Submission to the Joint Standing Committee on Treaties Inquiry into the Trans Pacific Partnership Agreement

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Dr Deborah Gleeson

School of Psychology and Public Health

La Trobe University VIC 3086

About the author

Dr Deborah Gleeson (BAppSc(MLS), Grad Dip Health Prom, MPH, PhD) is a Lecturer in Public Health at La Trobe University's School of Psychology and Public Health. Her research focuses on the intersection between trade policy and public health. Deborah is currently working on research funded by the Australian Research Council examining the relationship between trade policy, nutrition and health. Another major focus of her research is trade and access to medicines. She has been undertaking research on the Trans Pacific Partnership Agreement over the last five years. Her publications include a large number of peer-reviewed articles on trade and health, invited editorials in the Medical Journal of Australia and the New Zealand Medical Journal, many submissions to government departments and inquiries and over 25 opinion pieces published in Australian and international media outlets. A list of her peer-reviewed publications relevant to this submission is included in Appendix 1.

Dr Gleeson is national convener of the Political Economy of Health Special Interest Group of the Public Health Association of Australia (PHAA) and as part of this honorary role, often represents PHAA on issues related to trade agreements. In this capacity she has observed (from the sidelines) seven trade negotiating rounds and/or ministerial meetings for the TPP in Melbourne, San Diego, Auckland, Kota Kinabalu (Malaysia), Singapore, Canberra and Hawaii. A frequent media commentator, she has been interviewed on ABC Radio and quoted in the New York Times, the Sydney Morning Herald and the Guardian. She received a President's Award 2015 from the Public Health Association of Australia for public health leadership, engagement and commitment on the impact of international trade issues on health.

The views expressed in this submission are the author's own and do not represent the views of any organisation with which she is affiliated.

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Introduction

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 commenced in March 2010 and concluded in October 2015. The agreed text of the TPP (minus legal scrubbing) was publicly released on 5 November 2015 and the legally verified version on 26 January 2016. [1]

Throughout the negotiations, the TPP was subject to extensive criticism from health, development and consumer organisations, both internationally and within Australia.[2] 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.

In March 2015, a health impact assessment of the TPP,[3] 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.

Time and resources do not permit a full examination of the implications of the final text of the Trans Pacific Partnership for public health at this point in time. This submission focuses primarily on the three main parts of the TPP which have implications for access to affordable medicines for Australians. Where relevant it also highlights aspects of these parts of the text that have important implications for other countries in our region.

Three sections of the TPP are examined in depth in terms of their potential impact on access to affordable medicines:

- Chapter 18: Intellectual Property;
- Chapter 9: Investment; and
- Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices.

[1] New Zealand Ministry of Foreign Affairs and Trade (2015) Text of the Trans Pacific Partnership. Retrieved 11 March 2016, from http://www.mfat.govt.nz/Treaties-and-International-Law/01-Treaties-for-which-NZ-is-Depositary/0-Trans-Pacific-Partnership-Text.php

[2] 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).

[3] 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/

The TPP Intellectual Property Chapter: Implications for Access to Medicines

The primary concern for Australia arising from the TPP Intellectual Property Chapter is the provisions for biologic products (Article 18.51: 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.

Market exclusivity for biologic products: ambiguous and risky 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.[4] These drugs account for a growing share of PBS expenditure.[5]

The ten biologic drugs listed on Australia's Pharmaceutical Benefits Scheme accounting for the largest government expenditure in the 2013-14 financial year cost the Pharmaceutical Benefits Scheme approximately $1.29 billion AUD.[6] This represents approximately 14% of the $9.15 billion dollars in overall expenditure on the PBS during the same period.[7]

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.[6] Further information about the underpinning analysis can be found in Appendix 2.

[4] 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

[5] 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

[6] 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 (or available from the authors).

[7] 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

The United States was seeking to secure twelve years of market exclusivity for biologics in the TPP; 12 years was a key objective of the US-based pharmaceutical industry.[8] 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.[9]

Weissman and Brennan[10] 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[11] that an extended period was not justified.

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[12] 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.*

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[8] 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-

[9] 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

[10] 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

[11] 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

[12] Department of Foreign Affairs and Trade (2015) Trans Pacific Partnership Agreement: Outcomes: Biologics. Retrieved 11 March 2016, from http://dfat.gov.au/trade/agreements/tpp/Documents/outcomes-biologics.PDF

The Australian Government has been adamant that it has not agreed to change Australia's arrangements for biologics via the TPP, and the former 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.[13]

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

Article 18.51: Biologics[58]

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,[59,60] 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
(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.

[13] 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

[14] Trans Pacific Partnership (2016) Chapter 18: Intellectual Property. Retrieved from: https://www.mfat.govt.nz/assets/_securedfiles/trans-pacific-partnership/text/18.-intellectual-property-chapter.pdf

[58] Annex 18-B, Annex 18-C and Annex 18-D apply to this Article.
[59] 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.
[60] 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 18.51.1 outlines two options that countries can implement to protect new biologics, which can be summarised as follows (refer to Box 1 above for the exact legal text):

1) At least 8 years' protection of clinical trial data (Article 18.51.1(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 18.51.1(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 or following 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 biologics) off the market for eight years, in order to provide equivalent "effective market protection" and a "comparable outcome" to eight years of market exclusivity. This pressure may occur even before the TPP enters into force. 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.[15]

There are several risks associated with the ambiguity of the biologics provisions. If Article 18.51.1(b) is interpreted to provide for the equivalent of eight years of market exclusivity:

1) New impediments could be introduced to ensure that biosimilars do not reach the market in less than eight years after the original biologic has received marketing approval. Under current arrangements in Australia, it is *possible* for a biosimilar to enter the market 6-8 years after the original biologic has received marketing approval, although prevailing market circumstances mean that to date, it has generally taken longer than this. To provide a *guarantee* that a biologic would receive eight years of market exclusivity would require the introduction of new obstacles in the regulatory processes. The Australian Government has to date stated very strongly that it will not take this course of action. It is vital that the Government continues to maintain this commitment.

[15] 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

2) Disputes may arise over the interpretation of Article 18.51.1 in the event that a biosimilar reaches the market in less than eight years. It is difficult to predict how Art. 18.51.1 would be interpreted in the context of a tribunal, particularly given that the negotiating history is not publicly accessible. The ambiguity of the provisions may work in Australia's favour, or it may not.

3) The biologics provisions may have a chilling (deterrent) effect on the introduction of new measures to facilitate the faster availability of biosimilars. Such a chilling effect would be difficult to detect and verify but it would translate into substantial savings foregone for the PBS.

Article 18.51.2 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[16] 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 18.51.3 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.

Other intellectual property provisions: reducing future policy flexibility

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[14] include:

- Patents for new uses and new methods of using existing products (Article 18.37.2);[17]
- A low inventiveness threshold – potentially preventing countries from tightening the criteria for granting patents (Footnote 30);

[16] 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

[17] 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.

- Patents for inventions that are derived from plants (Article 18.37.4);[18]
- Patent term extensions to compensate for delays in granting patents (Article 18.46) and delays in marketing approval (Article 18.48);[19]
- 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);[20]
- Patent linkage provisions likely to result in delays in marketing approval for generic drugs (Article 18.53);[21]
- 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 18.51);[22] 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[23]. 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.[24] There are strong arguments for limiting secondary patents and raising the inventiveness standard to reduce evergreening and delays to generic entry.[24,25] 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). However it does add another unnecessary layer of international obligation to make secondary patents available.

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[18] This is an issue for food security in developing countries rather than access to medicines.
[19] 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.
[20] 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.
[21] 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.
[22] 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.
[23] 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
[24] Moir, H. (2013) The Promise to the Public: Generic Competition. Submission to the Pharmaceutical Patents Review.
[25] 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.

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

> [30] 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)

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[26] 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.[26]

Interestingly, a side letter agreed between the US and Australia[27] 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 Australian Government 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

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[26] 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

[27] 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

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.

Implications of the TPP intellectual property 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 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, however, 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.

Implications of the TPP intellectual property provisions for 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.[28]

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.[29] 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.

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[28] 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.msfaccess.org/about-us/media-room/press-releases/statement-msf-official-release-full-text-trans-pacific

[29] 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

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

The TPP Investment Chapter: Implications for Access to Medicines

The TPP's investment chapter[31] includes intellectual property in the definition of investment. The TPP also 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[32] 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[33] over the revocation of two patents illustrates the potential implications ISDS holds for domestic intellectual property settings. Claims like this appear to be possible under the TPP. It is important to note that US companies are the biggest users of ISDS[34] and many large pharmaceutical companies are headquartered in the US.[35]

Various legal 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

[30] 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
[31] 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
[32] Trans Pacific Partnership (2015) Investment Chapter (January 20, 2015 draft) [Leaked draft]. Retrieved 24 December 205, from: https://wikileaks.org/tpp-investment/WikiLeaks-TPP-Investment-Chapter.pdf
[33] 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
[34] 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
[35] 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

the absence of a comprehensive carve-out for health-related measures, the risk remains that pharmaceutical companies will use ISDS to seek to deter governments from regulating in the public interest. Problems with the ISDS legal safeguards are covered extensively in expert papers by the Columbia Center on Sustainable Investment[36] and Amokura Kawharu from the University of Auckland's Faculty of Law.[37] My preliminary analysis comparing the claims made by the Australian Government about the ISDS safeguards with the final legal text of the investment chapter is attached in Appendix 4.

Of particular concern is Article 9.8.5 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 TPP IP chapter. It is a very retrograde step to allow parties' interpretation and implementation of the TRIPS Agreement to be contested in the context of arbitral tribunals outside of the multilateral World Trade Organization process.

Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices

This section of the submission provides a summary of the findings of a detailed provision-by provision analysis of Annex 26-A which can be found in Appendix 3.

The intent of Annex 26-A of the Trans Pacific Partnership Agreement (TPP)[38] is to discipline national pricing and reimbursement schemes for pharmaceutical products and medical devices.

While the language of the Annex is framed around principles of transparency and fairness, the objectives of the pharmaceutical and medical device industries clearly go much further than this. The ultimate objective of the industry is expanded market access at monopoly prices dictated by industry: the target is mechanisms that impact on both market access and prices. The Annex was intended to achieve this objective through greater disclosure of information, greater industry participation, and ultimately more leverage for the industry in decision making regarding pricing, reimbursement and other decisions that impact on market share, such as the range of therapeutic indications for which a product is subsidised.

[36] Johnson, L, and Sachs, L. (2015) The TPP's Investment Chapter: Entrenching, rather than reforming, a flawed system. Columbia Center on Sustainable Development. Retrieved 11 March 2016, from http://ccsi.columbia.edu/2015/11/18/the-tpps-investment-chapter-entrenching-rather-than-reforming-a-flawed-system/

[37] Kawkaru, A. (2015) Expert Paper #2: TPPA: Chapter 9 on Investment. Trans-Pacific Partnership Agreement New Zealand Expert Paper Series. The Law Foundation New Zealand. Retrieved 11 March, 2016, from https://tpplegal.files.wordpress.com/2015/12/ep2-amokura-kawharu.pdf

[38] See pages 26-11 to 26-16, Trans Pacific Partnership Chapter 26: Transparency and Anti-Corruption. Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices. Retrieved from: http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/TPP-text/26.%20Transparency%20and%20Anti-Corruption%20Chapter.pdf

It is unlikely that the final Annex will go very far, at least in the first instance, towards achieving these industry objectives. The contents of the Annex have changed significantly since the first proposal, tabled by the United States, was leaked in 2011.[39]

The initial US proposal was based largely on text from the trade agreement between South Korea and the US (KORUS).[40] A later leaked draft from 2014[41] showed a significant 'watering down' of the original US proposal due to opposition by the non-US countries,[39] and some of the remaining concerns of public health and access to medicines advocates have been further mitigated in the final text.

Annex 26-A in its final form is in many respects closely modelled on Annex 2-C of the Australia-US Free Trade Agreement.[42] In contrast to KORUS, AUSFTA contains no provisions directly relating to pricing: it only pertains to the listing of pharmaceuticals for reimbursement.[40, 43]

There are some important differences between AUSFTA Annex 2-C and TPP Annex 26-A. Unlike Annex 2-C, the TPP Annex covers medical devices, although Australia and New Zealand have succeeded in carving out medical devices from their obligations. Interestingly, the TPP Annex includes some additional flexibilities that did not appear in AUSFTA Annex 2-C. But the inclusion of an investor-state dispute settlement (ISDS) mechanism in the TPP, which AUSFTA did not contain, raises new risks that the Annex may lend weight to ISDS claims by pharmaceutical and medical device companies that countries have breached the obligations of the Investment Chapter. The TPP Annex also includes a consultation obligation which may be not be circumscribed in the same way as the mechanism established under the AUSFTA.

I have previously argued[39,40] that it is inappropriate to have provisions like these in a trade agreement – the conduct of health programmes should be a matter for domestic and democratic policy making – and that the inclusion of such provisions sets a negative precedent for other trade agreements. It is a shame that the unanimous opposition to the first US proposal did not see the Annex abandoned altogether.

Nonetheless, the TPP Healthcare Transparency Annex has undergone such a transformation during the negotiations, as a result of immutable opposition to the initial US proposal, that it no longer represents the serious impingement on the functioning of national pharmaceutical pricing and reimbursement schemes that it threatened to be. Most importantly, there are no provisions

[39] For a comprehensive account of the changes made to the draft Annex between 2011 and December 2014, see Gleeson, D. (2015). Commentary on the Leaked TPP Transparency Chapter Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices dated December 17, 2014 and released by Wikileaks in June 2015. Retrieved 13 November 2015, from: https://wikileaks.org/tpp/healthcare/Analysis-Dr-Deborah-Gleeson/page-1.html

[40] Lopert R, Gleeson D. (2013). The high price of "free" trade: U.S. trade agreements and access to medicines. Journal of Law, Medicine and Ethics, 41(1), 199-223.

[41] Trans Pacific Partnership. (2014, December). TPP Transparency Chapter Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices [Leaked draft released by Wikileaks, June 2015]. Retrieved 13 November 2015, from: https://wikileaks.org/tpp/healthcare/

[42] See Annex 2-C of Chapter 2 (National Treatment and Market Access for Goods) of the Australia-US Free Trade Agreement, available at http://dfat.gov.au/trade/agreements/ausfta/official-documents/Pages/official-documents.aspx

[43] It is important to note, however, that for programmes that have a funding cap (such as PHARMAC, New Zealand's Pharmaceutical Management Agency), pricing is more integrally linked to listing than in programmes like Australia's Pharmaceutical Benefits Scheme, which is uncapped.

remaining that target pricing, and the Annex is not enforceable through the TPP's state-to-state dispute settlement process.

The implementation of the Annex in its final form will require no changes to Australia's Pharmaceutical Benefits Scheme, provided Australia successfully deflects any further pressure applied by the US during certification. While New Zealand's PHARMAC will need to introduce a statutory timeframe for considering applications and a new review process, considerable flexibility is built into the provisions, meaning that the impact on PHARMAC's existing operations will not be as extensive as initially feared. Provisions in other parts of the TPP such as the intellectual property chapter and the investment chapter are likely to have far greater impact.

However, the following concerns regarding Annex 26-A remain:

- Unlike the Australia-US Free Trade Agreement, the TPP includes an investor-state dispute settlement mechanism which provides the pharmaceutical and medical device industries with an avenue to bring claims, or threaten to bring claims, over pharmaceutical policy decisions they perceive as breaching their rights under the investment chapter. Various provisions in Annex 26-A may be used to support claims that the Investment Chapter obligations have been breached. While purported safeguards in the Investment Chapter aim to reduce the risk that such a claim would be successful, each of these safeguards contains flaws. The risk remains that an ISDS claim could be made, or that a company may threaten to use ISDS, in an effort to deter governments from regulating.

- The principles in Annex 26-A Article 2 (labelled Paragraph 26-A.1 in the version prior to legal scrubbing) are more heavily weighted in the interests of the industry rather than the public, and could help to bolster a claim made by a pharmaceutical or medical device company using the TPP's ISDS mechanism. All TPP countries appear to be exposed to this risk, not just the countries which have national healthcare programmes identified in the Schedule to the Annex. Countries could also face pressure over the interpretation of the principles through the consultation process in Article 5 (formerly Paragraph 26-A.4), or through avenues outside the TPP, such as the annual Special 301 Report.

- For New Zealand, and for other countries which introduce national programmes for listing pharmaceutical products and/or medical devices in future, there will be significant administrative costs involved in implementing the obligations of Article 3 (formerly Paragraph 26-A.2). New Zealand has estimated the cost of implementing the Annex at approximately $4.5 million NZD in initial establishment costs and $2.2 million each year in ongoing costs.[63] These costs are quite significant given that PHARMAC reported spending approximately $28.7 million in operating costs in the 2014-2015 financial year.[44] In addition to these costs, PHARMAC may also face pressure on its pharmaceutical budget resulting from commitments in the intellectual property chapter, such as patent term extensions and patent linkage (and extended market exclusivity for biologics, should New Zealand bow to pressure from the US to provide longer than the existing five years). Developing countries that introduce subsidy programmes in future are more likely to find the costs associated with implementing the Annex prohibitive and are less likely to have the human resource

[44] Pharmaceutical Management Agency (2015). Annual Report for the year ended 30 June 2015. Retrieved 11 December 2015 from https://www.pharmac.health.nz/assets/annual-report-2014-2015.pdf

capacity to administer the requirements without introducing opportunity costs in other areas of health policy.

- For New Zealand, certain provisions in Article 3 (formerly Paragraph 26-A.2) may also constrain PHARMAC's flexibility and facilitate industry lobbying and pressure from other TPP Parties. This is particularly the case for Article 3(a) (formerly Para 26-A.2 (a)), the requirement to consider proposals within a specified period of time. Much will depend on how this is implemented in NZ and PHARMAC's ability to continue to resist pressure from industry and/or other TPP Parties to adopt and adhere to a short timeframe. The impact of the new review process outlined in Article 3 (e) (formerly Paragraph 26-A.2 (e)) will likewise depend on how well New Zealand is able to use the flexibilities in the legal text to design the process in such a way as to minimise its effects.

- Article 4 (formerly Paragraph 26-A.3) does not prevent countries from prohibiting direct-to-consumer advertising of pharmaceuticals, but if a TPP country that has previously permitted pharmaceutical advertising subsequently prohibits or places new limits on it, this may be challenged using the ISDS mechanism.

- The consultation mechanism in Article 5 (formerly Paragraph 26-A.4) obliges countries to consult on receipt of a written request from another party on matters related to the Annex. This consultation process cannot be used to force a country to review or change decisions about specific applications for reimbursement. But unless countries insist on establishing committees with limited terms of reference like the Medicines Working Group established under the AUSFTA, countries may face ongoing pressure over their implementation of the Annex and their health care decision making more generally.

Concluding points

The final text of the Trans Pacific Partnership Agreement holds significant risks for access to affordable medicines in the TPP countries, including Australia. There will be implications for government expenditure in developed countries as well as access to medicines in developing countries.

The three parts of the TPP with the greatest implications for access to medicines are the Intellectual Property Chapter (Chapter 18), the Investment Chapter (Chapter 9) and Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices).

The final provisions related to biologic products in the intellectual property chapter are worryingly ambiguous and unclear. This ambiguity was intended to be a constructive ambiguity, but it may have unintended effects if the US interpretation prevails during the certification phase, in the event of a dispute, or if the provisions have a chilling effect on future regulatory reform to bring biosimilars to the market more speedily. The Australian Government insists that it has not agreed to eight years of market exclusivity for biologics and that it will not need to change current arrangements in Australia, and it is most important that this commitment is followed through. Even so, whether the Government's continued insistence will be sufficient to achieve this outcome is not clear.

Aside from the biologics provisions, there are a number of other provisions in the intellectual property chapter which will lock in existing policy settings and could potentially frustrate future

reform efforts to reduce pharmaceutical expenditure in Australia. Adopting detailed, prescriptive policy settings negotiated in a fraught political context, largely out of the view of stakeholders, and involving bargaining and trade-offs between the objectives of different sectors, does not amount to sensible health or intellectual property policy making which is attuned to current and future domestic needs.

Even more important is the effect the TPP's intellectual property settings can be expected to have on access to medicines in developing countries. While Australia has not been the demandeur of expanded intellectual property rights, it will be to Australia's shame if it enters into an agreement that costs large numbers of lives in developing countries.

The TPP's investment chapter, and in particular its investor-state dispute settlement mechanism, also bring new threats to the affordability of medicines. The TPP will be the first time we have an ISDS mechanism in an agreement with the US, home to many of the world's largest pharmaceutical companies. It is likely that multinational pharmaceutical companies will quickly take advantage of this new avenue to contest and frustrate Australia's pharmaceutical policy making. The size of the awards and the costs of arbitration are likely to have a deterrent effect on policies that reign in costs and impact on the profit margins of the pharmaceutical giants. While a number of legal safeguards have been included in the TPP to reduce the chance of successful ISDS claims over health and environmental measures, none of these (apart from the much-lauded tobacco control safeguard) provide any concrete assurance that claims over legitimate health policies will be prevented.

Finally, the TPP's Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) adds further complexity and uncertainty. While the final form of the annex is sufficiently similar to Annex 2-C of the Australia-US Free Trade Agreement that it will not require procedural changes to Australia's Pharmaceutical Benefits Scheme, its provisions may lend weight to the claims of a pharmaceutical company in the event of an ISDS dispute. It also includes a consultation mechanism that is not clearly circumscribed in the manner in which the Medicines Working Group set up under the Australia-US Free Trade Agreement was, and has the potential to expose our policy makers to ongoing pressure over pharmaceutical decision making.

From an *access to medicines* or *pharmaceutical policy* perspective, the TPP represents a poor deal for Australia and a far worse scenario for developing countries. This comes at a time when increasingly expensive drugs are entering the market and there is growing recognition at the global level that the current system of funding research and development through monopoly rights has failed to deliver affordable medicines to a large part of the world's population. A new global regime for funding research and development is needed, but the TPP takes us backwards rather than moving us towards a new future where affordable access to medicines is a reality for all.

Due to limited time and resources, this submission only covers the implications of the TPP for access to affordable medicines. There is a range of other potential health impacts that also need to be taken into account in making a decision about whether the TPP is in Australia's interests. A comprehensive, independent health impact analysis would be needed to fully explore these issues.