qualitative analysis' (2011) 195 Medical Journal of Australia 172.

\textsuperscript{15} Dispensed price as at 7 January 2013 according to Commonwealth Department of Health and Ageing <http://www.pbs.gov.au/medicine/item/4632T-4639E-4650R-4703M-7264H-7265J-7266K-7267L>{accessed 7 January 2013). Additional fees such as patient co-payment and other agreed fees are payable.
genetic research actually consented to commercialisation of their genetic sequence. We submit that the outcomes of expanding the breadth of patentable gene sequences could promote inventiveness in pharmacogenomics and pharmaceuticals, but this would be at the expense of markedly increasing the growing PBS’s pharmaceutical expenditure and therefore further community consultation need to be undertaken. The other alternative is that people would fund their own expensive treatment, which for example in the US often leads to bankruptcy of the family involved.

In regards to extension on methods of manufacturing and clinical use, pharmaceutical manufacturers often apply for separate patent protection on end-product and the process of manufacturing. It is also common practice for patent attorney/applicants to cover the field by stating overly broad claims to include all salts or derivatives of the end-product. Restriction on up-stream patents prevents downstream innovation. If the principle of having patent protection as endorsed by the United Nation is Lockean reward for creative labour, then further expansion to what is patentable would hinder genuine innovation. We consider that it is possible for patent seekers to apply for innovative patents as compared to standard patents for innovative methods of manufacturing or clinical use. This nonetheless raises the issue of building block patents which is discussed below.

We submit that the concern for economic growth should not be viewed in isolation from social determinations for health. There are many factors that contribute to health. These include access to essential items for good health as well as social measures which reduces susceptibility to ill-health. Therefore any discussion on patent protection should be considered within the body of international law and be implemented consistently with human rights such as right to health, to non-discrimination and to development.

Under the *TRIPS Agreement*\(^\text{16}\) the patent terms may be universal but the breadth and what is patentable are flexible enough to take into account other factors. For instance, Japan narrowly defined “patent”, promoted cross-licensing and managed to keep their pharmaceutical price

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low.\textsuperscript{17} India implemented a policy against ever-greening unless the new pharmaceutical can demonstrate to be of clear therapeutic advantage.\textsuperscript{18}

2. Is the length of the extension of term provided for appropriate?

Evergreening of pharmaceutical is encouraged under the \textit{Australia-US Free Trade Agreement (AUSFTA)},\textsuperscript{19} specifically:

\begin{itemize}
  \item article 17.9.8 which locks in preferential patent term extension,\textsuperscript{20} and
  \item article 17.10.4 which potentially has the effect of an indefinite prohibition on the Therapeutics Goods Administration (TGA) to approve any relevant patent claimed.\textsuperscript{21}
\end{itemize}

It is costly to defend patent rights, with an average cost of patent litigation estimated at US$4 million per party (2004).\textsuperscript{22} Nonetheless it appears that pharmaceutical manufacturers are more than ready, willing and able to defend such claims whenever there is a possibility that infringement may arise.\textsuperscript{23} It was reported that in the US for every US$2 million spent on pharmaceutical research and development, a similar amount is spent defending patent rights and a further US$144.1 million on political lobbying.\textsuperscript{24} Proponents for such practice cited:\textsuperscript{25}

\begin{footnotesize}
\textsuperscript{17} Xuan Li, 'The impact of higher standards in patent protection for pharmaceutical industries under the TRIPS Agreement - a comparative study of China and India' (2008) \textit{The World Economy} 1367,1379.

\textsuperscript{18} Mey, above 7,438-446 and \textit{Novartis AG v Union of India WP (Unreported, High Court of Judicature at Madras, 6 August 2007) 24760/06}.

\textsuperscript{19} \textit{Australia-United States Free Trade Agreement} [2005] ATS 1 (entered into force 1 January 2005).

\textsuperscript{20} Ken Harvey, 'Patents, pills and politics: the Australia-United States Free Trade Agreement and the Pharmaceutical Benefits Scheme' (2004) 28(2) \textit{Australian Health Review} 218,222.


\textsuperscript{24} Harvey, above 20,220.
\end{footnotesize}
• high pharmaceutical research and development cost,
• significant time lapse between invention and when the end-product is ready for market,
• to protect one’s invention and to beat competitors to the market, the patent is often obtained before the end-product is ready,
• high failure rate with only 1 in 5,000 inventions eventually getting to market,\(^{26}\)
• once the pharmaceutical end-product is on the market, it is relatively easy for competitors to reverse engineer; this unfairly enriches the competitors by spring-boarding on what is already done and known, and also potentially fair-ride on the reputation and marketing effort of the blockbuster pharmaceutical, and
• there is lengthy time lapse to have TGA approval,
• with PBS being the main purchaser of pharmaceuticals in Australia, the PBS’s F1-F2 pricing\(^ {27}\) created a monopolistically competitive market hence there is only a limited time when innovation is rewarded.

However in reality, the majority of new pharmaceuticals are modifications of existing blockbuster pharmaceuticals.\(^ {28}\) Scholars have questioned whether the research and development cost is indeed as high as what was commonly publicised.\(^ {29}\) Scholars also have questioned the investment in “me-too” pharmaceuticals which frequently offer no real clinical efficiency distinguishable from originator/ blockbuster pharmaceuticals.\(^ {30}\)

Furthermore, there is a trend for pharmaceutical manufacturers to buy patentable pharmaceutical invention from researchers instead of investing in the primary invention themselves. This has resulted in universities and the public system footing the bills for

\(^{25}\) Lim et al, above 1.


\(^{27}\) National Health Act 1953 (Cth) ss 85AB and 85AC.

\(^{28}\) Bebe Loff, 'How much is patent protection threatened by drug costs?' (2004) 5 Expert Opinion in Pharmacotherapy 69 ,70 cited that in 2000, the US Patent Office granted 6730 pharmaceutical patents but of which only 27 were for new compounds.

\(^{29}\) See for example Donald W Light and Rebecca Warburton, 'Demythologizing the high costs of pharmaceutical research' (2011) BioSocieties 1.

genuine inventiveness and innovation. Consequently there is little or no incentive for the pharmaceutical industry to invest in low prevalence orphaned/ neglected diseases, or pharmaceuticals that are needed to secure public health such as antibiotics. Specifically for the latter, the antibiotics pipeline is drying up and yet there are no new antibiotics in sight. Should a novel antibiotic be developed, it is unlikely that the new antibiotic will be made readily available for common infections but rather be reserved for when the bacterium is resistant to other front line antibiotic agents. Hence, the low volume and national interest may warrant for an extended patent terms beyond 20+5 years for future novel antibiotics, especially if its use is likely to be controlled.

Australia is a mainly a neoliberalistic society and the rationale for intellectual property protection in Australia is somewhat influenced by a pure economic rationale. The PBS is widely regarded as one of the most efficient schemes in the world in controlling cost growth of pharmaceuticals: the pharmaceutical cost in Australia is 2-3 times cheaper than in the US. The PBS is not a perfect competitive market due to the inherent oligopoly nature of the current pharmaceutical industry. The Australia Government implemented the National Medicines Policy in 2000. In this policy, the Government acknowledges the importance of a viable and responsible Australian pharmaceutical industry while at the same time recognising

31Harvey, above 20,220.


35See for example House Standing Committee on Industry, Science and Technology,’Genetic manipulation: the threat or the glory?’ (House of Representatives Committees, 1992); Matthew James and Ann Rann,’Cultivating innovation’ (Parliament of Australia, 2001).


37For instance the top ten pharmaceutical manufacturers account for 48% of pharmaceutical sales worldwide: Congressional Budget Office, above 32,39.
the public health needs for having safe and efficacious, and equitable access of pharmaceuticals to Australians.\textsuperscript{38} This may be seen as the Howard Government’s attempt to balance the economic imperatives of Kantian intellectual property protection against the public health needs of having safe and equitable access to pharmaceuticals. The World Health Organization also recognises the need for balance against patent protection and access to treatment especially for the world’s poorest and most vulnerable.\textsuperscript{39} This is reflected in the \textit{TRIPS Agreement}, specifically:

- the Bolar provision (article 30) which allows generic manufacturer to carry out research on patented pharmaceuticals, conduct clinical trials etc. before the blockbuster pharmaceutical patents expired,
- article 8 which allows members to formulate and amend laws to adopt measures necessary to protect public health and nutrition, and
- article 31\textit{bis} which allows for compulsory licensing and parallel importation of pharmaceuticals if it is in the national interest to do so.

The latter provision was utilised by the US in the anthrax crisis of 2001 when Bayer was forced to sell ciprofloxacin antibiotic at a substantially reduced price. However, Australia Government still has not rectified the article 31\textit{bis} offer.\textsuperscript{40}

If the pharmaceutical patent term is to be extended beyond the current 20+5 years, there would be delays in cheaper generic pharmaceuticals entering the Australian system. Pharmaceutical costs are rising globally in part due to the ageing population and technology advances. Australia is not immune to the rising pharmaceutical costs. A leaked US proposal for the \textit{Trans Pacific Partnership Agreement} suggested that the US is championing for longer pharmaceutical patent terms and expanding the breadth of what is patentable.\textsuperscript{41} We submit that if the Australian Government is to succumb to the economic pressure to widen length


\textsuperscript{39}Nielsen and Nicol, above 26,23.

\textsuperscript{40}General Council, \textit{Implementation of Para 6 of Doha Declaration on the TRIPS Agreement and Public Health} WT/L/540, 2 (fn 3) (World Trade Organization, 2003).

\textsuperscript{41}Deborah Gleeson and David Legge, 'Strengthening public health engagement in trade policy: PHAA’s policy on Trade Agreements and Health' (2012) 36(1) \textit{Australian and New Zealand Journal of Public Health} 7,8.
and breadth of pharmaceutical patents, then rectification of article 31bis **TRIPS Agreement**
would potentially provide the Australian Government with a fall-back position for parallel
importation when there is a national interest to do so, and/or at the same time an economic
bargaining chip for future international trade agreements. Pharmaceuticals used to have low
price elasticity of demand\textsuperscript{42} but recent evidence provided by our collaborators has
demonstrated that Australians most in need of pharmaceutical care are forgoing their
medications because of price.\textsuperscript{43} Therefore without such a safeguard, the Australian
intellectual property system would see greater move away from registration (of patent) to
litigation, and polarise the have’s and have-not’s.

3. Are the recent amendments to increase the thresholds for the grant of an Australia
patent appropriate in the context of pharmaceuticals? If not, why not and what further
changes are necessary?

Allegations were made against the pharmaceutical industry for selectively sponsoring
research studies (especially familiarisation of pharmaceutical c.f. genuine clinical
effectiveness and efficacy research), selectively published research findings which are
favourable to their product and burying unfavourable research.\textsuperscript{44} The latter unduly afford
copyright protection over unpublished material.

As alluded to in the *Background and Suggested Issues Paper*, it is too early for the recent
*Raising the Bar* amendments to be felt. Nonetheless, we submit that empirical data need to
be collected to ascertain whether the current 2012 amendments resulted in better disclosure.

\textsuperscript{42} See for example Peter Siminski, 'The price elasticity of demand for pharmaceuticals amongst high
income older people in Australia: a natural experiment' (University of Wollongong, 2008)

\textsuperscript{43} Anna Hynd et al, 'Increased patient co-payments and changes in the PBS-subsidised prescription
medicines dispensed in Western Australia' (2009) 33 *Australian and New Zealand Journal of Public
Health* 246.

\textsuperscript{44} See for example O Dyer, 'GlaxoSmithKline faces US lawsuit over concealment of trial results'
4. Do the systems for opposition and re-examination provide appropriate avenues for challenging the granting and validity of a pharmaceutical patent?

Proponents against standard patents have revenue under section 59 of the Act which set out grounds for opposition during examination or to challenge the validity of the grant under section 138. Proponents against innovative patents (though this is rarely used by the pharmaceutical manufacturers) challenge the validity of the grant when such patents right is being enforced. Furthermore, section 101(a) of the Act allows the Patent Commissioner to review the patent even if examination is not done at application. The main difference between a standard patent (20 years) and innovative patent (8 years) is when the rights are being challenged: standard patent at examination phase and innovative patent when the rights are sought to be enforced. Proponents against the concept of innovative patents have argued that patent application is not examined until the patent rights are sought to be enforced, consequently the Registry is likely to be filled with junk innovative patents which are not likely to survive examination. The leaked US proposal mentioned above preferred automatic granting of patents which is akin to the current Australian innovative patent. If such US’s preferred scheme is to be applied to Australia’s standard patent – arguably the intention of US; then the current Patent Registry may be potentially filled with junk pharmaceutical patents application which cannot be fully substantiated; especially when current practice is for pharmaceutical patents to be taken out before TGA approval. Hence we submit that any amendment to the challenge of validity of grant and opposition to registration needs to take into consideration other existing policies such as the National Medicines Policy and Australia’s international obligations such as human rights.

5. Do interlocutory injunctions, as the law is currently applied, provide appropriate relief in cases involving pharmaceuticals?

As mentioned above, it was suggested that pharmaceutical manufacturers are ready, willing and able to defend any potential infringement of patent rights. This delays patent registration and entry of generic pharmaceutical products. However, case law on interlocutory injunction and quia timet injunction have evolved over time to take into account the need to preserve status quo of the parties until the end of trial. This includes undertaking as to damages.45 The

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45 Castlemain Tooheys Ltd v South Australia (1986) 161 CLR 148.
sheer magnitude of potential damages suffered by blockbuster pharmaceutical manufacturers may dictate the arguably high number of interlocutory injunctions sought, but we submit that this is balanced by the applicant’s undertakings as to damages required under common law. Furthermore, the grant of interlocutory injunction is at the discretion of the court upon balancing other salient features such as prima facie case, balance of convenience and primary rights. We thereby submit that the Australian court is capable of advancing the common law on interlocutory injunction, and be flexible to take into consideration modern developments and public opinion on relevant contemporary issues.

6. Is Australian law on contributory infringement appropriate in relation to pharmaceuticals?

As outlined above if Australia is to rectify article 31bis TRIPS Agreement, this provision has the capacity to allow Australia Government to conduct parallel importation when national interest dictates so. National interest is not defined under the international agreement and may vary with time and necessity.

7. Are the current timeframes in which infringement proceedings must commence appropriate for pharmaceutical patents?

As indicated above, pharmaceutical manufacturers appear to be ready, willing and able to instigate proceedings to enforce their patent rights. Nonetheless, we submit that research needs to be conducted to ascertain the failure rate of pharmaceutical related proceedings and why such proceeding fail; for example, discontinued for latches. As an academic institution we are prepared to assist in collating such data.

8. Are follow-on patents being used to inappropriately extend protection for pharmaceuticals? If so, how? And, if they are, is this sound policy and what changes, if any, are needed?

We are uncertain whether our court system is able to distinguish between building block patents and genuine patents. Specifically, biotechnology patents draw a fine distinction between discovery and technique. As mentioned above, pharmaceutical patent attorney/
applicants can apply for standard patents or innovative patents even though innovative patents are not often applied for by pharmaceutical manufacturers. It may be possible under the current Act for pharmaceutical patent attorneys to seek a standard inventive patent for a novel pharmaceutical, follow up with a section 77 extension, and then an innovative patent for innovative clinical use or methods of manufacturing: 20+5+8 years. There is potentially no cap to the amount of innovative patents that a pharmaceutical manufacturer may take out (20+5+8) hence there is a potential for building block patents. We submit that the legislation on innovative patents, especially for pharmaceutical products, need to be clearer whether there is a cap on number of building block patents applications.

9. Is the law on data exclusivity appropriate?

TGA is prohibited under section 25A Therapeutic Goods Act (Cth) to disclose confidential information submitted by pharmaceutical patent applicants for five years. The recent 2012 amendments would have implications on this issue and further findings are required.

10. Are the laws on patent certificates appropriate?

We submit that the current system provides enough safeguard on procedural fairness especially for the large pharmaceutical manufacturers. This submission is based in the context that the pharmaceutical industry is diligent in protecting their intellectual property rights.

11. Are the laws on copyright of product information appropriate?

We are unable to comment on this issue at this stage of the consultation process as the amendment is relatively new (May 2011). Australian court’s interpretation of copyright has been to balance rewarding the author of original literacy work against policy consideration regarding public interest in maintaining a robust public domain in which further works are
produced.46 This is in contrast to the UK approach to copyright which appears to focus on rights of authors from reproduction of work without consent.47 Should the author of the originating Product Information and Consumer Medicine Information (often pharmaceutical manufacturer of blockbuster pharmaceutical) be compensated, and would the section 44BA Copyright Acts 1968 (Cth) amendments infringe Australia’s international public and private agreements?

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46 *IceTV Pty Ltd v Nine Network Australia Pty Ltd* (2009) 239 CLR 458

47 *Telstra v Phone Directories Co* [2010] FCA 44.
Recommendations

1. If there is a further move to expand the breadth of what is patentable, the economic benefits need to be balanced against community acceptance, and for genuine inventiveness.

2. Clearer direction needs to be provided by the Australian Government on its position on evergreening and building block patents, especially through registration of innovative patents.

3. Extending pharmaceutical patents beyond 20+5 years needs to be based on national interest especially in investment into research and development for rare diseases or matters of national interest such as antibiotics.

4. Rectification of article 31bis TRIPS Agreement may provide further safeguards against unforeseen circumstances.

5. Further research needs to be undertaken on the effectiveness of 2012 Raising the Bar amendments and the copyright of product information amendments.

6. Better integration of the Patents Act 1990 in line with other governmental policies such as National Medicines Policy is required.
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### Abbreviation used

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<tr>
<td>the Act</td>
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<td>AUSFTA</td>
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