

**Submission to the Department of Foreign Affairs and Trade:
The Trans Pacific Partnership Agreement,
Intellectual Property and Medicines**

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Executive summary

This submission sets out our organisations' views on the US proposals for intellectual property and medicines for the Trans Pacific Partnership Agreement (TPPA) negotiations, and our views on the position that should be taken by the Australian Government at the current stage in the negotiations.

The United States Trade Representative proposed a set of extreme pharmaceutical intellectual property (IP) provisions for the Trans Pacific Partnership Agreement in 2011. These proposals, which were subsequently leaked, were met with outrage by national and international health and development organisations as they would severely restrict access to affordable medicines in the TPPA countries. Our organisations are strongly opposed to all elements of the US proposals.

Recently there have been reports that a sub-set of TPPA countries have made a counter-proposal that is largely based on the World Trade Organization's Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS). This submission argues that the TRIPS Agreement is a far more appropriate standard for intellectual property than the US proposals as it allows significant flexibility for countries to determine the appropriate intellectual property regime for their own circumstances.

In this submission, we outline the risks the TPPA negotiations present for access to affordable medicines, and the opportunity they present for determining a more appropriate standard for IP that would enable countries to utilise the flexibilities available to them under the TRIPS Agreement. We argue that the level of IP protection currently reflected in the Australia-US Free Trade Agreement and in Australian law is inappropriately high for the developing countries and that the Australian Government should not pursue an AUSFTA-type outcome in the TPPA.

We set a number of general principles we believe the Australian Government should pursue in the negotiations on pharmaceutical IP. These are:

- Avoid provisions that would add to pharmaceutical expenditure in Australia;
- Ensure that the TPPA does not introduce 'TRIPS Plus' intellectual property rights in developing countries;
- Preserve and affirm countries' ability to use legal flexibilities under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health;
- Commit to transparency and civil society input in the TPPA negotiations; and
- Ensure aid effectiveness and regional responsibility.

The submission also outlines our views regarding particular provisions which may be discussed for the TPPA. We argue that:

- 1) No patent term extension provision should be included in the TPPA, as this adds significantly to pharmaceutical expenditure. Failing this, if a patent term extension provision is included, it should be non-mandatory, allowing flexible implementation, limited to patents disclosing the molecule, and not permitted in relation to putative delays in the regulatory approval process.
- 2) No 'TRIPS Plus' data protection should be included, as this results in unacceptable delays to the market entry of generics and presents an impediment to compulsory licensing.
- 3) No patent linkage provision should be considered for the TPPA.
- 4) The scope of patentability should not be expanded to cover new forms, uses or methods of using existing medicines, or to cover diagnostic and treatment methods. Pre-grant opposition should be retained.

It has been reported that the US may be considering proposing differential IP standards for developed and developing countries. Our organisations are opposed to this as it would still 'lock in' existing high levels of IP privileges in countries such as Australia, reducing domestic flexibility to alter them in future.

1. Introduction

This submission sets out our organisations' views on the US proposals for intellectual property and medicines for the Trans Pacific Partnership Agreement (TPPA) negotiations, and our views on the position that should be taken by the Australian Government at the current stage in the negotiations. Information about our organisations is included in the Appendix.

Our organisations indicated our positions regarding intellectual property (IP) and access to medicines in letters to ministers in the former Labor Government dated 27 February 2012 and 17 July 2012. These letters outlined the effects that proposals made by the US in 2011 for pharmaceutical IP (which were subsequently leaked) could be expected to have on access to medicines in Australia and the other TPPA countries.

It was recently reported by Inside US Trade¹ that Australian negotiators contributed to the development of a six-country "principles paper" that presents an alternative to the extreme proposals on IP and medicines tabled by the US in 2011. Inside US Trade¹ also reported that a number of countries, including Chile and New Zealand, jointly tabled legal text based on this principles paper at Round 19 of the TPP negotiations in Brunei in August 2013. While we have limited information about the contexts of either the principles paper or the legal text based on it, Inside US Trade suggests that it "largely reflects the World Trade Organization Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), but contains some additions".¹

Furthermore, commentary in Inside US Trade¹ suggests that the US is likely to very soon table a revised proposal which may propose "different IP standards for developed and developing TPP members" as well as a provision relating to data exclusivity for biologic drugs.

This submission outlines our views about the position that should be taken by the Australian Government in the light of these two competing proposals for pharmaceutical IP in the TPP negotiations.

The views expressed in this submission reflect the views of the Australian non-government health and fair trade organisations who have been working with the Department of Foreign Affairs and Trade over the last two years to identify and articulate concerns about the impact of reduced access to generic medicines on health improvements which have been achieved to date. These health improvements, in particular in relation to TB, HIV and non-communicable diseases, are a direct result of the ability of countries such as Thailand, Brazil and India to utilise flexibilities available to them under the World Trade Organization Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) the Doha Declaration on the TRIPS Agreement and Public Health.

The imperative to retain access to the production and sale of generic medications is expressed through numerous global agreements to which Australian governments have been signatories since 2000. The most significant of these, the Millennium Development Goals (MDGs), were endorsed by 189 countries, including Australia, as part of the 2000 UN Millennium Declaration. Goal 6 of the MDGs sets out by 2015 to have halted and begun to reverse the spread of HIV; and to have achieved, by 2010, universal access to treatment for HIV for all those who need it.

A global progress report released in September 2013 notes: Where rapid scale-up has occurred, dramatic public health gains have resulted. In 26 countries where HIV scale-up has been most pronounced, new HIV infections have fallen by more than 50% since 2001.² Further, "As of December

¹ Inside US Trade (September 11, 2013). Several TPP Countries Table Alternative Pharma IP Text Ahead of Mexico Intersessional.

² amfAR, the Foundation for AIDS Research; AVAC, Global Advocacy for HIV prevention (September 2013): An action agenda to end AIDS. Available at <http://www.avac.org/ht/a/GetDocumentAction/i/51763>

2012, an estimated 9.7 million people were on ART in low- and middle-income countries – an increase of 1.6 million over December 2011. This represents important progress but is slightly off the pace of what is needed to reach 15 million people on HIV treatment by 2015.”²

HIV scale-up, referring to increased access to and uptake of HIV antiretroviral medications in low income countries, is completely dependent on the availability, to people with HIV, of affordable medicines. This has been achieved through the production and sale of generic medicines, largely funded through the Global Fund for AIDS, TB and Malaria, and PEPFAR, the President's Emergency Plan for AIDS Relief, \$US15b fund established in 2003 by President G.W. Bush.

Subsequent UN Agreements have again endorsed this approach. Clause 36 of The 2011 Political Declaration on HIV/AIDS, endorsed by all UN members in June 2011, “Notes with concern that regulations, policies and practices, including those that limit legitimate trade in generic medicines, may seriously limit access to affordable HIV treatment and other pharmaceutical products in low- and middle-income countries, and recognize that improvements can be made, inter alia through national legislation, regulatory policy and supply chain management, noting that reductions in barriers to affordable products could be explored in order to expand access to affordable and good quality HIV prevention products, diagnostics, medicine and treatment commodities for HIV, including for opportunistic infections and co-infections”.³

“HIV and the law: Risks, rights and health”, the 2012 report of the Global Commission on HIV called on governments and the global community to “Develop an effective IP regime for pharmaceutical products. Such a regime must be consistent with international human rights law and public health needs, while safeguarding the justifiable rights of inventors.”⁴

2. Summary of our positions on the 2011 leaked US proposals for the TPPA and medicines

A key issue of concern for our organisations is the right to affordable medicines both in Australia and in other TPP countries. Medicines are a public good with positive externalities and it is well recognized that government intervention is essential to ensure that affordable medicines are available to all. Patents are a temporary and private monopoly right granted by governments to encourage innovation. The monopoly privileges of patent holders should not be extended in ways which impede the public health objective of affordable medicines for all.

These principles are reflected in Australia's Pharmaceutical Benefits Scheme (PBS), which has overwhelming public support, and were reaffirmed recently by the 2010 Productivity Commission report on Bilateral and Regional Trade Agreements.⁵

Policies on patents and medicines should be developed through public discussion and democratic parliamentary processes, not decided through confidential trade negotiations. Any attempt to use trade agreements to extend monopoly rights or to restrict the ability of governments to ensure affordable access to medicines meets with fierce opposition from our organisations and the Australian community generally.

We were disappointed to see that in the Trans-Pacific Partnership negotiations the US put forward extreme and unreasonable proposals on intellectual property with respect to prescription medicines,⁶

³ United Nations; (June 2011) 65/277. Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS.

⁴ Global Commission on HIV and the Law (July 2012), HIV and the Law: Risks, Rights & Health; Available at <http://www.hivlawcommission.org/resources/report/Executive-Summary-GCHL-EN.pdf>

⁵ Productivity Commission (2010), Bilateral and Regional Trade Agreements Final Report, Productivity Commission, Canberra, December.

proposals that would restrict the ability of governments to make these available at affordable prices through pharmaceutical coverage programs. These proposals reveal that the US does not recognize the underlying principle that medicines are a public good, and that the monopoly privileges of patent holders should be limited and should not impede the public health objectives. In its free trade negotiations with other countries, the US has made successively more extreme demands which favour the privileges of patent holders over those of consumers. These proposals would have even more devastating effects on developing countries in the TPP.

In summary, we oppose the 2011 US proposals on pharmaceutical intellectual property because they would:

- **Extend patentability** to cover new forms, uses and methods of using a known product (even without evidence of additional benefit, thus encouraging 'evergreening' and extending patent monopolies);
- **Allow patents for diagnostic, therapeutic and surgical methods**, meaning license fees or royalties may have to be paid to use the most efficacious diagnostic and treatment procedures;
- **Lengthen the term of patents** to compensate for delays in issuing patents or in obtaining marketing approval;
- **Prevent third parties from opposing patent claims before they are granted** (a safeguard that can be used to prevent unwarranted patents from being granted);
- **Extend data exclusivity periods** - provide least five years of data exclusivity for new pharmaceutical products, plus an additional three years for new uses of existing drugs, and up to twelve years for biologics; and
- **Link marketing approval for generic drugs to patent status** – requiring regulatory authorities to scan for existing patents, provide notification to patent holders, and delay granting marketing approval until any disputes are settled.

We oppose US proposals for pharmaceutical pricing and reimbursement schemes to:

- **preclude therapeutic reference pricing**, an important mechanism for ensuring that the prices paid for medicines reflect their clinical benefit;
- **introduce onerous obligations for so-called "transparency" and disclosure** (facilitating pharmaceutical industry influence over the process);
- **extend opportunities for manufacturers of pharmaceuticals and medical devices to influence decision making** regarding listing, pricing and reimbursement;
- **include review/appeals processes able to overturn listing and pricing decisions** made by health expert bodies;
- **legalize direct-to-consumer advertising via the internet** (which is currently prohibited in Australia due to concerns about the effect it can have on rational prescribing) and
- **establish mechanisms for ongoing influence** which are likely to have ongoing capacity to influence formulary decision making.

These proposals represent an unacceptable intrusion into domestic health policy making. In each of these areas, the US demands exceed the commitments negotiated in the Australia-US Free Trade Agreement.

⁶ Trans Pacific Partnership. Intellectual Property Rights Chapter: Draft – February 10, 2011. Available from: <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>; Trans Pacific Partnership. Intellectual Property Rights Chapter – Selected Provisions. September 2011. Available from: <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>

3. Risks and opportunities presented by provisions on pharmaceutical IP in the TPPA

The TPPA represents a significant threat to access to affordable medicines, particularly in developing countries. MSF has said “Unless certain damaging provisions are removed, the TPP has the potential to become the most harmful trade pact ever for access to medicines”.⁷

The U.S. consumer advocacy organization Public Citizen has undertaken comparative analyses of provisions proposed by the US for the TPPA with patent law in Australia, Vietnam, Malaysia and Peru,⁸ and shown the extent to which domestic law in these countries would need to change as a result of the U.S. TPPA proposals. Vietnam, for example, currently has no patent protection for new forms, uses or methods of using a known product, no provision for patent term adjustment, no patent linkage provision and data protection is currently provided for five years.⁹

Several empirical studies have shown the effects of similar TRIPS Plus provisions on medicine prices and access to medicines in developing countries. These include studies of the effects of TRIPS+ provisions in the US-Jordan FTA on medicine prices in Jordan,¹⁰ and the effect of the Central America Free Trade Agreement (CAFTA) on access to medicines in Guatemala, which have shown dramatic increases in prices for some medicines.¹¹ Economic modelling has also been used to estimate prospectively the impact of TRIPS provisions in trade agreements, for example in the Thai-US FTA¹² and the EU-Andean FTA¹³, and has predicted similar effects.

Oxfam found that IP provisions introduced in Jordan following its WTO accession and the Jordan–U.S FTA resulted in a 20 percent overall increase in medicine prices between 2001 and 2006, and that data protection led to the delayed introduction of generic equivalents for 79 percent of new medicines produced by 21 pharmaceutical companies between 2002 and mid-2006.¹⁰ The introduction of TRIPS-Plus provisions in Jordan did not result in greater foreign direct investment in Jordan’s pharmaceutical industry, further investment in R&D or earlier introduction of “innovative” medicines, as had been claimed at the time of the agreement.¹⁰

The introduction of TRIPS Plus provisions in the TPPA would have a major global impact given that more developing countries may join up and that the TPPA is likely to become the template for future free trade agreements.

⁷ Medecins Sans Frontieres (2013) *MSF Open Letter to TPP Countries: Don’t Trade Away Health*. Available from: <http://www.msfaccess.org/content/msf-open-letter-tpp-countries-dont-trade-away-health>

⁸ Kilic, B. and Maybarduk, P. (August 2011, updated March 2012) *Comparative Analysis of the United States’ TPPA Intellectual Property Proposal and Australian Law*; Public Citizen; Kilic, B. and Maybarduk, P. (2011) *Comparative analysis of the United States’ TPFTA Intellectual Property Proposal and Vietnamese Law*. Public Citizen; Kilic, B. & Maybarduk, P. (2011) *Comparative Analysis of the United States’ TPFTA Intellectual Property Proposal and Malaysian Law*; Public Citizen (2011) *Comparative Analysis of the U.S. Intellectual Property Proposal and Peruvian Law*. All available at: www.citizen.org/access

⁹ Kilic, B. and Maybarduk, P. (2011) *Comparative analysis of the United States’ TPFTA Intellectual Property Proposal and Vietnamese Law*. Public Citizen. Available at: www.citizen.org/access

¹⁰ Oxfam International (2007) *All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines*. Oxfam Briefing Paper.

¹¹ Shaffer, E.R. and Brenner, J.E. (2009) *A trade agreement’s impact on access to generic drugs*. *Health Affairs* 28(5):w957-968.

¹² Kessomboon, N., Limpanonont, J, Kulsomboon, V., Maleewong, U., Eksaengsri, A. and Paothong, P. (2010) *Impact on access to medicines from TRIPS-plus: A case study of Thai-US FTA*. *Southeast Asian J Trop Med Public Health*, 41(3): 667-77.

¹³ IFARMA (2009) *Impact of the EU-Andean Trade Agreement on Access to Medicines in Colombia*. Fundacion IFARMA, Fundacion Mision Salud, Minas Gerais.

There are moves to establish a better global regime for financing research and development (R&D), such as the global R&D treaty recommended by the WHO Consultative Expert Working Group¹⁴). If the TPPA expands IP privileges, it will be working against this and further entrench a system that cannot ensure either access to affordable medicines or R&D that meets the needs of developing countries.

There is an opportunity for the TPPA countries to decide on a more appropriate standard for IP that enables countries to utilise flexibilities available under TRIPS and affirmed by the Doha Declaration. And there is an opportunity to create space for a better global regime for R&D, or at least not to worsen the current situation.

4. Risks associated with adopting an AUSFTA-level outcome on pharmaceutical IP in the TPPA

The Australia-US Free Trade Agreement (AUSFTA) included much stronger intellectual property privileges than TRIPS, by expanding the scope of patentability, limiting grounds for revocation of patents, restricting the use of compulsory licensing, reinforcing patent term extension provisions and existing prohibitions on parallel importation and imposing a form of patent linkage. While some of these provisions did not change existing arrangements in Australia (as they were already reflected in Australian law), their inclusion in a trade agreement had the effect of reducing future domestic policy flexibility to modify or remove them.¹⁵

AUSFTA is significantly “TRIPS Plus” (ie. Includes provisions which confer intellectual property privileges beyond those in the TRIPS Agreement) and would not be an appropriate standard for many of the other TPPA countries.

These provisions, which are part of the status quo in Australia but which would represent significant changes for countries such as Vietnam, Malaysia and Peru, include:

- Patent protection for new uses or methods of using a known product;
- Patent term adjustment (to compensate for delays in patent examination or regulatory review);
- At least five years of data protection; and
- Patent linkage provisions (provisions which link regulatory approval of generics to patent status).

AUSFTA includes patent term extension, 5 years of data protection and a patent linkage mechanism. Patent term extension would add significantly to medicine costs in some countries, such as New Zealand. Many of the TPPA countries do not currently have a patent linkage mechanism.

Table 1 compares the intellectual property provisions in the TRIPS Agreement, AUSFTA and the 2011 leaked US proposals for the TPPA, with red text indicating the areas where AUSFTA is TRIPS Plus.

¹⁴ World Health Organization. (2012). Research and development to meet health needs in developing countries: strengthening global financing and coordination. Report of the consultative expert working group on research and development: financing and coordination. Geneva: World Health Organization.

¹⁵ Lopert, R and 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.

5. General principles that should be pursued by the Australian Government in negotiations on pharmaceutical IP

5.1 Avoid provisions that would add to pharmaceutical expenditure in Australia

Pharmaceuticals already represent a substantial proportion of health budget in Australia, and there are significant opportunity costs associated with directing more health resources to pharmaceuticals.

Empirical research indicates that disadvantaged people more vulnerable to rising medicine costs. If medicines have a high copayment, people in lower socioeconomic groups of a society may not be able to access these. Research has shown that when co-payments rise, use of prescription medicines falls and disadvantaged groups such as the poor and elderly are most affected.¹⁶

5.2 Ensure that the TPPA does not introduce 'TRIPS Plus' intellectual property privileges in developing countries

It is highly inappropriate for developed countries to require TRIPS+ provisions of developing countries, or to support the efforts of other countries to do so. The 2009 Report of the UN Special Rapporteur on the Right to Health¹⁷ stated that 'Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.' It is also important to note that Australia has never before required developing countries to agree to TRIPS Plus intellectual property provisions in its trade agreements. Furthermore, such requirements would be inconsistent with Australia's commitments as a signatory to the UN Political Declaration of the High Level Meeting on Prevention and Control of Non-communicable Diseases¹⁸ and the UN Political Declaration on HIV¹⁹.

5.3 Preserve and affirm countries' ability to use legal flexibilities under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and public health

TRIPS included some important flexibilities to enable countries to protect public health, which were re-affirmed in the 2001 Doha Declaration. These include permitting compulsory licensing and parallel importation,²⁰ exclusions to patentability, flexibility in applying high patentability standards and

¹⁶ Kemp, A. et al (2013). From the city to the bush: increases in patient co-payments for medicines have impacted on medicine use across Australia. *Australian Health Review*, 37: 4-10; Searles, A., et al (2013) The affordability of prescription medicines in Australia: are copayments and safety net thresholds too high? *Australian Health Review*, 37: 32-40.

¹⁷ United Nations (2009) Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover: Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development. Available from:
http://www.ifhhro.org/images/stories/ifhhro/documents_UN_special_rapporteur/3_4_1_en.pdf

¹⁸ United Nations (2011) Political Declaration of the High Level Meeting on Prevention and Control of Non-communicable Diseases <http://www.cfr.org/diseases-noncommunicable/political-declaration-high-level-meeting-general-assembly-prevention-control-non-communicable-diseases/p25953>

¹⁹ United Nations (2011) Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS. Available from:
http://www.unaids.org/en/media/unaids/contentassets/documents/document/2011/06/20110610_UN_A-RES-65-277_en.pdf

²⁰ Compulsory licensing refers to granting licenses to manufacture or import a patented product without the consent of the patent holder; parallel importation refers to importing a patented product without the consent of the patent holder (see: World Health Organization (2008) Intellectual Property Rights and Access to Medicines: A South-East Asia Perspective on Global Issues. WHO Regional Office for South-East Asia. Available from: http://www.searo.who.int/LinkFiles/IPT_TRH.pdf)

safeguards such as pre-grant opposition. Many of these flexibilities would be wound back under the US proposals for the TPPA, which are 'TRIPS Plus'.

There is also a risk that flexibilities in the text may be undermined by bilateral pressure from the US to adopt more stringent IPRs. Adopting more flexible language (e.g. 'may' instead of 'shall') might appear to be protective, but there is a risk that TPPA Parties' flexibility in the implementation of the provisions could still be undermined by unilateral pressure to implement stronger IPRs, for example through side letters or pressure applied through the Special 301 Report. This appears to have been the case with Peru, which introduced 5 years of data protection despite the flexible language adopted in its bilateral agreement with the US.²¹ Where any flexibilities are provided for in the TPPA, there must also be language to ensure that TPPA Parties are not subject to criticism or coercion by other Parties in the exercise of these flexibilities.

5.4 Commit to transparency and civil society input

We ask that the incoming government commits to the utmost transparency in the TPPA negotiations, and to consulting as fully as possible with civil society organisations. Our organisations call for release of the negotiating texts and for release of the final text for public and parliamentary scrutiny *before* it is signed by Cabinet.

5.5 Ensure aid effectiveness and regional responsibility

AusAID currently funds the Clinton Foundation which supplies paediatric anti retro viral medication to children living with HIV in Vietnam.²² Additionally AusAID has committed \$210 million over 2011-2013 to the Global Fund for AIDS, TB and malaria (GFATM) which provides medicines to treat HIV and TB.²³ The inclusion of TRIPS Plus measures in the TPPA threatens to increase the cost of these medicines and undermines the effectiveness of Australia's aid program. Australia has an ongoing responsibility to work with our neighbouring countries to prevent the spread of emerging infectious disease in the region.

6. Pharmaceutical IP standards: specific provisions

6.1 No patent term extension provision should be included

Patent term extension adds significantly to pharmaceutical expenditure. We understand that a review of the costs of patent term extension was being undertaken for the Pharmaceutical Patents Review. These estimates (and the final report of the Pharmaceutical Patents Review) have not been made publicly available. The Australian Government should consider releasing this report.

The Draft Report of IP Australia's Pharmaceutical Patents Review found no demonstrable link between extension of patent terms and investment in research and development and recommended reducing the patent term extension period and partly replacing it with a direct subsidy to support Australian-based pharmaceutical R&D.

It would be preferable for the TPPA not to include a patent term extension provision at all. The TRIPS Agreement did not include any provision for patent term extension.

If patent term extension must be included then there should be no set period and it should be coupled with a provision indicating that it should only apply to patents disclosing the molecule. Countries

²¹ Jorge, MF (2010). The Peruvian implementation of the US-Peru FTA: A model for the world with room for improvement. *Journal of Generic Medicines*, 7(1): 40-48.

²² AusAID. AusAID—Clinton Foundation Partnership. April 2012.
<http://www.ausaid.gov.au/aidissues/health/hivaids/pages/foundation.aspx>

²³ AusAID. The Global Fund and AusAID—saving lives by fighting AIDS, tuberculosis and malaria 22 August, 2012 <http://www.ausaid.gov.au/HotTopics/Pages/Display.aspx?QID=783>

should retain domestic flexibility to determine the appropriate timeframe and scope. Patent term extension should not be permitted in relation to putative delays in the marketing approval process as such delays where they occur may not be the responsibility of the regulator.

6.2 *Data protection results in unacceptable delays to generic market entry and presents an impediment to compulsory licensing: no TRIPS+ data protection should be included*

Data protection results in unacceptable delays to the market entry of generics and constitutes an absolute impediment to the effective use of compulsory licensing of medicines. Data protection regimes create monopoly privileges that are distinct from and effective even where a pharmaceutical product is no longer protected by a patent. Moreover, data protection provisions can preclude the approval of generic medicines by regulators even where a compulsory license has been granted.

It would be preferable for the TPPA to include no explicit data protection provision, but failing this, any such provision should not exceed the obligations of article 39.3 of the TRIPS Agreement. No minimum period should be specified, enabling domestic flexibility for each country to determine an appropriate regime. Data protection must not apply in the event of the issue of a compulsory license. Data protection should be limited in scope, applying only to new chemical entities and to undisclosed data (not to data in the public domain). It must not refer to “information about safety and efficacy”. There should be no distinct period for biologics.

6.3 *No patent linkage mechanism should be included*

The AUSFTA required Australia to introduce a form of patent linkage to prevent the marketing of a generic medicine while the originator is under patent. We are opposed in principle to patent linkage provisions, which can delay market entry of generics.

Patent linkage is not permitted in the EU and is an entirely US-centric phenomenon. Patent rights are private rights and if patent holders feel their rights are being infringed then they can seek redress through existing mechanisms.

Patent linkage is unnecessary and the current patent linkage system in Australia exposes employees of generics companies to criminal penalties if they make an error in a certificate. Unlike the US (where the patent linkage mechanism originated), searching for and identifying all relevant patents is not straightforward in Australia. Moreover, it is not appropriate for regulatory bodies such as the Therapeutic Goods Administration to enforce IP privileges as they are irrelevant to the regulatory remit of assessing issues of safety, quality and efficacy.

The US proposal for patent linkage in the TPPA is far more burdensome than the existing system in Australia. If this proposal were accepted, regulatory authorities would have to actively scan for existing patents, notify patent holders, and delay granting marketing approval until any dispute is settled. This proposal should be opposed.

6.4 *Other provisions relevant to pharmaceuticals*

The US has also made proposals to extend the scope of patentability to cover new forms, uses and methods of using existing medicines, and to cover diagnostic and treatment methods. There is also a proposal to eliminate pre-grant opposition.

Expanding patentability to cover new forms, uses and methods of using existing medicines would encourage “ever-greening” and delay the entry of generic medicines.⁸ Requirements to provide patents for diagnostic and treatment methods could delay access to the most effective medical

interventions, as well as adding significantly to costs.²⁴ A requirement to eliminate pre-grant opposition could remove a significant safeguard that can prevent inappropriate patent monopolies.⁸

Recent discussion and commentary has tended to overlook these proposals. However adopting them would be extremely damaging. These proposals should be rejected outright.

7. Differential standards for developed and developing countries

It has been suggested that the US may propose different standards of IP for developed and developing countries.¹ The TPPA countries represent a diverse mix in terms of size and development. If flexibilities only applied to developing countries (however defined), some TPPA parties which may be vulnerable to increased IP protection (such as New Zealand) would be unlikely to qualify.

If text were included allowing different standards for developed and developing countries, this would still 'lock in' stronger IPRs in developed countries (including Australia).

The Australia-US Free Trade Agreement (AUSFTA) included much stronger intellectual property privileges than TRIPS, by expanding the scope of patentability, limiting grounds for revocation of patents, restricting the use of compulsory licensing, reinforcing patent term extension provisions and existing prohibitions on parallel importation and imposing a form of patent linkage. While some of these provisions did not change existing arrangements in Australia (as they were already reflected in Australian law), their inclusion in a trade agreement had the effect of reducing future domestic policy flexibility to modify or remove them.¹⁵

Adopting even seemingly moderate provisions, similar to the AUSFTA, in the TPPA would introduce another layer of international commitments that make it increasingly difficult to change domestic policies and laws in future in response to changing circumstances such as shrinking health budgets, rising costs of healthcare technologies (including pharmaceuticals), or epidemics of new diseases.

Other compromises that may be considered for developing countries, such as phasing in TRIPS+ IPRs over longer periods, are also problematic as such phase-ins make the assumption that countries will develop at a certain rate and that access to medicines will not be such a problem in the future – a scenario that has not been realised in many developing countries which signed up to the TRIPS Agreement. Exemptions or carve-outs for developing countries are also problematic as they would still 'lock in' high levels of IPRs in countries that are not exempt, reducing domestic flexibility in the future.

8. Conclusions

Given the significance of the TPPA in shaping access to medicines across the region, and perhaps at the global level, the best option for the TPPA would be to completely exclude pharmaceuticals from the agreement. Failing this, then the IPRs conferred should be no stronger than those in the WTO TRIPS Agreement. This means:

- No patent term extension; (failing this, non-mandatory, allowing flexible implementation, limited to patents disclosing the molecule; and not permitted in relation to putative delays in the regulatory approval process)
- No minimum period for data protection; data protection applying only to new chemical entities and undisclosed data;
- No patent linkage mechanism;

²⁴ Gleeson, D.H., Tienhaara, K.S. and Faunce, T.A. (2012) Challenges to Australia's national health policy from trade and investment agreements. MJA 196(5): 354-356. Available from: <https://www.mja.com.au/journal/2012/196/5/challenges-australia-s-national-health-policy-trade-and-investment-agreements>

- No requirement to make patents available for new forms, uses or methods of using a known product;
- No requirement to make patents available for diagnostic, therapeutic and surgical methods; and
- Retention of pre-grant opposition.

Our organisations are opposed to differential standards for developed and developing countries. This would still lock in high levels of IP privileges in developed countries, restricting domestic flexibility in future.

This submission was prepared in the context of partial information about the status of the negotiations and options under consideration and without access to negotiating texts. We reiterate our request that the TPPA negotiating texts be made available for public scrutiny, debate and analysis, and for the release of the final text for public and parliamentary discussion before it is signed by Cabinet.

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Table 1: Comparison of selected intellectual property provisions in TRIPS, AUSFTA and US TPPA proposals

Provision	TRIPS	AUSFTA	TPPA (US proposal)	Notes
Patents for New Forms, Uses, or Methods of Using a Known Product	No provision	Patents to be available for new uses or methods of using a known product (Art 17.9.1)	Patents to be available for new forms, uses and methods of using a known product (Art 8.1)	Both AUSFTA and the US TPPA proposal are TRIPS+ “Patents for new forms, uses, and methods of using known medicines can enable patent “evergreening” and particularly when enhanced efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies” (Kilic & Maybarduk, 2012)
Patentability of Diagnostic, Therapeutic and Surgical Methods	Allows members to exclude diagnostic, therapeutic and surgical methods from patentability (Art. 27.3)	Allows parties to exclude diagnostic, therapeutic and surgical methods from patentability (Art. 17.9.2)	Patents to be made available for diagnostic, therapeutic and surgical methods (Art 8.2)	The TPPA provision would eliminate TRIPS flexibilities enabling methods of treatment to be excluded from patentability – potentially requiring payment of license fees or royalties for use of diagnostic methods and treatments
Patent Term Adjustment	No provision	Art 17.9.8(a) allows for patent term adjustments to compensate for ‘unreasonable delays’ in the issuing of patents (more than four years from the date of filing or two years after a request for examination of the application has been made). Art. 17.9.8(b) provides for patent term adjustment to compensate for ‘unreasonable curtailment of the effective patent term’ resulting from delays in marketing approval	Extends patent term adjustments to compensate for delays in marketing approval beyond new pharmaceutical products to patents that cover methods of making or using pharmaceutical products	Both AUSFTA and US TPPA proposals are TRIPS+ (and the TPPA proposal is AUSFTA+). Patent term adjustment can add significantly to the duration of patents, delaying the introduction of generic equivalents.
Elimination of Pre-grant Opposition (third party opposition to the validity of patent applications)	No provision	No provision	Eliminates pre-grant opposition (Art 8.7)	“Pre-grant opposition is a safeguard against patent abuse, improvidently granted patents and unwarranted pharmaceutical monopolies” (Kilic & Maybarduk, 2012)

Provision	TRIPS	AUSFTA	TPPA (US proposal)	Notes
Data Protection/ Exclusivity for a New Pharmaceutical Product	No provision (but Art. 39.3 provides for protecting undisclosed data from unfair commercial use)	At least five years of data protection from the date of marketing approval (Art. 17.10.01), limited to undisclosed data	At least five years of data protection from the date of marketing approval (Art. 9.2) The TPPA proposal covers data that is in the public domain as well as undisclosed data.	Both AUSFTA and the US TPPA proposals are TRIPS+; TPPA is also AUSFTA+.
Data Protection/ Exclusivity relating to a pharmaceutical product with a chemical entity that has been previously approved for marketing in another pharmaceutical product	No provision	Although Art. 17.10.2 provides for at least three years of data protection for new uses or indications for an existing pharmaceutical products, a footnote permits Australia to maintain its existing system which does not require the additional 3 years for submission of new clinical information.	The TPPA proposal provides for at least 3 years of data exclusivity for new uses/indications of a pharmaceutical product. There is also a placeholder for specific provisions applying to biologics (Art. 9.9) and the US is reportedly seeking up to 12 years' data exclusivity for biologics.	The US TPPA proposal is TRIPS+ and AUSFTA+
Linking Marketing Approval to Patent Status ("Patent Linkage")	No provision	AUSFTA introduced a patent linkage provision linking marketing approval of generic drugs to patent status. Generic manufacturers applying for marketing approval must provide certification that they will not market their products in a way that will infringe a valid patent claim, or that they have notified the patent holder of the application.	The US TPPA proposal contains a much stronger patent linkage provision that requires regulatory authorities to scan for existing patents, provide notification to patent holders, and delay granting marketing approval until disputes are settled.	Both AUSFTA and the US TPPA proposal are TRIPS+; TPPA is also AUSFTA+

Red = TRIPS+ provisions

Adapted from: Rosenberg, S. (2011) Comparative Chart of Pharmaceutical Patent and Data Provisions in the TRIPS Agreement, Free Trade Agreements between Trans-Pacific FTA Negotiating Countries and the U.S., and the U.S. Proposal to the trans-Pacific FTA. Public Citizen. Available from: <http://www.citizen.org/documents/Comparative-chart-of-TPFTA-TRIPS-FTAs.pdf>; and Kilic, B. and Maybarduk, P. (August 2011, updated March 2012). Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Australian Law. Public Citizen. Available from: <http://www.citizen.org/documents/Australia-TPPA-chart.pdf>

Appendix: About Our Organisations

The Public Health Association of Australia

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles.

Public health includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the Association's role.

PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups concerned with the promotion of health at a population level. Key roles of the organisation include capacity building, advocacy and the development of policy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. PHAA has been a key proponent of a preventive approach for better population health outcomes championing such policies and providing strong support for the Australian Government and for the Preventative Health Taskforce and National Health and Medical Research Council (NHMRC) in their efforts to develop and strengthen research and actions in this area across Australia.

PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

Australian Fair Trade and Investment Network (AFTINET)

The Australian Fair Trade and Investment Network (AFTINET) is a national network of 60 community organisations, including unions, public health, church, pensioner, environment, and other community organisations, and many more individuals, supporting fair regulation of trade, consistent with human

rights, labour rights and environmental protection. AFTINET welcomes this opportunity to make a submission to the Pharmaceutical Patents Review.

AFTINET supports the development of trading relationships with all countries and recognises the need for regulation of trade through the negotiation of international rules. However trade negotiations take place behind closed doors, and are not subject to public and parliamentary discussion until after the text has been agreed and signed by Cabinet. Public policy issues like the regulation of patents and medicines, which are central to access to medicines and public health, should be decided through democratic processes of public and parliamentary debate, not through trade negotiations. AFTINET promotes these goals through community education, public events, media debate and dialogue with all levels of government.

The Australian Federation of AIDS Organisations

The Australian Federation of AIDS Organisations (AFAO) is the national federation for the HIV community response. AFAO's members are the AIDS Councils in each state and territory; the national association of people with HIV Australia (NAPWHA); the Australian Injecting & Illicit Drug Users League (AIVL); the Anwernekenhe Aboriginal and Torres Strait Islander HIV/AIDS Alliance (ANA); and Scarlet Alliance, Australian Sex Workers Association. AFAO also advocates to AusAID, other global HIV donors and governments and in the Asia Pacific region for resources and political will to fight HIV and to remove laws that enable HIV transmission by criminalising sex workers, gay men, people who inject drugs and people with HIV.

Médecins Sans Frontières Australia

Médecins Sans Frontières is the world's leading independent organisation for medical humanitarian aid. Every day more than 24,000 Médecins Sans Frontières field staff are providing assistance to people caught in crises around the world. We have offices in 19 countries supporting these teams, including our office in Sydney. Every year around one hundred Australians and New Zealanders are sent to and supported in the field by Médecins Sans Frontières Australia.

The Asia Pacific Network of People Living with HIV (APN+)

The Asia Pacific Network of People Living with HIV (APN+) with a membership from thirty countries represents the interests and advocates for the needs of all people living with HIV in Asia and the Pacific. In working to improve the lives of people living with HIV in the region APN+ in particular fights for affordable access to treatment for all those people living with HIV who need it and want it, and for their human rights to be upheld.

Palliative Care Australia

Palliative Care Australia (PCA) is the peak national organisation representing all state and territory palliative care organisations, the Australian and New Zealand Society of Palliative Medicine, and the interests and aspirations of all who share the ideal of quality care at the end of life.

Our vision is to achieve quality care at the end of life for all. PCA's mission is to influence, foster and promote the delivery of quality care at the end of life for all. PCA advocates for equitable, needs based delivery of quality care at the end of life through promotion of the principles of palliative care; development of evidence and needs based service provision models; workforce capacity building; awareness and community capacity building; appropriate funding and resourcing.

Palliative care has been defined by the World Health Organization (WHO) as:

An approach that improves the quality of life of patients and their families facing the problems associated with life threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

Australian Medical Students' Association (AMSA)

The Australian Medical Students' Association (AMSA) is the peak representative body for medical students in Australia. The key mandate of AMSA is to connect, inform and represent each of Australia's 17,000 medical students at Australia's 20 medical schools. AMSA's core operations include advocacy, events and programs, and publications.

AMSA advocates for medical students through policy development, advocacy campaigns and representation to governments, universities and relevant medical bodies. Additionally, AMSA organises renowned educational, social and leadership opportunities for students. These include programs aimed at improving medical student health and wellbeing and others to increase awareness of community, rural and global health issues. AMSA believes that all communities have the right to the best attainable health. Accordingly, AMSA actively seeks to advocate on issues that may impact health outcomes.