

The Trans-Pacific Partnership: Intellectual Property, Public Health, and Access to Essential Medicines

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The mega-regional agreement, the Trans-Pacific Partnership, put forward a radical model for the regulation of intellectual property and access to medicines across the Pacific Rim. The trade agreement makes reference to the framework established by the TRIPS Agreement 1994, the Doha Declaration on the TRIPS Agreement and Public Health 2001, and the WTO General Council Decision 2003 (which has been incorporated into the TRIPS Agreement 1994 as an amendment in 2017). Nonetheless, it does little to positively advance public health and access to medicines. The Trans-Pacific Partnership seeks to maximize the intellectual property rights of pharmaceutical drug companies. The agreement has extensive provisions on patentable subject matter, patent standards, patent term extensions and evergreening, patent registration linkages and border measures. There has also been controversy over measures related to data protection, the protection of biologics, and trade secrets. The World Health Organization and the United Nations Secretary-General's High Level Panel on Access to Medicines have highlighted the need to ensure that public health and access to medicines are not undercut by regional trade agreements, such as the Trans-Pacific Partnership.

L'Accord du partenariat transpacifique a mis de l'avant un modèle radical pour la réglementation de la propriété intellectuelle et de l'accès aux médicaments dans le littoral du Pacifique. L'accord commercial fait référence au cadre établi par l'Accord sur les aspects des droits de propriété intellectuelle (ADPIC) de 1994, la Déclaration sur l'accord sur les ADPIC et la santé publique de

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2001, et la Décision du Conseil général de l'OMC de 2003 (qui a été incorporée en 2017 à l'Accord sur les ADPIC de 1994 sous forme d'amendement). Néanmoins, il ne contribue guère à améliorer la santé publique et l'accès aux médicaments. Le Partenariat transpacifique vise à maximiser les droits de propriété intellectuelle des sociétés pharmaceutiques. L'accord contient de nombreuses dispositions concernant les objets susceptibles d'être brevetés, les normes de brevets, les extensions de la durée des brevets et leur renouvellement, et les liens entre les brevets et les mesures transfrontalières. De plus, les mesures liées à la protection des données, des produits biologiques et des secrets commerciaux ont suscité la controverse. L'Organisation mondiale de la santé et le Groupe d'experts de haut niveau mis en place par le Secrétaire général des Nations Unies sur l'accès aux médicaments ont souligné la nécessité de veiller à ce que la santé publique et l'accès aux médicaments ne soient pas compromis par des accords commerciaux régionaux comme le Partenariat transpacifique.

1. INTRODUCTION

The *Trans-Pacific Partnership* [TPP] was a proposal for a mega-regional agreement, involving a dozen countries across the Pacific Rim.¹ Participants included the United States, Canada, Mexico, Chile, Peru, Australia, New Zealand, Japan, Singapore, Brunei Darussalam, Vietnam and Malaysia. A number of other countries, such as Indonesia, the Philippines, Taiwan and South Korea, were contemplated as future participants in the agreement. The sweeping trade agreement covers a score of topics, including such matters as intellectual property, investment, transparency in health

¹ The United States Trade Representative, "The Trans-Pacific Partnership", online: <<https://ustr.gov/tpp/>>. For commentary, see Jane Kelsey, ed., *No Ordinary Deal: Unmasking the Trans-Pacific Partnership Free Trade Agreement* (Wellington: Bridget Williams Books Inc., 2010); Tania Voon, ed., *Trade Liberalisation and International Co-operation: A Legal Analysis of the Trans-Pacific Partnership Agreement* (Cheltenham, U.K. and Northampton, Mass.: Edward Elgar, 2013); C.L. Lim, Deborah Elms & Patrick Low, eds., *The Trans-Pacific Partnership: A Quest for a Twenty-First Century Trade Agreement* (Cambridge: Cambridge University Press, 2012); Jane Kelsey, *Hidden Agendas: What We Need to Know about the Trans-Pacific Partnership Agreement (TPPA)* (Wellington: Bridget Williams Books Limited, 2013); and Scott Sinclair & Stuart Trew, eds., *The Trans-Pacific Partnership and Canada: A Citizen's Guide* (Toronto: James Lorimer & Company Ltd., 2016).

procedures, and trade in services. The TPP will have a significant impact upon the health of everyone in the Pacific Rim — particularly insofar as it affects timely access to affordable medicines. There has been much concern that citizens, consumers, and seniors have suffered from high pricing of medicines by multinational pharmaceutical drug companies.² The fear has been that the high cost of medicines would be exacerbated by global trade deals like the TPP.

After many years of secret negotiations, representatives from a dozen countries around the Pacific Rim came to an agreement on the adoption of the TPP in a Westin Hotel in Atlanta, the United States in 2015.³ The Ministers put out a statement, emphasizing:

After more than five years of intensive negotiations, we have come to an agreement that will support jobs, drive sustainable growth, foster inclusive development, and promote innovation across the Asia-Pacific region. Most importantly, the agreement achieves the goal we set forth of an ambitious, comprehensive, high standard and balanced agreement that will benefit our nation's citizens.

TPP brings higher standards to nearly 40 percent of the global economy. In addition to liberalizing trade and investment between us, the agreement addresses the challenges our stakeholders face in the 21st century, while taking into account the diversity of our levels of development. We expect this historic agreement to promote economic growth, support higher-paying jobs; enhance innovation, productivity and competitiveness; raise living standards; reduce poverty in our countries; and to promote transparency, good governance, and strong labor and environmental protections.⁴

² Heath Aston, “Drug Companies Won’t Deny Australia is being ‘Ripped Off’ on Medicines” *The Canberra Times* (1 July 2015), online: < <http://www.canberra-times.com.au/federal-politics/political-news/drug-companies-wont-deny-australia-is-being-ripped-off-on-medicines-20150701-gi2fnz.html> > .

³ Jessica Glenza and agencies, “TPP Deal: US and 11 Other Countries Reach Landmark Pacific Trade Pact” *The Guardian* (5 October 2015), online: < <http://www.theguardian.com/business/2015/oct/05/trans-pacific-partnership-deal-reached-pacific-countries-international-trade> > .

⁴ United States Trade Representative, “Trans-Pacific Partnership Ministers’ Statement” (October 2015), online: < <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/trans-pacific-partnership-ministers> > .

The final texts of the agreement were subsequently released in November 2015.⁵ The TPP agreement has been controversial, both because of the secretive nature of the negotiations and the substance of the final agreement. Of particular concern has been the impact of the TPP on public health and access to essential medicines.

Outside the closed Atlanta negotiations to finalize the TPP, there was a dramatic protest by Zahara Heckscher, a breast cancer patient, writer and educator, who was concerned about access to essential medicines.⁶ She was wearing a t-shirt reading “I HAVE CANCER. I CAN’T WAIT 8 YEARS,” and holding an IV pole that read “TPP: Don’t Cut My IV.”⁷ Zahara Heckscher refused to leave the Westin Hotel, which was hosting the negotiations between the dozen trade ministers from around the world. She demanded that the negotiators show her the final text of the TPP, so she could verify for herself how the agreement would affect access to essential medicines. Zahara Heckscher said at the event:

I am not going to leave until the USTR shows me the secret death sentence clause, so I can verify that the TPP is not going to prevent women like me with cancer from accessing the medicines we need to stay strong and stay alive.⁸

The breast cancer patient was arrested for her protest at the Atlanta TPP negotiations. Zahara Heckscher and Hannah Lyon were also later arrested at the headquarters of the PHRMA lobby, protesting the clauses the pharmaceutical industry inserted into the TPP.⁹ In the wake of the action, Zahara Heckscher urged the

⁵ The *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

⁶ Public Citizen, “Cancer Patient Demanding to see TPP ‘Death Sentence Clause’ Arrested at Ministerial Negotiations” *Eyes on Trade*, Public Citizen’s Blog (30 September 2015), online: <<http://citizen.typepad.com/eyesontrade/2015/09/cancer-patient-arrested-tpp-ministerial.html>> .

⁷ *Ibid.*

⁸ Amy Goodman, “Breast Cancer Patient Arrested for Protesting TPP: ‘This is Price Gouging at the Cost of Lives’” *Democracy Now!* (6 October 2015), online: <http://www.democracynow.org/2015/10/6/breast_cancer_patient_arrested_for_protesting> .

⁹ Lori Wallach, “Cancer Patient Lays Bare the Danger of TPP and the ‘Pharma Bro’ Problem” *The Huffington Post* (11 February 2016), online: <http://www.huffingtonpost.com/lori-wallach/-cancer-patient-lays-bare_b_9211092.html> .

United States Congress to reject the passage of the TPP.¹⁰ She warned: “[f]or people in the US and around the world to die unnecessar[ily] in this new millennium because of the TPP is a cruel, premeditated, and avoidable catastrophe.”¹¹

There was substantial debate in the United States political system over the passage of the TPP. After expending significant political capital, President Barack Obama obtained a fast-track authority for negotiating trade deals like the TPP from the United States Congress — with the help of Republicans, and a few defectors from his own party, the Democrats.¹² The agreement still needed to pass the United States Congress in a straight vote. Progressive Democrats criticized the trade agreement — particularly with respect to public health. House Democrat leader Nancy Pelosi argued that we need a new model for trade.¹³ Senior House United States Democrat Sandy Levin stressed that the TPP “should not be loaded up with new anti-competitive provisions when governments struggle to manage health care costs.”¹⁴ Senator Elizabeth Warren has expressed concern that the TPP has been rigged in favour of multinational companies.¹⁵

¹⁰ Zahara Heckscher, “TPP Threatens Access to Medicines” *Public Citizen* (11 January 2016), online: < <http://www.citizen.org/documents/heckscher-media-statement-at-press-conference-january-2016.pdf>.

¹¹ *Ibid.*

¹² Paul Lewis, “Barack Obama Given ‘Fast-Track’ Authority over Trade Deal Negotiations” *The Guardian* (25 June 2015), online: < <http://www.theguardian.com/us-news/2015/jun/24/barack-obama-fast-track-trade-deal-tpp-senate> > .

¹³ Nancy Pelosi, “Trade Promotion Authority on its Last Legs” *USA Today* (15 June 2015), online: < <http://www.usatoday.com/story/opinion/2015/06/15/congress-trade-fast-track-tpa-pelosi-column/71270294/> > .

¹⁴ Sander Levin, “Is TPP the Most Progressive Trade Agreement in History? Not if We Need Access to Affordable Medicines” *The Huffington Post* (28 May 2015), online: < http://www.huffingtonpost.com/rep-sander-/is-tpp-the-most-progressive-trade-agreement-in-history-_b_7461734.html > . See also Sander Levin, “The Trans-Pacific Partnership Negotiations: The Need for Congress to Get Fully in the Game” Council on Foreign Relations, 18 September 2014.

¹⁵ George Zornick, “Elizabeth Warren Reveals Inside Details on Trade Talks” *The Nation* (15 May 2014), online: < <http://www.thenation.com/blog/179885/elizabeth-warren-reveals-inside-details-trade-talks> > .; Elizabeth Warren, *A Fighting Chance* (New York: Metropolitan Books, 2014); Senator Elizabeth Warren, “The Trans-Pacific Partnership Agreement” United States, (26 February 2015), online: < <https://www.youtube.com/watch?>

The TPP was a matter of fierce debate in the presidential races. Bernie Sanders has expressed his opposition to the trade deal, warning that “prescription drug prices will increase, access to life saving drugs will decrease, and the profits of drug companies will go up.”¹⁶ Presidential aspirant Hillary Clinton expressed reservations about the TPP and Investor-State Dispute Settlement clauses.¹⁷ She has stressed that “we should avoid some of the provisions sought by business interests, including our own, like giving them or their investors the power to sue foreign governments to weaken their environmental and public health rules.”¹⁸ However, there has been discussion as to whether Hillary Clinton would support the TPP if she ultimately won the Presidency.¹⁹

A number of Republican candidates were concerned about the TPP, albeit for different reasons than concerns about public health.

v = xzfxv2XQoPg > ; Senator Elizabeth Warren, “Congress Should Oppose the TPP Deal” United States Senate (2 February 2016), online: < https://www.youtube.com/watch?v=AWXJJy_Tq-U > .

¹⁶ Senator Bernie Sanders, “The Trans-Pacific Trade Agreement Must Be Defeated”, online: < <http://www.sanders.senate.gov/download/the-trans-pacific-trade-tpp-agreement-must-be-defeated?inline=file> > . See also Senator Bernie Sanders, “The Trans-Pacific Partnership Must Be Defeated” *The Huffington Post* (21 May 2015), online: < http://www.huffingtonpost.com/rep-bernie-sanders/the-tpp-must-be-defeated_b_7352166.html > and Ross Barkan, “Bernie Sanders Calls Agreement of Trans-Pacific Partnership ‘Disastrous’” *Observer* (10 May 2015), online: < <http://observer.com/2015/10/bernie-sanders-calls-agreement-of-trans-pacific-partnership-disastrous/> > and Bernie Sanders, *Our Revolution: A Future to Believe In* (London: Profile Books, 2016) at 280-96.

¹⁷ Hillary Rodham Clinton, *Hard Choices* (New York: Simon & Schuster, 2014) at 428. On the *Trans-Pacific Partnership*, Clinton says: “We should avoid some of the provisions sought by business interests, including our own, like giving them or their investors the power to sue foreign governments to weaken their environmental and public health rules, as Philip Morris is already trying to do in Australia.” She emphasized: “The United States should be advocating a level and fair playing field, not special favors.”

¹⁸ Zach Carter, Amanda Terkel & Ryan Grim, “Hillary Clinton agrees with Elizabeth Warren on Trade Dispute With Obama” *The Huffington Post* (30 April 2015), online: < http://www.huffingtonpost.com.au/entry/hillary-clinton-trans-pacific-partnership_n_7173108.html?section=australia > .

¹⁹ Robert Naiman, “Chamber of Commerce Lobbyist Tom Donohue: Clinton Will Support TPP After Election” *The Huffington Post* (28 January 2016), online: < http://www.huffingtonpost.com/robert-naiman/chamber-of-commerce-lobby_b_9104096.html > .

The populist Donald Trump, for instance, opposed the deal on the basis that it advantaged trading rivals such as China, and failed to address issues such as currency manipulation.²⁰ The victory of Donald Trump in the presidential election 2016 may well doom the TPP. One of the first decisions of the new United States President Donald Trump in 2017 was to sign an executive order, withdrawing the United States from the TPP negotiations.²¹ It remains to be seen whether the agreement can survive the departure of the United States.

In this context, this article considers the debate over the TPP, considering intellectual property, global public health and access to essential medicines. As Professor Lawrence Gostin has noted in his classic work on *Global Public Health*, this is an area of longstanding debate:

[Trade] opens markets not only to life-saving products such as vaccines and medicines, but also to life-threatening products such as tobacco or asbestos. Trade agreements also can make essential medicines so expensive that they are out of reach for the poor.²²

The TPP raises significant new issues in this cross-over field between intellectual property, public health and trade. This discussion focuses upon the Intellectual Property Chapter of the TPP. Part (a) addresses the text on public health and access to essential medicines, and rules on transitional periods. Part (b) considers issues relating to patentable subject matter, patent standards, patent term extensions and evergreening, patent

²⁰ David Dayen, “Trump Was Right about TPP Benefitting China” *The Intercept* (12 November 2015), online: < <https://theintercept.com/2015/11/11/trump-was-right-about-tpp-benefitting-china/> >; John Brinkley, “Donald Trump: Stalking the Wild TPP” *Forbes* (12 November 2015), online: < <http://www.forbes.com/sites/johnbrinkley/2015/11/12/donald-trump-stalking-the-wild-tpp/#47d1ec2070cc> > . and Matthew Boyle, “Exclusive — Donald Trump: Obama’s Trans-Pacific Free-Trade Deal is ‘Insanity’” *Breitbart* (9 November 2015), online: < <http://www.breitbart.com/big-government/2015/11/09/exclusive-donald-trump-obamas-trans-pacific-free-trade-deal-insanity/> > .

²¹ The White House, “Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement,” Press Release (23 January 2017), online: < <https://www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-withdrawal-united-states-trans-pacific> > .

²² Lawrence Gostin, *Global Health Law* (Cambridge, Mass. and London: Harvard University Press, 2014) at 270.

registration linkages and border measures. Part (c) looks at data protection, the protection of biologics and trade secrets. Part (d) considers the response of the World Health Organization to the TPP, as well as the report of United Nations Secretary-General's High Level Panel on Access to Medicines. The policy report points toward alternative means of supporting research, development and dissemination of essential medicines. The conclusion considers the larger overall framework in respect of intellectual property, public health, investment and trade. The decision by President Donald Trump to withdraw the United States from the TPP has raised questions about its future viability. The collapse of the regional trade agreement provides an opportunity to rethink our approach to intellectual property, public health, and trade in the Pacific Rim.

(a) The Trans-Pacific Partnership and Access to Essential Medicines

There is a long history of geopolitical conflict over international law, intellectual property, public health and access to essential medicines.²³ Memorably, the world's largest pharmaceutical companies brought legal action against South Africa's efforts to obtain supplies of generic medicines from India.²⁴ This conflict is well recounted in the documentary *Fire in the Blood*.²⁵ In the face of international pressure, the action by the pharmaceutical drug companies was withdrawn. The World Trade Organization passed the *Doha Declaration on the TRIPS Agreement and Public Health* in 2001 to recognize that countries could take action under the *TRIPS*

²³ Thomas Pogge, Matthew Rimmer & Kim Rubenstein, ed., *Incentives for Global Public Health: Patent Law and Access to Medicines* (Cambridge: Cambridge University Press, 2010); Frederick Abbott, Thomas Cottier & Francis Gurry, *International Intellectual Property in an Integrated World Economy* (Wolters Kluwer Law & Business, 2015); Burcu Kilic, *Boosting Pharmaceutical Innovation in the Post-TRIPS Era: Real-Life Lessons for the Developing World* (Cheltenham, U.K. and Northampton, Mass.: Edward Elgar, 2014); Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Farnham and Burlington: Ashgate, 2015); and Ellen t'Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (AMB: Diemen, 2016), online: <<http://www.amb-press.nl/Webwinkel-Product-173747881/85->> .

²⁴ Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan, 2002).

²⁵ Dylan Mohan Grey, *Fire in the Blood* (Sparkwater India, 2014), online: <<http://www.imdb.com/title/tt1787067/>> .

Agreement 1994 to address public health concerns.²⁶ The *WTO General Council Decision* 2003 was designed to facilitate the export of essential medicines to developing countries and least developed countries.²⁷ There was a discussion of the formalization of this decision with the *TRIPS Waiver* in 2005.²⁸ The *TRIPS Agreement* 1994 was finally amended in 2017 to incorporate this export mechanism.²⁹ Despite such declarations and decisions, there have remained significant conflicts with respect to access to essential medicines. There has been substantial debate over patents related to infectious diseases such as HIV/AIDS, malaria, and tuberculosis. Equally, there have been battles over patents relating to non-communicable diseases, such as cancer. There has also been a concern about “neglected diseases.” There was a race to patent the SARS virus, and much debate over the ownership of patents related to the SARS virus.³⁰ There have been similar conflicts a decade later over experimental research to address the Ebola virus.³¹ There have been emerging legal issues in respect of the Zika virus surrounding access to essential medicines.³²

²⁶ *Ministerial Declaration: Adopted on 14 November 2001*, WTO Doc WT/MIN(01)/DEC/1 [3] (2001) (*Doha Declaration*); and Frederick Abbott, “The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO” (2002) 5 J. Int’l. Econ. L. 469-505.

²⁷ *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (2003) (Decision of the General Council of 30 August 2003) (‘WTO General Council Decision of 30 August 2003’).

²⁸ *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (2005) (Decision of 6 December 2005 of the General Council) (‘TRIPS Waiver’).

²⁹ World Trade Organization, “WTO IP Rules Amended to Ease Poor Countries’ Access to Affordable Medicines” (23 January 2017), online: <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> .

³⁰ Matthew Rimmer, “The Race To Patent The SARS Virus: The TRIPS Agreement And Access To Essential Medicines” (2004) 5(2) *Melbourne Journal of International Law* 335-74.

³¹ Matthew Rimmer, “The Ebola Public Health Crisis: the World Health Organization, Intellectual Property, Bioethics, and Access to Essential Medicines” *Biosecurity in a Globalised World*, QUT (27-28 July 2015), online: <<http://ihr2015.com/program/>> .

³² Lawrence Gostin & Alexandra Phelan, “Zika Virus: The Global and United States Domestic Response” Subcommittee on Oversight and Investigations, United States House of Representatives (2 March 2016), online: <<http://docs.house.gov/meetings/IF/IF02/20160302/104594/HHRG-114-IF02->

In light of the history of international conflict in respect of access to essential medicines, there was a concern that the final TPP agreement rolls back protection for national states to make use of intellectual property flexibilities to address public health concerns.

In the wake of the controversy over the action by pharmaceutical drug companies against the Government of South Africa, a number of important declarations were made in the context of the intellectual property framework established by the World Trade Organization.

Article 18.6 of the TPP deals with “Understandings Regarding Certain Public Health Measures.”³³ It is important to consider the exact, precise language of the clause — and not merely paraphrase the text — because it will govern the relationship between the regional agreement, and the multilateral framework. Article 18.6.1 provides that the “[p]arties affirm their commitment to the *Declaration on TRIPS and Public Health*.”³⁴ Article 18.6.1(a) emphasizes: “[t]he obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health.”³⁵ Moreover, “[a]ccordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party’s right to protect public health and, in particular, to promote access to medicines for all.”³⁶ Article 18.6.1(a) stresses: “[e]ach Party has the right to determine what

Wstate-GostinL-20160302.pdf > and Knowledge Ecology International and others, “An exclusive license to patents on a new Zika vaccine to Sanofi is contrary to the provisions of 35 U.S.C. 209(a)(1)” Submitted to Federal Register notice (81 FR 89087) posted 9 December 2016, titled “Intent to Grant an Exclusive License of U.S. Government-Owned Patents”, online: <<http://keionline.org/sites/default/files/Zika-12Jan2016-KEI-AFSCME-PFAM-UAEM-BAKER-35USC209a1.pdf>> .

³³ Article 18.6 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

³⁴ Article 18.6.1 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

³⁵ Article 18.6.1(a) of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

³⁶ *Ibid.*

constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”³⁷ The agreement, though, does not provide for any positive duty upon Pacific Rim nations to take effective action to implement the *Doha Declaration on TRIPS and Public Health*.

Article 16.8.1(b) of the TPP also discusses the *WTO General Council Decision 2003*:

[i]n recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of August 30, 2003 on the *Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health* (WT/L/540) and the WTO General Council Chairman’s Statement Accompanying the Decision (JOB(03)/177, WT/GC/M/82), as well as the Decision of the WTO General Council of December 6, 2005 on the *Amendment of the TRIPS Agreement*, (WT/L/641) and the WTO General Council Chairperson’s Statement Accompanying the Decision (JOB(05)319 and Corr. 1, WT/GC/M/100) (collectively, the “TRIPS/health solution”), this Chapter does not and should not prevent the effective utilisation of the TRIPS/health solution.³⁸

The language in this statement is peculiar. There is no obligation here upon member states in the TPP to take action in respect of the *WTO General Council Decision 2003* for the export of essential medicines.

It is notable that half-a-dozen members of the TPP have implemented their obligations with respect to access to essential medicines. Canada was a leader in the field, with Canadian Prime Minister Paul Martin passing *The Jean Chrétien Pledge to Africa Act* in 2004.³⁹ However, there have been problems with the operation of the regime, with only the generic manufacturer Apotex

³⁷ *Ibid.*

³⁸ *Ibid.*, article 18.6.1(b).

³⁹ Matthew Rimmer, “The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid” (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889-09.

employing the statutory scheme established by the Canadian Parliament.⁴⁰ Singapore's *Patents Act* 2005 (Singapore) enables the country to act as an importing member in situations of national emergency or other circumstances of extreme urgency. In New Zealand, Articles 171 to 178 of the *Patents Act* 2013 (NZ) No. 68 provide a legal basis to act as an exporting member. After protracted debate, Australia finally implemented a regime, with the passage of the *Intellectual Property Laws Amendment Act* 2015 (Cth) and the *Intellectual Property Legislation (TRIPS Protocol and Other Measures) Regulation* 2015 (Cth). Japan has guidelines which provide for the grant of non-exclusive licences for reason of public interest. Disappointingly, the United States still has not implemented the *WTO General Council* 2003, more than a decade after its inception.

Article 16.8.1 (c) of the TPP provides:

With respect to the aforementioned matters, if any waiver of any provision of the *TRIPS Agreement*, or any amendment of the *TRIPS Agreement*, enters into force with respect to the Parties, and a Party's application of a measure in conformity with that waiver or amendment is contrary to the obligations of this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the waiver or amendment.⁴¹

Article 16.8.2 stipulates:

[e]ach Party shall notify, if it has not already done so, the WTO of its acceptance of the *Protocol amending the TRIPS Agreement*, done at Geneva on December 6, 2005.⁴²

The United States Trade Representative [USTR] maintained that the final agreement promoted the development and availability of innovative and generic medicines:

The Intellectual Property chapter also includes commitments to promote not only the development of innovative, life-saving drugs and treatments, but also robust generic medicine markets.

⁴⁰ Matthew Rimmer, "Race Against Time: The Export of Essential Medicines to Rwanda" (2008) 1(2) *Public Health Ethics* 89-103.

⁴¹ Article 18.6.1(b) of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

⁴² Article 18.6.1 (b) of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

Drawing on the principles underlying the “May 10, 2007” Congressional-Executive Agreement, included in agreements with Peru, Colombia, Panama, and Korea, the chapter includes transitions for certain pharmaceutical IP provisions, taking into account a Party’s level of development and capacity as well as its existing laws and international obligations.⁴³

The USTR also argued that the regime enabled public health protections: “[t]he chapter incorporates the *Doha Declaration on the TRIPS Agreement and Public Health*, and confirms that Parties are not prevented from taking measures to protect public health, including to respond to epidemics such as HIV/AIDS.”⁴⁴ Such claims, though, have been treated with scepticism in the public debate. The USTR could be accused of “redwashing” — trying to portray the agreement as good for access to essential medicines, when it fails to achieve such objectives.

Many Democrats in the United States Congress have been concerned that the Obama Administration’s position in the TPP does not even live up to the standards of the May 2007 decision of the Bush Administration. Elder statesman of the Democrats, Sander Levin, observed:

The May 10th Agreement provided strengthened protections for intellectual property, but also recognized the need for balance, particularly when it comes to access to affordable medicines. It also recognized that while developing countries should strengthen their intellectual property (IP) protections, they should not be expected to provide the same level of protection the United States and other developed countries provide. We have been battling for years now to persuade our negotiators to respect the May 10th Agreement - and we continue to have concerns that the TPP medicines provisions will fall short.⁴⁵

Peter Maybarduk from Public Citizen commented: “[f]rom very early on in the TPP negotiations, and to the ire of health advocates,

⁴³ The United States Trade Representative, “Overview. Intellectual Property Chapter of the Trans-Pacific Partnership”, online: < <https://medium.com/the-trans-pacific-partnership/intellectual-property-3479efdc7adf#.lcowp4odl> > .

⁴⁴ *Ibid.*

⁴⁵ Sander Levin, “Is TPP the Most Progressive Trade Agreement in History? Not if We Need Access to Affordable Medicines” *The Huffington Post* (28 May 2015), online: < http://www.huffingtonpost.com/rep-sander-/is-tpp-the-most-progressive-trade-agreement-in-history-_b_7461734.html > .

it became apparent that the Office of the U.S. Trade Representative (USTR) was abandoning the May 10 Agreement template.”⁴⁶ He noted: “[w]ith today’s publication of the final version of the TPP IP chapter by WikiLeaks, for the first time the public can see precisely which rules negotiators agreed to and, importantly, how far beyond the May 10 Agreement the provisions extend pharmaceutical intellectual property obligations in developing countries.”⁴⁷

The USTR has promoted transition periods for developing countries. Maybarduk commented: “[f]orcing expansive pharmaceutical monopoly rules on countries that can scarcely afford high drug prices has not always been U.S. trade policy, and in the past U.S. policymakers have recognized that the needs of developing countries should not always be subordinate to U.S. pharmaceutical industry profits.”⁴⁸ He noted: “[s]ome rare public servants from TPP countries fought back and stood for health in this negotiation. Their efforts saved lives.”⁴⁹ Maybarduk warned: “[y]et in the end, the TPP will still trade away our health.”⁵⁰ He also emphasized that the transition periods were limited, and would only last between three to ten years, and only apply to a few of the rules under discussion.

Presidential candidate Bernie Sanders warned that “the TPP would substantially raise the price of prescription drugs for some of the most desperate people in the world.”⁵¹ He was concerned about the inordinate influence of the pharmaceutical drug industry on the text of the trade agreement: “[p]harmaceutical companies are doing everything they can to extend their monopoly and market-exclusivity rights to make it harder for people to access lower-cost generic drugs, even if it means that thousands will die because they cannot afford the drugs they need.”⁵² Sanders insisted that

⁴⁶ Public Citizen, “WikiLeaks Publication of Complete, Final TPP Intellectual Property Text Confirms Pact Would Raise Costs, Put Medicines Out of Reach”, Press Release (9 October 2015), online: <<http://www.citizen.org/tpp-ip-wikileaks-oct2015>> .

⁴⁷ *Ibid.*

⁴⁸ *Ibid.*

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ Bernie Sanders, *Our Revolution: A Future to Believe In* (London: Profile Books, 2016) at 294.

⁵² *Ibid.*, 294.

“health care is a *right* of all people, not a privilege.”⁵³ Far from being a template for the Pacific Rim, Sanders thought that the United States’ healthcare was in desperate need of further reform to provide for universal healthcare.

United Nations Independent Expert Alfred de Zayas stressed: “[t]rade is not an end in itself, but must be seen in the context of the international human rights regime, which imposes binding legal obligations on States, including the *International Covenant on Civil and Political Rights*, and the *International Covenant on Economic, Social and Cultural Rights*.”⁵⁴ He has also emphasized that trade agreements must satisfy “fundamental principles of international law, including transparency and accountability.”⁵⁵ He has stressed that such agreements “must not delay, circumvent, undermine or make impossible the fulfilment of human rights treaty obligations.”⁵⁶

(b) The *Trans-Pacific Partnership* and Patent Law

The Intellectual Property Chapter of the TPP is a lengthy, expansive and prescriptive chapter. The regime covers copyright law, trade mark law, patent law, trade secrets, data protection and intellectual property enforcement.⁵⁷ A number of elements of the Intellectual Property Chapter of the TPP will impact upon public health. In particular, there has been much debate over the patent measures in the TPP, including significant argument over eligible patentable subject matter; patent standards and the problem of evergreening; patent term extensions; and border measures.

⁵³ *Ibid.*, 318.

⁵⁴ Alfred de Zayas, “Statement by the Independent Expert on the Promotion of a Democratic and Equitable International Order on the Upcoming Signing of the Trans-Pacific Partnership” (2 February 2016), online: <<http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=17005&LangID=E>>.

⁵⁵ *Ibid.*

⁵⁶ *Ibid.*

⁵⁷ Kimberlee Weatherall, “Section-by-Section Commentary on the TPP Final IP Chapter”, 2015, Section 1, online: <<http://works.bepress.com/kimweatherall/32/>> Section 2, online: <<http://works.bepress.com/kimweatherall/32/>>, Section 3, online: <<http://works.bepress.com/kimweatherall/33/>>.

(i) Patentable Subject Matter

Initially, in the negotiations over the Pacific Rim Treaty, the United States proposed a broad approach to patent law, demanding that plants, animals and medical procedures be subject to patent protection by Pacific Rim members. This could result, particularly for medical procedures, in greater patent litigation against doctors, surgeons and medical professionals.⁵⁸ However, the United States retreated from this aggressive stance in respect of patentable subject matter — particularly in light of a series of decisions of the Supreme Court of United States on patentable subject matter,⁵⁹ as well as opposition from a number of Pacific Rim countries to such a broad approach.

Article 18.37 of the TPP deals with patentable subject matter:

1. Subject to paragraphs 3 and 4, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application.
2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as 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. A Party may limit those new processes to those that do not claim the use of the product as such.
3. A Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by its law. A Party may also exclude from patentability:

⁵⁸ Alexandra Phelan & Matthew Rimmer, “Pacific Rim Treaty Threatens Public Health: Patent Law and Medical Procedures” *Edward Elgar Blog* (27 November 2013), online: <<http://elgarblog.wordpress.com/2013/11/27/pacific-rim-treaty-threatens-public-health-patent-law-and-medical-procedures-by-alexandra-phelan-and-matthew-rimmer/>> .

⁵⁹ *Alice Corp. v. CLS Bank International*, 134 S.Ct. 2347 (2014); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013); *Bilski v. Kappos*, 561 U.S. 593 (2010); *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012).

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.

4. A Party may also exclude from patentability plants other than microorganisms. However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants.⁶⁰

There will remain a number of domestic and international conflicts in relation to the boundaries of patentable subject matter in the Pacific Rim. Emerging technologies in relation to information technology, business methods, methods of human treatment, biotechnology and synthetic biology remain particularly contentious.⁶¹

There also remain significant concerns about software patents.⁶² In the Supreme Court of the United States in 2016, Justice Breyer lamented that the United States Congress had not properly developed special rules to address software patents: “[t]oday’s patent world is not a steam engine world.”⁶³ Breyer J. observed: “[w]e have decided to patent tens of thousands of software products and similar things where hardly anyone knows what the patent’s really about.”⁶⁴ New Zealand has sought to ban software patents.

The topic of methods of human treatment is touchy. Australia allows for patents regarding methods of human treatment.⁶⁵ In the

⁶⁰ Article 18.37 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

⁶¹ Matthew Rimmer & Alison McLennan, eds., *Intellectual Property and Emerging Technologies: The New Biology* (Cheltenham, U.K. and Northampton, Mass.: Edward Elgar, January 2012).

⁶² *Alice Corp. v. CLS Bank International*, 134 S.Ct. 2347 (2014); and Jasper Tran, “Software Patents: A One-Year Review of *Alice v. CLS Bank*” (2016) 97 *Journal of the Patent and Trademark Office Society* 532-50.

⁶³ David McCabe & Mario Trujillo, “Supreme Court on Software Patents” *The Hill* (21 February 2016), online: <<http://thehill.com/policy/technology/overnights/270498-overnight-tech-debate-starts-over-commission-on-encryption>> .

⁶⁴ *Ibid.*

⁶⁵ *Apotex Pty Ltd. v. Sanofi-Aventis Australia Pty Ltd.*, [2013] HCA 50 (4 December 2013).

2013 case of *Apotex Pty Ltd. v. Sanofi-Aventis Australia Pty Ltd.*, French C.J. observed:

The exclusion from patentability of methods of medical treatment represents an anomaly for which no clear and consistent foundation has been enunciated. Whatever views may have held in the past, methods of medical treatment, particularly the use of pharmaceutical drugs, cannot today be conceived as “essentially non-economic”. Although Barwick CJ’s reference in *Joos* to the national economic interest in “the repair and rehabilitation of members of the work force” may be seen as reducing human beings to economic units, there is no gainsaying the economic significance of medical treatments independently of the flow-on benefits of a well-maintained work force. Recognition of the economic dimensions of this question is not inconsistent with the concurrent recognition of the large public policy questions which it raises. They may involve competing philosophies of proprietorship and instrumentalism and the relative values to be accorded to different public goods: alleged incentives to innovation on the one hand, and the widest possible availability of new methods of medical treatment to relieve suffering on the other. To decide that the concept of “manner of new manufacture” does not logically exclude methods of medical treatment from patentability does not engage with those large questions, although it may have significant consequences for public policy. This is a case in which such considerations are best left to the legislature. In my opinion the application of the rubric “manner of new manufacture” in a logically and normatively coherent way is not served by excluding from its scope methods of medical treatment of human beings. Methods of medical treatment can fall within the scope of a manner of new manufacture within the meaning of s 6 of the Statute and therefore within s 18(1)(a) of the 1990 Act.⁶⁶

The United States allows for patents in respect of methods for human treatment, but has a defence for medical practitioners. Canada and New Zealand have case law that rejects surgical procedures from patentability. Other negotiating parties — Brunei Darussalam, Chile, Japan, Malaysia, Mexico, Peru, Singapore and Vietnam — all expressly exclude surgical procedures from patentability. It is therefore no surprise that there was a lack of agreement on that particular issue in the final text of the TPP.

⁶⁶ *Apotex Pty Ltd. v. Sanofi-Aventis Australia Pty Ltd.*, [2013] HCA 50 (4 December 2013).

In a dramatic turn in jurisprudence, superior courts across the Pacific Rim in the United States⁶⁷ and Australia⁶⁸ have made significant rulings against gene patents. There was also a challenge against gene patents in Canada,⁶⁹ which has been resolved through a settlement.⁷⁰ There has been a striking movement by superior courts to limit the boundaries of patentable subject in respect of biotechnology. Nobel Laureate Professor Joseph Stiglitz has been concerned about the health implications of a broad approach to patentable subject matter.⁷¹

The Intellectual Property Rights Advisory Committee to the USTR was disappointed by the flexibilities available for nation states under the TPP to exclude subject matter from patent protection.⁷²

⁶⁷ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013); and Robert Cook-Deegan, “After Myriad: Genetic Testing in the Wake of Supreme Court Decisions about Gene Patents” (2014) 2(4) *Current Genetic Medicine Reports* 223-41.

⁶⁸ *D’Arcy v. Myriad Genetics Inc.*, [2015] HCA 35 (7 October 2015), Brad Sherman, “What does it mean to invent nature?” (2015) 5(5) *UC Irvine Law Review* 1193-1230; and Matthew Rimmer, “An Exorbitant Monopoly: The High Court of Australia, Myriad Genetics, and Gene Patents” in Duncan Matthews & Herbert Zech, eds., *Research Handbook on Intellectual Property and the Life Sciences* (Cheltenham, U.K. and Northampton, Mass.: Edward Elgar, May 2017) (forthcoming).

⁶⁹ *Children’s Hospital of Eastern Ontario v. University of Utah Research Foundation & Ors*, No T.2249-14 (Toronto Registry), online: <http://www.cheo.on.ca/uploads/genetics/Gene%20patent/Statement%20of%20Claim%20_Issued.pdf> .

⁷⁰ Children’s Hospital of Eastern Ontario, “Ground-breaking Settlement Changes Landscape for Genetic Medicine in Canada” Press Release (9 March 2016), online: <<http://www.cheo.on.ca/en/newsroom?newsid=656>> ; Kristy Kirkup, “Ontario Hospital Settles Gene Patent Lawsuit in ‘Win’ for Patients” *The Toronto Star* (9 March 2016), online: <<http://www.thestar.com/news/canada/2016/03/09/ontario-hospital-settles-gene-patent-lawsuit-in-win-for-patients.html>> .

⁷¹ Joseph Stiglitz, *Rewriting the Rules of the American Economy: An Agenda for Growth and Shared Prosperity* (New York and London: W.W. Norton & Company, 2016); and Joseph Stiglitz, “The New Geo-Economics” *Project Syndicate* (8 January 2016), online: <<https://www.project-syndicate.org/commentary/hope-for-better-global-governance-by-joseph-e-stiglitz-2016-01>> and *The Guardian* (10 January 2016), online: <<http://www.theguardian.com/business/2016/jan/10/in-2016-better-trade-agreements-trans-pacific-partnership>> .

⁷² The United States Trade Representative, “Intellectual Property Rights

(ii) Patent Standards and Evergreening

There have been longstanding conflicts over intellectual property, trade, health and access to essential medicines.⁷³ WikiLeaks has published a draft text of the Intellectual Property Chapter of the TPP.⁷⁴ The Intellectual Property Chapter contains a number of measures which support the position of pharmaceutical drug companies and the biotechnology industry.⁷⁵ Prominently, the United States has pushed for extensions of the patent term in respect of pharmaceutical drugs, including where there have been regulatory delays. There has been a concern that the TPP will impose lower thresholds for patent standards and result in a proliferation of evergreening. There has also been a concern about patent-registration linking to marketing regimes. The United States has pushed for the protection of undisclosed data for regulatory purposes, and there has been wide concern that the TPP will result in skyrocketing costs for healthcare systems in the Pacific Rim.

The Intellectual Property Chapter of the TPP provides for strong protection of patent rights and data exclusivity for pharmaceutical drug companies and the biotechnology industry. WikiLeaks published drafts of the Intellectual Property Chapter in 2013 and 2014. Michael Grunwald from *Politico* received a draft copy of the latest version of the chapter.⁷⁶ He observed: “[a] recent draft of the TPP free-trade deal would give U.S. pharmaceutical firms unprecedented protections against competition from cheaper

Industry-Advisory Committee Report on the Trans-Pacific Partnership” 2015, online: < <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/advisory-group-reports-TPP> and < <https://ustr.gov/sites/default/files/ITAC-15-Intellectual-Property.pdf> > .

⁷³ See Thomas Pogge, Matthew Rimmer & Kim Rubenstein, ed., *Incentives for Global Public Health: Patent Law and Access to Medicines* (Cambridge: Cambridge University Press, 2010).

⁷⁴ WikiLeaks, “Advanced Intellectual Property Chapter for All 12 Nations with Negotiating Positions (30 August 2013 consolidated bracketed negotiating text)”, online: < <https://wikileaks.org/tpp/> > .

⁷⁵ Alexandra Phelan & Matthew Rimmer, “Trans-Pacific Partnership #TPP #TPPA Drafts Reveal a Surgical Strike against Public Health” *East Asia Forum* (2 December 2013), online: < <http://www.eastasiaforum.org/2013/12/02/tpp-draft-reveals-surgical-strike-on-public-health/> > .

⁷⁶ Michael Grunwald, “Leaked: What’s in Obama’s Trade Deal” *Politico* (1 July 2015), online: < <http://www.politico.com/agenda/story/2015/06/tpp-deal-leaked-pharma-000126> > .

generic drugs, possibly transcending the patent protections in U.S. law.”⁷⁷ Grunwald commented that “the draft chapter will provide ammunition for critics who have warned that TPP’s protections for pharmaceutical companies could dump trillions of dollars of additional health care costs on patients, businesses and governments around the Pacific Rim.”⁷⁸ He also emphasized that the leaked text revealed that “U.S. negotiators have fought aggressively and, at least until Guam, successfully on behalf of Big Pharma.”⁷⁹

The civil society group Knowledge Ecology International published a leaked draft of the Intellectual Property Chapter in August 2015, before the final deal.⁸⁰ The director, James Love, was concerned that the text revealed that the United States “continues to be the most aggressive supporter of expanded intellectual property rights for drug companies” and that “the proposals contained in the TPP will harm consumers and in some cases block innovation.”⁸¹ James Love feared that “[i]n countless ways, the Obama Administration has sought to expand and extend drug monopolies and raise drug prices.”⁸² He maintained: “[t]he astonishing collection of proposals pandering to big drug companies make more difficult the task of ensuring access to drugs for the treatment of cancer and other diseases and conditions.”⁸³

Love called for a different approach to intellectual property and trade:

Rather than focusing on more intellectual property rights for drug companies, and a death-inducing spiral of higher prices and access barriers, the trade agreement could seek new norms to expand the funding of medical R&D as a public good, an

⁷⁷ *Ibid.*

⁷⁸ *Ibid.*

⁷⁹ *Ibid.*

⁸⁰ Knowledge Ecology International, “Knowledge Ecology International Leaks TPP Text on Intellectual Property” Press Release (4 August 2015), online: <<http://keionline.org/node/2308>> .

⁸¹ *Ibid.*

⁸² *Ibid.*

⁸³ *Ibid.*

area where the United States has an admirable track record, such as the public funding of research at the NIH and other federal agencies.⁸⁴

MSF has expressed concern about the lowering of standards for patentability: “[t]he TPP requires countries to grant secondary patents on modifications of existing medicines for at least one of the following: new uses, methods of use or new processes of a known product.”⁸⁵ MSF warned that “[t]his provision is designed to prevent countries from using public health safeguards in their national patent laws and judicial decisions that limit abusive patent evergreening.”⁸⁶ MSF was concerned: “[t]he effect will keep medicine prices high by delaying the availability of price-lowering generics.”⁸⁷

The former High Court of Australia Justice Michael Kirby observed in the *Alphapharm* case that patent law “should avoid creating fail-safe opportunities for unwarranted extensions of monopoly protection that are not clearly sustained by law.”⁸⁸ His comment highlighted that the patent regime was designed to have temporal limits in order to further the larger public interest in access to inventions, including those in the sphere of public health.

The Australian *Pharmaceutical Patents Review Report* also addressed the pernicious problem of evergreening, a situation where patent owners seek to indirectly extend the life of patent protection beyond its natural monopoly.⁸⁹ The report noted:

In most developed countries, including the United States and Europe, there are concerns about pharmaceutical manufacturers using patents and other management approaches to obtain advantages that impose large costs on the general community. The cost arises because these actions impede the entry of generic drugs to the market. Although some find the term to be a

⁸⁴ *Ibid.*

⁸⁵ MSF, “Open Letter to ASEAN Governments Don’t Trade Away Health” Geneva (4 February 2016), online: <http://www.msfaaccess.org/sites/default/files/MSF_assets/IP/Docs/IP_TPP_ASEANOpenLetter_web.pdf> .

⁸⁶ *Ibid.*

⁸⁷ *Ibid.*

⁸⁸ *Aktiebolaget Hassle v. Alphapharm Pty Ltd.*, [2002] HCA 59 <<http://www.austlii.edu.au/au/cases/cth/HCA/2002/59.html>> .

⁸⁹ Tony Harris, Dianne Nicol & Nicholas Gruen, *Pharmaceutical Patents Review Report* (Canberra, 2013), online: <http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf> .

pejorative, relevant literature has dubbed such actions ‘evergreening’: steps taken to maintain the market place of a drug whose patent is about to expire.⁹⁰

The report further noted that “[i]t is probable that less than rigorous patent standards have in the past helped evergreening through the grant of follow-on patents that are not sufficiently inventive.”⁹¹ The report called for improvements in the oversight of patent quality standards: “[t]he Panel sees a need for an external body, the Patent Oversight Committee, to audit the patent grant processes to help ensure these new standards are achieved, and to monitor whether they inhibit the patenting of follow-on pharmaceuticals which promote evergreening with no material therapeutic benefit.”⁹²

The Productivity Commission also focused on patent quality in its draft Report and its final report on Intellectual Property arrangements in 2016.⁹³ The final report found: “[i]ncremental patenting (or evergreening) is likely occurring to some extent in Australia and is best addressed through proposed changes to the inventive step for patents.”⁹⁴ The Productivity Commission emphasized that there is a strong case for further raising the threshold for granting a patent, and called for refinements to the standard of an inventive step.⁹⁵ The Productivity Commission also agreed that the Australian Government and IP Australia should set patent fees to promote broader intellectual property objectives.

⁹⁰ *Ibid.*

⁹¹ *Ibid.*

⁹² *Ibid.*

⁹³ Productivity Commission, *Intellectual Property Arrangements — Draft Report*, Melbourne: Productivity Commission, 2016, online: <<http://www.pc.gov.au/inquiries/current/intellectual-property/draft/intellectual-property-draft.pdf>> and Productivity Commission, *Intellectual Property Arrangements*, Melbourne: Productivity Commission, Report No. 78, 2016, online: <<http://www.pc.gov.au/inquiries/completed/intellectual-property/report>> .

⁹⁴ Productivity Commission, *Intellectual Property Arrangements*, Melbourne: Productivity Commission, Report No. 78, 2016, 285, online: <<http://www.pc.gov.au/inquiries/completed/intellectual-property/report>> .

⁹⁵ *Ibid.*, 34.

(iii) Patent Term Extensions

The TPP provides for patent term extensions. Article 18.46 deals with patent term adjustment for patent office delays.⁹⁶ Article 18.48 addresses patent term adjustment for unreasonable curtailment.⁹⁷

Under MSF's analysis, the TPP demanded that countries create two mechanisms to extend patent terms beyond 20 years for pharmaceuticals.⁹⁸ The advocacy group stressed that "extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from competition."⁹⁹

The Australian *Pharmaceutical Patents Review Report* makes a number of important recommendations relating to patent term extensions.¹⁰⁰ Under Australian law, the patent term lasts for 20 years. Since 1998, pharmaceutical drug companies can obtain additional patent term extensions for up to a further five years. The inquiry noted:

An important part of the terms of reference of this inquiry is to evaluate the extension of term (EOT) that the Australian patent system allows. It applies to some pharmaceuticals for which patentees have taken at least five years from the effective patent filing date to obtain regulatory approval for the pharmaceutical's use. The current scheme dates from 1998. It aims to attract investment in pharmaceutical R&D in Australia, as well as providing an effective patent term for pharmaceuticals more in line with that available to other technologies. The scheme currently provides an effective patent term of up to 15 years.¹⁰¹

⁹⁶ Article 18.46 of the *Trans-Pacific Partnership* 2015, online: < <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> > .

⁹⁷ Article 18.48 of the *Trans-Pacific Partnership* 2015, online: < <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> > .

⁹⁸ MSF, "Open Letter to ASEAN Governments Don't Trade Away Health", Geneva (4 February 2016), online: < http://www.msfacecess.org/sites/default/files/MSF_assets/IP/Docs/IP_TPP_ASEANOpenLetter_web.pdf > .

⁹⁹ Michael Geist, "The Trouble with the TPP, Day 7: Patent Term Extensions" University of Ottawa (12 January 2016), online: < <http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-7-patent-term-extensions/> > .

¹⁰⁰ Tony Harris, Dianne Nicol & Nicholas Gruen, *Pharmaceutical Patents Review Report*, Canberra, 2013, online: < http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf > .

¹⁰¹ *Ibid.*

The report noted that patent term extensions were expensive for the Australian Government: “[t]he estimate for 2012-13 is around \$240 million in the medium term and, in today’s dollars, around \$480 million in the longer term.”¹⁰² The report stressed: “[t]he total cost of the EOT to Australia is actually about 20 per cent more than this, because the PBS is only one source of revenue for the industry.”¹⁰³ The report emphasized: “[u]sing the patent scheme to preferentially support one industry is inconsistent with the TRIPS rationale that patent schemes be technologically neutral.”¹⁰⁴

The inquiry recommended that “[t]he Government should change the current EOT to reduce the maximum effective patent life provided from 15 years.”¹⁰⁵ There was a difference of opinion between the members of the review: “Harris and Gruen support reducing the effective life to 10 years, whereas Nicol supports reducing the effective life to 12 years.”¹⁰⁶ The report advised that “[t]he length of the extension should be calculated as being equal the number of days between the patent date and the date of first inclusion on the Australian Register of Therapeutic Goods minus 20 years less the maximum effect patent life.”¹⁰⁷ The report noted: “[t]he current 5 year cap on extensions should remain, providing a maximum of 25 years patent term for extended patents.”¹⁰⁸

The *Pharmaceutical Patents Review Report* emphasized that there could be significant savings to Australian taxpayers from the reform of Australian patent term extensions. The recommendation by Harris and Gruen was predicted to provide for massive savings:

Mr Harris and Dr Gruen recommend reducing the effective patent life from 15 to 10 years. Over time this would save the PBS approximately \$200 million a year, in today’s dollars, based on current pricing arrangements (that the entry of generics will lead to price falls of 35 per cent) which the Government has agreed with Medicines Australia. The savings would grow in line with PBS costs which are growing at 4.5% per annum, substantially faster than real GDP. If the Government secured all of the pricing benefits allowed by the entry of generics,

¹⁰² *Ibid.*

¹⁰³ *Ibid.*

¹⁰⁴ *Ibid.*

¹⁰⁵ *Ibid.*

¹⁰⁶ *Ibid.*

¹⁰⁷ *Ibid.*

¹⁰⁸ *Ibid.*

annual savings in today's dollars could amount to around \$400 million which would similarly be expected to grow with PBS costs. This is calculated on data that generics have led to a 70% price reduction in the United States. This is consistent with recent findings by the Grattan Institute that the price of generics paid by the PBS is several times the price secured by relevant Australasian Governments.¹⁰⁹

It is calculated that Professor Nicol's recommendation to shorten the effective patent life would result in significant savings: "[t]he estimated savings resulting from this reduction would be approximately \$130 million a year."¹¹⁰ Moreover, it was noted: "[i]f a 70% price reduction from generic entry was achieved as discussed above, the savings would be approximately \$260 million a year."¹¹¹

The *Pharmaceutical Patents Review Report* observed that "[l]arger developed countries that are major net IP exporters have tended to seek longer and stronger patents, not always to the global good."¹¹² The report warned: "[t]he acquiescence of Australia and other countries to that agenda means that some features of Australia's patent law are of little or no benefit to patentees but impose significant costs on users of patented technologies."¹¹³

The *Pharmaceutical Patents Review Report* was highly critical of Australia's passivity in international negotiations over intellectual property and trade. The report found:

In their negotiation of international agreements, Australian Governments have lacked strategic intent, been too passive in their IP negotiations, and given insufficient attention to domestic IP interests. For example, preventing MFE appears to have deprived the Australian economy of billions of dollars of export revenue from Australian based generic manufactures. Yet allowing this to occur would have generated negligible costs for Australian patentees. The Government does not appear to have a positive agenda regarding the IP chapters of the TPP Agreement.¹¹⁴

The report noted: "[t]he Government has rightly agreed to only include IP provisions in bilateral and regional trade agreements

¹⁰⁹ *Ibid.*

¹¹⁰ *Ibid.*

¹¹¹ *Ibid.*

¹¹² *Ibid.*

¹¹³ *Ibid.*

¹¹⁴ *Ibid.*

where economic analysis has demonstrated net benefits, however this policy does not appear to be being followed.”¹¹⁵

The *Pharmaceutical Patents Review Report* recommended that “the Government should ensure that future trade negotiations are based on a sound and strategic economic understanding of the costs and benefits to Australia and the world and of the impacts of current and proposed IP provisions, both for Australia and other parties to the negotiations.”¹¹⁶ The *Pharmaceutical Patents Review Report* stressed that “the Government should strongly resist changes — such as retrospective extensions of IP rights — which are likely to reduce world economic and social welfare and it should lead other countries in opposing such measures as a matter of principle.”¹¹⁷

Furthermore, the *Pharmaceutical Patents Review Report* recommended:

Given the current constraints placed on Australia by its international obligations, as an interim measure the Government should actively seek the cooperation of the owners of Australian pharmaceutical patents to voluntarily agree to enter into non-assertion covenants with manufacturers of generic pharmaceuticals seeking to manufacture patented drugs for export.¹¹⁸

In its view, “[t]his would help them avoid the embarrassment of Australia’s trade and investment performance being penalised by its previous agreement to strengthen IP rights.”¹¹⁹

The *Pharmaceutical Patents Review Report* warned: “[t]here are signs that these past failures are being replicated in the current *Trans-Pacific Partnership* (TPP) negotiations because small, net importers of intellectual property, including Australia, have not developed a reform agenda for the patent system that reflects their own economic interests — and those of the world.”¹²⁰

There has been further controversy over the costs associated with patent term extensions in Australia.¹²¹ The Productivity

¹¹⁵ *Ibid.*

¹¹⁶ *Ibid.*

¹¹⁷ *Ibid.*

¹¹⁸ *Ibid.*

¹¹⁹ *Ibid.*

¹²⁰ *Ibid.*

¹²¹ Peter Martin, “Drug Patents Costing Billions” *The Sydney Morning Herald* (2

Commission raised such concerns in its draft report and its final report on Intellectual Property arrangements in 2016.¹²² In its draft recommendation, the Productivity Commission suggested that the Australian Government should reform extensions of patent term for pharmaceuticals.¹²³ The Productivity Commission was also wary of anti-competitive arrangements to delay the introduction of pharmaceutical drugs.¹²⁴

In its final report, the Productivity Commission recommended:

The Australian Government should reform extensions of patent term for pharmaceuticals such that they are only:

(i) available for patents covering an active pharmaceutical ingredient, and

(ii) calculated based on the time taken by the Therapeutic Goods Administration

for regulatory approval over and above 255 working days (one year).¹²⁵

Furthermore, the Productivity Commission suggested that “the Australian Government should reform s. 76A of the Patents Act 1990 (Cth) to improve data collection requirements for extensions of term, drawing on the model applied in Canada.”¹²⁶ In its view,

April 2013), online: < <http://www.smh.com.au/national/health/drug-patents-costing-us-billions-20130402-2h52i.html> > .

¹²² Productivity Commission, *Intellectual Property Arrangements — Draft Report*, Melbourne: Productivity Commission, 2016, online: < <http://www.pc.gov.au/inquiries/current/intellectual-property/draft/intellectual-property-draft.pdf> > and Productivity Commission, *Intellectual Property Arrangements*, Melbourne: Productivity Commission, Report No. 78, 2016, online: < <http://www.pc.gov.au/inquiries/completed/intellectual-property/report> > .

¹²³ Productivity Commission, *Intellectual Property Arrangements — Draft Report*, Melbourne: Productivity Commission, 2016, online: < <http://www.pc.gov.au/inquiries/current/intellectual-property/draft/intellectual-property-draft.pdf> > .

¹²⁴ *Ibid.*

¹²⁵ Productivity Commission, *Intellectual Property Arrangements*, Melbourne: Productivity Commission, Report No. 78, 2016, online: < <http://www.pc.gov.au/inquiries/completed/intellectual-property/report> > .

¹²⁶ *Ibid.*

“no extensions of term should be granted until data is received in a satisfactory form.”¹²⁷ The Productivity Commission also recommended that “the Australian Government should introduce a system for transparent reporting and monitoring of settlements between originator and generic pharmaceutical companies to detect potential pay-for-delay agreements.”¹²⁸

Professor Michael Geist from the University of Ottawa considered the impact of patent term extensions from a Canadian perspective.¹²⁹ He commented that the TPP required several significant changes to Canadian patent law:

Article 18.48 creates a requirement for a patent term adjustment for delays due to marketing approvals (described as unreasonable curtailment). The Canadian government believes that CETA’s two year patent restoration provision will meet the TPP requirement. The effect of the TPP is therefore to lock in CETA’s patent restoration extension even if CETA is never ratified or implemented. According to one study, the impact of these provisions in CETA could lead to increased drug costs of between \$850 million and \$1.6 billion annually.¹³⁰

Moreover, Geist pointed out that “[a]rticle 18.46 requires a patent term adjustment due to patent office delays.”¹³¹ He noted that “[t]he section provides that ‘an unreasonable delay at least shall include a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later.’”¹³² Geist observed: “[n]o similar extension is found under current Canadian law nor within CETA.”¹³³ He observed that “the escalation in patent protections is set to occur just as drug prices hit all-time highs in

¹²⁷ *Ibid.*

¹²⁸ *Ibid.*

¹²⁹ Michael Geist, “The Trouble with the TPP, Day 7: Patent Term Extensions” University of Ottawa (12 January 2016), online: <<http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-7-patent-term-extensions/>> .

¹³⁰ *Ibid.*

¹³¹ *Ibid.*

¹³² *Ibid.*

¹³³ *Ibid.*

Canada and pharmaceutical investment in research and development sinks to decade-long lows.”¹³⁴ He cited a recent report released by the Patent Medicines Panel Review Board (PMPRB).¹³⁵ Geist observed: “[t]he concern over Canadian pharmaceutical policy is long overdue as the evidence leaves little doubt that catering to the demands of the largely foreign-based companies have yielded few benefits.”¹³⁶ He was worried about the economic impact of the regime: “Canadians pay significantly more for pharmaceutical drugs than consumers in many other developed countries and the promised increased investment in research and development has not materialized.”¹³⁷ Geist expressed concern: “[y]et despite the costly state of affairs, the government is set to reward the industry with even stronger protections through the TPP that will result in an extension of the higher prices.”¹³⁸

Likewise, Scott Sinclair has argued that extended patent terms would be the most directly harmful aspect of the TPP’s Intellectual Property Chapter.¹³⁹ He warned: “[a]ccepting the patent extensions required by the TPP would increase costs to consumers and patients at home and abroad, reward broken promises by the brand-name pharmaceutical industry, perpetuate a failed approach to consumer protection and industrial policy, and diminish Canada’s standing globally.”¹⁴⁰ Joel Lexchin added that such problems were compounded by other chapters of the TPP, impacting upon health regulation.¹⁴¹

¹³⁴ *Ibid.*

¹³⁵ Patented Medicines Annual Review Board, *Annual Report 2014*, Ottawa: Patented Medicines Annual Review Board, 2014, online: < http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2014/2014_Annual_Report_Final_EN.pdf > .

¹³⁶ Michael Geist, “The Trouble with the TPP, Day 7: Patent Term Extensions”, University of Ottawa (12 January 2016), online: < <http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-7-patent-term-extensions/> > .

¹³⁷ *Ibid.*

¹³⁸ *Ibid.*

¹³⁹ Scott Sinclair, “The TPP and Health Care”, Scott Sinclair & Stuart Trew, eds., *The Trans-Pacific Partnership and Canada: A Citizen’s Guide* (Toronto: James Lorimer & Company Ltd., 2016) 46-65 at 51.

¹⁴⁰ *Ibid.*, 51.

¹⁴¹ Joel Lexchin, “The TPP and Regulation of Medicines in Canada” in Scott Sinclair & Stuart Trew, eds., *The Trans-Pacific Partnership and Canada: A Citizen’s Guide* (Toronto: James Lorimer & Company Ltd., 2016) at 66-80.

(iv) *Patent-Registration Linkage*

The TPP seeks to embed aspects of the *Drug Price Competition and Patent Term Act* 1984 (US) — the *Hatch-Waxman Act* — into other legal systems across the Pacific Rim.

Article 18.51.1 of the TPP deals with patent-registration linkage, providing:

1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory, that Party shall provide:

(a) a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;

(b) adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and

(c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.¹⁴²

Article 18.51.2 of the TPP deals with patent-registration linkage, providing:

As an alternative to paragraph 1, a Party shall instead adopt or maintain a system other than judicial proceedings that precludes, based upon patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office, the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent

¹⁴² Article 18.51.1 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

claiming that product, unless by consent or acquiescence of the patent holder.¹⁴³

Ruth Lopert and Deborah Gleeson have been concerned that “[p]atent linkage mechanisms create an unwarranted nexus between the grant of marketing approval for a generic medicine and the patent status of the originator.”¹⁴⁴ Professor Brook Baker warns that patent linkage “prevents registration and marketing of more affordable generic equivalents even when the claimed patent is subject to invalidation or when the applicant asserts the patent would not be infringed.”¹⁴⁵

(v) *Border Measures*

The TPP also contains border measures, like its predecessor the *Anti-Counterfeiting Trade Agreement*.¹⁴⁶ MSF has warned about the dangers of such provisions:

The *TPP* contains a variety of obligations that increase the risk of unwarranted interruptions and delays in the flow of legitimate trade in generic medicines, and limits countries’ judicial systems’ capacity to balance commercial interests and public health interests in intellectual property disputes. These provisions strip away the ability of governments to define their own enforcement provisions as allowed by international law. These new forms of IP enforcement are reminiscent of the stalled *Anti-Counterfeiting Trade Agreement (ACTA)*, a plurilateral treaty that sought to impose stringent IP rules.¹⁴⁷

¹⁴³ Article 18.51.2 of the *Trans-Pacific Partnership* 2015, online: < <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> > .

¹⁴⁴ Ruth Lopert & Deborah Gleeson, “The High Price of ‘Free Trade’: U.S. Trade Agreements and Access to Medicines” (2013) 41(1) *J.L. Med. & Ethics* 199-223 at 201.

¹⁴⁵ Brook Baker, “Health GAP Submission to the US House of Representatives Ways and Means on the Trans-Pacific Partnership and Access to Medicine”, U.S. House of Representatives Ways and Means on the Trans-Pacific Partnership and Access to Medicine (8 December 2015), online: < <http://infojustice.org/archives/35504> > .

¹⁴⁶ Matthew Rimmer, “Trick or Treaty? The Australian Debate over the Anti-Counterfeiting Trade Agreement (ACTA)” in Pedro Roffé & Xavier Seuber, eds., *The ACTA and The Plurilateral Enforcement Agenda: Genesis and Aftermath, Geneva: International Centre for Trade and Sustainable Development* (Cambridge: Cambridge University Press, 2014) at 169-201.

¹⁴⁷ MSF, “Open Letter to ASEAN Governments Don’t Trade Away Health”

Such concerns are not merely theoretical. There have previously been disputes over European Union countries engaging in the interdiction of shipments of generic medicines from India to developing countries. Professor Michael Geist was concerned about whether there was sufficient and adequate judicial oversight in respect of border measures.¹⁴⁸

(c) Data Protection, Market Exclusivity for Biologics, and Trade Secrets

In addition to the suite of patent protections, the TPP also provides for special protection in respect of data protection, market exclusivity for biologics and trade secrets. The Biotechnology Industry Organization stressed that “[t]rade secrets are legal protections given to information that is kept confidential.”¹⁴⁹ They emphasized: “[e]xamples of trade secrets that are important to biologics developers are details of manufacturing conditions and processes, formulation techniques for their products, and the like.”¹⁵⁰ The TPP includes criminal penalties and procedures for the protection of trade secrets. Amongst other things, the criminalization of trade secrets could have important ramifications for medical research, patient care, and the administration of healthcare.

One of the most controversial issues during the negotiation over the TPP was the protection of biologics. The USTR sought to impose a United States-style regime for the protection of biologics through the TPP. Such a directive was met with sustained resistance from other participating nations, civil society and the public health community.

Cancer patient and health advocate Zahara Heckscher was particularly incensed about the proposal for special protection of

Geneva (4 February 2016), online: < http://www.msfacecess.org/sites/default/files/MSF_assets/IP/Docs/IP_TPP_ASEANOpenLetter_web.pdf > .

¹⁴⁸ Michael Geist, “The Trouble with the TPP, Day 22: Expanding Border Measures without Court Oversight” University of Ottawa (2 February 2016), online: < <http://www.michaelgeist.ca/2016/02/the-trouble-with-the-tpp-day-22-expanding-border-measures-without-court-oversight/> > .

¹⁴⁹ BIO, “The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics,” online: < https://www.bio.org/sites/default/files/TPP%20White%20Paper%20_2_.pdf > .

¹⁵⁰ *Ibid.*

biologics: “I got arrested because I learned about this death sentence clause in the TPP that would make these life-saving cancer drugs unavailable to women around the world for a period of five years, eight years or 12 years.”¹⁵¹ She commented: “[w]e call it the death sentence clause because it would actually condemn women to death, because they cannot afford or their healthcare systems can’t afford the medicines.”¹⁵²

Ruth Lopert has discussed the nature of the *sui generis* protection for market exclusivity in respect of biologics:

In the United States, biologics are protected from competition by follow-on products (known as biosimilars, which are akin to generic medicines) for 12 years from the time they’re first granted marketing approval by the nation’s drug regulator, the Food and Drug Administration (FDA). This form of protection from competition is distinct from a patent. It prevents a follow-on product from entering the market even when any patents on the originator product have expired. These 12 years are known as the market exclusivity period.¹⁵³

Academic work has highlighted the massive costs associated with providing extra protection for biologics.¹⁵⁴

The pharmaceutical drug industry — led by the peak association PHRMA — pushed for 12 years of protection for biologics under

¹⁵¹ Amy Goodman, “Breast Cancer Patient Arrested for Protesting TPP: ‘This is Price Gouging at the Cost of Lives’” *Democracy Now!* (6 October 2015), online: < http://www.democracynow.org/2015/10/6/breast_cancer_patient_arrested_for_protesting > .

¹⁵² *Ibid.*

¹⁵³ Ruth Lopert, “Why biologics were such a big deal in the Trans Pacific Partnership” *The Conversation* (5 October 2015), online: < <https://theconversation.com/why-biologics-were-such-a-big-deal-in-the-trans-pacific-partnership-48595> > .

¹⁵⁴ Deborah Gleeson, Ruth Lopert & Hazel Moir, “Proposals for Extending Data Protection for Biologics in the TPPA: Potential consequences for Australia” Submission to the Department of Foreign Affairs and Trade (13 December 2014), online: < http://dfat.gov.au/trade/agreements/tpp/submissions/Documents/tpp_sub_gleeson_lopert_moir.pdf > . Deborah Gleeson & Ruth Lopert, “How the battle over biologics helped stall the Trans Pacific Partnership” *The Conversation* (6 August 2015), online: < <https://theconversation.com/how-the-battle-over-biologics-helped-stall-the-trans-pacific-partnership-45648> > ; Burcu Kilic & Courtney Pine, “Decision Time On Biologics Exclusivity: Eight Years Is No Compromise” *IP-Watch* (27 July 2015), online: <http://www.ip-watch.org/2015/07/27/decision-time-on-biologics-exclusivity-eight-years-is-no-compromise/> > .

the TPP.¹⁵⁵ The peak body observed: “[o]ver the past two years, members from both Parties and both Houses of Congress, as well as Governors from 11 states, have expressed their support to the Administration for strong intellectual property protections for the biopharmaceutical industry to be included in the text of the *Trans-Pacific Partnership* (TPP).”¹⁵⁶ PHRMA maintained that “America’s leading policy makers are committed, on a bipartisan basis, to extending these protections to our trading partners, through the TPP’s high quality, comprehensive agreement.”¹⁵⁷ PHRMA was concerned about divisions within the Obama administration over protection for biologics:

The Biologics Price Competition and Innovation Act of 2009 (BPCIA), which was passed as part of the U.S. health care reform package, provides 12 years of regulatory data protection for biologics. Despite strong bipartisan support in favor of 12 years of regulatory data protection for biologics, the U.S. Trade Representative has yet to propose a specific period of data protection for biologics in the TPP text.¹⁵⁸

PHRMA said that it applauded “the commitment of the Representatives, Senators, and Governors who have consistently advocated for robust intellectual property protections for biopharmaceuticals in the United States’ domestic laws and its international agreements.”¹⁵⁹ PHRMA maintained: “[t]hese protections allow our member companies to continue to develop and supply cutting-edge medicines that improve the health and quality of life of people around the globe.”¹⁶⁰

The Biotechnology Industry Organization (BIO) — the peak biotechnology industry association — also lobbied hard in respect of the protection of biologics.¹⁶¹ The association stressed their

¹⁵⁵ PHRMA, “12 Years of Data Protection: Note to Media on Elected Officials Support for 12 Years of Data Protection in TPP,” online: <<http://phrma.org/note-media-elected-officials-support-12-years-data-protection-tpp>> .

¹⁵⁶ *Ibid.*

¹⁵⁷ *Ibid.*

¹⁵⁸ *Ibid.*

¹⁵⁹ *Ibid.*

¹⁶⁰ *Ibid.*

¹⁶¹ BIO, “The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics,” online: <https://www.bio.org/sites/default/files/TPP%20White%20Paper%20_2_.pdf> .

belief that “the recent experience of the United States, particularly the deliberations leading to the enactment of the BPCIA, provide insight into the necessary intellectual property infrastructure required to encourage discovery and development of new biological products.”¹⁶² In its view, that infrastructure must “provide a minimum of 12 years of data protection for new biological products.”¹⁶³ BIO sought to dismiss criticism from the Federal Trade Commission about the impact of special protection of biologics on competition.

The USTR pushed for longer protection of biologics in the TPP. Initially, the USTR argued for 12 years of protection. Then, as a fall-back position, the USTR called for eight years of protection. The USTR provided this gloss on the negotiations:

On biologics, as you know, this is one of the most challenging issues in the negotiation. We’ve worked cooperatively with all of our TPP parties—partners to secure a strong and balanced outcome that both incentivizes the development of these new life-saving drugs, while ensuring access to these pioneering medicines and their availability. And this is the first trade agreement in history to ensure a minimum period of protection for biologics and, in doing so, will help set a regional model and will create an environment in which, through comparable treatment, there will be an effective period of protection to encourage both innovation and access.¹⁶⁴

However, other participating nations in the TPP were reluctant to accede to the demands of the United States.

Public health advocacy organizations and civil society groups expressed concern about longer protection for biologics. MSF Australia spokesman Jon Edwards observed that “Australia’s resistance to this element of the trade deal is critical in minimising the negative impact it could have on health across the region.”¹⁶⁵

¹⁶² *Ibid.*, 39.

¹⁶³ *Ibid.*, 39.

¹⁶⁴ Amy Goodman, “Breast Cancer Patient Arrested for Protesting TPP: ‘This is Price Gouging at the Cost of Lives’” *Democracy Now!* (6 October 2015), online: <http://www.democracynow.org/2015/10/6/breast_cancer_patient_arrested_for_protesting> .

¹⁶⁵ MSF Australia, “Prime Minister Malcolm Turnbull’s First Test on Trade: Australia Must Stand Strong Against Aggressive Demands of Big Pharma” Press Release (25 September 2015), online: <<http://www.msf.org.au/media-room/press-releases/press-release/article/prime-minster-malcolm-turnbulls-first-test-on-trade-australia-must-stand-strong-against-aggressi.html>> .

He warned that “increased costs in poorer TPP negotiating countries could mean millions of patients would not be able to access essential medicines.”¹⁶⁶ Moreover, he commented that “Australia has a broader responsibility in these negotiations than simply improving Australia’s trade figures.”¹⁶⁷ He reflected: “[l]ike it or not, [t]he Australian Government’s success or otherwise in rejecting the aggressive demands of the brand name pharmaceutical lobby will affect the future health outcomes of millions of vulnerable people across the region.”¹⁶⁸ He called upon the Australian Government: “[f]or the sake our patients and those like them we urge Australia to stand strong.”¹⁶⁹

The *Sydney Morning Herald’s* John Garnaut provided an inside account of the final negotiations over biologics in respect of the TPP, after interviewing the Australian Trade Minister, Andrew Robb.¹⁷⁰ He observed that “Robb was prepared to kill the deal if the Americans had refused to back down on their demands to extend monopoly rights over expensive, innovative drugs known as ‘biologics’, which would have made the Pharmaceutical Benefits Scheme more expensive.”¹⁷¹ In response to questions from John Garnaut, Andrew Robb observed:

If it wasn’t resolved it probably would have killed the deal. You do need to seek some balance, sometimes you need to take some pain, but there was no rationale for us making any changes because our system is delivering all and more than the US is seeking to achieve. The PBS, the approval process, it’s part of a system, the whole health system, and not a stand-alone thing you can just play with.¹⁷²

United States President Barack Obama personally lobbied Australian Prime Minister Malcolm Turnbull over the protection

¹⁶⁶ *Ibid.*

¹⁶⁷ *Ibid.*

¹⁶⁸ *Ibid.*

¹⁶⁹ *Ibid.*

¹⁷⁰ John Garnaut, “The Arm Wrestle over Drugs: Inside the TPP Deal” *The Sydney Morning Herald* (7 October 2015), online: <<http://www.smh.com.au/national/the-arm-wrestle-over-drugs-inside-the-tpp-deal-20151006-gk2dnt.html>> .

¹⁷¹ *Ibid.*

¹⁷² *Ibid.*

of biologics.¹⁷³ Nonetheless, to his credit, Turnbull resisted such demands by the United States Government.

The Australian *Pharmaceutical Patents Review Report* inquiry also considered the vexed question of data protection for pharmaceutical drugs.¹⁷⁴ The report noted:

When an originator seeks regulatory approval for a drug, it must provide data to the TGA demonstrating the drug's safety and efficacy. Although these data remain confidential to the TGA, it may use them after a five year period to approve a generic or equivalent drug. This saves the pointless replication of tests to show safety and efficacy.¹⁷⁵

The pharmaceutical drugs industry argued that the five-year period of data exclusivity in Australia was too short.

The *Pharmaceutical Patents Review Report* found that there was no need to extend data protection in respect of pharmaceutical drugs: “[a] policy of subsidising drug development discussed above seems more appropriate.”¹⁷⁶ The report noted that “[t]he Government should actively contribute to the development of an internationally coordinated and harmonised system where data protection is provided in exchange for the publication of clinical trial data.”¹⁷⁷

The Productivity Commission has raised concerns about the issue in its draft report and its final report on Intellectual Property arrangements in 2016.¹⁷⁸ In its draft report, the Productivity Commission recommends: “[t]here should be no extension of the

¹⁷³ Francis Keany, “Pharmaceuticals Patent Protection Dispute Could Make or Break TPP: Andrew Robb” *ABC News* (5 October 2015), online: <<http://www.abc.net.au/news/2015-10-04/pharmaceuticals-dispute-could-disrupt-tpp-andrew-robb-says/6826278>> .

¹⁷⁴ Tony Harris, Dianne Nicol & Nicholas Gruen, *Pharmaceutical Patents Review Report* (Canberra, 2013), online: <http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf> .

¹⁷⁵ *Ibid.*

¹⁷⁶ *Ibid.*

¹⁷⁷ *Ibid.*

¹⁷⁸ Productivity Commission, *Intellectual Property Arrangements — Draft Report*, Melbourne: Productivity Commission, 2016, online: <<http://www.pc.gov.au/inquiries/current/intellectual-property/draft/intellectual-property-draft.pdf>> and Productivity Commission, *Intellectual Property Arrangements*, Melbourne: Productivity Commission, Report No. 78, 2016, online: <<http://www.pc.gov.au/inquiries/completed/intellectual-property/report>> .

period of data protection, including that applicable to biologics.”¹⁷⁹ The Productivity Commission observes further that, “in the context of international negotiations, the Australian Government should work with other nations towards a system of eventual publication of clinical trial data in exchange for statutory data protection.”¹⁸⁰ The Productivity Commission concluded in its final report: “[t]here are no grounds to extend the period of data protection for any pharmaceutical products, including biologics.”¹⁸¹

The Department of Foreign Affairs and Trade in Australia maintained that it had defended Australia’s regulatory autonomy in respect of the TPP.¹⁸² In its briefing note, the Department of Foreign Affairs and Trade commented:

In the TPP, Australia has negotiated protections that are consistent with existing Australian law and practice. Australia is not required to change any part of its current law, including data protection for biologics, or our patent regime. There will be no adverse impact on the Pharmaceutical Benefits Scheme and no price increases for medicines.¹⁸³

However, there was academic and policy debate about whether the final text is so clear-cut. There have been concerns about ambiguities in the final text. Such a finding has a broader significance, given the push by the United States for stronger data protection in the TPP.

The final text of the TPP in Article 18.52 on the protection of biologics is complicated.¹⁸⁴ Article 18.52.1 provides:

¹⁷⁹ Productivity Commission, *Intellectual Property Arrangements — Draft Report*, Melbourne: Productivity Commission, 2016, online: <<http://www.pc.gov.au/inquiries/current/intellectual-property/draft/intellectual-property-draft.pdf>> .

¹⁸⁰ *Ibid.*

¹⁸¹ Productivity Commission, *Intellectual Property Arrangements*, Melbourne: Productivity Commission, Report No. 78, 2016, 35, 312-318, online: <<http://www.pc.gov.au/inquiries/completed/intellectual-property/report>> .

¹⁸² The Department of Foreign Affairs and Trade, “The *Trans-Pacific Partnership Agreement: Outcomes — Biologics*” (6 October 2015), online: <<https://dfat.gov.au/trade/agreements/tpp/Documents/outcomes-biologics.PDF>> .

¹⁸³ *Ibid.*

¹⁸⁴ Article 18.52 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

With regard to protecting new biologics, a Party shall either: (a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively, (b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection: (i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party, (ii) through other measures, and (iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.¹⁸⁵

Article 18.52.2 provides: “[f]or the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.”¹⁸⁶ Article 18.52.3 provides:

Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.¹⁸⁷

¹⁸⁵ Article 18.52.1 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

¹⁸⁶ Article 18.52.2 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

¹⁸⁷ Article 18.52.3 of the *Trans-Pacific Partnership* 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>> .

In other words, there will be scope for a reconsideration of the protection of biologics at a future date.

Article 18.50.3 of the TPP provides a statement about access to essential medicines:

Notwithstanding paragraphs 1 and 2 and Article 18.52 (Biologics), a Party may take measures to protect public health in accordance with: (a) the *Declaration on TRIPS and Public Health*; (b) any waiver of any provision of the *TRIPS Agreement* granted by WTO Members in accordance with the WTO Agreement to implement the *Declaration on TRIPS and Public Health* and that is in force between the Parties; or (c) any amendment of the *TRIPS Agreement* to implement the *Declaration on TRIPS and Public Health* that enters into force with respect to the Parties.¹⁸⁸

It is hard to know how these measures will operate in respect of access to essential medicines and the treatment of data protection, biologics, and trade secrets.

United States Republican Congressional Powerbroker Orrin Hatch was upset at the final text in relation to the protection of biologics in the TPP. He lamented, “I am afraid this deal appears to fall woefully short.”¹⁸⁹ He threatened to derail the agreement in the United States Congress if his demands were not met. Likewise, the House of Representatives Speaker, Paul Ryan, has argued that the TPP should be renegotiated to provide for longer periods of protection for biologics.¹⁹⁰

There is also a side-letter between Vietnam and the United States on biologics.¹⁹¹ The countries agreed that Vietnam would

¹⁸⁸ Article 18.50.3 of the *Trans-Pacific Partnership* 2015, online: < <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> > .

¹⁸⁹ John Garnaut, “The Arm Wrestle over Drugs: Inside the TPP Deal” *The Sydney Morning Herald* (7 October 2015), online: < <http://www.smh.com.au/national/the-arm-wrestle-over-drugs-inside-the-tpp-deal-20151006-gk2dnt.html> > .

¹⁹⁰ Mike Masnick, “House Speaker Paul Ryan Demands TPP be Renegotiated, Neglects to Mention It Was His Bill that Makes that Impossible” *Techdirt* (17 February 2016), online: < <https://www.techdirt.com/articles/20160217/18442033628/house-speaker-paul-ryan-demands-tpp-be-renegotiated-neglects-to-mention-it-was-his-bill-that-makes-that-impossible.shtml> > .

¹⁹¹ United States-Vietnam Letter Exchange on Biologics, online: < <https://ustr.gov/sites/default/files/TPP-Final-Text-US-VN-Letter-Exchange-on-Biologics.pdf> > .

apply Article 9.6 from Chapter 2 of the *Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations*, which reads: “[e]ach Party shall provide that for data of a type referenced in paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no other applicant for product approval may, without permission of the person that submitted them, rely on that data in support of an application for product approval during a reasonable period of time after their submission.”¹⁹² This clause stipulates that “a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking into account the nature of the data and the person’s efforts and expenditures in producing them.”¹⁹³

There have been significant internal divisions with the USTR Intellectual Property Rights Advisory Committee on the topic of the protection of biologics.¹⁹⁴ The Committee noted: “[c]ertain of the ITAC-15 Members had differing views on Article 18.52 and the perspective that U.S. negotiators might take toward its implementation in TPP Parties.”¹⁹⁵

Certain ITAC-15 Members were of the view that there needed to be stronger protection of biologics. This faction insisted: “[a] major negotiating objective for the U.S. was to establish in the TPP a uniform standard requiring TPP Parties to provide a period of regulatory data protection for pharmaceutical products that are biologicals of at least 12 years from the date of the approval of the product in each TPP Party.”¹⁹⁶ This industry group maintained

¹⁹² *Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations*, online: <<https://ustr.gov/sites/default/files/US-VietNam-BilateralTradeAgreement.pdf>> .

¹⁹³ *Ibid.*

¹⁹⁴ The United States Trade Representative, “Intellectual Property Rights Industry-Advisory Committee Report on the Trans-Pacific Partnership” 2015, online: <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/advisory-group-reports-TPP> and <https://ustr.gov/sites/default/files/ITAC-15-Intellectual-Property.pdf>> .

¹⁹⁵ *Ibid.*, 19.

¹⁹⁶ *Ibid.*, 19.

that “[t]he existing U.S. standard is supported by a broad, bipartisan majority of Members of Congress, and is an articulated negotiating objective for the TPP.”¹⁹⁷ The industry lobby group insisted: “[t]he certainty of a 12-year regulatory data protection period for pharmaceutical products that are biologics has been recognized as being essential to encourage the continued clinical development of biological products.”¹⁹⁸ The industry representatives lamented that “the standard established in the TPP falls short of this clear negotiating objective.”¹⁹⁹ Such views reflect, it would seem, the opinions of the pharmaceutical industry and biotechnology sector.

However, other members of the industry advisory group took a different stance. Apparently, “[t]hese ITAC-15 Members would have preferred not to express an opinion or otherwise advocate within this report that the U.S. negotiators press for a specific data protection period, and simply commended the U.S. negotiators for reaching a balanced and equitable agreement in the context of a highly contentious and sensitive, but critically important, substantive area for which a widely divergent set of positions exist.”²⁰⁰ This group observed that “the odds of achieving [12 years of biologics protection] were always slim.”²⁰¹ They noted that “U.S. negotiators were candid with Members of the ITAC, as well as Members of Congress, in expressing their doubt that they could impose 12 years of biologic exclusivity on the eleven other TPP Parties, four of which have no exclusivity for 19 biologics in their domestic law, five of which have 5 years and two of which have 8 years.”²⁰² Furthermore, “[g]iven the diversity of policies on biologic exclusivity among the TPP Parties, the outcome reached by the negotiators is significant.”²⁰³ In this context, “[t]hese Members also note that this is the first time biologic exclusivity has been included in any U.S. trade agreement.”²⁰⁴ This industry group observed that there were significant costs involved with longer protection of

¹⁹⁷ *Ibid.*, 19.

¹⁹⁸ *Ibid.*, 19.

¹⁹⁹ *Ibid.*, 19.

²⁰⁰ *Ibid.*, 20.

²⁰¹ *Ibid.*, 20.

²⁰² *Ibid.*, 20.

²⁰³ *Ibid.*

²⁰⁴ *Ibid.*

biologics: “[t]he excessiveness of 12 years of exclusivity (in addition to patent protection) for biologic products, which would have resulted in increased costs for and reduced access to medicines, was also recognized by the eleven other TPP Parties, resulting in a shorter period of protection.”²⁰⁵

Public Citizen warned that stronger protection of biologics would raise the costs of medicine.²⁰⁶ Burcu Kilic warned that the “purposefully ambiguous language is meant to provide USTR a means to harass countries in the future, and keep pushing for longer monopolies and industry profits at the expense of people’s health.”²⁰⁷ Public Citizen warned: “[t]hese data obligations grant a distinct monopoly protection to medicines, even when patents no longer apply or exist, giving companies a new way to keep prices high for longer and further delaying competition.”²⁰⁸

Professor Michael Geist from the University of Ottawa has highlighted the dangers of locking in biologics protection.²⁰⁹ He warned that “binding policy, which comes at a still early stage of new technological development, may create long term health costs to the detriment of patients, innovation, and marketplace competition.”²¹⁰

Mike Palmedo has pointed out that President Barack Obama’s 2017 Budget Proposal actually proposes to reduce the period of biologics exclusivity:

The Budget proposes . . . three previously proposed reforms designed to increase access to generic drugs and biologics by stopping companies from entering into anti-competitive deals intended to block consumer access to safe and effective generics, by awarding brand biologic manufacturers seven years of exclusivity, rather than 12 years under current law, and by

²⁰⁵ *Ibid.*

²⁰⁶ Public Citizen, “WikiLeaks Publication of Complete, Final TPP Intellectual Property Text Confirms Pact Would Raise Costs, Put Medicines Out of Reach” Press Release (9 October 2015), online: <<http://www.citizen.org/tpp-ip-wikileaks-oct2015>> .

²⁰⁷ *Ibid.*

²⁰⁸ *Ibid.*

²⁰⁹ Michael Geist, “The Trouble with the TPP, Day 8: Locking in Biologics Protection”, the University of Ottawa” (13 January 2016), online: <<http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-8-locking-in-biologics-protection/>> .

²¹⁰ *Ibid.*

prohibiting additional periods of exclusivity for brand biologics due to minor changes in product formulations. These proposals would save the Federal Government \$21 billion over 10 years.²¹¹

There seems to be inconsistency and dissonance between President Barack Obama's budgetary proposal in respect of biologics exclusivity, and the aggressive stance of the USTR to lengthen the term of protection for biologics under the TPP.

Senator Orrin Hatch has been lobbying to renegotiate the provisions on biologics in the TPP.²¹² The biotechnology industry will be deeply disappointed about the collapse of the TPP under President Donald Trump.

(d) The World Health Organization and The United Nations Secretary-General's High Level Panel On Access to Medicines

In response to the TPP, there has been significant responses from key international public health organizations. The World Health Organization has sought to raise concerns about access to medicines during the TPP negotiations. The United Nations Secretary-General's High Level Panel on Access to Medicines has made a number of significant recommendations to transcend the conflicts between the right to health, trade, intellectual property and public health objectives.

(i) The World Health Organization

The World Health Organization has been conscious of the challenge posed by mega-regional agreements such as the TPP to global public health. Addressing the UN Economic and Social Council, Dr. Margaret Chan was concerned about the impact of private stakeholders on public health.²¹³ She warned: "[t]he

²¹¹ Mike Palmedo, "TPP Implementation, and Obama's 2017 Budget Proposal to Reduce the Period of Biologics Exclusivity in the U.S." *Infojustice.org* (9 February 2016), online: <<http://infojustice.org/archives/35735>>.

²¹² Michael Vincent, "TPP: Australia Wants to Steal US Medicine Patents, Senator Orrin Hatch Says" *ABC News* (15 July 2016), online: <<http://www.abc.net.au/news/2016-07-15/orrin-hatch-accuses-australia-of-using-tpp-to-steal-patents/7629740>> and Stephanie Anderson, "TPP: Steve Ciobo Dismisses Concerns Over Deal Amid Opposition from Key US Senator Orrin Hatch" *ABC News* (15 July 2016), online: <<http://www.abc.net.au/news/2016-07-15/steven-ciobo-dismisses-concerns-over-tpp-amid-us-opposition/7631490>>.

²¹³ Margaret Chan, "The Changing Development Landscape: What Will It Mean

influence of stakeholders, especially the private sector, in multiple sectors is growing very rapidly at a time when the institutional and regulatory capacity of many countries remains weak.”²¹⁴ Chan observed that “[i]n the absence of adequate legislation, human and regulatory capacity, the private sector takes on an enlarged role, with little control by the government over the quality and costs of the services being provided.”²¹⁵ She expressed worry that “the vital role of government in protecting the public interest is diminished.”²¹⁶ Chan commented: “[i]n one especially alarming trend, provisions for the settlement of investor-state disputes are being used to handcuff governments and restrict their policy space.”²¹⁷ She concluded that “[w]hen private economic operators have more say over domestic affairs than the policies of a sovereign government, we need to be concerned.”²¹⁸

In May 2014, Dr. Chan reiterated such concerns in an address to the Sixty-Seventh World Health Assembly.²¹⁹ She observed that “[i]nternational trade has many consequences for health, both positive and negative.”²²⁰ Chan was worried: “[o]ne particularly disturbing trend is the use of foreign investment agreements to handcuff governments and restrict their policy space.”²²¹ She noted that “[s]ome Member States have expressed concern that trade agreements currently under negotiation could significantly reduce

for Specialized Agencies in a Post-2015 Era with Focus on Sustainable Development” UN Economic and Social Council (25 February 2014), online: <<http://www.who.int/dg/speeches/2014/economic-social-council/en/>> .

²¹⁴ *Ibid.*

²¹⁵ *Ibid.*

²¹⁶ *Ibid.*

²¹⁷ *Ibid.*

²¹⁸ *Ibid.*

²¹⁹ Margaret Chan, “Health Has an Obligatory Place on Any Post-2015 Agenda” Address to the Sixty-Seventh World Health Assembly, Geneva, Switzerland (19 May 2014), online: <<http://www.who.int/dg/speeches/2014/wha-19052014/en/>> .

²²⁰ *Ibid.*

²²¹ *Ibid.*

access to affordable generic medicines.” Chan observed that “[i]f these agreements open trade yet close access to affordable medicines, we have to ask: Is this really progress at all, especially with the costs of care soaring everywhere?”²²²

In a speech to Georgetown University in Washington D.C. on the 30th September 2015, Dr. Chan expressed concern about the threat posed by corporate power to public health.²²³ The speech took place just before the conclusion of negotiations to the TPP in Atlanta. Chan observed: “[t]he newer threats to health also lie beyond the traditional domain of sovereign nations accustomed to governing what happens in their territories.”²²⁴ Chan noted: “[i]n a world of radically increased interdependence, all are transboundary threats.”²²⁵ She noted: “[s]ome multinational corporations can be another transboundary threat.”²²⁶ Chan warned that mechanisms for settling investor-state disputes are being used to sue governments for public health policies. Chan stressed: “[w]hat is at stake here is nothing less than the sovereign right of a nation to enact legislation that protects its citizens from harm.”²²⁷

In a speech the following month, in October 2015, Dr. Chan highlighted her concerns about trade and public health at a joint technical symposium on public health, intellectual property, and TRIPS at 20.²²⁸ She focused on the issue of access to essential medicines:

Medicines have been making the headlines for two other reasons: strikingly high prices, especially for new drugs for various cancer indications and for hepatitis C, and speculation about how the *Trans-Pacific Partnership* agreement might affect the market for generics and biosimilars and increase the cost of

²²² *Ibid.*

²²³ Margaret Chan, “Governance: Global Health’s 21st Century Challenge” Global Futures Initiative, Georgetown University, Washington D.C. (30 September 2015), online: <<http://www.who.int/dg/speeches/2015/georgetown-university-lecture/en/>> .

²²⁴ *Ibid.*

²²⁵ *Ibid.*

²²⁶ *Ibid.*

²²⁷ *Ibid.*

²²⁸ Margaret Chan, “Opening Remarks at a Joint WHO/ WIPO/ WTO Technical Symposium on Public Health, Intellectual Property and TRIPS at 20” Geneva, Switzerland (28 October 2015), online: <<http://who.int/dg/speeches/2015/intellectual-property-trips/en/>> .

medicines. When new bilateral and regional trade and investment agreements are negotiated, I ask WHO Member States to scrutinize their provisions very closely for any potential impact on access to affordable medical products. I ask Member States to scrutinize mechanisms for the settlement of investor-state disputes that might interfere with a government's sovereign right to adopt legislation that protects citizens from harmful products, like tobacco.²²⁹

Chan said that access to essential medicines raised larger issues in respect of equality, fairness and development. "For public health," she noted, "the biggest question is this: how to extend the benefits of these medicines to the developing world, where the vast majority of infected people live?"²³⁰ Chan stressed: "[t]he overarching objective of the agenda for sustainable development is to put the world's poor and vulnerable populations first, not last."²³¹ She called for the fair and equitable interpretation and implementation of trade agreements affecting intellectual property and public health.

(ii) *The United Nations Secretary-General's High Level Panel on Access to Medicines*

The *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* was finally released in September 2016.²³² The report laudably seeks to employ a human rights approach to dealing with a number of the challenges in respect of intellectual property and public health. The Panel has formulated a set of concrete recommendations designed to help improve research and development of health technologies and people's access to medicines.

The report calls for countries to make use of flexibilities within intellectual property laws to address access to health technologies. The expert panel also discusses the importance of publicly-funded

²²⁹ *Ibid.*

²³⁰ *Ibid.*

²³¹ *Ibid.*

²³² Ruth Dreifuss *et al.*, *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, September 2016, online: <<http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>> .

research, and the use of open access, open innovation and open data. The report also calls for new incentives for research and development of health technologies, and promotes governance, accountability and transparency in respect of innovation and access to health technologies.

The report expressed concerns about the TPP, observing:

The recent *Trans-Pacific Partnership Agreement*, which is yet to come into force, is emblematic of the new generation of bilateral and multilateral trade and investment agreements which include ‘TRIPS-plus’ provisions that progressively ratchet up intellectual property and enforcement. This new generation of trade and investment agreement often includes dispute settlement mechanisms that establish arbitration processes outside of national courts and allow private firms to challenge national laws for depriving them of future profits. Other provisions significantly reduce the scope of measures that national governments can use to pursue public health priorities and fulfil the right to health. Ensuring that future trade agreements do not interfere with policies that guarantee the right to health for all is essential for resolving the incoherence between trade agreements and the human right to health.²³³

President Ruth Dreifuss reflected: “[p]olicy incoherencies arise when legitimate economic, social and political interests and priorities are misaligned or in conflict with the right to health.”²³⁴ She observed that, while “governments seek the economic benefits of increased trade,” “the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives and the right to health.”²³⁵ The press release for the new report noted: “[w]hether it’s the rising price of the EpiPen, or new outbreaks of diseases, like Ebola, Zika and yellow fever, the rising costs of health technologies and the lack of new tools to tackle health problems, like antimicrobial resistance, is a problem in rich and poor countries alike.”²³⁶

Malebona Precious Matsoso, Director General of the National Department of Health of South Africa, commented: “[o]ur report

²³³ *Ibid.* 19.

²³⁴ United Nations, “The United Nations Secretary-General’s High Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies” Press Release (14 September 2016), online: <<http://www.uns-gaccessmeds.org/final-report/>> .

²³⁵ *Ibid.*

²³⁶ *Ibid.*

calls on governments to negotiate global agreements on the coordination, financing and development of health technologies to complement existing innovation models, including a binding R&D Convention that delinks the costs of R&D from end prices.”²³⁷

Former High Court of Australia judge, Michael Kirby, was a member of the High-Level Panel and chair of the Expert Advisory Group. He recommended:

WTO Members must make full use of TRIPS flexibilities as reaffirmed by the Doha Declaration on TRIPS and Public Health. This is essential to promote access to health technologies. In particular, governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. WTO Members must register complaints against undue political and economic pressure. They need to take strong, effective measures against offending Members.²³⁸

Kirby’s involvement in the report represents a long-standing interest in the topic of intellectual property, human rights, and access to medicines.²³⁹

Likewise, Canada’s Stephen Lewis has stressed that access to medicines is crucial.²⁴⁰ He discussed his own experiences in Canada and in the United Nations. In his view, the Panel report made it clear that people should have access to medicine, regardless of their status or income.

Professor Ruth Okediji from the University of Minnesota observed: “[w]e need to galvanize new thinking about strategies —

²³⁷ *Ibid.*

²³⁸ *Ibid.*

²³⁹ Matthew Rimmer, “Michael Kirby’s Challenge: Intellectual Property, HIV/AIDS, and Human Rights” *Medium* (22 July 2014), online: <<https://medium.com/@DrRimmer/michael-kirbys-challenge-intellectual-property-hiv-aids-and-human-rights-2284d092397b>> .

²⁴⁰ Stephen Lewis, “High Level Panel Spotlight” United Nations Secretary-General’s High Level Panel on Access to Medicines (18 April 2016), online: <https://www.youtube.com/watch?v=udukRKT_acw> . See also Stephen Lewis, *Race against Time: Searching for Hope in AIDS-Ravaged Africa* (House of Anansi Press, 2015); Matthew Rimmer, “The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid” (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889-909; and Matthew Rimmer, “Race Against Time: The Export of Essential Medicines to Rwanda” (2008) 1(2) *Public Health Ethics* 89-103.

there are many legitimate complementary ends between patent laws and the universal right to healthcare.”²⁴¹

Nobel Laureate and Columbia University Professor Joseph Stiglitz welcomed the report, and the push for models of innovation, which promoted equality of health outcomes.²⁴² He said that the recommendations should be implemented swiftly.

Winnie Byanyima, the executive director of Oxfam International, observed: “I am still haunted by the memory of my Ugandan friends dying from HIV years ago because high prices kept the medicines they needed out of reach.”²⁴³ She hoped that the report was “a serious chance to rethink the global research and development (R&D) system to ensure all people have access to affordable medicines.”²⁴⁴

The Government of India has been enthusiastic about the report, saying that it should inform discussions about access to medicines in a range of fora in the United Nations. Generic drug manufacturers such as Cipla have also welcomed the report.

Disappointingly, the State Department of the Obama Administration has responded negatively to the report. The United States Government instead promoted an intellectual property maximalist vision, arguing: “[r]obust intellectual property policies found in the United States and other economies support the development of innovative new treatments that save and improve lives around the world.”²⁴⁵

²⁴¹ Ruth Okediji, “High Level Panel Spotlight” United Nations Secretary-General’s High Level Panel on Access to Medicines (18 April 2016), online: < <https://www.youtube.com/watch?v=WfGe6iKoAao> > .

²⁴² United Nations Secretary-General’s High Level Panel on Access to Medicines, “The Role of Health Technology, Innovation, and Access in the 2030 Agenda” (5 October 2016), online: < <https://www.youtube.com/watch?v=NNg-DMD5cfQ> > .

²⁴³ Winnie Byanyima, “People are Dying Because They Can’t Access Life-Saving Drugs. That Has to Change” World Economic Forum (23 September 2016), online: < <https://www.weforum.org/agenda/2016/09/people-are-dying-access-to-drugs-this-has-to-change> > .

²⁴⁴ *Ibid.*

²⁴⁵ U.S. Department of State, “US Disappointed Over Fundamentally Flawed Report of the UN Secretary-General’s High Level Panel on Access to Medicines” Press Release (16 September 2016), online: < <https://www.state.gov/r/pa/prs/ps/2016/09/262034.htm> > .

The report was also met with hostility from the United States Chamber of Commerce, brand-name pharmaceutical drug companies, and the biotechnology industry.²⁴⁶

Doctors groups, though, were delighted by the recommendations. Rohit Malpani, Director of Policy and Analysis for the MSF Access Campaign, commented:

The report should serve as a call to action for the UN Secretary General and governments attending the UN General Assembly this week as they work to find global solutions to combat drug-resistant infections: it's time for governments to implement policies and incentives that will promote health-driven innovation and improve access for people in need no matter where they live. Governments must go beyond the challenge of drug-resistant infections and make bold, broad reforms in the way medical research and development is conducted, so we can stop failing humanity on such a basic need.²⁴⁷

The Lancet commented that “the panel’s recommendations are an important first step and it will be imperative for Ban Ki-moon to endorse them quickly.”²⁴⁸

Suerie Moon applauds the courage of Ban Ki moon in convening the panel. She notes that “the report’s fate in the UN system is uncertain, given that there is a new secretary general, a new U.S. president, and a new director general of the World Health Organization in 2017.”²⁴⁹ Moon is hopeful that the report will inspire reform: “[t]his report comes at a time when the public

²⁴⁶ Catherine Saez, “UN High-Level Panel on Access to Medicines Issues ‘Landmark’ Report” *Intellectual Property Watch* (14 September 2016), online: < <http://www.ip-watch.org/2016/09/14/un-high-level-panel-on-access-to-medicines-issues-landmark-report/> > .

²⁴⁷ MSF, “MSF Response to Report from UN Secretary-General’s High Level Panel on Access to Medicines” Press Release (14 September 2016), online: < <http://www.msfacecess.org/about-us/media-room/press-releases/msf-response-report-un-secretary-generals-high-level-panel> > .

²⁴⁸ Editorial, “Access to Medicines — the Status Quo is no Longer an Option” (2016) 388 *The Lancet* 1250, online: < [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(16\)31705-6.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31705-6.pdf) > .

²⁴⁹ Suerie Moon, “Powerful Ideas for Global Access to Medicines” *The New England Journal of Medicine* (18 January 2017), online: < <http://www.nejm.org/doi/full/10.1056/NEJMp1613861#t=article> > .

appetite for change is growing, the pharmaceutical industry's reputation is in the doldrums, and demand for a more equitable global trade system is building."²⁵⁰

2. CONCLUSION

The *Trans-Pacific Partnership* poses a significant threat to global public health. The Intellectual Property Chapter strengthens the rights of pharmaceutical drug companies and biotechnology companies. As discussed, there are significant obligations in respect of patent law and related rights associated with data protection, biologics and trade secrets. In addition to the Intellectual Property Chapter, the Investment Chapter provides foreign companies with special investor rights, which enable them to challenge government decisions and regulations.²⁵¹ The Health Annex provides procedural rights to private health companies in respect of government decision-making.²⁵² The Competition Chapter does little to protect patients, consumers, and citizens in relation to the pricing of medical and pharmaceutical products. The TPP provides for inadequate protection for access to essential medicines.

Considering the agreement as a whole, Professor Brook Baker found that "IP maximization in the TPP will harm access to more affordable medicines in both the US and its trading partners."²⁵³ He stressed that "[p]olicy space on both sides of the Pacific will be reduced while opportunities for excessive pricing will increase dramatically with predictable adverse consequence for the right to health."²⁵⁴ He observed further: "[a]rmed with knowledge about the details of the TPP's anti-access provisions, there is still time for

²⁵⁰ *Ibid.*

²⁵¹ Gus van Harten, "Foreign-Investor Protections in the TPP" in Scott Sinclair & Stuart Trew, eds., *The Trans-Pacific Partnership and Canada: A Citizen's Guide* (Toronto: James Lorimer & Company Ltd., 2016) at 131-44.

²⁵² Joel Lexchin, "The TPP and Regulation of Medicines in Canada" in Scott Sinclair & Stuart Trew, eds., *The Trans-Pacific Partnership and Canada: A Citizen's Guide* (Toronto: James Lorimer & Company Ltd., 2016) at 66-80.

²⁵³ Brook Baker, "Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere" *Public Library of Science Medicine* (8 March 2016), online: < <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001970> > .

²⁵⁴ *Ibid.*

health advocates to convince the US Congress and TPP partners that the TPP's monopoly-enhancing measures must be rejected."²⁵⁵ Belinda O'Donnell expressed similar concerns in 2016, writing for the Harvard T.H. Chan School of Public Health.²⁵⁶ She suggested: "[t]he anxieties aggravated by the signing of the TPP agreement capture a central debate in global health: What's the right balance between incentivizing innovation in the production of life saving drugs, and the very urgent requirement that these drugs are made accessible to those that depend on them for their wellbeing or survival?"²⁵⁷ In her view, "[w]hen considering the TPP from a global health perspective, it is essential to ask if the agreement has managed to strike that balance."²⁵⁸

With the election of Donald Trump as President in 2016, the TPP appears to have collapsed.²⁵⁹ The access to essential medicines movement has been credited as one of the factors behind the failure of the trade agreement.²⁶⁰ President Donald Trump has issued an executive order in January 2017, telling the USTR:

I hereby direct you to withdraw the United States as a signatory to the *Trans-Pacific Partnership* (TPP), to permanently withdraw the United States from TPP negotiations, and to begin pursuing, wherever possible, bilateral trade negotiations to promote American industry, protect American workers, and raise American wages.²⁶¹

²⁵⁵ *Ibid.*

²⁵⁶ Belinda O'Donnell, "HIV and the TPP" Harvard T.H. Chan School of Public Health (24 February 2016), online: < <http://aids.harvard.edu/hiv-and-the-tpp/> > .

²⁵⁷ *Ibid.*

²⁵⁸ *Ibid.*

²⁵⁹ Peter Martin, "TPP: Trans-Pacific Partnership is Dead, Before Trump even Takes Office" *The Sydney Morning Herald* (13 November 2016), online: < <http://www.smh.com.au/federal-politics/political-news/transpacific-partnership-dead-before-trump-even-takes-office-20161113-gso9kn.html> > .

²⁶⁰ James Trimarco, "How a Battle Over Affordable Medicine Helped Kill the TPP" *Yes Magazine* (18 November 2016), online: < <http://www.yesmagazine.org/new-economy/how-a-battle-over-affordable-medicine-helped-kill-the-tpp-20161118> > .

²⁶¹ The White House, "Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement" Press Release (23 January 2017), online: < <https://www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-withdrawal-united-states-trans-pacific> > .

Trump's views on access to medicines are complicated. He has vowed to dismantle President Barack Obama's *Patient Protection and Affordable Care Act* 2010 (U.S.). Nonetheless, Trump has complained about the high cost of drug prices, and has threatened to take action against the pharmaceutical industry.²⁶²

The demise of the TPP provides an opportunity to rethink our future approach to intellectual property, public health and trade. As Professor Michael Geist has noted, there is a need for open, transparent, accountable and democratic deliberations in respect of intellectual property, public health and trade.²⁶³ The Australian Productivity Commission has recommended reforms to Australia's system of trade negotiations.²⁶⁴

A number of TPP nations — including Australia and New Zealand — are exploring the possibility of forging a TPP, without the participation of the United States.²⁶⁵ Such an endeavour will be difficult to achieve. It will take much more than merely revising the rules on the entry into force of the agreement. The United States was responsible for the template of the TPP. In return for market access, the USTR demanded the inclusion of many of the measures, designed to boost the position of pharmaceutical companies and biotechnology developers. It is questionable whether the concessions and compromises in the TPP will make sense without the inclusion of the USTR. Canada's Foreign Minister Chrystia

²⁶² Kimberly Leonard, "Trump Speaks Out On Drug Prices" *US News* (11 January 2017), < <http://www.usnews.com/news/health-care-news/articles/2017-01-11/donald-trump-takes-on-drug-prices-says-industry-getting-away-with-murder> > .

²⁶³ Michael Geist, "In Ottawa, TPP's Death Could Open the Door to Transparent Trade Dealing" *The Globe and Mail* (16 November 2016), online: < <http://www.theglobeandmail.com/report-on-business/rob-commentary/in-ottawa-tpps-death-could-open-the-door-to-transparent-trade-dealing/article32860162/> > .

²⁶⁴ Productivity Commission, *Intellectual Property Arrangements*, Melbourne: Productivity Commission, Report No. 78, 2016, online: < <http://www.pc.gov.au/inquiries/completed/intellectual-property/report> > .

²⁶⁵ Henry Belot, "Trans-Pacific Partnership: Government 'Flat Out' to Revise TPP Deal without Donald Trump's Support" *ABC News* (23 January 2017), online: < <http://www.abc.net.au/news/2017-01-23/government-to-seek-revised-tpp-deal/8202440> > and New Zealand Herald, "PM Bill English Says Some Form of Trade Deal Could Still Go Ahead" *New Zealand Herald* (23 January 2017), online: < http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=11786988 > .

Freeland has said that Canada will not be involved in the TPP without U.S. participation.²⁶⁶ Likewise, Japan has expressed scepticism about the formation of the TPP without the inclusion of the U.S.²⁶⁷

The fate of the TPP is thus fraught. Even if the agreement expires, the threats to affordable access to medicines continue unabated.²⁶⁸ There remains concern that the text of the TPP on medicines will be revived by the pharmaceutical industry and biotechnology companies in future agreements. The United Nations Secretary-General's High Level Panel on Access to Medicines highlights that there are alternative models to promote health research and development, and access to medicines.

On the 17th March 2017, a Tribunal issued its award in an Investor-State Dispute Settlement matter between Eli Lilly and Canada under NAFTA. Eli Lilly had objected to the rejection of key drug patents in Canada. The Tribunal unanimously dismissed Eli Lilly's claims and confirmed that Canada was in compliance with its NAFTA obligations. The decision will no doubt be significant in considerations about the interaction between intellectual property, investment, and access to medicines in NAFTA, the TPP, and beyond.

²⁶⁶ Bill Curry, "Canada Talking Trade with Asia after Trump Withdraws from TPP" *The Globe and Mail* (24 January 2017), online: <<http://www.theglobeandmail.com/news/politics/canada-talks-trade-with-asia-after-tpps-collapse/article33715363/>> .

²⁶⁷ Reiji Yoshida, "Tokyo Turns Down Australian Proposal for TPP Without U.S., Vows to Keep Pushing Trump" *The Japan Times* (24 January 2017), online: <<http://www.japantimes.co.jp/news/2017/01/24/national/politics-diplomacy/tokyo-turns-australian-proposal-tpp-without-u-s-vows-keep-pushing-trump/>> .

²⁶⁸ Ruth Lopert, Deborah Gleeson & Burcu Kilic, "TPP May Be Dead — But Its Impact Lingers" *Intellectual Property Watch* (6 December 2016), online: <<http://www.ip-watch.org/2016/12/06/tpp-may-dead-impact-lingers/>> .