

# **THE TRANS PACIFIC PARTNERSHIP AGREEMENT, INTELLECTUAL PROPERTY AND ACCESS TO AFFORDABLE MEDICINES**

Submission to the Productivity Commission Inquiry into Australia's Intellectual Property Arrangements

Dr Deborah Gleeson  
School of Psychology and Public Health  
La Trobe University

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## **1. INTRODUCTION**

This submission addresses the implications of regional free trade agreements for Australia's intellectual property arrangements for pharmaceuticals, focusing particular on the potential impact of the recently concluded (but not yet ratified) Trans Pacific Partnership Agreement (TPP). It outlines ways in which the intellectual property and investment chapters of the TPP may serve to lock in place and in some ways, extend intellectual property rights of pharmaceutical companies at the expense of the public and taxpayers. It examines the way in which the TPP entrenches and extends a global intellectual property regime that fails to deliver affordable medicines for much of the world's population. It provides a critique of the final TPP text in the light of the principles proposed by the Productivity Commission, and concludes that the TPP imposes unnecessary constraints on the degree of flexibility to design intellectual property policy in the public interest. Other regional trade agreements under negotiation, or soon to be negotiated, risk repeating the flawed approach of the TPP unless the transparency and accountability of the trade negotiating process is improved, including independent assessment of the costs and benefits and the potential health and human rights impacts.

## **2. THE TRANS PACIFIC PARTNERSHIP AGREEMENT AND INTELLECTUAL PROPERTY FOR PHARMACEUTICALS**

The Trans Pacific Partnership Agreement (TPP) is a proposed large regional trade agreement involving twelve countries from around the Pacific Rim: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. Negotiations concluded in October 2015 and the agreed text of the TPP (minus legal scrubbing)<sup>1</sup> was publicly released on 5 November 2015.

Throughout the negotiations, the TPP was subject to extensive criticism from health, development and consumer organisations, both internationally and within Australia.<sup>2</sup> Much of this criticism focused on the proposed content of the TPP, particularly provisions proposed by the United States for the intellectual property and investment chapters. Criticism also focused on the lack of transparency in the negotiations and the imbalance in terms of input from large corporations and industry associations in contrast with the public.

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<sup>1</sup> New Zealand Ministry of Foreign Affairs and Trade (2015) Text of the Trans Pacific Partnership. Retrieved 14 December 2015, from <http://www.mfat.govt.nz/Treaties-and-International-Law/01-Treaties-for-which-NZ-is-Depositary/0-Trans-Pacific-Partnership-Text.php>

<sup>2</sup> Examples include international organisations such as Médecins Sans Frontières (MSF), Oxfam, and US consumer organisation Public Citizen; and Australian health and consumer organisations such as the Public Health Association of Australia, the Australian Medical Association, Choice, and the Australian Fair Trade and Investment Network (AFTINET).

In March 2015, a health impact assessment of the TPP,<sup>3</sup> based primarily on leaked negotiating documents, was released by a group of Australian academics and non-government organisations. This health impact assessment found potential for negative impact in each of the four areas studied: the cost of medicines, tobacco control, alcohol policy and food labelling. While some of the more extreme proposals for the TPP were abandoned or mitigated during the negotiations, the final text of the TPP bears out many of the concerns raised by experts and community organisations during the negotiations.

## **2.1 Chapters of the TPP with implications for intellectual property and pharmaceuticals**

There are many parts of the TPP that have implications for intellectual property and regulatory arrangements for pharmaceuticals, including the Intellectual Property Chapter (Ch 18), the Investment Chapter (Ch 9), the Government Procurement Chapter (Ch 15) the annex to the Transparency and Anti-Corruption Chapter (Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) and an annex to the Technical Barriers to Trade Chapter (Annex 8-C: Pharmaceuticals). Due to limited time, this submission will only discuss the chapters most relevant to the Productivity Commission Inquiry: chapters 18 and 9. My analysis of Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices can be found on the Infojustice website.<sup>4</sup>

## **2.2 The TPP Intellectual Property Chapter**

The primary concern for Australia arising from the TPP Intellectual Property Chapter is the provisions for biologic products (Article 18.52: Biologics). This is the first time such provisions have been included in a trade agreement. A second area of concern is the potential for the IP provisions more generally to lock in existing intellectual property settings and limit the options for reform. A third and very important concern is the impact of the IP chapter on delaying access to affordable medicines in developing countries, which should also be of concern to all Australians. These issues are examined in turn below.

### *2.2.1 Biologics provisions*

Biologic products are produced through biological processes and include many new treatments for cancer and immune conditions such as rheumatoid arthritis. They include some of the most expensive medicines on the market, some of which cost hundreds of thousands of dollars per patient per year.

According to a fact sheet prepared by the Department of Foreign Affairs and Trade, there are now more than 70 biologic drugs listed on the Pharmaceutical Benefits Scheme.<sup>5</sup> These drugs account for a growing share of PBS expenditure.<sup>6</sup>

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<sup>3</sup> Hirono K, Haigh F, Gleeson D, Harris P and Thow, AM (2015) Negotiating Healthy Trade in Australia: Health Impact Assessment of the Proposed Trans Pacific Partnership Agreement. Centre for Health Equity Training Research and Evaluation, part of the Centre for Primary Health Care and Equity, Faculty of Medicine, UNSW Australia. Retrieved 14 December 2015, from: [http://hiaconnect.edu.au/research-and-publications/tpp\\_hia/](http://hiaconnect.edu.au/research-and-publications/tpp_hia/)

<sup>4</sup> Gleeson D. (2015) Preliminary analysis of the final TPP Healthcare Transparency Annex: Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices. Retrieved 24 December 2015, from <http://infojustice.org/wp-content/uploads/2015/12/Gleeson-Preliminary-Analysis-Transparency-Annex-12-Dec-2015-1.pdf>

<sup>5</sup> Department of Foreign Affairs and Trade. (2015) Trans Pacific Partnership Agreement: Outcomes: Biologics. Retrieved 14 December 2015, from <https://dfat.gov.au/trade/agreements/tpp/Documents/outcomes-biologics.PDF>

The ten biologic drugs listed on Australia's Pharmaceutical Benefits Scheme which accounted for the largest government expenditure in the 2013-14 financial year cost the Pharmaceutical Benefits Scheme approximately \$1.29 billion AUD.<sup>7</sup> This represents approximately 14% of the \$9.15 billion dollars in overall expenditure on the PBS during the same period.<sup>8</sup>

When the first follow on (generic or biosimilar) product is listed on the PBS, a 16% price cut is applied to all versions of the product. If follow on (biosimilar) products had been available for these ten drugs, over \$205 million in taxpayer-funded subsidies would have been saved in the 2013-14 financial year alone.

The United States was seeking to secure 8-12 years of market exclusivity for biologics in the TPP; 12 years was a key objective of the US-based pharmaceutical industry.<sup>9</sup> Twelve years also reflects the current market exclusivity period for biologics in the US, although the White House Budget has sought over several years to wind this back to seven years. The White House Budget for Fiscal Year 2016 included the following:

...the Budget includes two proposals designed to increase access to generic drugs and biologics by stopping companies from entering into anti-competitive deals intended to block consumer access to safe and effective generics, by awarding brand biologic manufacturers seven years of exclusivity, rather than 12 years under current law, and by prohibiting additional periods of exclusivity for brand biologics due to minor changes in product formulations. These two proposals will save the Federal Government \$16 billion over 10 years, including savings in Medicare and Medicaid.<sup>10</sup>

Weissman and Brennan<sup>11</sup> describe how the biopharmaceutical industry was able to secure 12 years of market exclusivity for biologics in the US by political lobbying during the passage of the Affordable Care Act through Congress, despite the fact that the Federal Trade Commission had determined in 2009<sup>12</sup> that an extended period was not justified.

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<sup>6</sup> See, for example, comments by Health Minister The Hon Sussan Ley reported by ABC News: <http://www.abc.net.au/news/2015-06-19/biosimilar-drugs-new-class-of-generic-biological-medicines/6557532>

<sup>7</sup> Gleeson D, Lopert R & Moir H. Proposals for extending data protection for biologics in the TPPA: Potential consequences for Australia. Submission to the Department of Foreign Affairs and Trade, 15 December 2014. Retrieved 23 December, 2015, from: [http://dfat.gov.au/trade/agreements/tpp/negotiations/Documents/tpp\\_sub\\_gleeson\\_lopert\\_moir.pdf](http://dfat.gov.au/trade/agreements/tpp/negotiations/Documents/tpp_sub_gleeson_lopert_moir.pdf) (or available from the authors).

<sup>8</sup> Department of Health. Expenditure and prescriptions twelve months to 30 June 2014. Canberra: PBS Information Management Section, Pharmaceutical Policy Branch, Australian Government Department of Health, 2014. Retrieved 23 December 2015, from: <http://www.pbs.gov.au/statistics/2013-2014-files/expenditure-and-prescriptions-12-months-to-30-june-2014.pdf>

<sup>9</sup> Pharmaceutical Research and Manufacturers of America (2013) PhRMA Urges Trans-Pacific Partnership Negotiators to Adopt a Strong Intellectual Property Framework. Retrieved 23 December 2015, from: <http://phrma.org/media/releases/phrma-urges-trans-pacific-partnership-negotiators-adopt-strong-intellectual-property->

<sup>10</sup> United States Government (2015). Fiscal Year 2016 Budget of the U.S. Government. Retrieved 24 December 2015, from: <https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/budget.pdf>

<sup>11</sup> Weissman, R and Brennan H. (2014) Competition Inhibitors: How Biologics Makers are Leveraging Political Power to Maintain Monopolies and Keep Prices Sky-High. Public Citizen. Retrieved 24 December 2015, from <http://www.citizen.org/documents/report-biologics-industry-leverages-political-power-to-maintain-monopolies-and-inflate-prices.pdf>

<sup>12</sup> United States Federal Trade Commission (2009) Emerging Health Care Issues: Follow-on Biologic Drug Competition. Retrieved 24 December 2015, from <https://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report>

The mechanism through which the US has sought to extend market exclusivity for biologics through the TPP is known as data protection or data exclusivity. This is a different type of monopoly protection to a patent: it involves protecting the clinical trial data submitted to regulatory agencies (such as Australia's Therapeutic Goods Administration) to demonstrate the safety and efficacy of a pharmaceutical. During the period of data protection, manufacturers of follow-on products cannot rely on the clinical trial data submitted by the originator to obtain marketing approval for their version of the product.

Battles over the length of data protection for biologics plagued the TPP negotiations, and proved to be an almost insurmountable stumbling block over the final days.

The [Australian Government's brief](#) about the TPP outcomes for biologics says:

*In the TPP, Australia has negotiated protections that are consistent with Australian law and practice. Australia is not required to change any part of its current law, including data protection for biologics, or our patent regime. There will be no adverse impact on the Pharmaceutical Benefits Scheme and no price increase for medicines.*

The Australian Government has been adamant that it has not agreed to change Australia's arrangements for biologics via the TPP, and the Minister for Trade and Investment has made repeated statements to this effect. For example, The Guardian reported on 7 November 2015:

"We have absolutely no intention of increasing the cost of medicines to the Australian public by seeing any increase in the period of data protection," Robb said. [...] Robb has insisted Australia did not move "one iota" on the issue and has protected the five-year rule.<sup>13</sup>

But the final text of the TPP's Intellectual Property (IP) Chapter<sup>14</sup> contains some problematic language and troubling ambiguities. The biologics provisions of the TPP and associated footnotes are reproduced in Box 1 below.

<sup>59</sup>

**Article 18.52: Biologics**

1. With regard to protecting new biologics, a Party shall either:

- (a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic,<sup>60,61</sup> provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,
- (b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:
  - (i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party,
  - (ii) through other measures, and

<sup>13</sup> Australian Associated Press (2015) US senator's claims Australia is being greedy over trade deal rejected. The Guardian, 7 November 2015. Retrieved 24 December 2015, from; <http://www.theguardian.com/australia-news/2015/nov/07/us-senators-claims-australia-is-being-greedy-over-trade-deal-rejected>

<sup>14</sup> Trans Pacific Partnership (2015) Chapter 18: Intellectual Property. [subject to legal review and authentication]. Retrieved 24 December 2015, from: [https://www.mfat.govt.nz/assets/\\_securedfiles/trans-pacific-partnership/text/18.-intellectual-property-chapter.pdf](https://www.mfat.govt.nz/assets/_securedfiles/trans-pacific-partnership/text/18.-intellectual-property-chapter.pdf)

(iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.

2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

3. Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.

<sup>59</sup> Annex 18-B, Annex 18-C and Annex 18-D apply to this Article.

<sup>60</sup> Nothing requires a Party to extend the protection of this paragraph to:

(a) any second or subsequent marketing approval of such a pharmaceutical product; or

(b) a pharmaceutical product that is or contains a previously approved biologic.

<sup>61</sup> Each Party may provide that an applicant may request approval of a pharmaceutical product that is or contains a biologic under the procedures set forth in Article 18.50.1(a) and Article 18.50.1(b) (Protection of Undisclosed Test or Other Data) within five years of the date of entry into force of this Agreement for that Party, provided that other pharmaceutical products in the same class of products have been approved by that Party under the procedures set forth in Article 18.50.1(a) and Article 18.50.1(b) before the date of entry into force of this Agreement for that Party.

**Article 18.52.1** (p. 18-30 to 18-31) outlines two options that countries can implement to protect new biologics:

- 1) At least 8 years' protection of clinical trial data (Article 18.52.1(a)); or
- 2) At least 5 years' protection of clinical trial data along with *other measures to "provide effective market protection" and "deliver a comparable outcome in the market"* (Article 18.52.1(b))

Whatever the understanding reached between parties in the negotiating room, according to the agreed legal text, it appears that the TPP parties are obliged to ensure the same market exclusivity outcomes regardless of which option they choose. What was probably intended to be a constructive ambiguity (allowing the negotiations to successfully conclude despite the unresolved conflict between the US and Australia) may well backfire if the US interpretation of the text prevails during the certification phase, or in disputes arising during implementation.

The legal language provides room for the United States to continue to pressure the other TPP countries to ensure that they keep biosimilars (more affordable follow-on products) off the market for eight years, in order to provide equivalent "effective market protection" and a "comparable outcome" to eight years of data protection. This pressure may occur even before the TPP is enforced. In the past, the US has applied pressure to countries to adopt stronger IP protection

during the period between signing and ratification. For example, the U.S. forced Australia to make further changes to its copyright laws during certification of the Australia-US Free Trade Agreement.<sup>15</sup>

**Article 18.52.2** (p. 18-31) of the leaked IP chapter requires countries to apply the provision on biologics to a very broad range of products:

*For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.*

Including any product that is, or contains, a protein produced using biotechnology processes captures a very broad array of products, and reduces the prospect for governments to narrow the scope of the obligation and define for themselves which products it applies to. Previously leaked text<sup>16</sup> showed that the TPP countries were considering a footnote that would have allowed countries some room to determine the definition of biotechnology processes – but this footnote has been removed from the final version of the text. Since biotechnology processes are not defined in the TPP text, it is unclear whether the definition is left to national law by default.

**Article 18.52.3** (p. 18-31) provides for a review of both the length of the monopoly protection and its scope by the TPP Commission after 10 years (“or as otherwise decided by the TPP Commission”). This could result in countries being pressured to provide market exclusivity for more products, or to lengthen the period of protection.

### 2.2.2 Other intellectual property provisions

Despite resistance by the majority of TPP countries to the US pharmaceutical industry agenda throughout the negotiations, many provisions remain in the final text that affect access to affordable medicines, particularly in developing countries. Harmful provisions still remaining in the TPP’s final Intellectual Property Chapter include:

- Patents for new uses and new methods of using existing products (Article 18.37.1);<sup>17</sup>
- A low inventiveness threshold – potentially preventing countries from tightening the criteria for granting patents (Footnote 30);
- Patents for inventions that are derived from plants (Article 18.37.4);<sup>18</sup>
- Patent term extensions to compensate for delays in granting patents (Article 18.46) and delays in marketing approval (Article 18.48);<sup>19</sup>

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<sup>15</sup> Kelsey, J. (2015) How the US Forced Australia to Rewrite Aspects of its Copyright Law During Certification of Compliance with the AUSFTA. Retrieved 24 December, 2015, from: <http://tppnocertification.org/wp-content/uploads/2015/03/AUSFTA-certification-memo-Feb-2015.pdf>

<sup>16</sup> Trans Pacific Partnership (2015) Intellectual Property Rights Chapter, Consolidated Text (October 5, 2015) [Leaked text] Retrieved 24 December, 2015, from <https://wikileaks.org/tpp-ip3/WikiLeaks-TPP-IP-Chapter/WikiLeaks-TPP-IP-Chapter-051015.pdf>

<sup>17</sup> This provision has improved in comparison with early drafts. Rather than mandating patents for new forms, uses and methods of using existing products, TPP countries must make patents available for at least one of the following: ‘new uses of a known product, new methods of using a known product, or new processes of using a known product’. It still exceeds the requirements of the TRIPS Agreement.

<sup>18</sup> This is an issue for food security in developing countries rather than access to medicines.

<sup>19</sup> This provision has been mitigated somewhat and is more flexible than early drafts. In some cases, countries may be able to avoid patent term extensions by expediting administrative processes. However it is still TRIPS+ and will potentially delay access to generic and biosimilar medicines.

- Data protection for small molecule drugs – at least 5 years for new pharmaceutical products plus either 3 years for new indications, formulations or methods of administration *or* five years for combination products containing a chemical entity that has not previously been approved (Article 18.50);<sup>20</sup>
- Patent linkage provisions likely to result in delays in marketing approval for generic drugs (Article 18.51);<sup>21</sup>
- Market exclusivity for biologics, provided through one of two options: at least 8 years of data protection, or at least 5 years of data protection and other measures to “deliver a comparable outcome in the market” (Article 18.52);<sup>22</sup> and
- Enforcement measures that go well beyond the World Trade Organization’s TRIPS Agreement (Section I).

The Australian Government asserts that “The TPP Intellectual Property Chapter is consistent with Australia’s existing intellectual property regime” and that Australia’s intellectual property laws will not need to be amended as a result of the TPP<sup>23</sup>. Setting aside uncertainty about the implications of the biologics provisions, this claim appears to be consistent with the provisions of the final IP chapter that apply to pharmaceuticals. The question is whether the TPP text will limit options for future reform.

Australia already allows patents for new uses and new methods of using existing products, and has a low inventiveness threshold.<sup>24</sup> There are strong arguments for limiting secondary patents and raising the inventiveness standard to reduce evergreening and delays to generic entry.<sup>24,25</sup> The Australia-US Free Trade Agreement (AUSFTA) already requires parties to make patents available for new uses or methods of using a known product (AUSFTA Article 19.9.1) and the comparable TPP provision allows more flexibility, since it only requires patents to be made available for one of new uses, new methods of using, or new processes of using a known product (TPP Article 18.37.2).

But the TPP footnote regarding the standard of inventiveness includes more problematic language than AUSFTA:

<sup>30</sup> For the purposes of this Section, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful” respectively. In determinations regarding inventive step, or non-obviousness, each Party shall consider whether the claimed invention would have been obvious to a person skilled, or having ordinary skill in the art, having regard to prior art. (TPP Chapter 18, Footnote 30)

<sup>20</sup> Providing the option of a least five years for combination products may reduce the impact of this provision for countries that choose this option. However it is still TRIPS+ and will potentially delay access to generic medicines.

<sup>21</sup> The original US proposal has been mitigated; regulatory agencies such as the Therapeutic Goods Administration will not have to act as patent police. Still TRIPS+ and likely to delay generic entry.

<sup>22</sup> This is the first time a provision for market exclusivity for biologic products has ever appeared in a trade agreement – and this is a new obligation for many TPP countries. The biologics provisions are problematic and ambiguous, and leave room for the US to continue to pressure countries to use administrative delays to keep affordable medicines off the market for an equivalent period of time.

<sup>23</sup> Department of Foreign Affairs and Trade. (2015) Trans Pacific Partnership Agreement: Intellectual Property FAQs.[webpage]. Retrieved 24 December 2015, from: <http://dfat.gov.au/trade/agreements/tpp/outcomes-documents/Pages/intellectual-property-faqs.aspx>

<sup>24</sup> Moir, H. (2013) The Promise to the Public: Generic Competition. Submission to the Pharmaceutical Patents Review.

<sup>25</sup> Gleeson D, Moir H and Lopert R (2015) Costs to Australian taxpayers of pharmaceutical monopolies and proposals to extend them in the Trans-Pacific Partnership Agreement. Medical Journal of Australia, 202(6): 1-4.

While the first sentence is similar to AUSFTA, the second sentence in this footnote has no parallel in AUSFTA. It would be a shame if this language cemented low patentability standards in place. The fact that 'obvious' is not defined may however leave sufficient flexibility to work around this provision.

TPP Articles 18.46 and 18.48 require parties to provide patent term extensions to compensate for "unreasonable or unnecessary delays" in issuing patents or processing applications for marketing approval (respectively). In some respects these TPP provisions provide more flexibility than the corresponding provisions in AUSFTA, and there is no mandatory length specified, but they do add another layer of international obligation to provide patent term extensions. The Pharmaceutical Patents Review<sup>26</sup> conducted under the previous government estimated that in 2012-2013, patent term extensions had cost the PBS approximately \$240 million in the short term and \$480 million in the long term. The PPR recommended that patent term extensions be wound back or that effective patent life be reduced to better align the patent system with the public interest.<sup>26</sup>

Interestingly, a side letter agreed between the US and Australia<sup>27</sup> indicates that Articles 18.46(3)-(4) (Patent Term Adjustment for Patent Office Delays) of the TPP will replace the corresponding provision of AUSFTA (Article 17.9.8(a)). An unreasonable delay in issuing a patent is defined in the TPP as a delay of more than five years from the date of filing an application or three years after a request for examination of an application, whichever is later. AUSFTA Art. 17.9.8(a), which has now been replaced, defined an unreasonable delay as more than four years from the date of filing or two years after a request for examination. It is possible that there may be scope to apply patent term extensions to fewer products as a result of this side letter (assuming that a significant proportion of patent term extensions are granted due to patent office delays).

It is important to note that the patent term extension provisions of neither AUSFTA nor the TPP specify a minimum length of the extension of term that needs to be granted to compensate for either patent office delays or marketing approval delays. The Productivity Commission should carefully consider the scope for implementing the recommendations of the Pharmaceutical Patents Review with respect to reducing the length of patent term extensions or reducing effective patent life.

Other existing intellectual property settings which are entrenched by the TPP include five years' protection of clinical trial data for small molecule drugs and a requirement to provide either an additional 3 years for new indications, or at least five years for products containing a chemical entity that has not been previously approved (Art 18.50). The TPP also requires patent linkage (Art 18.51), although the final provisions allow more flexibility in the implementation than those in AUSFTA.

### *2.2.3 Implications of the TPP IP provisions for Australia*

The provisions relating to biologics are problematic and ambiguous. They appear to commit countries to providing either eight years of clinical trial data protection, or five years of clinical trial data protection along with other measures to deliver comparable outcomes. While the Australian Government has said that the regime for biologics in Australia will not change, the language leaves

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<sup>26</sup> Harris T, Nicol D, Gruen N. Pharmaceutical Patents Review report. Canberra: Commonwealth of Australia, 2013: 160. [http://www.ipaustralia.gov.au/pdfs/2013:-05-27\\_PPR\\_Final\\_Report.pdf](http://www.ipaustralia.gov.au/pdfs/2013:-05-27_PPR_Final_Report.pdf)

<sup>27</sup> Trans Pacific Partnership (2015) Side letters between the United States and Australia: Intellectual Property: Regulatory Review Exception, Technical Protection Measures, Unreasonable patent office delays. Retrieved 24 December 2015, from: <http://dfat.gov.au/trade/agreements/tpp/official-documents/Documents/australia-us-intellectual-property-regulatory-review-exception-technical-protection-measures-patent-office-delays.PDF>

room for continued pressure by the United States to ensure that TPP countries prevent biosimilars from entering the market for eight years. The definition of biologics is very broad and likely to limit countries' flexibility in determining the scope of the obligation. A review by the TPP Commission of both the length and scope of protection after ten years provides a further mechanism for US pressure to expand and extend monopolies on expensive biologics. It is vitally important to ensure that the Australian Government does not buckle to pressure to extend market exclusivity for biologics, which would delay the market entry of biosimilars, add to the costs of the PBS for taxpayers and potentially cause delays in new drugs being listed on the PBS.

With the possible exception of the biologics provisions, in most respects, the TPP intellectual property chapter is consistent with existing intellectual property arrangements in Australia and with the obligations of the Australia-US Free Trade Agreement (AUSFTA). In fact the minimal impact of the TPP's IP chapter on Australia's existing intellectual property arrangements is largely due to the fact that Australia has a pre-existing trade agreement with the US. There is a risk that the TPP obligations will lock in current intellectual property standards, making it more difficult to reform our system to improve access to affordable medicines in future. Nevertheless, the Productivity Commission should carefully examine the TPP text for the degree of flexibility it provides to reform Australia's intellectual property arrangements, and in particular to implement the recommendations of the Pharmaceutical Patents Review.

#### *2.2.4 Implications for other TPP countries, particularly developing countries*

Doctors Without Borders/Médecins Sans Frontières (MSF) has repeatedly warned that the TPP could be disastrous for access to medicines in developing countries. At the conclusion of the negotiations, MSF issued a statement including the following comment:

MSF remains gravely concerned about the effects that the Trans-Pacific Partnership trade deal will have on access to affordable medicines for millions of people, if it is enacted. Today's official release of the agreed TPP text confirms that the deal will further delay price-lowering generic competition by extending and strengthening monopoly market protections for pharmaceutical companies.<sup>28</sup>

All countries will eventually have to adopt all the rules in the intellectual property chapter. There are transition periods for the four poorest countries (Malaysia, Mexico, Peru and Vietnam) but these are far too short for the realities these countries face (only 3-10 years) and apply to only a few of the TPP's obligations.<sup>29</sup> For example, Vietnam will only have 3 years to implement patent linkage provisions and 5 years to implement patent term extensions for patent office delays (with a possible extension of one additional year). It appears that countries will have to graduate to the higher level IP protections regardless of their rate of development.

The pharmaceutical industry has expressed disappointment over the failure of the U.S. to obtain 12 years of market exclusivity for biologics,<sup>30</sup> but in reality it has gained enormous concessions. If the TPP countries ratify the deal, Big Pharma will have succeeded in cementing intellectual property

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<sup>28</sup> Médecins Sans Frontières (2015) Statement by MSF on the official release of the full text of the Trans-Pacific Partnership trade agreement. Retrieved 24 December 2015, from <http://www.msfacecess.org/about-us/media-room/press-releases/statement-msf-official-release-full-text-trans-pacific>

<sup>29</sup> Public Citizen (2015). TPP Transition Periods on Pharmaceutical Intellectual Property Rules: Bad Rules Coming Soon in a TPP Country Near You. Retrieved 24 December 2015, from <https://wikileaks.org/tpp-ip3/pharmaceutical-transition/TPP%20Transition%20Periods%20on%20Pharmaceuticals.pdf>

<sup>30</sup> PhRMA (2015) PhRMA Statement On the TransPacific Partnership Negotiations. Retrieved 24 December 2014, from: <http://phrma.org/media-releases/phrma-statement-on-the-transpacific-partnership-negotiations>

standards that will stymie access to medicines for up to 800 million people in the short term, and more if additional countries sign up in future. Furthermore, the TPP's intellectual property chapter sets a new norm that is likely to become the template for future trade agreements: its implications are global as well as regional.

The governments of TPP countries have been complicit in a global health disaster of unimaginable proportions - a deal that will prevent untold numbers of people from obtaining medicines that those in many developed countries take for granted. The Productivity Commission should be mindful of the potential impact of the TPP intellectual property chapter on access to medicines in developing countries in the region. Of particular concern is the potential impact on countries such as Thailand and Indonesia which are considering acceding to the TPP, and which, as later entrants, may not be able to negotiate the same degree of flexibility in implementing the obligations as the founding parties, or suitable transition periods for implementation.

## 2.2 Investment Chapter

The TPP's investment chapter<sup>31</sup> includes intellectual property in the definition of investment. The TPP includes an investor-state dispute settlement (ISDS) mechanism which can be used to challenge laws and regulatory measures that a foreign investor perceives to have harmed its investments. While an earlier leaked draft of the TPP investment chapter<sup>32</sup> showed that Australia was attempting to exclude certain Australian health programs from ISDS (the Medicare Benefits Scheme, the Pharmaceutical Benefits Scheme, the Therapeutic Goods Administration and the Office of the Gene Technology Regulator), these exemptions were abandoned in the final text.

The ISDS claim brought by US pharmaceutical company Eli Lilly against the Canadian Government<sup>33</sup> over the revocation of two patents illustrates the potential implications ISDS holds for domestic intellectual property settings. Various "safeguards" included in the final TPP Investment chapter may assist a government to succeed in defending an ISDS claim and may go some way towards deterring frivolous claims, but in the absence of a comprehensive carve-out, the risk remains that pharmaceutical companies will use ISDS to seek to deter governments from regulating in the public interest. US companies are the biggest users of ISDS<sup>34</sup> and many large pharmaceutical companies are headquartered in the US.<sup>35</sup>

Of particular concern is Article 9.7.5 of the TPP Investment Chapter which attempts to carve out compulsory licenses or the "revocation, limitation or creation of intellectual property rights", however this clause also indicates that such actions must be consistent with the TPP intellectual property chapter and the TRIPS Agreement. This means that pharmaceutical companies may be able to use ISDS to contest a country's interpretation of the TRIPS agreement or its obligations under the

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<sup>31</sup> Trans Pacific Partnership (2015) Chapter 9: Investment. Retrieved 24 December 2015, from:

<https://mfat.govt.nz/assets/securedfiles/trans-pacific-partnership/text/9.-investment-chapter.pdf>

<sup>32</sup> Trans Pacific Partnership (2015) Investment Chapter (January 20, 2015 draft) [Leaked draft]. Retrieved 24 December 2015, from: <https://wikileaks.org/tpp-investment/WikiLeaks-TPP-Investment-Chapter.pdf>

<sup>33</sup> Eli Lilly and Company v. The Government of Canada, UNCITRAL, ICSID Case No. UNCT/14/2 Retrieved 24 December 2015, from: <http://www.italaw.com/cases/1625>

<sup>34</sup> United Nations Conference on Trade and Development (2015). Recent trends in IIAs and ISDS. Retrieved 24 December 2015, from: [http://unctad.org/en/PublicationsLibrary/webdiaepcb2015d1\\_en.pdf](http://unctad.org/en/PublicationsLibrary/webdiaepcb2015d1_en.pdf)

<sup>35</sup> Gleeson D, Neuwelt P, Monasterio E and Lopert R. (forthcoming) How the Transnational Pharmaceutical Industry Pursues its Interests Through International Trade and Investment Agreements: A Case Study of the Trans Pacific Partnership. Handbook of Research on Transnational Corporations, Alice De Jonge and Roman Tomasic (eds), Edward Elgar Publishing Ltd. Retrieved 24 December 2015, from [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2668576](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2668576)

TPP IP chapter. It is a very retrograde step to allow countries' interpretation and implementation of the TRIPS Agreement to be contested in the context of arbitral tribunals outside of the multilateral World Trade Organization process.

### 3. CONCLUDING COMMENTS

The proposed framework outlined in the Productivity Commission Issues Paper<sup>36</sup> outlines four principles that should be applied to the IP system to achieve the objective of maximising the well-being of Australians. How well does the TPP measure up against these principles?

- *The system should be effective:*  
Judged against this principle, the TPP intellectual property provisions fall short. There is no convincing evidence that stronger intellectual property rights (IPRs) encourage true innovation or dissemination of IP in ways that advance the public interest. On the contrary, there is evidence that stronger intellectual property rights do not provide incentives for true innovation, particularly innovation that benefits people in developing countries.<sup>37</sup>
- *The system should be efficient:*  
There are large scale costs to government and consumers associated with expanding IPRs.
- *The system should be adaptable:*  
Trade agreements tend to lock in policy settings that do not necessarily suit the domestic context.
- *Governance arrangements should be accountable and transparent:*  
The TPP and other bilateral and regional trade agreements are negotiated under conditions of confidentiality and without public and expert scrutiny. Experts have been reliant on leaked draft texts for information about the issues under negotiation.

The Productivity Commission's 2010 Review of Bilateral and Regional Trade Agreements<sup>38</sup> recommended that the Australian Government should:

- 'only pursue bilateral and regional trade agreements where they are likely to afford significant net economic benefits' (Recommendation 1);
- 'only include IP provisions ' in cases where a rigorous economic analysis shows that the provisions would likely generate overall net benefits for the agreement partners' (Recommendation 4b);

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<sup>36</sup> Australian Government Productivity Commission (2015) Intellectual Property Arrangements: Productivity Commission Issues Paper, October 2015. Retrieved 24 December 2015, from:

<http://www.pc.gov.au/inquiries/current/intellectual-property/issues/intellectual-property-issues.pdf>

<sup>37</sup> See, for example, Shadlen, K et al. (2011) Globalization, Intellectual Property Rights, and Pharmaceuticals: Meeting the Challenges to Addressing Health Gaps in the New International Environment. Edward Elgar Publishing; Kyle MK and McGahan AM, Investments in Pharmaceuticals Before and After TRIPS. Review of Economics and Statistics, NBER Working Paper No. 15468, October 2009, available at:

<http://www.nber.org/papers/w15468.pdf>; and Government Accountability Office. New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts, GAO-07-49, November 2006, available at: <http://www.gao.gov/new.items/d0749.pdf>.

<sup>38</sup> Productivity Commission (2010) Bilateral and Regional Trade Agreements. Productivity Commission Research Report. Retrieved 24 December 2015, from; <http://www.pc.gov.au/inquiries/completed/trade-agreements/report/trade-agreements-report.pdf>

- ‘Commission and publish an independent and transparent assessment of the final text of the agreement, at the conclusion of the negotiations, but before an agreement is signed’ (Recommendation 5c).

Such independent and transparent analysis of the final TPP text has not been undertaken despite many calls for such independent assessment (including health and human rights impact assessment) by experts and community organisations.

The 2015 Senate Inquiry report *Blind agreement: Reforming Australia's Treaty-making Process*<sup>39</sup> also strongly criticised the secrecy with which trade agreements are negotiated and made a number of recommendations for improving the transparency and accountability of the trade negotiating process.

In addition to the recently-concluded TPP, the Australian Government has been negotiating the Regional Comprehensive Economic Partnership (RCEP) with 15 countries in the region and has announced the commencement of discussions toward a trade agreement with the European Union. Intellectual property proposals tabled for the RCEP by Japan and South Korea suggest that it may also involve an expansion of IPRs that could be disastrous for the developing countries involved<sup>40</sup>. It would be a great shame if these trade agreements repeat the same flawed approach as the TPP and contribute to expanding and/or locking in an IP regime that allows neither domestic flexibility in setting IP policy nor access to affordable medicines for much of the world’s population.

#### 4. RECOMMENDATIONS

- 1) The Productivity Commission should carefully examine the potential impact of the provisions of the proposed TPP on Australia’s intellectual property arrangements, and on developing countries. This is particularly important given that the Australian Parliament is likely to be considering the TPP at the time when the draft report from the inquiry is released.
- 2) An independent impact assessment of the final TPP should be undertaken, including its impact on health and human rights.
- 3) Changes to the treaty-making process should be considered to make the negotiation of bilateral and regional trade and investment agreements more transparent and accountable and to improve opportunities for scrutiny of proposed provisions by experts and the public.
- 4) The Productivity Commission should carefully consider the scope for implementing the recommendations of the Pharmaceutical Patents Review, particularly with respect to reducing the length of patent term extensions or reducing effective patent life.
- 5) Ongoing efforts by the pharmaceutical industry to lengthen monopolies, particularly market exclusivity for biologic products, are not in the public interest and should continue to be resisted.

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<sup>39</sup> Commonwealth of Australia (2015) *Blind agreement: Reforming Australia's Treaty-making Process*. Retrieved 24 December 2015, from: [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Foreign\\_Affairs\\_Defence\\_and\\_Trade/Treaty-making\\_process/Report](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/Treaty-making_process/Report)

<sup>40</sup> Townsend B, Gleeson D & Lopert R. (2015) Pharma's next frontier? New threats to public health in the Regional Comprehensive Economic Partnership agreement. *Australian and New Zealand Journal of Public Health*, DOI: 10.1111/1753-6405.12453.

- 6) The Productivity Commission should examine international initiatives to identify and implement alternative ways to fund pharmaceutical research and development, such as those recommended by the *Report of the World Health Organization's Consultative Expert Working Group on Research and Development: Financing and Coordination*<sup>41</sup> and consider recommending changes to Australia's intellectual property arrangements that facilitate such initiatives in future.<sup>42</sup>

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<sup>41</sup> World Health Organization (2012) Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. Retrieved 24 December 2015, from [http://www.who.int/phi/CEWG\\_Report\\_5\\_April\\_2012.pdf](http://www.who.int/phi/CEWG_Report_5_April_2012.pdf)

<sup>42</sup> The United Nations Secretary-General has also established a High Level Panel on Access to Medicines, with the objective "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies." A draft report is to be released in April 2016 and a final report in June 2016. See <http://www.unsgaccessmeds.org/#homepage>