

MEDICINES

Australia

Better Health through Research and Innovation

**Submission to the Department of Industry,
Innovation and Science on the Productivity
Commission's Final Report on Intellectual Property
Arrangements in Australia**

February 2017

Executive Summary

Medicines Australia appreciates the Government's invitation for stakeholder views on issues raised in the Productivity Commission's Final Inquiry Report into Intellectual Property (IP) Arrangements in Australia. We also take this opportunity to acknowledge the Productivity Commission's efforts in their analysis of the Australian IP system.

However, we continue to express our reservations and concerns about the Productivity Commission's Final Report and recommendations in relation to the patent system generally and the pharmaceutical industry specifically.¹ Of the nine recommendations which affect these two areas, Medicines Australia wishes to draw particular attention to six recommendations: 7.1, 7.2, 7.4, 8.1, 10.1 and 18.2. We believe that these six recommendations in particular: fail to appreciate the **value** of patents in encouraging innovation; increase **regulatory burdens**; and create an environment of **regulatory uncertainty**. Together, these recommendations would result in significant and irreparable harm to the innovative medicines and medical research sector in Australia, and would be a retrograde step for Australia and the Government's National Innovation & Science Agenda. These recommendations also would have a negative impact on global investment in Australia's R&D. In the health context, these recommendations would likely delay patient access to innovative medicines, which contradicts the achievement of better health outcomes for Australians, one of the fundamental policy objectives across the whole-of-government.

Medicines Australia reiterates the importance of the IP system to create a domestic environment that harnesses competition and innovation, embraces growth and cements our status as a modern, knowledge-based economy, and therefore submit that the Government should take into account the following principles.

1. Recognise the value that IP and patents deliver to the Australian economy, particularly in the innovative medicines sector by retaining the existing strong IP system;
2. Encourage collaborations with industry to better understand and strengthen the IP and patent frameworks in Australia;
3. Ensure the domestic IP environment encourages innovators to share their discoveries and creations with the community in exchange for a period of exclusivity;
4. Strengthen the domestic IP framework to promote and increase Australia's attractiveness for R&D investment by strengthening Regulatory Data Protection;
5. Maintain the current extension of patent term arrangements in Australia;
6. Minimise regulatory burdens or uncertainty, which have a negative effect on innovation, industry and patient accessibility to innovative medicines;
7. Ensure current and future policies respect and adhere to the trade agreements clauses as negotiated in good faith between Australia and its trade partners; and
8. In negotiating future trade agreements, ensure that IP policies reflect and maintain the balance of rights between patient and industry.

¹ See Chapter 7: The patent system – getting the fundamentals right; Chapter 8: The innovation patent system; Chapter 10: Pharmaceuticals – getting the right policy prescription and Chapter 18: International cooperation in IP.

Medicines Australia's submission will focus on the shortfalls and unintended consequences that would eventuate should the Productivity Commission's recommendations be implemented. We would be pleased to meet with the Department to clarify or elaborate our statements or recommendations in this or previous submissions, and we welcome the opportunity to work with the Government and the Department in formulating appropriate domestic policies that best support Australia's innovative medicines industry.

Introduction

Medicines Australia recognises that IP laws must strike a balance between allowing access to inventions and new products at competitive prices, while also ensuring that product originators are sufficiently compensated for the resources they dedicate to research and invention. In our previous submissions² to the Australian Government, its institutions and the Parliament on this issue, Medicines Australia has consistently outlined a number of reasons as to why strengthening Australia's IP system would better support the social, health and economic wellbeing of all Australians.

As outlined in our June 2016 submission to the Commission's Draft Report:

- *Strong and stable IP systems play an important role in stimulating innovation.* Together with other policy tools and levers, strong IP systems encourage medical research leading to diseases being treated, and the resulting treatments being accessed. Recommendations that stand to undermine the incentives to research cures for disease will have a negative impact on national wellbeing and economy. In this context the Productivity Commission has ignored the shared benefits that come from a strong IP system.
- *A number of studies confirm the importance of IP in accelerating the global diffusion of new medicines.* A 2005 study covering a large number of developed, as well as developing countries found that stronger patent protection increased the speed of new drug launches.³ Similarly, a comprehensive 2014 study of drug launch data comprising over 600 drugs in almost 80 countries from 1983-2002 showed that robust patent protection accelerates new product launches in higher and lower income countries alike.⁴

The Australian Government aspires to make Australia a more innovative country with an economy driven by inventive, research-driven, knowledge-based industries. Medicines Australia contends that the Government should be upholding a strong, effective and stable IP protection regime that aligns with international best practice to drive the National Innovation & Science Agenda (NISA) and supports the pharmaceutical industry – one of the six industry sectors that the Government has included in its Industry Growth Centres Initiative. Medicines Australia members contribute to the NISA through significant investment in Australia's world-class scientists, research collaborations, and local biotechnology and advanced manufacturing capabilities. Medicines Australia members are leading employers of Science Technology, Engineering and Mathematics (STEM) graduates.

² Medicines Australia's June 2016 submission to the Productivity Commission's Draft Report available [here](#); Medicines Australia's December 2015 submission to the Productivity Commission's Issues Paper available [here](#); Medicines Australia's September 2015 submission to the Public Consultation on the Advisory Council on Intellectual Property Recommendation on the Innovation Patent System available [here](#); Medicines Australia's September 2012 submission to IP Australia on the Draft Intellectual Property Laws Amendment (TRIPS Protocol) Bill 2012 available [here](#); and Medicine Australia's April 2011 submission to IP Australia on the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 available [here](#).

³ Lanjouw, JO "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry" (2005) <<http://www.nber.org/papers/w11321>> accessed 6 June 2017.

⁴ Cockburn, IA, Lanjouw, JO and Shchankerman, M "Patents and the Global Diffusion of New Drugs" (2014) <<http://nber.org/papers/w20492>> accessed 6 June 2017. Strong patent protection is defined as providing for product patents (as opposed to only providing for process-only patents) and the duration of patent terms.

At a time when the Australian economy is transitioning towards knowledge and science based industries, it is important that appropriate incentives are in place to drive investment and create jobs. Changing the policy environment around patents in the manner as recommended by the Productivity Commission would send a signal that Australia does not value innovation, and that Australia not serious about fulfilling the NISA.

Medicines Australia is concerned that there has been inadequate consideration or understanding of the flow-on impacts that the measures recommended by the Productivity Commission would have on this sector and on the wider economy. Furthermore, there has still been limited opportunity for affected stakeholders to undertake full analysis of the recommendations from the Final Report and the potential unintended consequences.

As Medicines Australia has highlighted in previous submissions to this inquiry,⁵ the Productivity Commission appears to have based their final recommendations on incorrect, biased or incomplete information and assumptions or, in some cases, made recommendations despite expressly acknowledging the lack of supporting evidence. An example is the purported pay-for-delay activities, for which there is no existing evidence or reason to believe that such behaviour is occurring in Australia. We would submit that existing mechanisms allow for sufficient monitoring of competitive relationships and detecting misconduct. Overall, this exercise has resulted in misunderstandings about the complexity, nature and role of IP in the pharmaceutical sector and misleading assertions.

Medicines Australia proposes that the Government carefully and critically examine the Commission's final recommendations to avoid taking a retrograde step in the development of appropriate domestic policy.

Comments on specific recommendations

In response to the Government's request for further comments on specific final recommendations, Medicines Australia wishes to draw particular attention to the following six recommendations and their negative effects upon the innovative medicines industry.

Final recommendation 7.1: the Australian government should incorporate an objects clause into the *Patents Act 1990 (Cth)*. The objects clause should describe the purpose of the legislation as enhancing the wellbeing of Australians by promoting technological innovation and the transfer and dissemination of technology

While we agree with the theoretical underpinnings of this objective, Medicines Australia opposes this recommendation to incorporate an objects clause. Given its reliance upon substantial evidence sets and subjective assessments, it is impractical and has the potential to create significant uncertainty. It is difficult to see how patent examiners can be expected to assess whether the patent application balances the interests of the patent applicant, the users of technology and Australian society as a whole. Whilst the inclusion of the principles from TRIPS that patents should focus on technological advancements is an improvement on the original proposed clause by the Commission in their Draft Report, there is still substantial subjectivity and ambiguity in how this clause would be interpreted and applied by both patent examiners and the judiciary.

⁵ Please see Appendix A in Medicines Australia's June 2016 submission to the Commission's Draft Report available [here](#).

Final recommendation 7.2: the Australian government should amend sections 7(2) and 7(3) of the *Patents Act 1990* (Cth) such that an invention is taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art

The Final Report quotes a number of cases that have interpreted the scintilla of invention test element of the validity of a patent. These cases indicate that if the advancement made is not obvious by a person skilled in the craft then, along with the other three elements of the inventive step for a valid patent, the invention is considered to not be obvious. However, the Commission argues that this threshold of innovation is not sufficiently high enough to grant a valid patent, and that greater levels of innovation must be required to justify granting a valid patent.

Medicines Australia disagrees with the Commission's views. First, with the passing of the *Raising the Bar Act 2012*, the level of inventive step required is now commensurate with that required by Australia's major trading partners. The Commission's recommendation to further increase the threshold would put Australia out of step internationally and undermines the advancement of Australian's wellbeing by discouraging innovation and the knowledge spill-overs.

Second, the legislative changes forming the *Raising the Bar Act 2012* only came into effect in 2013. The impact of this legislation is still being understood by the judiciary and industry. To introduce further changes so soon after these amendments – and without a solid evidence base for change – would result in significant uncertainty and instability for *all* relevant parties and stakeholders. The evidence presented by the Commission in its comparison between IP Australia and the European Patent Office was prior to the *Raising the Bar Act*. This further supports the argument that it is still too soon to be able to effectively consider changing the inventive step.

Final recommendation 7.4: The Australian Government and IP Australia should set patent fees to promote broader intellectual property policy objectives, rather than the current primary objective of achieving cost recovery.

Medicines Australia does not support changes to the fee structure for patents. We submit that the proposed changes will make Australia's system less competitive internationally, as the costs associated with managing IP will no longer be as competitive as it was. For pharmaceuticals that have a high sunk cost and long development times, the proposed rising scale of patent fees will impact on the attractiveness of investing in early stage research and impact on the commercialisation opportunities for the biopharmaceutical industry. In turn this could have a serious flow-on effect to the amount of investment in R&D in Australia, as an element of the decision making incorporates the costs of applying for, and managing, IP. This recommendation is out of step with the Government's current innovation and industry policies (such as the NISA and the Industry Growth Centres) and would send a negative signal to invest in innovation.

Additionally, we submit that the current fee structure provides historical stability and certainty in the decision making process for companies when submitting an application to patent a medicine in Australia.

Final recommendation 8.1: abolish innovation patent system

Medicines Australia does not support this recommendation. The recommendation implies that the Commission does not consider innovation patents as providing sufficient benefits, and that only 'high value' patents provide social benefits.

Final recommendation 10.1 (part 1): The Australian Government should reform extensions of patent term for pharmaceuticals such that they are only: 1) available for patents covering an API; and 2) calculated based on the time taken by the Therapeutic Goods Administration for regulatory approval over and above 255 working days

Medicines Australia strongly opposes both components of this part of recommendation 10.1.

Patent extension terms should *not* be limited to APIs

Whilst we agree with the Commission that an EoT should be available when the costs associated with research and development have not been sufficiently recompensed, we disagree that this right should only be limited to APIs.

Restricting patents to APIs limits the scope and incentive for pharmaceutical companies to invest, discover and develop new pharmaceutical substances. As an example, a number of combination products have been developed, which, although scientifically not creating a new API, had extensive inventiveness that led to improved patient health outcomes. Additionally, the invention of new pharmaceutical substances can allow different methods of administration that treat completely new indications. For instance, an injectable anaesthetic API was transformed into a new pharmaceutical substance that allowed for topical application of this API as a multi-day patch to treat chronic pain in cancer. Such initiatives enables broader patient access to medicines. Without appropriate durations of patent protection, there will be negative consequences for patient access, economic growth and ongoing investment in R&D.

Furthermore, there are questions over how such a system would be administered, as changes could potentially increase regulatory requirements in an already overburdened system. It was unclear from the Commission's Final Report as to how many patents would be affected by this change. Medicines Australia therefore recommends that a more detailed investigation be undertaken to explore the impact of any proposed change.

Patent extension terms should *not* only be calculated with reference to regulatory delay

The Commission outlined an emerging approach where pharmaceutical term extensions are granted only where there has been regulatory delays, and looked favourably to Singapore as a primary example. It is highly questionable whether the Singapore model would be adequate and result in the most appropriate patent term extension for Australia. Singapore only compensates patentees for delays in administrative processes for obtaining market approval and excludes the clinical testing phase from the calculated term of the process of obtaining marketing approval. This approach ignores the very rationale for patent term extension in the first place. Clinical trials represent an indispensable part of the development process that are unique to the medical industry. There is a regulatory requirement to be able to provide clinical trial data as part of the marketing approval process which is required to obtain a product licence for a pharmaceutical product. Accordingly, excluding the period taken to conduct clinical trials in the calculation of eligibility for patent term extension reduces incentives for innovation and investment in R&D in Australia.

Furthermore, whilst inclusion on the Australian Register of Therapeutic Goods (ARTG), provides market authorisation, Australia operates in a publicly supported, universal health care system whereby medicines are additionally assessed for cost effectiveness before they are available through the Pharmaceutical Benefits Scheme (PBS). Medicines are not widely accessible to patients until they are listed on the PBS. The evaluation and assessment process for listing on the PBS is complex and costly and frequently delays access by at least another year. Reducing the patent term extension period fails to acknowledge the unique Australian R&D and marketing regime, and would severely compromise the existing balance between the incentive to innovate and delivering affordable new innovative medicines to Australian patients.

Manufacture for export

Medicines Australia takes this opportunity to reiterate our position on Manufacture for Export (MFE)⁶. Specifically, we express our concern about the Commission's support for MFE measures, including the Commission's favourable view of the European Commission's consideration of a Supplementary Protection Certificate (SPC) manufacturing waiver for manufacturing for export purposes.

First, generic companies already have the option of approaching patent holders to negotiate a licensing agreement or non-enforcement agreement. The holder of the patent will examine the specifics of the case and, if parties agree, can licence out the product through a voluntary licence. One of the main advantages of this approach is that it often includes transfer of the know-how needed to ensure high-quality medicines are produced efficiently.

It would be difficult and burdensome, if not impossible, to enforce such a measure to ensure that products manufactured under this exemption are only exported to, and remain in countries without patent protection. For example, it would be difficult to distinguish whether manufacturing activities are being carried out for export to countries without IP protection; in support of export to countries where there is still IP protection; or to stockpile products to be launched in the domestic market immediately upon protection expiry.

Finally, there are risks of facilitating infringement in countries with weak judicial enforcement systems. If such a recommendation was implemented, it would be difficult or impossible for Australian courts to assess the existence and/or validity of patent claims in the importing countries to ensure that the exception is not used in a manner to facilitate infringement in the importing country.

Estimated savings

We also query the method and approach taken by the Commission in estimating the potential savings that could be achieved from changes to the extension of term. The savings do not automatically occur; rather they are triggered when a generic product enters the market. The report's modelling assumes that generic manufacturers are waiting to launch competitor products immediately for all patented molecules, which may not be the case.

In addition, unless previously extended patent terms are retrospectively taken from patent holders (noting this would be completely contrary to the application of a procedurally fair legislative change), savings will take on average around 12 years to accrue. Given that 12

⁶ Please see Medicines Australia's submission to the Draft Productivity Commission Report [here](#).

years is also the average effective life of a patent, we submit that investing in medical innovation rather than saving measures would offer a more worthwhile return over this period of time.

Final recommendation 10.1 (part 2): The Australian Government should reform s 76A of the *Patents Act 1990* (Cth) to improve data collection requirements for extensions of term, drawing on the model applied in Canada. Thereafter no extensions of term should be granted until data is received in a satisfactory form.

Medicines Australia supports harmonisation of legislation and definitions and a simpler approach to applying for an EoT. Medicines Australia does not agree, however, with the Commission's recommendation that data collection requirements should be based on the model applied by Canada's Patented Medicine Prices Review Board. It is concerning that the Commission is 'cherry picking' selected components of other jurisdiction's models, without considering the flow on and unintended impact of these elements to the broader Australian economy.

The Canadian Patented Medicine Prices Review Board (PMPRB) has a dual mandate. It sets the maximum non-excessive price for patented drugs in Canada, which is determined with reference to the prices of other developed nations. It also measures the R&D to sales ratio of patentees in Canada. Neither of these roles are relevant to the issue of patent extensions. In contrast, in Australia, s 76A of the *Patent Act 1990* is focused solely on the question of patent and extension of terms. Medicines Australia would submit that these are two totally different objectives. It is, therefore, incorrect to apply the PMPRB's data requirements to the question of EoT in Australian patent law. While the Canadian system might show it is possible to collect "standardised and worthwhile data", the collection of this data by the PMPRB is for a different purpose, would seem to serve no useful purpose in Australia, and is not a model to emulate.

Second, as noted in the final report, the Canadian Patented Medicine Prices Review Board collects data on a patentee basis rather than a 'per drug' basis. The comprehensive requirements for providing commercially in confidence data poses a risk for both companies and the Government in managing this information. Medicines Australia continues to hold the view that if such a system was to be brought to Australia, it would result in an unnecessary increase in regulatory burden. It is not clear what the justification is for the collection of additional detailed and comprehensive information, beyond that which is already collected by the Department of Health, IP Australia and the Australian Taxation Office. It is also not clear as to why sales revenue and total R&D expenditure for the firm would be required to grant an EoT for an individual product. The current 'per drug' approach under s 76A ensures that the corresponding data is collected, rather than the broad brush approach that is employed in Canada.

Final recommendation 10.2: The Australian Government should introduce a system for transparent reporting and monitoring of settlements between originator and generic pharmaceutical companies to detect potential pay-for-delay agreements. This system should be based on the model used in the United States, administered by the Australian Competition and Consumer Commission

As noted by the Productivity Commission's final report, there is no evidence of pay for delay activities in Australia. Whilst Medicines Australia supports transparency measures in

principle, it is unclear why additional regulation and administrative burden is required, along with the allocation of Government resources in a tight fiscal environment, for an area that is already covered by the Australian Competition and Consumer Commission (ACCC).

Final recommendation 18.2: The Australian Government should play a more active role in international forums on intellectual property policy including:

- **review of TRIPS Agreement; explore opportunities to further raise threshold for inventive step for patents;**
- **pursuing the steps needed to explicitly allow the manufacture for export of pharmaceuticals in their patent extension period;**
- **working towards a system of eventual publication of clinical trial data for pharmaceuticals in exchange for statutory data protection**

Medicines Australia acknowledges the Productivity Commission's recognition of how trade agreements are also relevant in the shaping of intellectual property policies. An important point raised by Commission is that any changes to the Australian system should not breach our current trade agreement provisions.

As observed in the Final Report, there is a strong argument that MFE provisions would contravene Australia's obligations under two separate international trade agreements – TRIPS and AUSFTA – thus harming Australia's competitiveness as a destination for global R&D investment. As a result, the Commission called for Australia's negotiating approach to future trade agreements to include allowance for MFE during the patent extension of terms.

In making this recommendation, the Commission appears to adopt a very one-sided approach in what the objectives of free-trade agreements are. For instance, proposals for MFE are not consistent with ensuring a strong IP system, but rather would weaken IP rights in Australia thereby jeopardizing innovation, and should be avoided. Medicines Australia submits that a balance between consumers and industry must be acknowledged and sought in the negotiation and drafting of such agreements.

As outlined in our submission to the Commission's Draft Report, the innovative medicines industry is wholly committed to publishing clinical trial data. There are a number of avenues through which clinical trial data is published, and Medicines Australia's members comply with a range of industry codes and guides for sharing this data. Two such examples are the principles for responsible clinical trial data sharing⁷, and the Yale Open Data Access project.⁸

Clinical trial data may be published in the medical press and is made available to doctors. In addition to the publication of data through the press and as made available online through clinical trial registries, clinical trial data is also submitted to the TGA as part of the regulatory approval process. It is important that this data, as submitted, be kept commercially in confidence. Even after the data protection period has expired, the clinical trial data as submitted to the TGA is not made public by the TGA. Neither are generic manufacturers provided with copies of this data. However, once the data protection period has finished, generic manufacturers are able to rely upon this data when making their submissions for an

⁷ For the Principles of Clinical Trial Data Sharing, please see <http://www.phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf>

⁸ For further information on the Yale Open Data Access project, please see <http://yoda.yale.edu/>

equivalent medicine where they meet the required regulatory standards to demonstrate equivalence and/or comparability.

Trade agreements are important to Australia's growth and prosperity. Ensuring that Australia's regulatory and IP systems align with comparable jurisdictions will help to foster greater investment, leading to more opportunities for employment growth, especially as we transition from a resources dependent economy. Trade agreements are important for growing Australia's pharmaceutical industry, as well as for expanding access to medicines and vaccines across our region. Medicines Australia submits that trade agreements must also take into account the protection of health by encouraging and incentivising innovation in health technology and medicines.

These comments represent some of our key concerns about the Final Report but are not exhaustive. We repeat our belief that the Government should carefully and critically examine the Commission's final recommendations to avoid implementing policies which have a negative impact on Australia's innovation, economic and health agendas. Thank you for your consideration of our submission. As indicated at the beginning of our submission, Medicines Australia would be pleased to clarify or elaborate our statements or recommendations in this or previous submissions, and we welcome the opportunity to work with the Government and the Department in formulating appropriate domestic policies that best support Australia's innovative medicines industry.