



Article

The Trans Pacific Partnership Agreement, intellectual property and medicines: Differential outcomes for developed and developing countries

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Abstract

The final text of the Trans Pacific Partnership Agreement (TPP), agreed between the 12 negotiating countries in 2016, included a suite of intellectual property provisions intended to expand and extend pharmaceutical company exclusivities on medicines. It drew wide criticism for including such provisions in an agreement that involved developing countries (Vietnam, Peru, Malaysia, Mexico, Chile and Brunei Darussalam) because of the effect on delaying the introduction of low-cost generics. While developing nations negotiated transition periods for implementing some obligations, all parties would have eventually been expected to meet the same standards had the TPP come into force. While the TPP has stalled following US withdrawal, there are moves by some of the remaining countries to reinvigorate the agreement without the United

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States. The proponents may seek to retain as much as possible of the original text in the hope that the United States will re-join the accord in future. This article presents a comparative analysis of the impact the final 2016 TPP intellectual property chapter could be expected to have (if implemented in its current form) on the intellectual property laws and regulatory regimes for medicines in the TPP countries. Drawing on the published literature, it traces the likely impact on access to medicines. It focuses particularly on the differential impact on regulatory frameworks for developed and developing nations (in terms of whether or not legislative action would have been required to implement the agreement). The article also explores the political and economic dynamics that contributed to these differential outcomes.

Keywords

Access to medicines, developing countries, intellectual property, pharmaceuticals, Trans Pacific Partnership Agreement

Introduction

Ever since the negotiation of the World Trade Organization's (1994) TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement in the 1990s, civil society groups have raised concerns about the impact that trade agreements have on access to medicines, particularly in developing countries. TRIPS set a new global benchmark for intellectual property (IP) rights, with the introduction of 20-year patent terms for all fields of technology, including pharmaceuticals (Smith et al., 2009). Longer periods of patent protection mean delaying the introduction of low-cost generics. Generic competition is generally the best way of delivering medicines at an affordable cost in developing countries (Waning et al., 2009). Yet the two decades since TRIPS came into force have seen an expansion of 'TRIPS-Plus' IP rights via a plethora of subsequent bilateral and regional trade agreements, particularly those negotiated by the United States and European Union, where the majority of the world's largest originator pharmaceutical companies are based (Lopert and Gleeson, 2013).

The Trans Pacific Partnership Agreement (TPP) was a proposed regional trade and investment agreement involving 12 countries from around the Pacific Rim: Australia, Brunei Darussalam, 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 (prior to legal scrubbing) was publicly released on 5 November 2015 and the legally verified version on 26 January 2016 (New Zealand Ministry of Foreign Affairs and Trade, 2016a). The agreement was signed in principle in February 2016 by the 12 countries. The text specified that for the TPP to enter into force, at least 6 of the original 12 negotiating countries, accounting for at least 85% of the collective Gross Domestic Product (GDP) of the TPP parties, must ratify the agreement within 2 years of signing.

Owing to the controversy surrounding the TPP in the United States during its pre-election period, and opposition from both Republicans and Democrats making passage through Congress unlikely, President Obama did not put the TPP to a vote before the US election in November 2016 (Yuhas, 2016). On 23 January 2017, President Trump signed

an executive order making good on his election commitment to withdraw the United States from the TPP (The White House, 2017). Following the US withdrawal, prospects for reviving the TPP initially appeared dim, given the many concessions made by various countries in exchange for access to US markets. However, in May 2017, following a meeting in Hanoi, the 11 remaining TPP trade ministers issued a statement agreeing ‘to launch a process to assess options to bring the comprehensive, high quality Agreement into force expeditiously, including how to facilitate membership for the original signatories’, and tasking their trade officials to complete this assessment before the November 2017 Asia-Pacific Economic Cooperation (APEC) meeting (New Zealand Government, 2017). At the time of writing (August 2017), it is unclear whether the TPP will be successfully revived, and if it is, then to what extent the original text will be re-negotiated. Media reports suggest that Japan, at least, is determined to re-open as little as possible of the original agreement (Moir, 2017). Japan was a strong supporter of the US proposals for IP and medicines in the TPP and is promoting TRIPS-Plus provisions for another regional trade agreement – the Regional Comprehensive Economic Partnership, involving the 10 members of the Association of Southeast Asian Nations and the six countries with which it has free trade agreements (Townsend et al., 2016).

Throughout the negotiations, the TPP was subject to extensive criticism from health, development and consumer organizations, such as *Médecins Sans Frontières* (MSF), *Oxfam* and the US-based *Public Citizen*. Much of this criticism focused on the proposed content of the TPP, particularly provisions proposed by the United States for the IP and investment chapters. Proposals by the United States for the IP chapter, leaked in 2011, led to claims by MSF in its August 2012 issue brief that ‘the TPP will set a damaging precedent with serious implications for developing countries’ (MSF, 2012). In particular, the United States was criticized for reneging on the bipartisan congressional commitment in 2007 to allow developing countries flexibility in determining IP settings suited to their level of development (Lopert and Gleeson, 2013; MSF, 2012).

Criticism also focused on the lack of transparency in the negotiations and the imbalance between input from large corporations and industry associations and that of the public and civil society (Bradner, 2015). Aside from the leaks of certain draft chapters, civil society organizations had no access to draft texts and little information about the positions that various countries were taking in the negotiations (Hern and Rushe, 2013).

Successive leaks of the draft IP chapter in 2013 and 2014 showed some mitigation of the initial US proposals, but many of the problematic provisions remained in the text (Gleeson et al., 2015; Luo and Kesselheim, 2015). The US demands were blunted to the extent that the pharmaceutical industry expressed its disappointment with the outcomes, referring to it in terms such as ‘failure’ (Biotechnology Industry Organization, 2015) and ‘missed opportunity’ (Inside U.S. Trade, 2016a). The ‘failure’ to secure a longer period of exclusivity for biologic products proved an obstacle to the efforts of the Obama Administration to bring the TPP to Congress for ratification in 2016, resulting in calls for renegotiation or ‘clarification’ of the text through side letters (Inside U.S. Trade, 2016b).

Nonetheless, following the conclusion of the negotiations, various analyses of the TPP’s IP chapter confirmed that the final provisions could be expected to have a significant harmful effect on access to medicines (Baker, 2016; Labonte et al., 2016; Ruckert et al., 2017). As the negotiations wound up in October 2015, MSF (2015) concluded that

Although the text has improved over the initial demands, the TPP will still go down in history as the worst trade agreement for access to medicines in developing countries, which will be forced to change their laws to incorporate abusive intellectual property protections for pharmaceutical companies.

Our purpose in this article is to analyse the final legal text of the TPP to draw out the differential impact of the pharmaceutical IP provisions on the patent laws of the developed and developing countries involved in the negotiations. While several analyses of the TPP IP chapter have been published, these have either presented a summary analysis of the issues (Baker, 2016; Labonte et al., 2016) or analysed the impact on specific countries (Lexchin and Gleeson, 2016; Moir et al., 2016). There has been no comprehensive analysis conducted to date examining the impact on all 12 countries' IP laws. Such an analysis is particularly timely now, given current efforts to revive the TPP, amidst speculation about whether the text will be re-opened and some of the provisions originally proposed by the United States altered.

There are several other sections of the TPP with implications for pharmaceutical policy and potentially for access to medicines, which have been reviewed elsewhere but are not the focus of this article. For example, the investment chapter (Chapter 9) includes an investor-state dispute settlement provision which provides an avenue for pharmaceutical companies to seek compensation in a supranational tribunal if they believe their investments have been harmed by a policy or law that breaches the Treaty – as in the case of the claim brought by Eli Lilly and Co. against the Canadian Government under the North American Free Trade Agreement (Baker, 2016).¹ The Technical Barriers to Trade Chapter (Chapter 8) and its annex on pharmaceuticals (Annex 8-C) include procedural obligations for the assessment of safety and efficacy, marketing approval processes and post-market surveillance and inspections and Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) target procedures for the inclusion of medicines in reimbursement formularies (Lexchin and Gleeson, 2016).

Method

We examined the final TPP IP chapter (Chapter 18: Intellectual Property) (Trans Pacific Partnership, 2016) and identified those provisions which, based on analyses of previous trade agreements and of the TPP text, could be expected to have an impact on the scope and length of pharmaceutical monopolies and on the time to market entry of generic or biosimilar (copies of biologic) medicines. For each of these provisions, we examined the following:

- Which of the TPP parties may need to implement legislative changes if the TPP were to come into force in the form agreed among the 12 participating nations in 2016;
- Whether a transition period would apply for particular countries, and if so, the length of the transition period;
- The likely effect of the provision on access to affordable medicines, based on a review of existing evidence in the literature regarding IP stringency.

For the purpose of this article, we classified countries as developed or developing economies based on the United Nations' (UN, 2015) World Economic Situation and Prospects 2015 country classification. While both Chile and Brunei Darussalam are deemed high-income countries by the World Bank (n.d.), under the UN classification scheme both are categorized as developing economies, along with Vietnam, Malaysia, Peru and Mexico. This classification scheme was deemed to be more reflective of the countries' ability to take advantage of the IP protections in the TPP and their situation in terms of access to medicines, than the World Bank income classifications.

TPP IP provisions with implications for access to medicines

Despite resistance by the majority of TPP countries to the US pharmaceutical industry agenda throughout the negotiations, many provisions remained in the final text of the IP chapter (Trans Pacific Partnership, 2016) which extend or expand exclusivities on medicines and can be expected to affect affordable access, including the following:

- Secondary patents: patents for new uses, new methods or new processes of using an existing product (Article 18.37.2);
- Patent term extensions, to compensate for delays in granting patents (Article 18.46) and delays in marketing approval (Article 18.48);
- Exclusivity on undisclosed test data (small-molecule drugs) – at least 5 years for new pharmaceutical products plus either 3 years for new indications, formulations or methods of administration *or* 5 years for combination products containing a chemical entity that has not previously been approved (Article 18.50);
- Exclusivity on undisclosed test data (biologics), provided through one of the two options: at least 8 years of exclusivity or at least 5 years of exclusivity and other measures to 'deliver a comparable outcome in the market' (Article 18.51);
- Patent linkage provisions, that is, preventing regulatory agencies from granting marketing approval for generic drugs when patent holders claim potential patent infringement (Article 18.53).

The TPP text provides transition periods for some, but not all, of these provisions for five countries: Brunei Darussalam, Malaysia, Mexico, Peru and Vietnam.

Below, we examine the five key TRIPS-Plus IP provisions contained in the final text of the TPP, the evidence of the effects of these types of provisions on access to medicines and the likely need for changes to the IP laws of various TPP countries. For each of the TPP parties, Table 1 shows the GDP per capita (in descending order), whether legislative action would be likely to be required to implement the TPP's main TRIPS-Plus IP provisions and the transition periods provided to implement changes to domestic laws, where relevant.

Secondary patents

The final TPP text requires countries to 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' (Article 18.37). The final text of this provision is

Table 1. Final TPP IP provisions, consistency with existing national IP law in TPP parties and transition periods to implement changes.

TPP party	GDP per capita (2015, World Bank, current US\$)	Secondary patents (Article 18.37)	Patent term adjustment for patent prosecution period (Article 18.46)	Patent term Adjustment for regulatory review period (Article 18.48)	Exclusivity on undisclosed test data (small-molecule drugs) (Article 18.50)	Exclusivity on undisclosed test data (biologics) (Article 18.51)	Patent linkage (Article 18.53)
Australia	56,290.6	NLAR	NLAR	NLAR	NLAR	NLAR	NLAR
United States	56,115.7	NLAR	NLAR	NLAR	NLAR	NLAR	NLAR
Singapore	52,888.7	NLAR	NLAR	NLAR	NLAR	NLAR	NLAR
Canada	43,315.7	NLAR	NLAR	May require legislative action (already agreed under CETA)	NLAR	NLAR	NLAR
New Zealand	37,808.0	NLAR	May require legislative action, ^a no transition period	May require legislative action, ^a no transition period	NLAR	NLAR	NLAR
Japan	34,523.7	NLAR	May require legislative action, no transition period	NLAR	NLAR	NLAR	NLAR
Brunei Darussalam	30,554.7	NLAR	NLAR	May require legislative action, no transition period	May require legislative action Transition period: 4 years (Art 18.83.4a(iv))	May require legislative action Transition period: 4 years (Art 18.83.4a(v))	May require legislative action Transition period: 2 years (Art 18.83.4a(vi))
Chile	13,416.2	NLAR	NLAR	NLAR	NLAR	NLAR	NLAR
Malaysia	9768.3	NLAR	May require legislative action, no transition period	May require legislative action Transition period: 4.5 years (Art 18.83.4b(vi))	May require legislative action Transition period: 5 years (Art 18.83.4b(vii))	May require legislative action Transition period: 4.5 years (Art 18.83.4b(viii))	May require legislative action Transition period: 4.5 years (Art 18.83.4b(viii))

(Continued)

Table I. (Continued)

TPP party	GDP per capita (2015, World Bank, current US\$)	Secondary patents (Article 18.37)	Patent term adjustment for patent prosecution period (Article 18.46)	Patent term Adjustment for regulatory review period (Article 18.48)	Exclusivity on undisclosed test data (small-molecule drugs) (Article 18.50)	Exclusivity on undisclosed test data (biologics) (Article 18.51)	Patent linkage (Article 18.53)
Mexico	9005.0	NLAR	May require legislative action, no transition period	May require legislative action Transition period: 4.5 years (Art 18.83.4c(iii)) NLAR	May require legislative action Transition period: 5 years (Art 18.83.4c(iv))	May require legislative action Transition period: 5 years (Art 18.83.4c(v))	NLAR
Peru	6027.1	May require legislative action (may conflict with the Andean community rules), ^b no transition period	May require legislative action (to broaden scope of existing provision to cover pharmaceuticals), no transition period	NLAR	May require legislative action Transition period: 5 years (Art 18.83.4e(f))	May require legislative action Transition period: 10 years (Art 18.83.4e(ii))	NLAR
Vietnam ^c	2110.9	May require legislative action, no transition period	May require legislative action Transition period: 5 years (Art 18.83.4f(v))	May require legislative action Transition period: 5 years (Art 18.83.4f(ix))	May require legislative action Transition period: 10 years (Art 18.83.4f(x))	May require legislative action Transition period: 10 years (Art 18.83.4f(xi))	May require legislative action Transition period: 3 years (Art 18.83.4f(xii))

TPP: Trans Pacific Partnership Agreement; IP: intellectual property; GDP: Gross Domestic Product; NLAR: No legislative action required; CETA: Comprehensive Economic and Trade Agreement.

^aNew Zealand's Trans Pacific Partnership Amendment Act 2016 provides for patent term extensions. This Act amends the Patent Act 2013 to include Subpart 10A – Extension of Term. See <http://www.legislation.govt.nz/bill/government/2016/0133/latest/versions.aspx>.

^bAndean Community (2000). Andean Community Decision No. 486 Establishing the Common Industrial Property Regime. Available from: <http://www.wipo.int/wipolex/en/details.jsp?id=9451> (accessed 9 June, 2017).

^cVietnam has some special arrangements for requesting short extensions to transition periods for implementing Articles 18.46, 18.50 and 18.51.

significantly less onerous than the original US proposal (which sought to require patents to be made available for *each of* new uses, new methods use and new forms of existing products) (Article 8.1, Trans Pacific Partnership, 2011). It also provides the Parties some flexibility in determining the type of secondary patenting they will allow, which means that a larger number of Parties would likely to be able to meet this obligation within their existing laws than would have been the case under the original US proposals.

Along with the requirement to provide secondary patenting is a footnote which establishes a lower threshold for inventiveness than is currently generally accepted:

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)

Secondary patenting is widely acknowledged to have a significant effect on the length of pharmaceutical monopolies and on the entry of generic medicines to the market (Gleeson et al., 2015). In countries where secondary patents are permitted, it is common for pharmaceutical products to be protected by a large array of patents in addition to the patent on the original active pharmaceutical ingredient. For example, in the United States, researchers found a total of 108 patents (granted or applied for) associated with two key HIV drugs (ritonavir and lopinavir/ritonavir), many of which were of minimal inventiveness (Amin and Kesselheim, 2012). These patents were expected to prolong the monopolies on these drugs for 12 years beyond the expiry of the patents on the original pharmaceutical products. An Australian study of patents on 15 high-cost drugs found an average of 49 secondary patents for each of them (Christie et al., 2013).

Most developed countries already allow secondary patents of some description, and mandatory patents for new uses and new methods of using existing products have become a standard TRIPS-Plus feature of trade agreements negotiated by the United States (Lopert and Gleeson, 2013). TPP countries which already allow secondary patenting include Australia (Kilic and Maybarduk, 2011b), Canada (Scassa, 2001), New Zealand (Kilic and Maybarduk, 2012a) and Malaysia (Kilic and Maybarduk, 2011c). If the TPP IP chapter were to be implemented, Peru (Kilic and Maybarduk, 2011d) and Vietnam (Kilic and Maybarduk, 2011a) may be required to loosen their patentability criteria to allow more secondary patents (see Table 1). No transition periods are provided in the TPP text to make these changes.

While the developed countries involved in the TPP would not have to change their patent laws to meet the obligations of TPP Article 18.37, the requirement to continue to provide secondary patents limits future policy flexibility to reduce evergreening, that is, the process whereby patent holders are able to extend their monopolies through minor – often trivial – modifications to existing products. But for developing countries that must grant additional patents as a result of this commitment, significant delays in market entry for generics would be likely. For example, Vietnam would likely have to grant additional patents for minor modifications to HIV drugs, contributing to prolonged monopolies, delaying access to cheaper generics and ultimately providing treatment to fewer people

living with HIV (Moir et al., 2016). Anecdotal evidence suggests that some secondary patents have already been granted, despite the fact that Vietnam is not obliged to grant these patents under its current patent law (Kilic and Maybarduk, 2011a).

Patent term extensions for unreasonable granting authority delays and for unreasonable curtailment

Under the TPP, parties are required to provide patent term extensions (adjustments) to compensate for ‘unreasonable or unnecessary delays’ in the patent examination process (Article 18.46) or in processing applications for marketing approval (Article 18.48).

Even for wealthy countries, patent term extensions come at a considerable cost. An independent review of pharmaceutical patents (Harris et al., 2013) commissioned by the (former) Australian Government in 2012 found that patent term extensions were costing the national medicines reimbursement programme (the Pharmaceutical Benefits Scheme [PBS]) approximately AUD\$240 million in the short term and AUD\$480 million in the long term. Once the Comprehensive Economic Trade Agreement between Canada and the European Union is ratified, a provision allowing for up to a 2-year patent term extension in Canada will come into effect (Lexchin and Gagnon, 2014). Based on the spending patterns in 2010, this is expected to add just under 5% to expenditure on patented medicines.

The TPP’s final patent term extension provisions are both less onerous and more flexible than the original US proposals, which means countries have some room to implement the provisions in ways that limit the number of patent term extensions granted and therefore the costs of extending monopolies. For example, delays that are not attributable to the actions of the authority granting patents do not have to be taken into account in the determination of a delay in patent examination (Article 18.46.4), and the definition of an ‘unreasonable’ delay in the marketing approval process is left to be determined at domestic level (Article 18.48).

With the exception of New Zealand, once Canada ratifies Comprehensive Economic and Trade Agreement (CETA), all of the developed countries will already have in place patent term extensions for pharmaceuticals for perceived delays in the regulatory approval process that comply with the TPP (see Table 1). For New Zealand, which does not have a pre-existing trade agreement with the United States, patent term extension for perceived delays in regulatory approval will be a new obligation (New Zealand Ministry of Foreign Affairs and Trade, 2016b).

Brunei Darussalam, Malaysia, Mexico, Peru and Vietnam would each be likely to need legislative changes to meet their obligations under Article 18.46 and/or Article 18.48 (see Table 1). Some of these countries have negotiated transition periods for one or more of these obligations, but the overall picture is very patchy. Malaysia succeeded in obtaining a transition period of 4.5 years to implement patent term extensions to compensate for marketing approval delays (Article 18.48), but did not secure a similar transition period for patent office delays (Article 18.46). Mexico also obtained a 4.5-year transition period for Article 18.48. Peru’s patent law is already consistent with 18.48, but it would need to implement term extensions for patent office delays once the TPP enters

into force, and legislative amendments may be required due to conflict with the Andean Community rules (Kilic and Maybarduk, 2011d). Vietnam would need to introduce patent term extensions to compensate for both patent office and marketing approval delays and has negotiated transition periods of 5 years to do so. Vietnam would also be able to request a one-off extension of the transition period of up to 1 year to implement term extensions for patent office delays. It is clear that the impact of this provision will be borne by the developing countries and that transition periods will only delay this impact to a limited extent, and only in some cases.

Exclusivity of undisclosed test data (small-molecule drugs)

The TPP provides exclusivities that are significantly TRIPS-Plus. TRIPS requires only that test data be protected from ‘unfair commercial use’ (World Trade Organization, 1994). Similar to many other trade agreements negotiated by the United States, Article 18.50.1 (Protection of Undisclosed Test or Other Data) requires Parties to prevent marketing approval of generic medicines based on reliance on clinical trial data submitted by the originator to a regulatory agency, for a period of at least 5 years. Article 18.50.2 goes further than many other trade agreements in extending the application of exclusivity periods. Parties have a choice of two options under 18.50.2: either they can provide an extra 3 years of protection for additional clinical information submitted in support of an application for marketing approval for a new clinical indication, formulation or method of administration, or they can provide exclusivity for at least 5 years for combination products that contain a chemical entity that has not previously been approved.

The original US proposals did not include the second option for complying under 18.50.2. This option is manifestly less onerous for Parties wishing to reduce the impact on pharmaceutical costs as it only applies to the small number of combination products containing at least one new chemical entity (noting that were the same new chemical entity to be registered as a standalone product, it would receive 5 years of exclusivity anyway). Another way in which the original US proposal for data exclusivity has been mitigated is that the provisions apply only to undisclosed data, that is, data that are not already in the public domain. This means that in those countries that currently permit them, literature-based submissions² by generic manufacturers would be unaffected.

Data exclusivity can create a significant impediment to generic market entry and confer an absolute monopoly even when there is no patent in place, as unlike a patent, data exclusivity cannot be subject to legal challenge (Gleeson et al., 2015). Few developing countries have adopted these exclusivity arrangements to date. Evidence suggests that the introduction of data exclusivity in Jordan in 2001, along with other TRIPS-Plus measures, delayed generic medicine availability for 79% of medicines launched during the 4-year period 2002–2006 (Oxfam International, 2007). A later study by Abbott et al. (2012) found a 17% increase in medicine expenditure in Jordan between 1999 and 2004, which was largely attributable to the adoption of data exclusivity.

Most of the developed TPP countries and two developing countries (Chile and Malaysia) already provide data exclusivity going beyond the TPP obligation (see Table 1). But certain aspects of the TPP’s exclusivity requirements would be new obligations for four countries: Brunei Darussalam, Mexico, Peru and Vietnam. Each of these countries

negotiated a transition period to implement Article 18.50, ranging from 4 years (Brunei Darussalam) to 10 years (Vietnam). Vietnam would also be able to request (with justification) an extension of this period of up to 2 years and submit a further request for an additional year.

Exclusivity of undisclosed test data (biologics)

TPP Article 18.51 provides exclusivity arrangements for biologics. The TPP represents the first time provisions specific to biologics have been included in a trade agreement (Labonte et al., 2016). Biologic products are produced from cells and tissues using biotechnological processes and include many very expensive medicines for cancer and immune conditions such as rheumatoid arthritis (Gleeson et al., 2015).

The United States was seeking to secure 12 years of exclusivity for biologics in the TPP; this was a key objective of the US-based biopharmaceutical industry (Pharmaceutical Research and Manufacturers of America, 2013). Twelve years also reflects the current market exclusivity period for biologics in the United States,³ although for several years President Obama sought to wind this back to 7 years in his annual budget proposals (US Government, 2015). Securing 12 years of exclusivity in the TPP would effectively preclude subsequent attempts to shorten this period through changes to US law.

The US proposal for biologics proved to be one of the most controversial issues discussed in the TPP negotiations and generated fierce public debate and opposition in many countries (Gleeson and Lopert, 2015). At this stage, there is little evidence available to evaluate the effects that introducing or lengthening exclusivity for biologics would have on the time to market entry of biosimilars. However, it is clear that lengthening monopolies on these products, many of which are very expensive, would be associated with large costs. In a submission to the Australian Government Department of Foreign Affairs and Trade, Gleeson et al. (2014) found that the 10 biologic drugs listed on Australia's PBS which accounted for the largest government expenditure in the 2013–2014 financial year cost the PBS approximately AUD\$1.29 billion. This represents approximately 14% of the AUD\$9.15 billion in overall PBS expenditure over the same period. When the first follow-on (generic or biosimilar) product is listed on the PBS, a 16% price reduction is applied to all versions of the product.⁴ If follow-on (biosimilar) products had been available for these 10 drugs, over AUD\$205 million in taxpayer-funded subsidies would have been saved in the 2013–2014 financial year alone (Gleeson et al., 2014).

The final text of the TPP sets out two options for biologics. Parties can either provide at least 8 years of exclusivity for biologics (Article 18.51.1(a)) or provide at least 5 years of exclusivity supplemented with unspecified 'other measures' to 'deliver a comparable outcome in the market' (Article 18.51.1(b)). The text indicates that market circumstances can be taken into account in contributing to this 'comparable outcome'. This vaguely worded provision appears to have been intended to create constructive ambiguity; however, it has led to ongoing controversy over exactly what the TPP countries would need to implement in order to comply. Footnote 160 to Article 18.83 (Final Provisions) attempts to clarify this by stating,

Only the following Parties have determined that, in order to implement and comply with Article 18.51.1 (Biologics), they require changes to their law, and thus require transition periods: Brunei Darussalam, Malaysia, Mexico, Peru and Viet Nam.

Compliance with the TPP biologics obligations is clear for the United States which provides 12 years of data exclusivity for biologics; Canada, which provides 8 years of exclusivity for all drugs (with a provision for another 6 months if companies have conducted clinical trials of the drug in a paediatric population); and Japan, which has an 8-year period of Postmarketing Surveillance, the functional equivalent of data exclusivity, during which a generic manufacturer cannot submit an application for approval of a follow-on product.

Australia and New Zealand have asserted that their respective regimes are compliant with the provisions (Australian Government Department of Foreign Affairs and Trade, 2016; New Zealand Ministry of Foreign Affairs and Trade, 2016b). In both countries, no distinction is made between small molecule and biological medicines, both being eligible for 5 years of data exclusivity. A variety of factors, however (including patent protection, the time taken for regulatory approval and evaluation for listing on national reimbursement programmes, and other factors related to the size of markets), have meant that in practice, it has taken far longer than 5 years for biosimilars to reach the 'market' in these two countries. However, these countries face risks associated with the ambiguity of the provisions if they are adopted in their current form; particularly if the United States were to re-join the agreement in future, the interpretation of the provisions could become a matter of dispute.

Like Australia and New Zealand, Chile provides 5 years of data exclusivity for pharmaceutical products, and this also applies to biologics, since its definition of new chemical entities does not distinguish between small-molecule drugs and biologics (Kilic and Maybarduk, 2012b: 9). Brunei Darussalam, Malaysia, Mexico, Peru and Vietnam would have to provide exclusivity for biologics for the first time if the TPP were to be implemented in its current form. Brunei Darussalam has a 4-year transition period, Malaysia and Mexico have negotiated 5 years and Peru and Vietnam 10 years. As for Article 18.50, Vietnam would also be able to request (with justification) an extension of this period of up to 2 years and submit a further request for an additional year.

Patent linkage

Article 18.53 requires parties to implement a system for providing notice to a patent holder (or for a patent holder to be notified) prior to marketing approval of a pharmaceutical product that relies on safety and efficacy data submitted to a regulator by the patent holder marketing the originator. Parties must also provide time for the patent holder to seek remedies if it is alleged that market entry would constitute patent infringement and provide procedures for the timely resolution of disputes (Article 18.53.1). As an alternative, parties can provide some other system (e.g., direct coordination between the marketing approval authority and the patent office) to prevent the marketing of a follow-on pharmaceutical product without the consent of the patent holder where a patent exists on the originator product (Article 18.53.2). These types of provisions are known as 'patent

linkage' mechanisms because they create a link between marketing approval and the patent status of the originator drug. Evidence suggests that linkage regimes can be very successful in assisting pharmaceutical firms in protecting their high-value medicines from competition (Bouchard et al., 2010). Once again, with respect to patent linkage, the final text of the TPP is less onerous than the original proposal put forward by the United States, which sought to make all countries' regulatory agencies responsible for preventing patent infringements. The final form of wording was sufficiently flexible to accommodate existing arrangements in most countries. However, Brunei Darussalam, Malaysia and Vietnam would need to introduce new arrangements to comply with 18.53. Brunei Darussalam has 2 years to comply, Vietnam 3 years and Malaysia 4.5 years (see Table 1).

Discussion

Based on the analysis of five TRIPS-Plus pharmaceutical provisions in the IP chapter presented above, the developing countries involved in the agreement can be expected to bear the brunt of the impact of implementing the TPP's IP provisions if they are adopted in the form agreed among the 12 parties in 2015 and signed in 2016.

The discourse about the TPP often refers to parties meeting the same standards. For example, a fact sheet prepared by the Office of the US Trade Representative claimed that 'The TPP establishes high standard trade rules that level the playing field . . .' (Office of the United States Trade Representative, 2016). The *impact*, however, would not be distributed equally.

Table 1 shows that overall, the developing countries in the TPP may need to introduce far more substantial changes to their domestic laws than the developed countries if the TPP IP chapter is adopted in its current form. While some countries negotiated (relatively short) transition periods, these provide patchy and time-limited delays rather than any meaningful long-term relief. With the exception of Vietnam, which has the option of requesting a short extension to the transition period for a few provisions, the transition periods are fixed and provide no allowance for a slower than expected pace of economic development.

Overall, the developed countries participating in the agreement seem likely to experience little change in terms of access to medicines as a result of implementing the obligations of the TPP (unless continued tension over the implementation of the biologics provisions results in some developed countries introducing new impediments to ensure that biosimilars do not reach the market in less than 8 years). However, the TPP provisions would lock all parties into high levels of IP protection, limiting their future flexibility to modify domestic settings in the face of competing policy priorities.

The exception to this conclusion about limited impact is New Zealand, which will need to introduce patent term extension for the first time. The New Zealand Ministry of Foreign Affairs and Trade (2016b) National Interest Analysis estimated the cost of complying with the patent term extension obligations as 'approximately NZ\$1 million per annum (averaged over many years)'. It is difficult to evaluate this projection as no details were provided for how the figure was arrived at. The TPP biologics provisions, if interpreted as guaranteeing 8 years of market exclusivity, would also be likely to create additional costs for the national pharmaceutical coverage programmes of both Australia and

New Zealand, possibly amounting to hundreds of millions of dollars per annum (see Gleeson et al., 2014). While the costs for the national drug programmes of these countries can be relatively easily estimated, the cost to *society as a whole* is likely to be much higher for the developing country parties.

Based on the available evidence, the TRIPS-Plus provisions in the TPP IP chapter, newly implemented mainly by developing countries, would delay the market entry of generics and biosimilars and increase costs for individuals and governments. While developed countries may arguably be able to absorb most of these additional costs, the impact would be felt most in the countries which are already least able to provide affordable access to medicines for their populations.

There is no way of knowing whether the putative economic benefits of TPP participation would in fact outweigh the increased costs to the health care system and to individuals, and it seems unlikely that any economic benefits that countries do accrue would be used to offset increased costs for medicines. Econometric studies have predicted small aggregate economic benefits for most TPP countries. A widely cited study by Petri and Plummer (2016) estimated that the welfare benefit to the United States (the biggest beneficiary of the agreement) would be US\$131 billion or 0.5% of GDP by 2030. A study by the World Bank Group (2016), which drew in part on the work by Petri and Plummer, estimated the average impact on TPP countries as 1.1% of GDP by 2030. This report estimated the gains as 10% and 8%, respectively, for Vietnam and Malaysia, but the average for Canada, Mexico and the United States would be 0.6% of GDP by 2030. The models on which these projections are based assume full employment and invariant income distribution. A study by Capaldo and Izurieta (2016) using a different model, which allowed for changes in employment and income distribution, found smaller benefits for most countries and negative income growth for the United States and Japan. A review of seven studies estimating the economic impact of the TPP (Ciuriak, 2016) concluded that those studies which were based more closely on the final TPP text make smaller estimates of impact. Ravenhill (2017) points out that the models for these studies do not account for the costs associated with IP protection, which could well outweigh the estimated economic benefits, at least for some countries.

Furthermore, implementing the obligations of the TPP would involve significant administrative costs and strain the scarce resources and capacity of governments. As (Walls et al., 2015) argue, the implementation of trade agreements 'is expensive, skill-intensive and requires considerable infrastructure, which smaller and poorer states especially struggle to find'. Administering complex arrangements such as patent term extensions absorbs time and money that would be better spent providing health services, particularly in countries with health budgets that are already under pressure.

If the TPP pharmaceutical IP provisions are adopted in a revived TPP or any subsequent agreement, the greatest costs are likely to be borne by developing countries that accede *in the future*. To a certain extent, the existing participating countries were able to soften the effects of the TPP IP provisions by proposing language that accommodated their existing policy settings and by (at least in the early stages) presenting a united front against the US proposals. Developing countries seeking later accession would have neither of these opportunities and may also have more difficulty negotiating transition periods in the context of bilateral negotiations which would not attract the same level of

public attention as the original TPP negotiations did. In addition, if faced with challenges over rules in the TPP, developing countries may not have the human resources to effectively defend their positions.

Why did the developing countries accept such a poor deal in the TPP? The ultimate acquiescence of the developing countries to the pharmaceutical industry agenda in the TPP can be seen as the continuation of a historical trajectory that began well before TRIPS and has continued since (Jawara and Kwa, 2004). The answer to this question also lies partly in the wider context for the initiation of the TPP negotiations: the failure of wealthy countries to successfully prosecute their agenda through multilateral forums and the retreat to regional trade agreements in which a smaller group of like-minded, typically wealthy, countries could agree to a set of standards to which other countries could later be persuaded to adopt (Baldwin and Thornton, 2008). This is part of a pattern of forum shifting that has continued since the TRIPS Agreement was concluded in 1994 (Drahos, 2007). It is also partly due to the generally weaker bargaining power and capacity of developing countries to ‘influence the standard-setting process’ in trade negotiating forums, as described by Drahos (2002) in relation to the negotiations for the TRIPS Agreement. Such imbalances in negotiating power are even more pronounced in bilateral and regional trade agreements where developing countries often have to make large concessions to obtain access to developed country markets (Ravenhill, 2014).

Splintering of the earlier unanimous opposition to the US IP proposals can be traced through successive drafts of the IP chapter and appeared to accelerate towards the end of the negotiations. The transition periods for developing countries, for example, seem to have been negotiated bilaterally (Public Citizen, 2015). The conditions for democratic bargaining as described by Drahos (2002) (all relevant interests are represented, all parties have full information about the consequences of decisions and no one party is dominant) were eroded in the context of aggressive negotiating strategies. These included intense bilateral lobbying by the United States rather than negotiations in plenary discussions, ‘green room’ tactics similar to those used by wealthy countries in the World Trade Organization negotiations (Kelsey, 2013) and negotiations that continued into all hours of the night, putting a strain on small countries with limited travel budgets and small negotiating teams.

Conclusion

There is no evidence that stronger IP rights in developing countries incentivize pharmaceutical companies to invest in developing treatments for diseases that are endemic in these countries: ‘(T)he introduction of patents in developing countries has not been followed by greater R&D investment in the diseases that are most prevalent there’ (Kyle and McGahan, 2012: 1157). Moreover, for developing countries, there is no relationship between patent protection and investment in research and development (R&D) (Park, 2007) or between the adoption of data exclusivity and the amount of investment by the pharmaceutical industry in that country (Palmedo, 2013).

Nevertheless, were the TPP to enter into force in its current form, the developing countries that have signed the agreement (with the exception of Chile) would have to implement TRIPS-Plus IP provisions. These provisions could be expected to delay

access to affordable generic and biosimilar medicines for their populations, as well as create a significant impact on scarce infrastructure and resources that could be better invested in more productive activity. In contrast, the developed countries (albeit with a few exceptions, most notably New Zealand) have largely managed to negotiate provisions that accommodate their existing policy settings. These differential impacts on regulatory regimes will exacerbate existing inequities in health and access to medicines.

Developing countries would be well advised to carefully weigh the consequences of accepting these outcomes, particularly given the dubious economic benefits offered by the TPP (World Bank Group, 2016). To date, there has been no officially commissioned or recognized health impact assessment of the TPP undertaken; such an assessment would provide better evidence on which to make decisions about the way forward.

If the TPP IP chapter is adopted in its current form, it will be important for developing countries to plan carefully for implementation to ensure that they mitigate the effects as much as possible. This effort will need to include attention to the distribution of economic benefits across the population and across sectors.

The short and time-limited transition periods for developing countries to implement the TPP's TRIPS-Plus provisions are a product of secret negotiations conducted by international trade negotiators with no training in health policy, in the context of competing priorities and trade-offs between different sectors. This approach needs a re-think, given the dismal outcomes for developing countries in the TPP – outcomes which could affect a much wider array of countries, including those which accede later and those participating in subsequent trade agreements which take the TPP as a model or template.

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Notes

1. Eli Lilly lost its claim against the Canadian Government in March 2017 (Webster, 2017).
2. A literature-based submission is one which relies solely, or predominantly, on bibliographic data (i.e. based on published literature) to support the safety and efficacy claims. See <https://www.tga.gov.au/publication/literature-based-submissions> (accessed 26 May 2017).
3. The exclusivity period for biologics in the United States comprises 4 years of data exclusivity plus 8 additional years of market exclusivity, as specified in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).
4. This will become a 25% price reduction from 1 October 2018. See Budget Paper No. 2, Budget Measures 2017–2018, pp. 113–114. Available at: <http://www.budget.gov.au/2017-18/content/bp2/html/> (accessed 27 May 2017).

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