Response to Questions Taken on Notice

Inquiry into the proposed Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP-11)

Dr Deborah Gleeson, Public Health Association of Australia

1 HANSARD, p. 4

Senator PATRICK: You may not be able to answer this, but, when Philip Morris took on the Australian government, they did so within our own legal system first, and the matter went all the way to the High Court, and, when they lost there, they attempted to invoke ISDS and litigate the matter again. Can you explain to me why they went down that particular pathway rather than simply going straight to ISDS? I'm just trying to understand the norms here. If alcohol labelling laws were to come into force here, would we expect them to go to our courts first and then fall back on ISDS, or do you think they would go to ISDS first? I'm just trying to work out what might go on.

Response:

I'm reluctant to speculate about the decision-making process of a particular tobacco company, but it's clear that the tobacco industry uses a variety of different avenues to attempt to prevent the implementation of tobacco plain packaging. I recommend to the Committee the following research paper by Eric Crosbie and colleagues, which is based on a review of tobacco industry documents, government documents and media reports in five countries, and shows how the tobacco industry uses a 'multipronged' strategy to fight the implementation of tobacco plain packaging:

Crosbie E, Eckford R, Bialous S. Containing diffusion: the tobacco industry's multipronged trade strategy to block tobacco standardised packaging. *Tobacco Control*, Published Online First: 21 April 2018. doi: 10.1136/tobaccocontrol-2017-054227

A trade dispute over an alcohol labelling measure would appear more likely to be raised using the state-to-state dispute settlement process in the CPTPP, rather than investor-state dispute settlement process, since the wine and spirits labelling provisions are located in an annex to the Technical Barriers to Trade chapter (which is not directly enforceable through ISDS). However, it may be possible, depending on the specific circumstances, for an ISDS claim to be made by an alcohol corporation using the CPTPP 'minimum standard or treatment' or expropriation provisions, which can be used as grounds for an ISDS claim under the CPTPP.

It seems possible that if the alcohol industry were dissatisfied by a mandatory alcohol labelling measure, industry actors may seek to use a variety of avenues to contest it, including litigating in the domestic courts, persuading a CPTPP party to raise a state-to-state dispute, and using the ISDS process if it is possible to make arguments in relation to the specific measure being introduced. This is not to say that arguments or claims made in any of these forums would have legal merit or would be likely to succeed, but that a range of available legal avenues may be used to raise objections. In the following paper, which I have also attached for the Committee, we discuss the range of legal strategies that have been used to date by the alcohol industry to attack restrictions on alcohol marketing, both through domestic courts and through international trade and investment law.

O'Brien, P., Gleeson, D., Room, R., Wilkinson C. Commentary on 'Communicating Messages About Drinking': Using the 'Big Legal Guns' to Block Alcohol Health Warning Labels. *Alcohol and Alcoholism*, 2018, 1-4. doi: 10.1093/alcalc/agx124

It is difficult to speculate about the order in which an alcohol corporation might prioritise the different legal forums available. While it seems unlikely that ISDS would be the first choice, I cannot see any requirement in the CPTPP text for ISDS claimants to have exhausted other avenues before making a claim.

2 HANSARD, p. 7

Senator MOORE: Can I put on notice the issue around the impact on Third World countries. I was struggling to see how it operated in the submission. One of the other submissions uses the example of Vietnam and HIV drugs. In the work I had in the submissions in front of me I couldn't quite make that connection. Is it possible to get some more commentary from you, because of the expertise you have, about how that works? What's the particular link in terms of that access to necessary medical facilities in Third World countries, a number of whom are party to this agreement.

Response:

I have attached the following two peer-reviewed research papers for the Committee.

Mor, H. V. J., Tenni, B., Gleeson, D. & Lopert, R. 2016. The Trans Pacific Partnership Agreement and access to HIV treatment in Vietnam. *Global Public Health*. http://dx.doi.org/10.1080/17441692.2016.1256418.

Gleeson D, Lexchin J, Lopert R & Kilic B. 2018. The Trans Pacific Partnership Agreement, intellectual property and medicines: Differential outcomes for developed and developing countries. *Global Social Policy*, 18(1) 7–27. http://journals.sagepub.com/doi/abs/10.1177/1468018117734153

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Commentary

Commentary

Commentary on 'Communicating Messages About Drinking': *Using the 'Big Legal Guns' to Block Alcohol Health Warning Labels*

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Abstract

Like the tobacco industry, the alcohol industry, with the support of governments in alcohol exporting nations, is looking to international trade and investment law as a means to oppose health warning labels on alcohol. The threat of such litigation, let alone its commencement, has the potential to deter all but the most resolute governments from implementing health warning labeling.

The recent Special Issue of *Alcohol and Alcoholism* (Hassan and Siu, 2018; Hobin *et al.*, 2018; Pham *et al.*, 2018; Vallance *et al.*, 2018) reviewed evidence on the role of health warnings, in particular, on labels. There is a particular legal aspect which deserves mention. The law has an intimate relationship with alcohol, and has been essential to many advances in alcohol control. But law is not only facilitative. It can be an obstacle to good alcohol policy and can be used to raise objections to new public health measures. This is particularly evident at present in relation to the labeling of alcoholic beverages with health information, including warning labels. The alcohol industry may claim that alcohol warning labels would be unlawful, threatening to commence a formal legal challenge in national, supra-national or international courts and tribunals. These claims may not have legal merit, and may not succeed if the challenge proceeded to final dispute settlement, but will be expensive, time-consuming and distracting if they do. Furthermore, the mere raising of these issues may deter governments from proceeding with labeling reforms.

The tobacco industry has shown governments around the world that it is serious about using law to challenge new tobacco control packaging and labeling measures. Although Australia has successfully defended legal challenges by the tobacco industry to its plain packaging measure in its highest court on constitutional law grounds (Liberman, 2013) and before an international arbitration tribunal on the basis of international investment law (Voon and Mitchell, 2016), and it seems likely that the World Trade Organization will decide in its favor (Reuters, 2017), it has been highly costly and time-consuming to defend these challenges (Sydney Morning Herald, 2017). When Uruguay was subject to an international investment law claim by Phillip Morris International (Voon, 2017) for its graphic tobacco warnings and single presentation requirement, it considered scaling back the regulations to appease the tobacco company, at least partly because it could not afford the onerous costs involved in defending the threatened claims. In the end, Uruguay stayed the course and was successful against the tobacco industry, but was highly dependent on support from the Bloomberg Foundation to do so (Crosbie *et al.*, 2017).

Sometimes, industry challenges are successful and public health measures have to be redrawn or abandoned. This was the case in the USA, with the Court of Appeals for the DC circuit accepting that graphic tobacco warnings breached the first amendment right to freedom of speech (Orentlicher, 2013). The US Food and Drug Administration has yet to produce a revised set of graphic warnings, but even if it does, delay in the introduction of new measures is a

win for the industry. 'Regulatory chill' can affect governments, who wait to see the outcome of industry challenges before pursuing similar public health measures (Liberman and Mitchell, 2010). In the words of Margaret Chan, former Director-General of the World Health Organization, '[w]hat industry is aiming for is a domino effect, where countries fall in their resolve, one after another, under the threat of legal action' (Bloomberg Philanthropies, 2016).

The alcohol industry also seems to have realized the power in raising legal arguments and claims against alcohol control policies. Litigation has previously been used to attack alcohol marketing restrictions (Alemanno, 2013), and taxation and retailing arrangements (McGrady, 2011). In Yukon Territory, in Canada, the alcohol industry succeeded in removing new labels warning that 'Alcohol can cause cancer, including breast and colon cancers' from bottles and cans by raising a 'large range of [legal] concerns' (Picard, 2018). The alcohol industry—with the support of governments in the major alcohol exporting nations—now seems to be increasingly turning to the body of international trade and investment law to push back against countries seeking to pursue labeling reforms.

The first clear evidence of this was in 2010, when Thailand proposed graphic health warnings, with confronting images and text warnings that, amongst other things, 'drinking alcohol causes liver cirrhosis', 'drinking alcohol leads to inferior sexual performance' and 'drinking alcohol is a bad influence on children and young people' (European Policy Alliance, 2010). Thailand's proposal was subject to intense and extensive discussion in the World Trade Organization's Technical Barriers to Trade Committee (TBT Committee). The TBT Committee is a diplomatic and not a legal forum where WTO members can raise trade concerns about regulatory proposals, but the raising of issues in the TBT Committee is a harbinger of future disputes. Australia, the European Union, New Zealand and USA all expressed strong opposition to the Thai labels on the grounds that they would not be consistent with *WTO Agreement on Technical Barriers to Trade* (TBT Agreement, 1994) because they were more restrictive of international trade than was necessary to achieve Thailand's public health goal of addressing harms from alcohol consumption (O'Brien, 2013). The objecting WTO members all suggested that less trade restrictive measures were available, which they claimed were equally effective, including public and school education campaigns, and inclusion of alcohol content information on the label. Given the threat of litigation the objections implied, the Thai warning proposal has not proceeded.

Since 2010, a further nine alcohol warning label proposals (by Kenya, India, Ireland, Israel, Korea, Mexico, South Africa and Turkey) have been subject to discussion in the TBT Committee about their consistency with international trade law. The major alcohol exporting nations repeatedly question specific features of the new alcohol labeling policies (e.g. see TBT Committee, Minutes of the Meeting 10–11 November 2016). The content of the warnings is always a contentious issue. If the warning is concerned with drink driving, underage drinking or drinking during pregnancy, there is usually no objection. However, if the warnings mention links between alcohol and cancer, there are persistent queries about the validity of the claim. Further, if there is a suggestion that drinking alcohol *per se* is a cause of health problems, there are further complaints. Warnings including graphics or pictograms also invite more comments from WTO members than those without, as do warning regimes that mandate prominent presentation and placement requirements, and regular rotation. Refusal by governments to allow warnings to be applied as stickers or supplementary labels rather than on the main label has also been a recurring theme.

International trade law imposes various disciplines on countries that are relevant to labeling, including that they not discriminate between local and imported goods, and that their domestic labeling laws and policies are not unnecessarily trade restrictive (TBT Agreement, 1994). International investment agreements require, among other things, fair and equitable treatment, and prohibit indirect expropriation of investments (Phillip Morris v Uruguay, 2016). Where warning labels are worded or designed to reflect good scientific evidence, a country can have some confidence that its warning policy would be found to be consistent with international trade and investment law if the matter proceeded to dispute settlement. But no absolute assurance can be given, and it is this uncertainty that the industry can exploit with threats of long, technical and expensive litigation if governments refuse to wind back their 'offending' public health measures.

A particular source of difficulty for governments defending new measures is the lack of clarity about the strength of the supporting evidence that will be demanded by international dispute bodies. Apart from the evidence on the connection between drinking and the specified harm, there is the issue of whether the label will have significant effects in changing behavior. For alcohol warnings, the evidence of behavior change from existing warning labels is weak in comparison with the evidence on tobacco warnings (O'Brien *et al.*, 2017). The evidence from consumer surveys on studies of prototype alcohol warning labels or from studies on tobacco, which points to increases in the specificity of the message and in the size and graphic nature of a label being associated with more caution about the product, may not be considered adequate (O'Brien *et al.*, 2017). In the face of these unknowns, there is a chance that a country may be convinced that it is too risky to experiment with labeling given the potential costs and imposts of litigation. This may be a particularly acute risk for low- or middle-income countries with few resources and those with little expertize in international trade and investment disputes. In these circumstances, it is important for intellectual and financial resources to be made available to equip and support countries (such as happened with Uruguay for tobacco) to pursue innovative alcohol control measures and to respond to claims that their measures are inconsistent with international trade law.

It now seems that the alcohol industry is not satisfied that existing international trade and investment law is providing sufficient protection of its labeling interests, and that it wants these rules to be strengthened in its favor. Additional rules governing wine and spirits labeling have been included in the *Trans-Pacific Partnership Agreement* ('TPP'), concluded in February 2016 between 12 parties, including USA, Australia, New Zealand and Canada (TPP, 2016). The USA has since withdrawn, but it seems that the TPP may proceed without the US (ABC, 2017). The wine and spirits labeling rules have also been included in the *Agreement to Amend the Singapore-Australia Free Trade Agreement* (SAFTA, 2016), and it seems likely that they are being considered for inclusion in the Regional Comprehensive Economic Partnership ('RCEP'), which is being negotiated between 16 countries, including the major economies of Asia, such as China, India and Japan.

These new rules require countries to allow manufacturers to apply country specific information on a 'supplementary label' on imported wine and spirits (TPP, 2016). This is intended to save manufacturers from having to design and apply different main labels for different markets. The rule seems a rather innocuous and commonsense provision at first glance. However, we argue that the industry may use the rule to raise a legal argument that countries are not entitled to set label presentation and placement requirements, because inherent in the concept of a 'supplementary label' is the idea

that the label must be able to fit around, and not interfere with, the main labels (O'Brien *et al.*, 2017). If so, the rule would not just mean that a warning is relegated to a supplementary label, rather than being on the main label (which might be problem enough), but that the supplementary label could be placed in some inconspicuous place on the container. This is how the industry, when left to regulate itself, is largely positioning warning labels about drinking during pregnancy in Australia (Siggins Miller, 2014). Although we hold the view that the industry argument would be unlikely to succeed if it were used in litigation, it is a plausible argument, an argument that government officials could not shrug off.

We also think that the industry may regard this supplementary labeling rule, whatever its intended *legal* meaning, as representing a *political* bargain between governments and industry: that governments will not seek to control the label space and will leave the industry's 'property' alone. We therefore wish to urge caution with the development of new trade and investment laws. At a minimum, the supplementary labeling rules, appearing in the TPP and being considered for inclusion in RCEP and possibly other regional trade agreements, should be revised to exclude limitations on information about human health (O'Brien *et al.*, 2017). It is essential that further bases for industry arguments against public health measures for alcohol are not opened up.

It is entirely predictable that the industry will continue to use law to deter governments from further regulation of alcohol. The raising of legal doubts, threats of litigation and the actual commencement of litigation all have the potential to sway all but the most the resolute and well-resourced governments from prioritizing public health over industry interests. At present, alcoholic beverages in most countries have little health-relevant information on the label. Often they are exempted even from requirements that foodstuffs be labeled with nutritive information. Warnings that alcohol is a risky commodity, and concerning specific health risks, are still rare. Given that alcohol drinking is among the leading risks to health globally (Lim *et al.*, 2012), governments are likely to move increasingly to require health warnings and information on alcohol labels. Impeding or stopping such moves through trade and investment treaties and disputes would be substantially against the public interest and public health.

CONFLICT OF INTEREST STATEMENT

No author has a conflict to declare.

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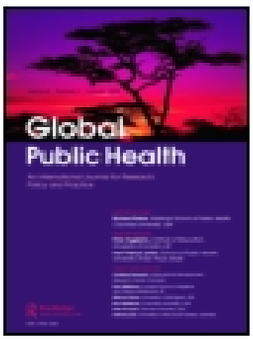

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The Trans Pacific Partnership Agreement and access to HIV treatment in Vietnam

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The Trans Pacific Partnership Agreement and access to HIV treatment in Vietnam

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ABSTRACT

In the Trans Pacific Partnership (TPP) Agreement negotiations, the USA successfully pursued intellectual property (IP) provisions that will affect the affordability of medicines, including anti-retrovirals (ARV) for HIV. Vietnam has the lowest GDP per capita of the 12 TPP countries and in 2013 provided ARVs for only 68% of eligible people living with HIV. Using the current Vietnamese IP regime as our base case, we analysed the potential impact of a regime making full use of legal IP flexibilities, and one based on the IP provisions of the final, agreed TPP text. Results indicate that at current funding levels 82% of Vietnam's eligible people living with HIV would receive ARVs if legal flexibilities were fully utilised, while as few as 30% may have access to ARVs under the TPP Agreement – more than halving the proportion currently treated.

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Introduction and background

The 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) removed the option of excluding pharmaceutical patents for countries acceding to the World Trade Organization (WTO). It also required WTO members to introduce other limitations on pharmaceutical competition, such as protection for 'test' data submitted to support regulatory approval. Concerns have been raised that provisions in recent trade agreements may further reduce access to medicines, particularly in developing countries (Chan, 2014; Médecines Sans Frontières, 2013a). Such TRIPS+ provisions lower the bar for the granting of patents and delay generic market entry by mandating longer periods of market exclusivity. Some agreements also limit the use of compulsory licensing, despite the affirmation of this and other flexibilities in the Doha Declaration on TRIPS and Public Health.

The Trans Pacific Partnership (TPP) Agreement is of particular concern (Baker, 2016; Bhardwaj & Oh, 2014; Lopert & Gleeson, 2013). Drafts of the IP chapter leaked during the negotiations[1] suggested that several participating countries had attempted to resist key US ambitions. But when the final text was released in late 2015, only some of the concerns regarding the pharmaceutical IP provisions had been mitigated (Baker, 2016; Labonté, Schram, & Ruckert, 2016).

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Vietnam, with a GDP per capita of only US$1911 in 2013,[2] and the poorest of the TPP parties, is arguably most vulnerable to provisions that constrain access to affordable medicines. This is of particular concern to people living with HIV. Vietnam's HIV positive population was 248,500 in 2011 (Duong et al., 2014) and was expected to reach 256,000 by the end of 2014 (Government of Vietnam, 2012). In 2013 approximately 121,600 met the clinical criteria for antiretroviral (ARV) treatment, and 68% were receiving treatment (National Committee for AIDS, Drugs, Prostitution Prevention and Control, 2014).

In 2012, 86% of the US$25.1 million spent on HIV treatment was funded through international aid – mainly from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the US President's Emergency Plan for AIDS Relief (PEPFAR). However, as noted by Nguyen, Nguyen, and Hua (2015), UNAIDS (2013), and the United States Secretary of State (2015), GFATM and PEPFAR funding are likely to be withdrawn following Vietnam's reclassification as a lower middle-income country. The Decision on Sustainable Financing for the HIV Response in 2013 outlined the government's plans to increase funding for HIV through national and provincial level budgets, by increasing the coverage of social health insurance and via social marketing (Government of Vietnam, 2013).

To date there has been little empirical work on the potential effects of proposed TPP provisions on ARV prices and access. Using a different methodology Nguyen et al. (2015) recently concluded that the TPP proposals would negatively affect both access to HIV medicines, and Vietnam's developing pharmaceutical industry.

This paper reports the findings of a study estimating the potential impact of the TPP on access to HIV treatment in Vietnam. Using the current Vietnamese IP regime as our base case, we analysed the potential impact of a regime making full use of legal IP flexibilities, and one based on the US proposals in the 2014 leaked draft of the TPP IP chapter, with the analysis updated to take account of the final text. Our study adds quantitative estimates to research by Nguyen et al. (2015).

TRIPS+ elements of the final TPP text

Key elements in the final text are:

- *Scope of patentability*: Requirement to make patents available for 'new uses of a known product, new methods of using a known product, or new processes of using a known product' (Article 18.37.2). Essentially this means that TPP countries are likely to grant more secondary patents.
- *Inventiveness requirement*: Mandates a very low test for inventiveness (not obvious to a person of ordinary skill) (Article 18.37.1, Footnote 30).
- *Presumption of validity*: All examined and granted claims must 'be considered prima facie to satisfy the applicable criteria of patentability', raising the bar for proving a patent invalid (Article 18.72.3).
- *Revocation of patents*: Article 18.39 is unclear as to whether parties continue to have the right to revoke a patent because of anti-competitive conduct.
- *Patent term extension*: Requirement to grant patent term extensions to compensate for 'unreasonable' delays in processing patent applications (Article 18.46) or marketing approval processes (Article 18.48).

- *Data protection and market exclusivity*: Requirement to provide data protection for 'undisclosed test or other data': (i) for at least five years for new products (Article 18.50.1); (ii) for at least three years for new uses or indications of a previously approved product, or five years for combination products (Article 18.50.2); and (iii) eight years of market exclusivity (or its equivalent) for biologics (Article 18.51).
- *Patent linkage*: Requirement to provide measures to prevent generic marketing approval during the originator patent term, and for patent holders to be notified of generic marketing applications (Article 18.53).

Of particular concern, is footnote 30 to Article 18.37, requiring patent eligibility to be determined, not on the basis of inventiveness, but on the basis of non-obviousness. This is the key provision giving rise to very poor quality patents (Moir, 2013). Such low standards lead to multiple patents on a single medicine, thereby delaying generic entry (Moir & Palombi, 2013). Patents are granted for (i) known chemical variants even where the original compound has already been patented, and (ii) for new uses or forms of already-patented compounds, even where the original patent provides full market exclusivity. Combining known compounds with known methods of delivery is also sufficient to obtain additional patents. The practice of extending patent life by obtaining secondary patents is referred to as evergreening (Hemphill & Sampat, 2012).

In November 2013 the US Trade Representative (USTR) announced a 'differential approach' for developed and developing countries in the TPP (USTR, 2013) by phasing in certain IP provisions for developing countries (Inside U.S. Trade, 2013). This approach drew heavy criticism from non-government organisations and academics as still requiring lower income countries to eventually adopt inappropriate IP standards (Baker, 2013; Médecins Sans Frontières, 2013b). While some provisions, such as those affecting the scope of patentability, will come into effect as soon as the TPP enters into force, the final text allows phase-in over 3–10 years for the more onerous provisions for some developing countries, including Vietnam (Article 18.83).

Empirical evidence of the impact of trade agreements on access to medicines

Since TRIPS, the US has concluded a number of preferential trade agreements that include various TRIPS+ provisions, prolonging effective monopoly periods for medicines, and delaying market entry of generics. A small number of studies have attempted to analyse their impact on access to medicines.[3]

Before 2000 Jordan relied heavily on generic medicines, but an Oxfam International (2007) study found that the US–Jordan Free Trade Agreement led to a 20% increase in medicine prices, and delayed generic entry for 79% of newly launched medicines.[4] Moreover, compared to Egypt, with no TRIPS+ policies, medicine prices were two to six times higher (Oxfam International, 2007, p. 10). Adjusting for sales volume and inflation, Abbott et al. (2012) found that between 1999 and 2004 there was a 17% increase in medicines expenditure in Jordan and concluded that data protection had had the most significant effect on the price of medicines.

Other treaties that have been analysed empirically are the Central America Free Trade Agreement (Godoy & Cerón, 2011; Shaffer & Brenner, 2009); the recently concluded

European Union (EU) – Canada agreement (Lexchin & Gagnon, 2014); and the EU trade treaties with Colombia and Peru (IFARMA and Fundacion Mision Salud, 2009a, 2009b). All found substantial costs to consumers from TRIPS+ provisions.

Thailand does not have a TRIPS+ trade agreement; negotiations with the US during 2004–2006 were abandoned after TRIPS+ proposals that would have led to increased prices for HIV medicines prompted civil unrest.[5] However key elements of the draft agreement have been extensively analysed. Using 2000–2003 data on domestic production and import volumes for 74 medicines Akaleephan et al. (2009) found that extending market exclusivity for five years would have increased 2002 medicine expenditure by 9–45%. Kessomboon et al. (2010) also estimated that by 2027 patent term extensions would have increased the medicines price index by 32%, outlays by US$11 million, and losses to domestic pharmaceutical companies by US$3 million.

This study adds to the limited literature examining the effects of trade agreements on access to medicines and is the first study to model the potential impact of the TPP on access to medicines.

Methods

Comparison scenarios

We estimated the impacts of three scenarios on the cost of ARVs in Vietnam (see Table 1 for details):

- Scenario 1 is based on full TRIPS flexibilities, as affirmed in the Doha Declaration;
- Scenario 2, the baseline, applies Vietnam's current IP laws;[6] and
- Scenario 3 is based on the provisions in the final TPP text.

Changes to patent laws take time, and the baseline scenario – Vietnam's current patent laws – has been stable for a number of years. In order to explain the practical impact of these three scenarios we look first at the medicines used in Vietnam for ARV treatment. We then turn to the patent landscape for these medicines, paying particular attention to patents granted or applied for in Vietnam. We then use this information to identify the impact of alternative patent policy scenarios on the cost of ARV medicines and hence on access to them. To do this we drew on the 2013 profile of people living with HIV and applied the 2012 Vietnamese budget for this programme as a funding constraint. The analysis estimates the different proportions of the eligible HIV population likely to have access to antiretroviral treatment (ART) given the prices likely to eventuate under different patent policy settings.

Medicines used to treat HIV in Vietnam

The Ministry of Health's (2009) Guidelines for Diagnosis and Treatment of HIV/AIDS and National ART Protocol outline the criteria for starting antiviral treatment. Both first-line and second-line regimens include combinations of three medicines (see Table 2).[7]

Patent landscape for prioritised first-line ARV medicines

The patent history of the priority ARV medicines provides key information for assessing whether patents would be granted under alternative patent regimes. We focus on the first-

Table 1. Assumptions in different scenarios.

Scenario	Elements included in the model	Assumptions
1. Full implementation of TRIPS flexibilities	Compulsory licensing of all second and subsequent line ARVs (i.e. all ARVs not currently available as generics) Ability to reject patents for combinations of known things unless they demonstrate synergy[a] No patent term extension No data protection	Assumes that Vietnam would adopt as a minimum: • the European synergy standard for combinations; • processes used in Brazil to ensure a reasonable inventiveness standard; and a requirement for at least enhanced efficacy in the inventiveness standard
2. Current IP provisions in Vietnam	Patents for products and processes, but not new uses or methods of using existing drugs 20 year patent term; no patent term extensions Protection for undisclosed data only for new chemical entities and new combinations of known entities No patent linkage	Data protection is not automatic, and must be applied for. Five years of data protection for undisclosed data is assumed to apply to all new chemical entities and new combinations of existing entities
3. Level of IP protection in the TPP	Patents for new uses, new methods of using, or new processes of using existing drugs Patent term extensions for new pharmaceutical products to compensate for 'unreasonable' patent office and marketing approval delays Five years of data protection for new pharmaceutical products, additional 3 years for new indications or 5 years for combination products	5 years of PTE for patents for any medicine requiring marketing approval 5 years data protection for undisclosed data plus additional 3 years for new indications (and 8 years for biologic products)

[a]The synergy doctrine requires that a new combination of known things demonstrate either a surprising effect or an effect biologic greater than the sum of the parts in order to pass the inventiveness requirement for a patent.

line regimen of tenofovir (TDF), lamivudine (3TC) and nevirapine (NVP), providing detailed patent information only where a patent has been granted in Vietnam.

Tenofovir: A combination of tenofovir and emtricitabine (FTC) was granted a patent in Vietnam despite being never being granted in the US,[8] and granted but later revoked by the European Patent Office (EPO).[9] Drahos (2008) cites Vietnam as one of several countries mentioning the EPO as a trusted office. This Vietnamese patent does not expire until 13 January 2024.

Lamivudine (3TC) has a complex patent history. The first application, in February 1989, claimed oxathiolane compounds (including optical isomers) with antiviral properties. Another 14 applications to the US Patent and Trademark Office (USPTO) over the next 16 years all derive from this first application, and 9 were granted. One of these additional patents – for a liquid form – was granted by the EPO and by several other countries including Vietnam, where it does not expire until March 2018.[10]

Nevirapine (NVP) also has one patent granted in Vietnam and another application pending. The nevirapine patents shed particular light on the very low standards of inventiveness in the patent system.

The first patent was filed in July 1993 in the USA by Boehringer Ingelheim.[11] Food and Drug Administration approval was obtained in June 1996, giving Boehringer just over 17 years of market exclusivity in the USA,[12] three years longer than the average (Harris, Nicol, & Gruen, 2013, p. 82). The equivalent European patent received a term extension of some 30 months. An application for a hemihydrate formulation of nevirapine was filed in the USA in 1997 and two patents were granted, expiring in August 2018 and March

Table 2. HIV treatment guidelines, Vietnam, 2011.

First-line ARV regimens:				
Prioritised regimen: Tenofovir disoproxil fumarate (TDF): 300 mg daily	+	Lamivudine (3TC) 2 × 150 mg daily	+	Nevirapine (NVP): 2 × 200 mg daily [a] or efavirenz (EFV): 1 × 600 mg at night [b]
Alternative regimen Zidovudine (AZT): 2 × 300 mg daily	+	Lamivudine (3TC) 2 × 150 mg daily	+	Nevirapine (NVP): 2 × 200 mg daily [a] or efavirenz (EFV): 1 × 600 mg at night [b]
Second-line ARV regimens:				
Zidovudine (AZT): 2 × 300 mg daily	+	Lamivudine (3TC) 2 × 150 mg daily	+	Lopinavir/ritonavir (LPV/r): 2 × 400/100 mg daily or ritonavir-boosted atazanavir (ATV/r): 300/100 mg daily
Tenofovir disoproxil fumarate (TDF) : 300 mg daily	+	Lamivudine (3TC) 2 × 150 mg daily	+	Lopinavir/ritonavir (LPV/r): 2 × 400/100 mg daily or ritonavir-boosted atazanavir (ATV/r): 300/100 mg daily

[a]Once daily for the first two weeks of treatment.
[b]If patient cannot tolerate nevirapine.

2020. The hemihydrate is simply another salt of the same base molecule and offers no difference in clinical benefit. Patents for this variant on the original molecule have been granted in Europe and in Vietnam. Vietnamese patents VN1-0002478-000 and VN1-0002431-000 expire in November 2018.

A third patent – for an extended release formulation – has been filed in Vietnam, based on a 2009 US application. Although eventually granted, the US application was initially rejected as unclear and obvious. The applicant then deleted 23 of 24 claims, but it was again rejected as obvious. The applicant then withdrew the single remaining claim and substituted a marginally different claim (see Box 1) with the major difference being a change from a composition to *the use* of the same composition to treat HIV.[13] By 2009 the use of nevirapine for treatment of HIV was well known and the extended release formulation had been rejected as obvious, but the USPTO granted this additional nevirapine patent. This patent does not prevent the manufacture of the formulation – *only its use to treat HIV*. The patent application is still pending in Vietnam.

Box 1. Extended release nevirapine: granted patent claim and differences from previously rejected obvious claim.

Nevirapine, extended release formulation. US patent application 12/523226
Rejected claim 15 and accepted claim 24
Claim ~~15~~24
A method for treating HIV-1 infection which comprises once daily administration to a human infected by HIV-1 a ~~A~~ tablet pharmaceutical dosage from wherein each tablet comprises:
(a) 400 mg of anhydrous nevirapine;
(b) 270 mg of hypromellose 2208
~~(Methocel™ K4M Premium CR)~~
(c) 400 mg of lactose monohydrate; and
(d) 10 mg of magnesium stearate
Wherein each tablet is compressed by a force of 10–25 kN.

Note: the claim number was changed from 15 to 24; the phrase "A method for treating HIV-1 infection which comprises once daily administration to a human infected by HIV-1 a" was added; and the trademark name was deleted.

Patent status of first-line ARVs under alternative patent policy scenarios

We now consider how the patent status of these medicines would pan out in Vietnam comparing three scenarios: use of the full TRIPS flexibilities, Vietnam's current policy settings, and policy settings resulting from the final TPP text.

For TDF, which has no Vietnamese patents, there is no difference between full TRIPS flexibility (scenario 1) and the baseline scenario (scenario 2). Under the TPP Agreement (scenario 3) a new patent might be granted for an ester variant (as has happened at the EPO), because of the very low inventive step required by the TPP. It might also be eligible for a term extension, depending on the timing of marketing approval.

3TC has a Vietnamese patent for the liquid form only, a simple variation in composition compared to the original patent. Under full TRIPS flexibility this would not be granted due to higher patenting standards, but in practice there would be little impact as the main form used in Vietnam is the tablet. Thus there is effectively no difference between the alternative patent regimes with respect to 3TC in tablet form.

For NVP a patent for the hemihydrate has been granted in Vietnam and will not expire until November 2018. Under full TRIPS flexibilities this patent could have been rejected as lacking an inventive step, or a compulsory license could have been issued for this formulation.[14] If the extended release formulation were granted a Vietnamese patent, it would not expire until 2029. Under the TPP provisions, a patent would be granted but not a term extension.

These alternative patent outcomes are summarised in Table 3.

ARV medicine prices in Vietnam

To understand ARV medicine prices in Vietnam, it must be recognised that Vietnam has had many state-owned enterprises producing medicines, and these are still transitioning to a market economy. Most local manufacturing is assembly, with 90% of active ingredients imported. Locally produced ARVs cost less than imported products but are still five to seven times higher than the lowest international prices (Nguyen, Knight, Mant, Cao, & Brooks, 2010; Nguyen, 2011).

As at August 2014, there were 26 different 300 mg TDF tablet products on the market in Vietnam,[15] with the price of a day's treatment ranging from US$1.05 to as high as US$ 5.47 (Table 4). As no TDF patent has been granted in Vietnam a price as high as US$5.47 is surprising. For 3TC, only four products are supplied in the 150 mg dose required by treatment guidelines. Again there is substantial price variation (Table 4). In contrast, there are only two NVP products on the market, with similar prices.

For the alternative first-line regimen, there is a single AZT product available at a daily treatment cost of US$0.75. There are, however, some combination products – two for combinations of AZT and 3TC and one product combining all three drugs. Priced at $US0.94 a day, this triple combination is not only the cheapest treatment option, but it also has the advantage of being a single tablet. The annual treatment cost is US$344. For the preferred first-line regime of TDF + 3TC + NVP the lowest priced option is US $618.

In Table 5 we compare the lowest available prices in Vietnam to some international benchmarks – the originator prices for category 1 and category 2 countries and the best

Table 3. First-line ARVs: patent status under alternative policy scenarios.

Medicine	Scenario 1: full TRIPS flexibilities	Scenario 2: current Vietnam (VN) regime	Scenario 3: TPP regime
TDF	Pure TDF: no change from current regime; TDF+FTC: no VN patent	No patents on TDF, but patent on TDF+FTC	Possible grant of patent for esters as per EPO Possible term extension for ester patent
3TC	No patents	Patent on liquid form expires 20 March 2018	As for current regime
NVP	No patents	Patent on hemihydrate form expires Nov 2018 Possible patent on extended release form (if granted, expiry 2029)	Patents on hemihydrate form as per current regime, with possible term extension Patent on extended release form, no term extension

available world price.[16] These data show that not only are Vietnamese prices markedly higher than the best available global prices, they are generally above category 1 and category 2 originator prices. The exception is NVP, which while it sells at a mark-up of 488% over the best global price (Table 6), is available at 50% of the category 1 originator price or 28% of the category 2 originator price.

Results and implications

Estimating ARV treatment costs under different scenarios

The data in Table 5 provide a basis for comparing the impact of alternative patent policy scenarios on the costs of ARVs. Under Scenario 1, which assumes full use of TRIPS flexibilities, the Vietnamese government would be able to obtain medicine supplies at or below world-best prices. Scenario 1, with world-best pricing, gives a per person treatment cost of US$252 ($76 in medicine costs plus $176 in non-medicine treatment costs).

Under scenario 2 – current Vietnamese patent policy – we begin by using the best available Vietnamese price for any first-line regimen. From Table 5, this price is US$344, using the combination product AZT + 3TC + NVP.[17] However, we also know the annual budget is US$25.1 million for almost 83,000 people with HIV, implying an average outlay of US $304 per person treated, including the cost of medicines, and suggesting that the Vietnamese government must be sourcing ARVs at well under $344 per person. The proportion

Table 4. First-line ARVs: current medicine costs and treatment costs per person.

Medicine	Current Vietnam regime per person treated	
	Daily cost (US$)	Annual cost (US$)
TDF: 300 mg daily	1.05–5.47	383–1995
3TC: 150 mg 2 × daily	0.30–1.24	108–453
NVP: 200 mg 2 × daily	0.35–0.47	127–172
Total daily regimen cost	1.70–7.18	618–2620
AZT: 300 mg 2 × daily	0.75	275
3TC: 150 mg 2 × daily	0.30–1.24	108–453
NVP: 200 mg 2 × daily	0.35–0.47	127–172
AZT (300 mg) + **3TC** (150 mg)	1.13–1.35	413–491
AZT (300 mg) + **3TC** (150 mg) + **NVP** (200 mg)	0.94	344
Total daily regimen cost	0.94–2.46	344–2620

Source: Calculated from data obtained from drug administration of Vietnam (http://www.dav.gov.vn/Default.aspx).

Table 5. First-line ARVs: annual treatment costs (US$s), Vietnam and globally.

Medicine	Lowest cost in Vietnam	Originator price		Best global price
		Country 1 category	Country 2 category	
TDF: 300 mg daily	383	207	365	26
3TC: 150 mg 2 × daily	108	75	–	24
NVP: 200 mg 2 × daily	127	219	438	26
Total daily regimen cost	618	501		
AZT: 300 mg 2 × daily	275	–	–	69
3TC: 150 mg 2 × daily	108	75	–	24
NVP: 200 mg 2 × daily	127	219	438	26
AZT (300 mg) + **3TC** (150 mg)	413	169	–	79
AZT (300 mg) + **3TC** (150 mg) + **NVP** (200 mg)	344	–	–	100
Total daily regimen cost	344–510			

Source: Calculated from data in MSF, 2014: Annex 1 and data in Table 4.

of treatment costs spent on ARV medicines is reported to be around 42% (Duong, et al., 2014), implying US$127 as the cost of medicines and US$176 for non-drug costs.[18] This estimate of US$127 is used for scenario 2 – the current Vietnamese patent policy setting. Even though the government appears to be sourcing ARVs at well below list prices, this cost (US$127) is still greater than the best available global price (US$76) identified as the price for scenario 1 – use of full TRIPS flexibilities.

Under scenario 3, TPP patent policies could lead to the grant of further patents and patent term extensions (see Table 3), delaying access to generic ARV medicines. Despite some modifications in the final TPP text,[19] we found that the likely outcomes for ARVs did not change substantially from the 2014 draft, as the changes were insufficient to attenuate the impact of the patent provisions. Current MSF data show originator company prices to be US$501 for the preferred regimen of TDF + 3TC + NVP in category 1 countries (Table 5). Depending on the supplier, Vietnam is considered a category 2 country, in which case prices would be higher. Against this, however, is the clear ability to obtain medicines at or below list price. We therefore took US$501 as the medicine cost for scenario 3.

The results of this analysis are presented in Table 7. As expected, if Vietnam were able to use full TRIPS flexibilities and obtain ARVs at world-best prices (Scenario 1), then the proportion of the population who could be treated within the current budget would

Table 6. Benchmarking Vietnam ARV prices: percentage of world best price.

Medicine	Lowest available price in Vietnam	Originator price Category 1 country	Originator price Category 2 country
TDF: 300 mg daily	1473%	185%	105%
3TC: 150 mg 2 × daily	450%	144%	
NVP: 200 mg 2 × daily	488%	58%	29%
Total daily regimen cost	813%		
AZT: 300 mg 2 × daily	399%		
AZT: (300 mg) + **3TC** (150 mg)	523%	144%	
AZT: (300 mg) + **3TC** (150 mg) + **NVP** (200 mg)	344%	244%	

Source: Based on Table 5.

Table 7. Alternative treatment capabilities depending on patent policy setting.

	Available budget	PLHIV eligible for ARVs	Number treated	Non-drug treatment costs ppy	Medicine cost ppy	% treated
Scenario 1	25,100,000	121,599	82,687	176	76	82
Scenario 2	25,100,000	121,599	99,579	176	127	68
Scenario 3	25,100,000	121,599	37,072	176	501	30
Scenario 3b	25,100,000	121,599	58,230	176	255	48
Scenario 3c	25,100,000	121,599	26,673	176	765	22

Notes: Budget data are for 2012. The estimated number of people living with HIV and eligible for ARV treatment are from 2013. While it would be preferable to have budget data for the same year as treatment data we have not found it possible to obtain 2013 budget data. The analysis is designed to demonstrate differences in the relativities between the scenarios. Changes in the budget would move outcomes for all scenarios in the same direction and are thus not critical for these results. Scenario 3b is based on drug prices increasing by a factor of two; in scenario 3c, drug prices increase by a factor of six as between the scenarios 2 baseline and the TPP scenario 3.

increase to 82%. Should Vietnam implement the patent provisions of the TPP (Scenario 3), prices could rise substantially. We have estimated a price increase to $501, in which case, given the budget constraint, treatment would be available to only 30% of the eligible population, or less than half the number currently being treated, a reduction of over 45,000 people.

Of course, prices might not rise quite so severely under scenario 3. In Jordan, Abbott et al. (2012) estimated an average price increase of 17%, which would bring the price only to US $149. If this were to eventuate, the proportion treated would fall by only 5%—some 5500 fewer people would be treated. But Oxfam International (2007) showed that prices could be between two and six times higher in Jordan than in neighbouring countries without TRIPS+ policies. For scenario 3, that would mean drug costs of US$255 to US$765 (shown in Table 7 as Scenario 3b and 3c, respectively). If drug costs were four times higher they would be $US510 – very close to our initial estimate for scenario 3.

Conclusion

Currently Vietnam is able to provide ARVs to only 68% of those meeting the clinical criteria for treatment. When the final TPP provisions are implemented we estimate that as few as 30% of Vietnam's HIV population will have continued access to ARVs, assuming the budget for HIV treatment remains constant. By contrast, with full use of TRIPS flexibilities, a scenario precluded by the TPP, an estimated 82% of the eligible HIV population could be treated.

The findings of this analysis complement the analysis by Nguyen et al. (2015), and substantiate concerns that the TPP will have a deleterious effect on access to medicines, particularly in lower income countries. Although the final TPP text is less damaging than previous drafts, we have shown that it will still significantly impede access to life-saving medicines.

TRIPS Article 7 states that patent policy should be balanced between the interests of producers and users of new technology. Not only will many of the TPP provisions make achieving this balance impossible, they will also preclude the attainment of two Millennium Development Goals – universal access to treatment for HIV/AIDS for all those who need it by 2010 (6B) and access to affordable essential medicines in developing countries (8E).

Notes

1. The 2013 leaked IP text is available at https://wikileaks.org/tpp/ and the May 2014 version is at https://www.wikileaks.org/tpp-ip2/#article_e4.
2. World Bank GDP in current $US at http://data.worldbank.org/indicator/NY.GDP.PCAP.CD.
3. For a detailed review of the literature see Moir, Tenni, Gleeson, and Lopert, 2014.
4. The trade agreement required patent term extensions to offset marketing approval delays, limits to parallel importing and compulsory licensing, five years of data protection (three years for new uses) and patent linkage notification (Oxfam International, 2007, p. 7).
5. See http://www.ustr.gov/countries-regions/southeast-asia-pacific/thailand.
6. This scenario is based on Vietnam's Law on Intellectual Property (No. 50/2005/QH11), the 2006 Regulation on Data Security of Drug Registration Records and the 2009 Law Amending and Supplementing a Number of Articles of the Law on Intellectual Property. We also drew on comparisons by Kiliç and Maybarduk (2011) of current Vietnamese law and the 2011 US TPP proposals in developing this scenario.
7. First-line treatments are those given initially; second-line drugs are prescribed if the patient develops resistance to first-line medications.
8. Altogether Gilead filed 10 US applications for combinations of TDF and FTC. Two are pending, four have been granted and four abandoned. The one granted in Vietnam (WO2004064845, US application 10/540794) was one of the abandoned US cases. Its child, application 12/204,174, was eventually granted by the USPTO, but only after being rejected five times as being obvious (numerous changes were made to the claims, including by the examiner, and a terminal disclaimer referring to an earlier application, meaning a shorter patent life).
9. Gilead has appealed the revocation (T0725/11), and the appeal is still pending as at 15 August 2016.
10. Vietnamese patent VN1-0002847-000 granted in July 2002.
11. Application 08/091418, granted as patent number 5,366,972 on 22 November 1994. The patent was also granted by the EPO.
12. Calculated as the period from marketing approval on 21 June 1996 to patent expiry on 13 July 2013.
13. The specification of the hypromellose component was also changed, but only by deleting the trademark name.
14. Note, however, the real-world challenges in issuing compulsory licenses even when importation is not involved (Arup & Plahe, 2016).
15. Drug Administration of Vietnam (http://www.dav.gov.vn/Default.aspx).
16. Depending on the supplier, Vietnam is classed either as a category 1 or as a category 2 country. Bristol Myers Squibb and Gilead class Vietnam as category 1, while Abbvie/Abbott, Boehringer-Ingelheim and Merck all class Vietnam as category 2 (Médecins Sans Frontières (MSF) 2013a: 73-77).
17. This is consistent with a 2012 Viet Nam Administration of HIV/AIDS Control (VAAC)/ US Centers for Disease Control and Prevention (CDC)/World Health Organization (WHO) study reporting first-line ART provision at US$365 per patient per year for the first year and US$312 for subsequent years.
18. Table 1 in Duong et al., 2014, showed the average cost of first-line treatment ARVs as 37% in the first year and 47% in subsequent years. Here we use the average of 42%. We also know that only 3% of people treated are on second-line ARVs. Because this is such a low proportion, and our estimates are quite rough, we have chosen to ignore second-line treatments in our calculations.
19. For example removal of the qualifier that patents could not be denied solely because they did not result in enhanced efficacy.

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Disclosure statement

DG often represents the Public Health Association of Australia (PHAA) on matters related to trade agreements and public health. She has accepted funding from various government and non-government (not-for-profit) sources to attend speaking engagements related to trade agreements. BT is affiliated with the PHAA and People's Health Movement Australia, which has been advocating for a more just trade agreement. HM and RL declare that they have no competing interests.

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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))	NLAR	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))

(*Continued*)

Table 1. (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))	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(i))	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.

[a]New 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.

[b]Andean 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).

[c]Vietnam 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 submissions[2] 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 Article18.50, 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 Sates 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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