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THE *TRANS-PACIFIC PARTNERSHIP*:

**INTELLECTUAL PROPERTY, PUBLIC HEALTH,
AND ACCESS TO ESSENTIAL MEDICINES**



Zahara Heckscher Protests against the TPP

DR MATTHEW RIMMER

PROFESSOR OF INTELLECTUAL PROPERTY AND INNOVATION LAW

FACULTY OF LAW

QUEENSLAND UNIVERSITY OF TECHNOLOGY

Queensland University of Technology

2 George Street GPO Box 2434

Brisbane Queensland 4001 Australia

Work Telephone Number: (07) 31381599

Executive Summary

This submission provides a critical analysis of a number of Chapters in the *Trans-Pacific Partnership* addressing intellectual property, public health, and access to essential medicines – including Chapter 18 on Intellectual Property, Chapter 9 on Investment, and Annex 26 on ‘Healthcare Transparency.’

The United States Trade Representative has argued: ‘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.’ The United States maintained: ‘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.’ The United States Trade Representative also argued that the agreement protected public health: ‘The 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.’

Australia’s Regulatory Impact Statement says that the *Trans-Pacific Partnership* is designed to ‘incentivise investment in new pharmaceutical inventions and products, while aiming to ensure TPP countries can take measures to protect public health and support timely and affordable access to medicines.’

In its National Interest Analysis, New Zealand maintains that there are sufficient and adequate safeguards for public health in respect of Intellectual Property, Investment, and ‘Health Transparency.’

Canada is currently holding an open consultation on the *Trans-Pacific Partnership*. Questions over intellectual property, public health, and access to essential medicines have been foregrounded by the incredible investor action by Eli Lilly against the Government of Canada under the *North American Free Trade Agreement* 1994.

This analysis raises concerns that the provisions in the *Trans-Pacific Partnership* will threaten access to essential medicines across the Pacific Rim.

Recommendation 1

Overall, the *Trans-Pacific Partnership* strengthens the substantive and procedural rights of pharmaceutical drug companies, medical manufacturers, and biotechnology organisations under the Intellectual Property, Investment, and ‘Transparency’ Chapters.

Recommendation 2

There has been a great deal of concern about the influence of pharmaceutical drug companies, medical manufacturers, and biotechnology organisations in the secret negotiations over the *Trans-Pacific Partnership*. There has been inadequate input from public health advocates and defenders into the final agreement.

Recommendation 3

The *Trans-Pacific Partnership* does little positive to provide for access to essential medicines across the Pacific Rim. Indeed, the combination of measures contained in the agreement will undermine access to essential medicines in the region.

Recommendation 4

The *Trans-Pacific Partnership* will seek to lengthen, broaden, and strengthen the patent rights of pharmaceutical drug companies, medical manufacturers, and biotechnology organisations across the Pacific Rim. This will affect patient care, freedom of research, and the administration and cost of health-care.

Recommendation 5

The *Trans-Pacific Partnership* also erects significant regulatory barriers – with data protection, market exclusivity for biologics, and civil and criminal remedies for trade secrets.

Recommendation 6

The *Trans-Pacific Partnership* also enables intellectual property owners to bring actions under the investor-state dispute settlement regime established by the Investment Chapter. The investor dispute between Eli Lilly and the Government of Canada under the *North American Free Trade Agreement 1994* highlights the dangers of such a regime.

Recommendation 7

The *Trans-Pacific Partnership* also contains a ‘Health Transparency’ Annex, which contains provisions, which will enable pharmaceutical companies to oversee government decisions in respect of medicines and medical devices.

Recommendation 8

The World Health Organization has expressed concerns about the impact of the *Trans-Pacific Partnership* and other mega-regional trade agreements upon the provision of public health-care.

Biography

Dr Matthew Rimmer is a Professor in Intellectual Property and Innovation Law at the Faculty of Law, at the Queensland University of Technology (QUT). He is a leader of the QUT Intellectual Property and Innovation Law research program, and a member of the QUT Digital Media Research Centre (QUT DMRC) the QUT Australian Centre for Health Law Research (QUT ACHLR), and the QUT International Law and Global Governance Research Program. Rimmer has published widely on copyright law and information technology, patent law and biotechnology, access to medicines, plain packaging of tobacco products, intellectual property and climate change, and Indigenous Intellectual Property. He is currently working on research on intellectual property, the creative industries, and 3D printing; intellectual property and public health; and intellectual property and trade, looking at the *Trans-Pacific Partnership*, the *Trans-Atlantic Trade and Investment Partnership*, and the *Trade in Services Agreement*. His work is archived at SSRN Abstracts and Bepress Selected Works.

Dr Matthew Rimmer holds a BA (Hons) and a University Medal in literature (1995), and a LLB (Hons) (1997) from the Australian National University. He received a PhD in law from the University of New South Wales for his dissertation on *The Pirate Bazaar: The Social Life of Copyright Law* (1998-2001). Dr Matthew Rimmer was a lecturer, senior lecturer, and an associate professor at the ANU College of Law, and a research fellow and an associate director of the Australian Centre for Intellectual Property in Agriculture (ACIPA) (2001 to 2015). He was an Australian Research Council Future Fellow, working on Intellectual Property and Climate Change from 2011 to 2015. He was a member of the ANU Climate Change Institute.

Rimmer is the author of *Digital Copyright and the Consumer Revolution: Hands off my iPod* (Edward Elgar, 2007). With a focus on recent US copyright law, the book charts the consumer rebellion against the *Sonny Bono Copyright Term Extension Act* 1998 (US) and the *Digital Millennium Copyright Act* 1998 (US). Rimmer explores the significance of key judicial rulings and considers legal controversies over new technologies, such as the iPod, TiVo, Sony Playstation II, Google Book Search, and peer-to-peer networks. The book also highlights cultural developments, such as the emergence of digital sampling and mash-ups, the construction of the BBC Creative Archive, and the evolution of the Creative Commons. Rimmer has also participated in a number of policy debates over Film Directors' copyright, the *Australia-United States Free Trade Agreement* 2004, the *Copyright Amendment Act* 2006 (Cth), the *Anti-Counterfeiting Trade Agreement* 2011, and the *Trans-Pacific Partnership*. He has been an advocate for Fair IT Pricing in Australia.

Rimmer is the author of *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar, 2008). This book documents and evaluates the dramatic expansion of intellectual property law to accommodate various forms of biotechnology from micro-organisms, plants, and animals to human genes and stem cells. It makes a unique theoretical contribution to the controversial public debate over the commercialisation of biological inventions. Rimmer also edited the thematic issue of *Law in Context*, entitled *Patent Law and Biological Inventions* (Federation Press, 2006). Rimmer was also a chief investigator in an Australian Research Council Discovery Project, 'Gene Patents In Australia: Options For Reform' (2003-2005), an Australian Research Council Linkage Grant, 'The Protection of Botanical Inventions' (2003), and an Australian Research Council Discovery Project, 'Promoting Plant Innovation in Australia' (2009-2011). Rimmer has participated in inquiries into plant breeders' rights, gene patents, and access to genetic resources.

Rimmer is a co-editor of a collection on access to medicines entitled *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, 2010) with Professor Kim Rubenstein and Professor Thomas Pogge. The work considers the intersection between international law, public law, and intellectual property law, and highlights a number of new policy alternatives – such as medical innovation prizes, the Health Impact Fund, patent pools, open source drug discovery, and the philanthropic work of the (Red) Campaign, the Gates Foundation, and the Clinton Foundation. Rimmer is also a co-editor of *Intellectual Property and Emerging Technologies: The New Biology* (Edward Elgar, 2012).

Rimmer is a researcher and commentator on the topic of intellectual property, public health, and tobacco control. He has undertaken research on trade mark law and the plain packaging of tobacco products, and given evidence to an Australian parliamentary inquiry on the topic.

Rimmer is the author of a monograph, *Intellectual Property and Climate Change: Inventing Clean Technologies* (Edward Elgar, September 2011). This book charts the patent landscapes and legal conflicts emerging in a range of fields of innovation – including renewable forms of energy, such as solar power, wind power, and geothermal energy; as well as biofuels, green chemistry, green vehicles, energy efficiency, and smart grids. As well as reviewing key international treaties, this book provides a detailed analysis of current trends in patent policy and administration in key nation states, and offers clear recommendations for law reform. It considers such options as technology transfer, compulsory licensing, public sector licensing, and patent pools; and analyses the development of Climate Innovation Centres, the Eco-Patent Commons, and environmental prizes, such as the L-Prize, the H-Prize, and the X-

Prizes. Rimmer is currently working on a manuscript, looking at green branding, trade mark law, and environmental activism.

Rimmer has also a research interest in intellectual property and traditional knowledge. He has written about the misappropriation of Indigenous art, the right of resale, Indigenous performers' rights, authenticity marks, biopiracy, and population genetics. Rimmer is the editor of the collection, *Indigenous Intellectual Property: A Handbook of Contemporary Research* (Edward Elgar, 2015).

Rimmer has supervised four students who have completed Higher Degree Research on the topics, *Secret Business and Business Secrets: The Hindmarsh Island Affair, Information Law, and the Public Sphere* (2007); *Intellectual Property and Applied Philosophy* (2010); *The Pharmacy of the Developing World: Indian Patent Law and Access to Essential Medicines* (2012); and *Marine Bioprospecting: International Law, Indonesia and Sustainable Development* (2014). He has also supervised sixty-seven Honours students, Summer Research Scholars, and Interns, and two graduate research unit Masters students.

Introduction

The *Trans-Pacific Partnership* is a mega-regional agreement, involving a dozen countries across the Pacific Rim.¹ The participants include 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 - are contemplating joining the agreement at a future date. The sweeping trade agreement covers a score of topics – including such matters as intellectual property, investment, transparency in health procedures, and trade in services. The *Trans-Pacific Partnership* will have a significant impact upon the health of everyone in the Pacific Rim – particularly insofar as it affects the timely access to affordable medicines. There has been much concern that citizens, consumers, and seniors have been ripped-off on the price of medicines by multinational pharmaceutical drug companies.² The problem is only likely to be exacerbated by global trade deals – like the *Trans-Pacific Partnership*.

¹ The United States Trade Representative, ‘The Trans-Pacific Partnership’, <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 (UK) and Northampton (Mass.): Edward Elgar, 2013; C.L. Lim, Deborah Elms and Patrick Low (ed.), *The Trans-Pacific Partnership: A Quest for a Twenty-First Century Trade Agreement*, Cambridge: Cambridge University Press, 2012; and Jane Kelsey, *Hidden Agendas: What We Need to Know about the Trans-Pacific Partnership Agreement (TPPA)*, Wellington: Bridget Williams Books Limited, 2013.

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

After many years of secret negotiations, representatives from a dozen countries from around the Pacific Rim came to an agreement on the adoption of the *Trans-Pacific Partnership* in a Westin Hotel in Atlanta, the United States.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

The final texts of the agreement were subsequently released in November.⁵ The *Trans-Pacific Partnership* agreement has been controversial, though, 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 *Trans-Pacific Partnership* upon public health and access to essential medicines.

³ Jessica Glenza and agencies, 'TPP Deal: US and 11 Other Countries Reach Landmark Pacific Trade Pact', *The Guardian*, 5 October 2015, <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, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/trans-pacific-partnership-ministers>

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

Outside the closed Atlanta negotiations to finalise the *Trans-Pacific Partnership*, 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 *Trans-Pacific Partnership*, 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 *Trans-Pacific Partnership* negotiations. Zahara Heckscher was particularly incensed about the proposal for special protection of 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

⁶ Public Citizen, ‘Cancer Patient Demanding to see TPP “Death Sentence Clause” Arrested at Ministerial Negotiations’, Eyes on Trade, Public Citizen’s Blog on 30 September 2015, <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, http://www.democracynow.org/2015/10/6/breast_cancer_patient_arrested_for_protesting

world for a period of five years, eight years or 12 years.’⁹ She commented: ‘We 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.’¹⁰

Zahara Heckscher and Hannah Lyon were also later arrested at the headquarters of the Pharma lobby, protesting the clauses the industry inserted into the *Trans-Pacific Partnership*.¹¹

In the wake of the action, Zahara Heckscher urged the United States Congress to reject the passage of the *Trans-Pacific Partnership*.¹² She warned: ‘The TPP will effectively take some patients backwards in time to the dark ages of cancer treatment.’¹³ Zahara Heckscher was concerned that the agreement ‘will prevent too many people with cancer – and other life threatening illnesses – from accessing the new treatments they need to stay alive’.¹⁴ Zahara Heckscher warned: ‘When science has the potential for them to be thrivers like me, living productive lives while in treatment, or to be cured, the TPP will be a death sentence.’¹⁵ Zahara Heckscher stressed: ‘The TPP is not a policy wonk issue’.¹⁶ In her view, ‘It is a

⁹ Ibid.

¹⁰ Ibid.

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

¹² Zahara Heckscher, ‘TPP Threatens Access to Medicines’, Public Citizen, 11 January 2016, <http://www.citizen.org/documents/heckscher-media-statement-at-press-conference-january-2016.pdf>

¹³ Ibid.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Ibid.

human issue that affects individuals like me who are fighting for our lives.’¹⁷ Zahara Heckscher also observed that the agreement ‘affects our families too.’¹⁸ Thinking about her own family, she reflected: ‘For my mother to die of breast cancer in the 1970s was a tragedy for our family.’¹⁹ Zahara Heckscher concluded: ‘For people in the US and around the world to die unnecessary in this new millennium because of the TPP is a cruel, premeditated, and avoidable catastrophe.’²⁰

At the time of writing, there remains fierce debate in the United States political system over the passage of the *Trans-Pacific Partnership*. After expending significant political capital, President Barack Obama has obtained a Fast-Track authority for negotiating trade deals like the *Trans-Pacific Partnership* from the United States Congress – with the help of Republicans, and a few defectors from his own party, the Democrats.²¹ The agreement still needs to pass the United States Congress in a straight vote. There has been, though, significant criticism from Democrats about the impact of the trade deal – particularly in respect of public health. House Democrat leader Nancy Pelosi has argued that we need a new model for trade.²² Senior House United States Democrat Sandy Levin has stressed that the *Trans-Pacific Partnership* ‘should not be loaded up with new anticompetitive provisions

¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Ibid.

²¹ Paul Lewis, ‘Barack Obama Given “Fast-Track” Authority over Trade Deal Negotiations’, *The Guardian*, 25 June 2015, <http://www.theguardian.com/us-news/2015/jun/24/barack-obama-fast-track-trade-deal-tpa-senate>

²² Nancy Pelosi, ‘Trade Promotion Authority on its Last Legs’, *USA Today*, 15 June 2015, <http://www.usatoday.com/story/opinion/2015/06/15/congress-trade-fast-track-tpa-pelosi-column/71270294/>

when governments struggle to manage health care costs.’²³ Senator Elizabeth Warren has expressed concern that the *Trans-Pacific Partnership* has been rigged in favour of multinational companies.²⁴

The *Trans-Pacific Partnership* has become a matter of fierce debate in the Presidential races. Independent 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.’²⁵ Presidential aspirant Hillary Clinton has expressed reservations about the *Trans-Pacific Partnership*, and investor-state dispute settlement

²³ 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, 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.

²⁴ George Zornick, ‘Elizabeth Warren Reveals Inside Details on Trade Talks’, *The Nation*, 15 May 2014, <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, <https://www.youtube.com/watch?v=xzfxv2XQoPg> Senator Elizabeth Warren, ‘Congress Should Oppose the TPP Deal’, United States Senate, 2 February 2016, https://www.youtube.com/watch?v=AWXJJy_Tq-U

²⁵ Senator Bernie Sanders, ‘The Trans-Pacific Trade Agreement Must Be Defeated’, <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, 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, <http://observer.com/2015/10/bernie-sanders-calls-agreement-of-trans-pacific-partnership-disastrous/>

clauses.²⁶ 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.’²⁷ However, there has been discussion as to whether Hillary Clinton would support the *Trans-Pacific Partnership* if she ultimately won the Presidency.²⁸ A number of Republican candidates have also been concerned about the *Trans-Pacific Partnership*, albeit for different reasons than concerns about public health. The populist Donald Trump, for instance, has been opposing the deal on the basis that it advantages countries such as China, and fails to address issues, as currency manipulation.²⁹ Much will depend upon the Presidential election to really determine the ultimate fate of the *Trans-Pacific Partnership*.

²⁶ Hillary Rodham Clinton, *Hard Choices*, New York: Simon & Schuster, 10 June 2014, 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.’

²⁷ Zach Carter, Amanda Terkel and Ryan Grim, ‘Hillary Clinton agrees with Elizabeth Warren on Trade Dispute With Obama’, *The Huffington Post*, 30 April 2015, http://www.huffingtonpost.com.au/entry/hillary-clinton-trans-pacific-partnership_n_7173108.html?section=australia

²⁸ Robert Naiman, ‘Chamber of Commerce Lobbyist Tom Donohue: Clinton Will Support TPP After Election’, *The Huffington Post*, 28 January 2016, http://www.huffingtonpost.com/robert-naiman/chamber-of-commerce-lobby_b_9104096.html

²⁹ David Dayen, ‘Trump Was Right about TPP Benefitting China’, *The Intercept*, 12 November 2015, <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, <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, <http://www.breitbart.com/big-government/2015/11/09/exclusive-donald-trump-obamas-trans-pacific-free-trade-deal-insanity/>

In this context, this article considers the debate over the *Trans-Pacific Partnership*, looking at 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.³⁰

The *Trans-Pacific Partnership* 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 *Trans-Pacific Partnership*. Part 1 addresses the text on public health and access to essential medicines, and rules on transitional periods. Part 2 considers issues relating to patentable subject matter, patent standards, patent term extensions and evergreening, patent registration linkages, and border measures. Part 3 looks at data protection, the protection of biologics, and trade secrets. Part 4 focuses upon the relationship intellectual property, public health, and investor-state dispute settlement. Part 5 considers the Health ‘Transparency’ Annex. The conclusion considers the larger overall framework in respect of intellectual property, public health, investment, and trade. It highlights the commentary of the World Health Organization upon the health impacts of the *Trans-Pacific Partnership*.

³⁰ Lawrence Gostin, *Global Health Law*, Cambridge (MA) and London: Harvard University Press, 2014, 270.

1. 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.³¹ Notably, the world's largest pharmaceutical companies took action over South Africa's efforts to obtain supplies of generic medicines from India.³² This conflict is well recounted in the documentary *Fire in the Blood*.³³ 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 recognise that countries could take action under the *TRIPS Agreement* 1994 to address public health concerns.³⁴ The *WTO General Council Decision* 2003 was designed to facilitate the export of essential medicines to developing countries and least developed countries.³⁵ There was a discussion of the

³¹ Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010; Frederick Abbott, Thomas Cottier, and Francis Gurry, *International Intellectual Property in an Integrated World Economy*, Wolters Kluwer Law & Business, 2015.

³² Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* Earthscan, 2002.

³³ Dylan Mohan Grey, *Fire in the Blood*, Sparkwater India, 2014, <http://www.imdb.com/title/tt1787067/>

³⁴ *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 *Journal of International Economic Law* 469-505.

³⁵ *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').

formalisation of this decision with the *TRIPS Waiver* in 2005.³⁶ Despite such declarations and decisions, there have remained significant conflicts in respect of access to essential medicines. There have been significant conflicts 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.³⁷ There have been similar conflicts a decade later over experimental research to address the Ebola virus.³⁸ There have been emerging legal issues in respect of the Zika virus surrounding access to essential medicines.³⁹

There was a concern that the final *Trans-Pacific Partnership* agreement rolls back protection in respect of access to essential medicines.

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.

³⁶ *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641 (2005) (Decision of 6 December 2005 of the General Council) ('TRIPS Waiver').

³⁷ 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* 335-374.

³⁸ 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, <http://ihr2015.com/program/>

³⁹ Lawrence Gostin and Alexandra Phelan, 'Zika Virus: The Global and United States Domestic Response', Subcommittee on Oversight and Investigations, United States House of Representatives, 2 March 2016, <http://docs.house.gov/meetings/IF/IF02/20160302/104594/HHRG-114-IF02-Wstate-GostinL-20160302.pdf>

Article 18.6 of the *Trans-Pacific Partnership* deals with ‘Understandings Regarding Certain Public Health Measures.’⁴⁰ Article 18.6.1 provides that the ‘Parties affirm their commitment to the *Declaration on TRIPS and Public Health*’.⁴¹ Article 18.6.1 (a) emphasizes: ‘The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health.’⁴² Moreover, ‘Accordingly, 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.’⁴³ Article 18.6.1 (a) stresses: ‘Each Party has the right to determine what 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.’⁴⁴ 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*.

⁴⁰ Article 18.6 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

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

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

⁴³ Article 18.6.1 (a) of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

⁴⁴ Article 18.6.1 (a) of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

Article 16.8.1 (b) of the *Trans-Pacific Partnership* also discusses the *WTO General Council Decision 2003*: ‘In 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’.⁴⁵ The language in this statement is odd and peculiar. There is no obligation here upon member states in the *Trans-Pacific Partnership* 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 *Trans-Pacific Partnership* have implemented their obligations with respect to access to essential medicines. Canada was a leader in the field – with early implementing legislation.⁴⁶ However, there have been problems with the operation of the regime – with only the generic manufacturer Apotex employing the scheme.⁴⁷ 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

⁴⁵ Article 18.6.1 (b) of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

⁴⁶ Matthew Rimmer, 'The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid' (2005) 15 (7) *Expert Opinion on Therapeutic Patents* 889-909

⁴⁷ Matthew Rimmer, 'Race Against Time: The Export of Essential Medicines to Rwanda' (2008) 1 (2) *Public Health Ethics* 89-103.

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 provides for the grant of non-exclusive licences for reason of public interest. Notably, the United States of America still has not implemented the *WTO General Council* 2003, despite it being over a decade since its inception.

Article 16.8.1 (c) of the *Trans-Pacific Partnership* 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.’⁴⁸ Article 16.8.2 stipulates: ‘Each 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.’⁴⁹

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

⁴⁸ Article 18.6.1 (b) of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

⁴⁹ Article 18.6.1 (b) of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

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. 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.⁵⁰

The United States Trade Representative also argued that the regime enabled public health protections: ‘The 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.’⁵¹ Such claims, though, have been treated with scepticism in the public debate. The United States Trade Representative 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 *Trans-Pacific Partnership* does not even live up to the standards of the May 2007 decision of the Bush Administration. Democrat Elder 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

⁵⁰ The United States Trade Representative, ‘Overview. Intellectual Property Chapter of the Trans-Pacific Partnership’, <https://medium.com/the-trans-pacific-partnership/intellectual-property-3479efdc7adf#.lcowp4odl>

⁵¹ Ibid.

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.⁵²

Peter Maybarduk from Public Citizen commented: ‘From very early on in the TPP negotiations, and to the ire of health advocates, it became apparent that the Office of the U.S. Trade Representative (USTR) was abandoning the May 10 Agreement template.’⁵³ He noted: ‘With 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.’⁵⁴

The United States Trade Representative has promoted transition periods for developing countries. Peter Maybarduk from Public Citizen commented: ‘Forcing 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.’⁵⁵ He noted: ‘Some rare public servants from TPP countries fought back and

⁵² 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, http://www.huffingtonpost.com/rep-sander-/is-tpp-the-most-progressive-trade-agreement-in-history-_b_7461734.html

⁵³ 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, <http://www.citizen.org/tpp-ip-wikileaks-oct2015>

⁵⁴ Ibid.

⁵⁵ Ibid.

stood for health in this negotiation. Their efforts saved lives.’⁵⁶ Maybarduk warned: ‘Yet in the end, the TPP will still trade away our health.’⁵⁷ 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.

United Nations Independent Expert Alfred de Zayas stressed: ‘Trade 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*.’⁵⁸ He has also emphasized that trade agreements must satisfy ‘fundamental principles of international law, including transparency and accountability’.⁵⁹ He has stressed that such agreements ‘must not delay, circumvent, undermine or make impossible the fulfilment of human rights treaty obligations.’⁶⁰

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ 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, <http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=17005&LangID=E>

⁵⁹ Ibid.

⁶⁰ Ibid.

2. The *Trans-Pacific Partnership* and Patent Law

The Intellectual Property Chapter of the *Trans-Pacific Partnership* is a lengthy, expansive and a prescriptive chapter. The regime covers copyright law, trade mark law, patent law, trade secrets, data protection, and intellectual property enforcement.⁶¹ A number of elements of the Intellectual Property Chapter of the *Trans-Pacific Partnership* will impact upon public health. Notably, there has been much debate over the patent measures in respect of the *Trans-Pacific Partnership*. There has been significant argument over eligible patentable subject matter; patent standards and the problem of evergreening; patent term extensions; border measures; and the treatment of anti-competitive conduct.

A. 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.⁶²

⁶¹ Kimberlee Weatherall, 'Section-by-Section Commentary on the TPP Final IP Chapter', 2015, Section 1, <http://works.bepress.com/kimweatherall/32/> Section 2 <http://works.bepress.com/kimweatherall/32/>, Section 3 <http://works.bepress.com/kimweatherall/33/>

⁶² Alexandra Phelan and Matthew Rimmer, 'Pacific Rim Treaty Threatens Public Health: Patent Law and Medical Procedures', *Edward Elgar Blog*, 27 November 2013, <http://elgarblog.wordpress.com/2013/11/27/pacific-rim-treaty-threatens-public-health-patent-law-and-medical-procedures-by-alexandra-phelan-and-matthew-rimmer/>

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,⁶³ and the opposition from a number of the Pacific Rim countries to a broad approach on patentable subject matter.

Article 18.37 of the *Trans-Pacific Partnership* 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:

(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.

⁶³ *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).

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.⁶⁴

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.⁶⁵

There remain significant concerns about software patents. 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.⁶⁶ He lamented: ‘Today’s patent world is not a steam engine world’.⁶⁷ Breyer J observed: ‘We have decided to patent tens of thousands of software products and similar things where hardly anyone knows what the patent’s really about.’⁶⁸ New Zealand has sought to ban software patents.

The topic of methods of human treatment is touchy. Australia allows for patents in respect of

⁶⁴ Article 18.37 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

⁶⁵ Matthew Rimmer and Alison McLennan (ed.), *Intellectual Property and Emerging Technologies: The New Biology*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, January 2012.

⁶⁶ David McCabe and Mario Trujillo, ‘Supreme Court on Software Patents’, 21 February 2016, <http://thehill.com/policy/technology/overnights/270498-overnight-tech-debate-starts-over-commission-on-encryption>

⁶⁷ Ibid.

⁶⁸ Ibid.

methods of human treatment.⁶⁹ In the 2013 case of *Apotex Pty Ltd v. Sanofi-Aventis Australia Pty Ltd*, French CJ 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.⁷⁰

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,

⁶⁹ *Apotex Pty Ltd v. Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50 (4 December 2013)

⁷⁰ *Apotex Pty Ltd v. Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50 (4 December 2013)

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 *Trans-Pacific Partnership*.

Notably, superior courts across Pacific Rim have made significant rulings against gene patents in the United States⁷¹ and Australia.⁷² There is also a challenge against gene patents in Canada,⁷³ which has been resolved through a settlement.⁷⁴ 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.⁷⁵

⁷¹ *Association for Molecular Pathology v. Myriad Genetics, Inc.* 133 S. Ct 2107 (2013).

⁷² *D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35 (7 October 2015).

⁷³ *Children's Hospital of Eastern Ontario v. University of Utah Research Foundation & Ors*, No T.2249-14 (Toronto Registry).
http://www.cheo.on.ca/uploads/genetics/Gene%20patent/Statement%20of%20Claim%20_Issued.pdf

⁷⁴ Children's Hospital of Eastern Ontario, 'Ground-breaking Settlement Changes Landscape for Genetic Medicine in Canada', Press Release, 9 March 2016, <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, <http://www.thestar.com/news/canada/2016/03/09/ontario-hospital-settles-gene-patent-lawsuit-in-win-for-patients.html>

⁷⁵ 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 Geoeconomics', *Project Syndicate*, 8 January 2016, <https://www.project-syndicate.org/commentary/hope-for-better-global-governance-by-joseph-e--stiglitz-2016-01> and *The Guardian*, 10 January 2016, <http://www.theguardian.com/business/2016/jan/10/in-2016-better-trade-agreements-trans-pacific-partnership>

The Intellectual Property Rights Advisory Committee to the United States Trade Representative was disappointed by the flexibilities available for nation states under the *Trans-Pacific Partnership* to exclude subject matter from patent protection.⁷⁶

B. Patent Standards and Evergreening

There have longstanding conflicts over intellectual property, trade, health, and access to essential medicines.⁷⁷

WikiLeaks has published a draft text of the Intellectual Property Chapter of the *Trans-Pacific Partnership*.⁷⁸ The Intellectual Property Chapter contains a number of measures, which support the position of pharmaceutical drug companies and the biotechnology industry.⁷⁹ Notably, 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 *Trans-Pacific Partnership* will impose lower thresholds for patent standards, and result in a proliferation of evergreening. There has also been a concern about patent-

⁷⁶ The United States Trade Representative, 'Intellectual Property Rights Industry-Advisory Committee Report on the Trans-Pacific Partnership', 2015, <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>

⁷⁷ See Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010.

⁷⁸ WikiLeaks, 'Advanced Intellectual Property Chapter for All 12 Nations with Negotiating Positions (30 August 2013 consolidated bracketed negotiating text)' <https://wikileaks.org/tpp/>

⁷⁹ Alexandra Phelan and Matthew Rimmer, 'Trans-Pacific Partnership #TPP #TPPA Drafts Reveal a Surgical Strike against Public Health', *East Asia Forum*, 2 December 2013, <http://www.eastasiaforum.org/2013/12/02/tpp-draft-reveals-surgical-strike-on-public-health/>

registration linking to marketing regimes. The United States has also pushed for the protection of undisclosed data for regulatory purposes. There has been wide concern that the *Trans-Pacific Partnership* will result in skyrocketing costs for health-care systems in the Pacific Rim.

The Intellectual Property Chapter of the *Trans-Pacific Partnership* 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 in 2014. Michael Grunwald from *Politico* received a draft copy of the latest version of the intellectual property chapter in the *Trans-Pacific Partnership*.⁸⁰ He observed: ‘A recent draft of the *Trans-Pacific Partnership* free-trade deal would give U.S. pharmaceutical firms unprecedented protections against competition from cheaper generic drugs, possibly transcending the patent protections in U.S. law.’⁸¹ 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’.⁸² 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.’⁸³

The civil society group Knowledge Ecology International published a leaked draft of the Intellectual Property Chapter of the *Trans-Pacific Partnership* in August 2015, before the

⁸⁰ Michael Grunwald, ‘Leaked: What’s in Obama’s Trade Deal’, *Politico*, 1 July 2015, <http://www.politico.com/agenda/story/2015/06/tpp-deal-leaked-pharma-000126>

⁸¹ Ibid.

⁸² Ibid.

⁸³ Ibid.

final deal.⁸⁴ 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.’⁸⁵ He was concerned that ‘the proposals contained in the TPP will harm consumers and in some cases block innovation.’⁸⁶ James Love feared: ‘In countless ways, the Obama Administration has sought to expand and extend drug monopolies and raise drug prices.’⁸⁷ He maintained: ‘The 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.’⁸⁸

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 area where the United States has an admirable track record, such as the public funding of research at the NIH and other federal agencies.’⁸⁹

MSF has been concerned about the lowering of standards for patentability: ‘The TPP requires countries to grant secondary patents on modifications of existing medicines for at least one of

⁸⁴ Knowledge Ecology International, ‘Knowledge Ecology International Leaks #TPP Text on Intellectual Property’, Press Release, 4 August 2015, <http://keionline.org/node/2308>

⁸⁵ Ibid.

⁸⁶ Ibid.

⁸⁷ Ibid.

⁸⁸ Ibid.

⁸⁹ Ibid.

the following: new uses, methods of use or new processes of a known product'.⁹⁰ MSF warned: 'This provision is designed to prevent countries from using public health safeguards in their national patent laws and judicial decisions that limit abusive patent evergreening'.⁹¹ MSF was concerned: 'The effect will keep medicine prices high by delaying the availability of price-lowering generics.'⁹²

The former High Court of Australia Justice Michael Kirby observed in a case that patent law 'should avoid creating fail-safe opportunities for unwarranted extensions of monopoly protection that are not clearly sustained by law.'⁹³

The Australian *Pharmaceutical Patents Review Report* also addressed the pernicious problem of evergreening – where patent owners seek to indirectly extend the life of patent protection, beyond its natural monopoly.⁹⁴ 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 pejorative, relevant

⁹⁰ MSF, 'Open Letter to ASEAN Governments Don't Trade Away Health', Geneva, 4 February 2016, http://www.msfacecess.org/sites/default/files/MSF_assets/IP/Docs/IP_TPP_ASEANOpenLetter_web.pdf

⁹¹ Ibid.

⁹² Ibid.

⁹³ *Aktiebolaget Hassle v. Alphapharm Pty Ltd* [2002] HCA 59 <http://www.austlii.edu.au/au/cases/cth/HCA/2002/59.html>

⁹⁴ Tony Harris, Dianne Nicol, and Nicholas Gruen, *Pharmaceutical Patents Review Report*, Canberra, 2013, http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf

literature has dubbed such actions ‘evergreening’: steps taken to maintain the market place of a drug whose patent is about to expire.⁹⁵

The report noted: ‘It 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.’⁹⁶ The report called for improvements in the oversight of patent quality standards: ‘The 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.’⁹⁷

C. Patent Term Extensions

The *Trans-Pacific Partnership* provides for patent term extensions. Article 18.46 deals with patent term adjustment for patent office delays.⁹⁸ Article 18.48 addresses patent term adjustment for unreasonable curtailment.⁹⁹

MSF observed: ‘The TPP requires countries to create two mechanisms to extend patent terms beyond 20 years for pharmaceuticals’.¹⁰⁰ The advocacy group said: ‘At present, patents on

⁹⁵ Ibid.

⁹⁶ Ibid.

⁹⁷ Ibid.

⁹⁸ Article 18.46 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

⁹⁹ Article 18.48 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

drugs in most countries last for 20 years from the date of filing'.¹⁰¹ MSF stressed: 'The 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.'¹⁰²

The *Australian Pharmaceutical Patents Review Report* makes a number of important recommendations relating to patent term extensions.¹⁰³ Under Australia law, the patent term lasts for twenty years. Since 1998, pharmaceutical drug patents can obtain additional term extensions for up to a further 5 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.¹⁰⁴

The report noted that patent term extensions were expensive for the Australian Government: 'The estimate for 2012-13 is around \$240 million in the medium term and, in today's dollars,

¹⁰⁰ MSF, 'Open Letter to ASEAN Governments Don't Trade Away Health', Geneva, 4 February 2016, http://www.msfacecess.org/sites/default/files/MSF_assets/IP/Docs/IP_TPP_ASEANOpenLetter_web.pdf

¹⁰¹ Ibid.

¹⁰² Michael Geist, 'The Trouble with the TPP, Day 7: Patent Term Extensions', the University of Ottawa, <http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-7-patent-term-extensions/>

¹⁰³ Tony Harris, Dianne Nicol, and Nicholas Gruen, *Pharmaceutical Patents Review Report*, Canberra, 2013, http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf

¹⁰⁴ Ibid.

around \$480 million in the longer term'.¹⁰⁵ The report stressed: 'The 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.'¹⁰⁶ The report emphasized: 'Using the patent scheme to preferentially support one industry is inconsistent with the TRIPS rationale that patent schemes be technologically neutral.'¹⁰⁷

The inquiry recommended: 'The Government should change the current EOT to reduce the maximum effective patent life provided from 15 years.'¹⁰⁸ 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.'¹⁰⁹ The report advised: 'The 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.'¹¹⁰ The report noted: 'The current 5 year cap on extensions should remain, providing a maximum of 25 years patent term for extended patents.'¹¹¹

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

¹⁰⁵ Ibid.

¹⁰⁶ Ibid.

¹⁰⁷ Ibid.

¹⁰⁸ Ibid.

¹⁰⁹ Ibid.

¹¹⁰ Ibid.

¹¹¹ Ibid.

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, 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.¹¹²

It is calculated that Professor Nicol's recommendation to shorten the effective patent life would result in significant savings: 'The estimated savings resulting from this reduction would be approximately \$130 million a year.'¹¹³ Moreover, it was noted: 'If a 70% price reduction from generic entry was achieved as discussed above, the savings would be approximately \$260 million a year.'¹¹⁴

The *Pharmaceutical Patents Review Report* observed that 'Larger developed countries that are major net IP exporters have tended to seek longer and stronger patents, not always to the global good.'¹¹⁵ The report warned: 'The acquiescence of Australia and other countries to that

¹¹² Ibid.

¹¹³ Ibid.

¹¹⁴ Ibid.

¹¹⁵ Ibid.

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.’¹¹⁶

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.¹¹⁷

The report noted: ‘The Government has rightly agreed to only include IP provisions in bilateral and regional trade agreements where economic analysis has demonstrated net benefits, however this policy does not appear to be being followed.’¹¹⁸

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.’¹¹⁹ The *Pharmaceutical Patents Review Report* stressed that ‘the Government should strongly resist changes – such as retrospective extensions of IP rights – which are

¹¹⁶ Ibid.

¹¹⁷ Ibid.

¹¹⁸ Ibid.

¹¹⁹ Ibid.

likely to reduce world economic and social welfare and it should lead other countries in opposing such measures as a matter of principle.’¹²⁰

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’.¹²¹ In its view, ‘This would help them avoid the embarrassment of Australia’s trade and investment performance being penalised by its previous agreement to strengthen IP rights.’¹²²

The *Pharmaceutical Patents Review Report* warned: ‘There 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.’¹²³

There was much controversy over the costs associated with patent term extensions in Australia.¹²⁴

¹²⁰ Ibid.

¹²¹ Ibid.

¹²² Ibid.

¹²³ Ibid.

¹²⁴ Peter Martin, ‘Drug Patents Costing Billions’, *The Sydney Morning Herald*, 2 April 2013, <http://www.smh.com.au/national/health/drug-patents-costing-us-billions-20130402-2h52i.html>

Professor Michael Geist from the University of Ottawa considered the impact of patent term extensions from a Canadian perspective.¹²⁵ He commented that the Trans-Pacific Partnership 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.¹²⁶

Moreover, Geist pointed out that 'Article 18.46 requires a patent term adjustment due to patent office delays'.¹²⁷ He noted the 'The 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."' ¹²⁸ Geist observed: 'No similar extension is found under current Canadian law nor within CETA.'¹²⁹ He observed that 'the escalation in patent protections is set to occur just as drug prices hit all-time highs in Canada and pharmaceutical investment in research and development sinks to decade-long lows'. He cited a recent report released by the Patent Medicines Panel Review Board

¹²⁵ Michael Geist, 'The Trouble with the TPP, Day 7: Patent Term Extensions', the University of Ottawa, <http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-7-patent-term-extensions/>

¹²⁶ Ibid.

¹²⁷ Ibid.

¹²⁸ Ibid.

¹²⁹ Ibid.

(PMPRB).¹³⁰ Geist observed: ‘The 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.’¹³¹ He was worried: ‘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.’¹³² Geist expressed concern: ‘Yet 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.’¹³³

D. Patent-Registration Linkage

Article 18.51.1 of the *Trans-Pacific Partnership* 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:

¹³⁰ Patented Medicines Annual Review Board, *Annual Report 2014*, Ottawa: Patented Medicines Annual Review Board, 2014, http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2014/2014_Annual_Report_Final_EN.pdf

¹³¹ Michael Geist, ‘The Trouble with the TPP, Day 7: Patent Term Extensions’, the University of Ottawa, <http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-7-patent-term-extensions/>

¹³² Ibid.

¹³³ Ibid.

(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.¹³⁴

Article 18.51.2 of the *Trans-Pacific Partnership* 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 claiming that product, unless by consent or acquiescence of the patent holder.¹³⁵

¹³⁴ Article 18.51.1 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

¹³⁵ Article 18.51.2 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

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’.¹³⁶

E. Border Measures

The *Trans-Pacific Partnership* also contains border measures – like its predecessor the *Anti-Counterfeiting Trade Agreement*.¹³⁷ 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.¹³⁸

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

¹³⁶ Brook Baker, ‘Health GAP Submission to the US House of Representatives Ways and Means on the Trans-Pacific Partnership and Access to Medicine’, US House of Representatives Ways and Means on the Trans-Pacific Partnership and Access to Medicine’, 8 December 2015, <http://infojustice.org/archives/35504>

¹³⁷ Matthew Rimmer, ‘Trick or Treaty? The Australian Debate over the Anti-Counterfeiting Trade Agreement (ACTA)’, in Pedro Roffe and Xavier Seuber (ed.), *The ACTA and The Plurilateral Enforcement Agenda: Genesis and Aftermath*, Geneva: International Centre for Trade and Sustainable Development, Cambridge: Cambridge University Press, 2014, 169-201.

¹³⁸ MSF, ‘Open Letter to ASEAN Governments Don’t Trade Away Health’, Geneva, 4 February 2016, http://www.msfacecess.org/sites/default/files/MSF_assets/IP/Docs/IP_TPP_ASEANOpenLetter_web.pdf

developing countries. Professor Michael Geist was concerned about judicial oversight in respect of border measures.¹³⁹

F. Competition

A recent controversy in the United States over drug pricing by Turing Pharmaceuticals AG has raised larger issues in respect of intellectual property, access to medicines, competition, and the *Trans-Pacific Partnership*.

In August 2015, Turing Pharmaceuticals AG – a private biopharmaceutical company with offices in New York, the United States, and Zug, Switzerland - acquired the exclusive marketing rights to Daraprim in the United States from Impax Laboratories Inc.

Martin Shkreli, Turing’s Founder and Chief Executive Officer, maintained: ‘The acquisition of Daraprim and our toxoplasmosis research program are significant steps along Turing’s path of bringing novel medications to patients with serious disorders, some of whom often go undiagnosed and untreated.’ He emphasized: ‘We intend to invest in the development of new drug candidates that we hope will yield an even better clinical profile, and also plan to launch an educational effort to help raise awareness and improve diagnosis for patients with toxoplasmosis.’

¹³⁹ Michael Geist, ‘The Trouble with the TPP, Day 22: Expanding Border Measures without Court Oversight’, the University of Ottawa, 2 February 2016, <http://www.michaelgeist.ca/2016/02/the-trouble-with-the-tpp-day-22-expanding-border-measures-without-court-oversight/>

In September 2015, there was much public controversy over the decision of Martin Shkreli to raise the price of a 62 year old drug, Daraprim, from \$US13.50 to \$US750 a pill.

The drug is particularly useful in respect of the treatment and prevention of malaria, and the treatment of infections, when treating individuals with HIV/AIDS. Daraprim is listed on the World Health Organization's List of Essential Medicines. In the face of much criticism, Martin Shkreli has said that he will reduce the price of Daraprim. He observed: 'We've agreed to lower the price on Daraprim to a point that is more affordable and is able to allow the company to make a profit, but a very small profit.' He maintained: 'We think these changes will be welcomed.' However, he has been vague and ambiguous about the nature of the commitment.

Notably, the lobby group, PHMRA, disassociated itself from the claims of Turing Pharmaceuticals. The group said: 'PhRMA members have a long history of drug discovery and innovation that has led to increased longevity and improved lives for millions of patients.' The group noted: 'Turing Pharmaceutical is not a member of PhRMA and we do not embrace either their recent actions or the conduct of their CEO.' The biotechnology peak body BIO also sought to distance itself from Turing Pharmaceuticals.

This controversy over Daraprim is unusual – given the age of drug concerned. Daraprim is not subject to patent protection. Nonetheless, there remains a monopoly in respect of the marketplace. Drug pricing is not an isolated problem. There have been many concerns about drug pricing – particularly in respect of essential medicines for HIV/AIDS, tuberculosis, and malaria. This controversy is part of a larger debate about access to affordable medicines. The

dispute raises larger issues about health-care, consumer rights, competition policy, and trade. The controversy has provided impetus for law reform in the United States.

US Presidential Candidate Hillary Clinton commented: ‘Price gouging like this in this specialty drug market is outrageous.’ In response to her comments, the Nasdaq Biotechnology Index fell sharply. Hillary Clinton has announced a prescription drug reform plan to protect consumers and promote innovation – while putting an end to profiteering. On her campaign site, she has emphasized that ‘affordable health care is a basic human right.’

Her rival progressive candidate, Bernie Sanders, was also concerned about the price hike. He wrote a letter to Martin Shkreli, complaining about the price increase for the drug Daraprim. Bernie Sanders said: ‘The enormous, overnight price increase for Daraprim is just the latest in a long list of skyrocketing price increases for certain critical medications.’ He has pushed for reforms to intellectual property to make medicines affordable.

It is disappointing that the *Trans-Pacific Partnership* – in the leaks that we have seen – has only limited recognition of the importance access to essential medicines. There is a need ensure that there are proper safeguards to provide access to essential medicines – particularly in respect of HIV/AIDs, malaria, and tuberculosis. Moreover, there must protection against drug profiteering and price gouging in any trade agreement. There should be strong measures against the abuse of intellectual property rights.

The dispute over Turing Pharmaceuticals AG and Daraprim is an important cautionary warning in respect of some of the dangers present in the secret negotiations in respect of the

Trans-Pacific Partnership. There is a need to preserve consumer rights, competition policy, and public health in trade negotiations over an agreement covering the Pacific Rim.

3. Data Protection, Market Exclusivity for Biologics, and Trade Secrets

In addition to the suite of patent protection, the *Trans-Pacific Partnership* also provides for special protection in respect of data protection, market exclusivity for biologics, and trade secrets. The Biotechnology Industry Organization stressed that ‘Trade secrets are legal protections given to information that is kept confidential’.¹⁴⁰ They emphasized: ‘Examples of trade secrets that are important to biologics developers are details of manufacturing conditions and processes, formulation techniques for their products, and the like’.¹⁴¹ The *Trans-Pacific Partnership* includes criminal penalties and procedures for the protection of trade secrets. Amongst other things, the criminalisation of trade secrets could have important ramifications in respect of medical research, patient care, and the administration of health-care.

One of the most controversial issues during the negotiation over the *Trans-Pacific Partnership* was the protection of biologics.

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

¹⁴⁰ BIO, ‘The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics’, https://www.bio.org/sites/default/files/TPP%20White%20Paper%202_.pdf

¹⁴¹ Ibid.

entering the market even when any patents on the originator product have expired. These 12 years are known as the market exclusivity period.¹⁴²

Academic work has highlighted the massive costs associated with providing extra protection for biologics.¹⁴³

The pharmaceutical drug industry – led by the peak association PHRMA – pushed for 12 years of protection for biologics under the *Trans-Pacific Partnership*.¹⁴⁴ The peak body observed: ‘Over 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).’¹⁴⁵ PHRMA maintained: ‘America’s leading policy makers are committed, on a bipartisan basis, to extending these protections to our

¹⁴² Ruth Lopert, ‘Why biologics were such a big deal in the Trans Pacific Partnership, *The Conversation*, 5 October 2015 <https://theconversation.com/why-biologics-were-such-a-big-deal-in-the-trans-pacific-partnership-48595>

¹⁴³ Deborah Gleeson, Ruth Lopert and 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. http://dfat.gov.au/trade/agreements/tpp/submissions/Documents/tpp_sub_gleeson_lopert_moir.pdf; Deborah Gleeson and Ruth Lopert, ‘How the battle over biologics helped stall the Trans Pacific Partnership’ *The Conversation*, 6 August 2015. <https://theconversation.com/how-the-battle-over-biologics-helped-stall-the-trans-pacific-partnership-45648>; Burcu Kilic and Courtney Pine, ‘Decision Time On Biologics Exclusivity: Eight Years Is No Compromise’, *IP-Watch*, 27 July 2015. <http://www.ip-watch.org/2015/07/27/decision-time-on-biologics-exclusivity-eight-years-is-no-compromise/>

¹⁴⁴ PHRMA, ‘12 Years of Data Protection: Note to Media on Elected Officials Support for 12 Years of Data Protection in TPP’, <http://phrma.org/note-media-elected-officials-support-12-years-data-protection-tpp>

¹⁴⁵ Ibid.

trading partners, through the TPP’s high quality, comprehensive agreement.’¹⁴⁶ 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.¹⁴⁷

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’.¹⁴⁸ PHRMA maintained: ‘These 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.’¹⁴⁹

The Biotechnology Industry Organization (BIO) – the peak biotechnology industry association – also lobbied hard in respect of the protection of biologics.¹⁵⁰ The association stressed: ‘We believe 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

¹⁴⁶ Ibid.

¹⁴⁷ Ibid.

¹⁴⁸ Ibid.

¹⁴⁹ Ibid.

¹⁵⁰ BIO, ‘The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics’, https://www.bio.org/sites/default/files/TPP%20White%20Paper%20_2_.pdf

products’.¹⁵¹ In its view, that infrastructure must ‘provide a minimum of 12 years of data protection for new biological products.’¹⁵² BIO sought to dismiss criticism from the Federal Trade Commission about the impact of special protection of biologics upon competition.

The United States Trade Representative pushed for longer protection of biologics in the *Trans-Pacific Partnership*. Initially, the United States Trade Representative argued for 12 years of protection. Then, as a fallback position, the United States Trade Representative called for 8 years of protection. The United States Trade Representative 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.¹⁵³

However, other participating nations in the *Trans-Pacific Partnership* were reluctant to acceded to the demands of the United States.

¹⁵¹ Ibid., 39.

¹⁵² Ibid., 39.

¹⁵³ Amy Goodman, ‘Breast Cancer Patient Arrested for Protesting TPP: “This is Price Gouging at the Cost of Lives’, *Democracy Now!*, 6 October 2015,

http://www.democracynow.org/2015/10/6/breast_cancer_patient_arrested_for_protesting

Public health advocacy organisations and civil society groups expressed concern about longer protection for biologics. MSF Australia spokesman Jon Edwards observed: ‘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.’¹⁵⁴ He warned that ‘increased costs in poorer TPP negotiating countries could mean millions of patients would not be able to access essential medicines.’¹⁵⁵ Jon Edwards commented: ‘Australia has a broader responsibility in these negotiations than simply improving Australia’s trade figures’.¹⁵⁶ He reflected: ‘Like it or not, The 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’.¹⁵⁷ He called upon the Australian Government: ‘For the sake our patients and those like them we urge Australia to stand strong.’¹⁵⁸

The *Sydney Morning Herald’s* John Garnaut provided an inside account of the final negotiations over biologics in respect of the *Trans-Pacific Partnership*, after interviewing the Australian Trade Minister, Andrew Robb.¹⁵⁹ 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

¹⁵⁴ 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, <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>

¹⁵⁵ Ibid.

¹⁵⁶ Ibid.

¹⁵⁷ Ibid.

¹⁵⁸ Ibid.

¹⁵⁹ John Garnaut, ‘The Arm Wrestle over Drugs: Inside the TPP Deal’, *The Sydney Morning Herald*, 7 October 2015, <http://www.smh.com.au/national/the-arm-wrestle-over-drugs-inside-the-tpp-deal-20151006-gk2dnt.html>

over expensive, innovative drugs known as "biologics", which would have made the Pharmaceutical Benefits Scheme more expensive.¹⁶⁰ 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.¹⁶¹

United States President Barack Obama personally lobbied Australian Prime Minister Malcolm Turnbull over the protection of biologics.¹⁶² 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.¹⁶³ 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

¹⁶⁰ Ibid.

¹⁶¹ Ibid.

¹⁶² Francis Keany, 'Pharmaceuticals Patent Protection Dispute Could Make or Break TPP: Andrew Robb', *ABC News*, 5 October 2015, <http://www.abc.net.au/news/2015-10-04/pharmaceuticals-dispute-could-disrupt-tpp-andrew-robb-says/6826278>

¹⁶³ Tony Harris, Dianne Nicol, and Nicholas Gruen, *Pharmaceutical Patents Review Report*, Canberra, 2013, http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf

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.¹⁶⁴

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:

It is conceivable that drugs might not be brought to Australia, for example, because regulatory and marketing costs cannot be recouped within five years. Medicines Australia submits that some of its members chose not to supply a total of 13 drugs to the Australian market because of the inadequacy of the data exclusivity period. However, they are only able to identify three of these, and the Panel's analysis - shown in chapter 8 - suggests they are not convincing. AbbVie offers a more compelling example, but even there the Panel believes that expanding data exclusivity for all or for a wide class of drugs is a poorly targeted response to issues affecting a small number of pharmaceuticals. A policy of subsidising drug development discussed above seems more appropriate.¹⁶⁵

The report noted: 'The 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.'¹⁶⁶

¹⁶⁴ Ibid.

¹⁶⁵ Ibid.

¹⁶⁶ Ibid.

The Department of Foreign Affairs and Trade in Australia maintained that it had defended Australia's regulatory autonomy in respect of the *Trans-Pacific Partnership*.¹⁶⁷ 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.¹⁶⁸

However, there was academic and policy debate about whether the final text is so clear-cut. There have been concerns about ambiguities in respect of the final text for the *Trans-Pacific Partnership*.

Such a finding has a broader significance, given the push by the United States for stronger data protection in the *Trans-Pacific Partnership*.

The final text of the *Trans-Pacific Partnership* in Article 18.52 on the protection of biologics is complicated.¹⁶⁹ Article 18.52.1 provides: '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

¹⁶⁷ The Department of Foreign Affairs and Trade, 'The *Trans-Pacific Partnership Agreement*: Outcomes – Biologics', 6 October 2015, <https://dfat.gov.au/trade/agreements/tpp/Documents/outcomes-biologics.PDF>

¹⁶⁸ Ibid.

¹⁶⁹ Article 18.52 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

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.¹⁷⁰ Article 18.52.2 provides: ‘For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.’¹⁷¹ 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

¹⁷⁰ Article 18.52.1 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

¹⁷¹ Article 18.52.2 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

categories of new pharmaceutical products that are or contain a biologic.’¹⁷² 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 *Trans-Pacific Partnership* 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.’¹⁷³ 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.

There is also a side-letter between Vietnam and the United States on biologics.¹⁷⁴

United States Republican Congressional Powerbroker Orrin Hatch was upset at the final text in respect of the protection of biologics in the *Trans-Pacific Partnership*. He lamented: ‘I am

¹⁷² Article 18.52.3 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

¹⁷³ Article 18.50.3 of the *Trans-Pacific Partnership* 2015 <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

¹⁷⁴ United States-Vietnam Letter Exchange on Biologics, <https://ustr.gov/sites/default/files/TPP-Final-Text-US-VN-Letter-Exchange-on-Biologics.pdf>

afraid this deal appears to fall woefully short.’¹⁷⁵ 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 *Trans-Pacific Partnership* should be renegotiated to provide for longer periods of protection for biologics.¹⁷⁶

There have been significant internal divisions with the United States Trade Representative Intellectual Property Rights Advisory Committee on the topic of the protection of biologics.¹⁷⁷ The Committee noted: ‘Certain 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.’¹⁷⁸

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

¹⁷⁵ John Garnaut, ‘The Arm Wrestle over Drugs: Inside the TPP Deal’, *The Sydney Morning Herald*, 7 October 2015, <http://www.smh.com.au/national/the-arm-wrestle-over-drugs-inside-the-tpp-deal-20151006-gk2dnt.html>

¹⁷⁶ Mike Masnick, ‘House Speaker Paul Ryan Demands TPP be Rengotiated, Neglects to Mention It Was His Bill that Makes that Impossible’, *Techdirt*, 17 February 2016, <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>

¹⁷⁷ The United States Trade Representative, ‘Intellectual Property Rights Industry-Advisory Committee Report on the Trans-Pacific Partnership’, 2015, <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>

¹⁷⁸ *Ibid.*, 19.

of the approval of the product in each TPP Party.’¹⁷⁹ This industry group maintained that ‘The existing U.S. standard is supported by a broad, bipartisan majority of Members of Congress, and is an articulated negotiating objective for the TPP.’¹⁸⁰ The industry lobby group insisted: ‘The 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’.¹⁸¹ The industry representatives lamented that ‘the standard established in the TPP falls short of this clear negotiating objective’.¹⁸² 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, ‘These 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.’¹⁸³ This group observed that ‘the odds of achieving [12 years of biologics protection] were always slim.’¹⁸⁴ This group commented: ‘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

¹⁷⁹ Ibid., 19.

¹⁸⁰ Ibid., 19.

¹⁸¹ Ibid., 19.

¹⁸² Ibid., 19.

¹⁸³ Ibid., 20.

¹⁸⁴ Ibid., 20.

domestic law, five of which have 5 years and two of which have 8 years'.¹⁸⁵ This group observed: 'Given the diversity of policies on biologic exclusivity among the TPP Parties, the outcome reached by the negotiators is significant'.¹⁸⁶ In this context, 'These Members also note that this is the first time biologic exclusivity has been included in any U.S. trade agreement'.¹⁸⁷ This industry group observed that there were significant costs involved with longer protection of biologics: 'The 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.'¹⁸⁸

Public Citizen warned that stronger protection of biologics would raise the costs of medicine.¹⁸⁹ 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.'¹⁹⁰ Public Citizen warned: 'These 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.'¹⁹¹

¹⁸⁵ Ibid., 20.

¹⁸⁶ Ibid.

¹⁸⁷ Ibid.

¹⁸⁸ Ibid.

¹⁸⁹ 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, <http://www.citizen.org/tpp-ip-wikileaks-oct2015>

¹⁹⁰ Ibid.

¹⁹¹ Ibid.

Professor Michael Geist from the University of Ottawa has highlighted the dangers of locking in biologics protection.¹⁹² 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.’¹⁹³

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 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.¹⁹⁴

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 United States Trade Representative to lengthen the term of protection for biologics under the *Trans-Pacific Partnership*.

¹⁹² Michael Geist, ‘The Trouble with the TPP, Day 8: Locking in Biologics Protection’, the University of Ottawa, 13 January 2016, <http://www.michaelgeist.ca/2016/01/the-trouble-with-the-tpp-day-8-locking-in-biologics-protection/>

¹⁹³ Ibid.

¹⁹⁴ 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, <http://infojustice.org/archives/35735>

4. Intellectual Property, Public Health, and Investor-State Dispute Settlement

In addition to the fears and worries about the Intellectual Property Chapter, there has been much concern about the Investment Chapter of the *Trans-Pacific Partnership*.

The investor-state dispute settlement regime would enable foreign investors to challenge government policy-making, which affected their investments. In the context of health care, there is a worry that pharmaceutical drug companies will deploy their investor rights to challenge public health measures – such as, for instance, initiatives to curb drug pricing and profiteering. Such concerns are not merely theoretical.

Eli Lilly has brought an investor action against the Canadian Government over the rejection of its drug patents under the investor-state dispute settlement regime of the *North American Free Trade Agreement* (NAFTA). The brand name pharmaceutical drug company Eli Lilly have deployed an investor clause under the *North American Free Trade Agreement* to challenge Canada's drug patent laws. There is a concern that the investor-state dispute settlement regime in the *Trans-Pacific Partnership* could be deployed to challenge public health measures, and reforms to the patent system designed to combat problems such as evergreening.

In a 2014 speech on investor-state dispute settlement, Chief Justice French of the High Court of Australia has highlighted his misgivings about the use of investor clauses by intellectual

property holders.¹⁹⁵ He specifically discusses the dispute over plain packaging of tobacco products, as well as the matter between Eli Lilly and the Government of Canada. Chief Justice French is concerned about the drug patent battle: ‘What did Eli Lilly want the arbitrator to do about the wayward Canadian judiciary? It wanted damages estimated in an amount of not less than \$500 million together with recovery of any payment it or its enterprises was required to make arising from the improvident loss of its patents and its inability to enforce them.’¹⁹⁶ Chief Justice French was concerned about the impact of investor-state dispute settlement upon domestic courts: ‘So far as I am aware the judiciary, as the third branch of government in Australia, has not had any significant collective input into the formulation of ISDS clauses in relation to their possible effects upon the authority and finality of decisions of Australian domestic courts.’¹⁹⁷ He suggested: ‘One approach would be to examine the possibility of including requirements in ISDS provisions in appropriate cases for: prior exhaustion of remedies in domestic courts of the Contracting State; preclusion of any challenge to the decision of a domestic court as constituting a breach of the relevant BIT or FTA provisions; and preclusion of any arbitral decision based upon a rejection of a decision on a question of law of a domestic appellate court binding on lower courts.’¹⁹⁸

A. Investor-State Dispute Settlement

¹⁹⁵ Chief Justice French, ‘Investor-State Dispute Settlement – A Cut Above the Courts?’, Supreme and Federal Courts Judges’ Conference, 9 July 2014, <http://www.hcourt.gov.au/assets/publications/speeches/current-justices/frenchcj/frenchcj09jul14.pdf>

¹⁹⁶ Ibid., 8.

¹⁹⁷ Ibid., 15.

¹⁹⁸ Ibid., 15.

There has been much concern about the inclusion of investor-state dispute settlement in the chapter on Investment in the *Trans-Pacific Partnership*. The draft text of this Chapter was revealed by WikiLeaks. The final text provides for an extensive regime dealing with investor-state dispute settlement. There has been concern that big pharmaceutical companies have deployed investor clauses against nation states over the regulation of public health. Notably, Eli Lilly has brought an investor action against the Government of Canada under the *North American Free Trade Agreement* 1994 over the rejection of its drug patents.

The release of the final text of the *Trans-Pacific Partnership* raised concerns about the relationship between intellectual property and investor-state dispute settlement. Professor Sean Flynn observed that the Investment Chapter ‘would expand the rights of private companies to challenge limitations and exceptions to copyrights, patents, and other intellectual property rights in unaccountable international arbitration forums’.¹⁹⁹ He worried: ‘The text contains broader provisions than are being used by Eli Lilly to challenge Canada’s invalidation of patent extensions for new uses of two medicines originally developed in the 1970s.’²⁰⁰ Sean Flynn observed that there were strange anomalies in the text: ‘The TPP includes a new footnote, not previously released as part of any other investment chapter and not included in the U.S. model investment text — clarifying that private expropriation actions can be brought to challenge “the cancellation or nullification of such [intellectual property] rights,” as well as “exceptions to such rights”’.²⁰¹ Flynn observed: ‘This expands the range of challenges that can be brought by companies against intellectual property limitations and

¹⁹⁹ Sean Flynn, ‘Statement on the Release of the Trans-Pacific Partnership Text’, InfoJustice.org, 5 November 2015, <http://infojustice.org/archives/35293>

²⁰⁰ Ibid.

²⁰¹ Ibid.

exceptions.’²⁰² He warned: ‘Instead of combatting the ability to bring cases such as Eli Lilly’s, the TPP’s investment chapter invites them’.²⁰³ Flynn commented: ‘Any time a national court – including in the U.S. – invalidates a wrongfully granted patent or other intellectual property right, the affected company could appeal that revocation to foreign arbitrators’.²⁰⁴ He feared: ‘The new language would also make clear that private companies are empowered by the treaty to challenge limitations and exceptions like the U.S. fair use doctrine, or individual applications of it.’²⁰⁵ Flynn concluded: ‘Adoption of this set of rules in the largest regional trade agreement of its kind would upset the international intellectual property legal system and should be subject to the most rigorous and open debate in every country where it is being considered.’²⁰⁶

B. Eli Lilly v. Canada

In its memorial, Eli Lilly contends that ‘Canada’s invalidation of the Zyprexa and Strattera patents constitutes an uncompensated expropriation, in violation of Article 1110 of NAFTA.’²⁰⁷ Furthermore, the drug company maintains that ‘Canada’s measures violate its obligations to afford “fair and equitable treatment” to Lilly’s investments under Article 1105 of NAFTA.’²⁰⁸ The company argued:

²⁰² Ibid.

²⁰³ Ibid.

²⁰⁴ Ibid.

²⁰⁵ Ibid.

²⁰⁶ Ibid.

²⁰⁷ *Eli Lilly v. Government of Canada*, Claimant’s Memorial, 29 September 2014, <http://www.italaw.com/sites/default/files/case-documents/italaw4046.pdf>

²⁰⁸ Ibid.

When Lilly made its investments in the Zyprexa and Strattera patents, it could not reasonably have expected that Canada would promulgate such a unique and arbitrary doctrine – particularly one that violates Canada’s international obligations. Lilly relied on Canada’s patent law when it sought patent protection for Zyprexa and Strattera and launched those drugs in Canada. It also relied on the Zyprexa and Strattera patents themselves, which were issued after a careful review by Canada’s patent examiners in light of Canada’s utility requirement at the time. Those expectations have been completely and radically contravened by Canada’s application of the promise utility doctrine.²⁰⁹

The company lamented: ‘When Lilly lost its patent protection for Zyprexa and Strattera, Lilly’s competitors were able to enter the market and sell copies of Zyprexa and Strattera – the very medicines that, according to the Canadian Federal Courts, were useless’.²¹⁰ The drugs company protested: ‘Lilly also lost the ability to enforce its patent rights against infringers and faced other consequences.’²¹¹ Eli Lilly threatened: ‘Under governing principles of international law, Lilly is entitled to full reparations for these damages, which are directly attributable to Canada’s breaches of Chapter 11.’²¹²

In its counter-memorial, the Government of Canada argued that this claim was ‘nothing more than an attempt by the Claimant to employ NAFTA Chapter Eleven as a vehicle to air its grievances concerning the evolution and policy orientations of Canadian patent law, which it sees as not sufficiently aligned with its own interests.’²¹³ The Government of Canada

²⁰⁹ Ibid.

²¹⁰ Ibid.

²¹¹ Ibid.

²¹² Ibid.

²¹³ *Eli Lilly v. Government of Canada*, Claimant’s Counter-Memorial, 27 January 2015,

<http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf>

observed: ‘The Tribunal in the exercise of its limited investment law jurisdiction cannot impose a substantive patent law harmonization that relevant international actors have failed to achieve.’²¹⁴ The Government of Canada called upon the investor action to be dismissed. The controversy has raised concerns about whether pharmaceutical drug companies will bring similar investor actions against nation states in the *Trans-Pacific Partnership*.

The Government of Canada has been particularly disturbed by the action brought by Eli Lilly under an investor-state dispute settlement mechanism over the rejection of drug patents. In June 2014, Canada published a statement of its defence in the Eli Lilly dispute.²¹⁵ In its preliminary statement, the Government of Canada observed:

Eli Lilly and Company (“Lilly” or “Claimant”) is a disappointed litigant. Having lost two patent cases before the Canadian courts, it now seeks to have this Tribunal misapply NAFTA Chapter Eleven and transform itself into a supranational court of appeal from reasoned, principled, and procedurally just domestic court decisions. Claimant argues that the domestic court decisions invalidating its patents are measures that violate NAFTA Chapter Eleven. Claimant does this on the basis of misstatements of the content of Canadian law and of Canada’s international obligations. Its claim is wholly without merit and should be dismissed, with full costs to Canada.²¹⁶

In its Statement of Defence, Canada provides: ‘(1) an overview in Canadian patent law, to provide context for Claimant’s misstatements regarding Canadian law on utility; (2) a description of the specific role played by the Federal Court in applying the Patent Act,

²¹⁴ Ibid.

²¹⁵ *Eli Lilly v. Government of Canada*, Statement of Defence, Defence, 30 June 2014, https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC4672_En&caseId=C3544

²¹⁶ Ibid.

establishing that the court is responsible for determining the validity and existence of the intellectual property right; (3) an outline of the facts relevant to the two court proceedings, demonstrating that Claimant received full due process and reasoned and principled decisions; and (4) brief comments on Canada's international intellectual property obligations under NAFTA Chapter Seventeen, TRIPS and the Patent Cooperation Treaty ("PCT"), confirming that these have no bearing on this case'.²¹⁷ Canada maintains that 'nothing in the two court decisions at issue in any way violates Canada's obligations under Chapter Eleven of NAFTA.'²¹⁸

There has been a public interest intervention by two public interest organisations, the Samuelson-Glushko Canadian Internet Policy and Public Interest Clinic and the Centre for Intellectual Property Policy at McGill University.²¹⁹ The legal clinics contended:

This arbitration raises important issues regarding the ability of NAFTA Parties to craft domestic patent laws that meet their unique social, economic, and legal circumstances. The Claimant's position places at issue the question of whether and to what extent NAFTA permits the continued evolution of the Parties' domestic laws and jurisprudence. This is a question of great import to the public interest. At stake is no less than the continued autonomy of each NAFTA Party to implement patent laws within its unique legal and social systems, and to permit patent law to evolve so as to respond to new technologies. This arbitration also raises questions about what NAFTA and other trade agreements have to say about the substantive content of patent law. Addressing these issues is crucial to maintaining a robust and dynamic marketplace for patented inventions. By implication, the Claimant

²¹⁷ Ibid.

²¹⁸ Ibid.

²¹⁹ 'IPPIC and the CIPP File Amicus Application in NAFTA Arbitration', Press Release, 12 February 2016, <https://cippic.ca/en/node/129424>

raises questions about the substantive content of other intellectual property laws addressed by NAFTA and by other international trade instruments.²²⁰

CIPPIC and CIPP offer four arguments that address these issues. First, the legal clinics maintain: ‘Throughout the history of Anglo-American patent law (including in Canada), courts have played a supervisory role to ensure that the State does not abuse the public by granting overly broad patents’.²²¹ In their view, ‘This is why the Courts, and not the Patent Office, have the last word on the patentability of inventions and underlying determinations of fact.’ Second, the legal clinics contend that ‘NAFTA was never intended to prescribe substantive patentability requirements that are frozen in time.’²²² The legal clinics insist: ‘Rather, Chapter 17 of NAFTA establishes minimum requirements that each Party must address in its domestic patent laws that specifically eschew a common substantive standard of patentability; how to implement NAFTA standards are up to its Member States’.²²³ Third, the legal clinics contend that ‘Trade law requires comparison of the overall effect of NAFTA Parties’ patent laws, not their individual patent rules’.²²⁴ Thus, ‘The relevant question for the Tribunal is, therefore, whether Canadian patent law overall has a different effect from that of its trading partners.’²²⁵ Fourth, the legal clinics conclude that ‘A functional comparison of Canadian, American, and Mexican patent law reveals that utility in Canadian law is functionally equivalent to (a) the United States requirements of the utility branch of

²²⁰ Ibid.

²²¹ Ibid.

²²² Ibid.

²²³ Ibid.

²²⁴ Ibid.

²²⁵ Ibid.

enablement, and (b) the Mexican requirements that an invention be capable of industrial application, have an inventive step, and be sufficiently described.’²²⁶

Professor Richard Gold and Michael Shortt have provided a comprehensive analysis of the patent issues at stake in the controversy.²²⁷

In a commentary, Professor Michael Geist from the University of Ottawa considers the controversy over the Eli Lilly dispute, Investor-State Dispute Settlement Rules, and the Canada-EU Trade Agreement.²²⁸ He concluded that ‘it may be in everyone’s interest to go back to the drawing board on CETA by eliminating ISDS altogether.’²²⁹

In June 2013, the United States-based brand name pharmaceutical drug company Eli Lilly deployed an investor clause under the *North American Free Trade Agreement* to challenge Canada’s drug patent laws.²³⁰ Eli Lilly and Company is alleging that the invalidation of its Strattera and Zyprexa pharmaceutical patents under Canadian patent law is inconsistent with Canada’s commitments under the *North American Free Trade Agreement*. Eli Lilly alleged:

²²⁶ Ibid.

²²⁷ E. Richard Gold and Michael Shortt, ‘The Promise of the Patent in Canada and Around the World’, (2014) 30 Canadian Intellectual Property Review 35
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2361146

²²⁸ Professor Michael Geist, ‘Crumbling CETA Investor-State Dispute Settlement Rules Threaten to Take Down the Canada-EU Trade Agreement’, the University of Ottawa, 28 July 2014,
<http://www.michaelgeist.ca/2014/07/crumbling-ceta-investor-state-dispute-settlement-rules-threaten-to-take-canada-eu-trade-agreement/>

²²⁹ Ibid.

²³⁰ *Eli Lilly and Company v. Government of Canada* (2013) <http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng>

Canada, through its own actions and through the actions of the Canadian courts, is responsible for measures inconsistent with its commitments under NAFTA Chapter Eleven, including without limitation: (1) the Judge-made law on utility (the ‘promise doctrine’) according to which the Canadian Courts have invalidated the Strattera and Zyprexa Patents; (2) the failure of the Government of Canada to rectify the Judge-made law on utility in a manner that is consistent with Canada’s treaty obligations; and (3) Canada’s incorporation of the Judge-made law on utility into Canadian law. These measures breach Canada’s investment obligations under Article 1110 (Expropriation and Compensation), as well as Articles 1105 (Minimum Standard of Treatment) and 1102 (National Treatment).

The exclusive rights conferred by the Strattera and Zyprexa Patents constitute intangible property acquired in the expectation or used for the purposes of economic benefit or other business purposes. By reason of Canada’s breach of its investment obligations, Eli Lilly and Company, an investor of a Party, has incurred damages in relation to its investments. Lilly must be compensated for Canada’s failure to comply with its NAFTA Chapter Eleven obligations.²³¹

This is a disturbing action – particularly because Canada has a well-developed patent system. The Supreme Court of Canada – renowned for expertise in intellectual property law – has carefully delineated the threshold standard of utility under patent law.

Mike Masnick at *TechDirt* has been incredulous at the demands of Eli Lilly for a half-a-billion dollars in respect of the action against Canada:

The Canadian court reasonably felt that it shouldn't give Eli Lilly a patent on something that wasn't determined to be useful. Normally, if a country doesn't give you a patent, you move on. However, Eli Lilly used a questionable part of NAFTA, the so-called investor-state dispute resolution mechanism, to

²³¹ ‘Notice of Intent to submit a Claim to Arbitration under NAFTA Chapter Eleven’ in *Eli Lilly and Company v. Government of Canada* (2013) <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-02.pdf>

argue that Canada was ‘expropriating its property,’ and thus demanded compensation -- starting at \$100 million, which it then raised to \$500 million.

A few weeks ago, Eli Lilly's CEO wrote an op-ed piece, claiming that by not granting his company a monopoly, Canada was ‘suffocating life-saving innovation.’ That's wrong. And it's obnoxious. For years we've covered how the pharmaceutical industry has actually used patents to hold back life-saving innovations by locking them up, blocking advances, jacking up the price to absolutely insane rates, and by using a variety of other questionable practices (including patenting historical folk medicines). But, more importantly, every country gets to determine what is and what is not patentable. For Eli Lilly to use *trade policies* to effectively try to negate Canada's patent validity standards is a blatant attack on Canadian sovereignty.²³²

Glyn Moody comments that the case has disturbing implications: ‘As this makes clear, what started out as a series of measures for a few special cases in order to protect Western companies in countries with weak legal systems and a high risk of tangible investments being expropriated by the state, has been twisted to an entirely different use: enabling deep-pocketed multinationals to circumvent any kind of legislation they don't like, even in countries with fair and independent judiciaries.’²³³

Professor Richard Gold of McGill University is critical of the Eli Lilly action: ‘I believe they are fighting this to satisfy their shareholders.’²³⁴ He commented:

²³² Mike Masnick, ‘Eli Lilly Officially Sues Canada for “Lost Profits” because Canada Rejected Eli Lilly’s Patents’, *TechDirt*, 13 September 2013, <https://www.techdirt.com/articles/20130913/11204224509/eli-lilly-officially-sues-canada-because-canada-rejected-patent-that-unfairly-diminishes-eli-lillys-profits.shtml>

²³³ Glyn Moody, ‘How Investor-State Dispute Resolution Threatens Access to Medicines, and Much Else’, *TechDirt*, 9 May 2013, <https://www.techdirt.com/articles/20130505/02445622949/how-investor-state-dispute-mechanisms-threaten-access-to-medicine-much-else.shtml>

²³⁴ Marc-Andre Seguin, ‘The \$500-million Doctrine’, *National Magazine*, September-October 2013, [http://www.nationalmagazine.ca/Articles/Sept-Oct-2013/The-\\$500-million-doctrine.aspx](http://www.nationalmagazine.ca/Articles/Sept-Oct-2013/The-$500-million-doctrine.aspx)

There is no such thing as an international concept of utility. Everything points to the ability of the states to do what they want. Legally, they have no case, not under NAFTA and not under TRIPS [Agreement on trade-related aspects of intellectual property rights]. Neither cover this issue.²³⁵

According to Gold, Eli Lilly was trying to set a political precedent. ‘Canada represents two to three per cent of the world market. The company has to appease its shareholders, and it has to try to prevent other countries from following Canada’s lead and developing a doctrine that goes against its interests.’²³⁶

In a systematic piece of analysis, ‘Sovereignty Under Siege’, Professor Cynthia Ho has explored corporate challenges to domestic intellectual property decisions. Cynthia Ho observed: ‘Eli Lilly’s case against Canada exposes important policy problems with permitting investors to use investor-state arbitrations to challenge domestic intellectual property decisions’.²³⁷ She commented: ‘Although a tribunal should deny Eli Lilly’s claims, investor-state tribunals often make broad and unpredictable rulings’.²³⁸ She was worried about the larger implications of investor actions for public health: ‘Moreover, even if a panel rules properly, public health may still be compromised if other companies follow Eli Lilly’s lead in challenging other domestic decisions concerning intellectual property rights.’²³⁹

²³⁵ Ibid.

²³⁶ Ibid.

²³⁷ Cynthia Ho, ‘Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions’ (2015) *Berkeley Technology Law Journal* 214-304 at 303 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2480202

²³⁸ Ibid.

²³⁹ Ibid.

C. Access to Essential Medicines

There is a concern that the investor-state dispute settlement regime in the *Trans-Pacific Partnership* could be deployed to challenge public health measures, and reforms to the patent system designed to combat problems such as drug pricing, and evergreening.

In 2013, Professor Brook Baker from the Northeastern University School of Law provided an analysis of the danger of investment clauses to access to medicines.²⁴⁰ He commented: ‘Although access to medicines activists have been wise to focus our attention intently on convincing low- and middle-income countries to adopt and use all possible TRIPS-compliant flexibilities and to oppose the TRIPS-plus IP chapters in free trade agreements, we have neglected to interrogate another chapter in free trade agreements and bilateral investment treaties that perhaps pose an even greater threat to our collective access to medicines – investment chapters.’²⁴¹ Baker highlighted the threat posed investor-state dispute settlement to access to essential medicines:

Under investment chapters, foreign IP investors, like Novartis and Bayer, are recognized as ‘investors’ who have made ‘investments’ involving expenditures and expectations of profit [xv]. Suddenly intellectual property rights, already hugely protected, are given another mantle of protection, namely protections as investments. In addition, investors are given rights to bring claims for private arbitration directly against governments whenever their expectations of IP-based profits are frustrated by government decisions and policies. Decisions of these private arbitral tribunals consisting of three

²⁴⁰ Brook Baker, ‘Investors’ IP Rights Unbound: The Danger of Investment Clauses to Access to Medicines’, *Equilibri*, GESPAM, 24 April 2013, <http://www.equilibri.net/nuovo/articolo/investors%E2%80%99-ip-rights-unbound-danger-investment-clauses-access-medicines>

²⁴¹ Ibid.

international trade lawyers are not subject to judicial review, but are reducible into court judgments that can be levied against government property.²⁴²

Professor Brook Baker recommends: ‘Preferably, investment chapters will be rejected in their entirety, as they are becoming a corporate sword of Damocles that hangs over the head of rich and poor governments alike’.²⁴³ He insists: ‘At the very least, IP should be totally defined out of “investments” and no investor claims whatsoever should be available for alleged frustration of IP-based expectations.’²⁴⁴ Professor Brook Baker makes the excellent point that ‘IP right holders already have multiple forms of enforcement including private lawsuits, border seizures, criminal prosecution, and state-state dispute resolution.’²⁴⁵ He insists that ‘Expanded and unbound investment rights for Big Pharma under the cover of under-scrutinized investment chapters is a grave threat – a threat with deadly consequences to millions of patients who rely on governments’ rights to regulate IPRs and to use any and all TRIPS-compliant flexibilities to ensure affordable access to medicines for all.’²⁴⁶

Professor Brook Baker insists: ‘At the very least, IP should be totally defined out of ‘investments’ and no investor claims whatsoever should be available for alleged frustration of IP-based expectations.’²⁴⁷ Professor Brook Baker makes the excellent point that ‘IP right

²⁴² Ibid.

²⁴³ Ibid.

²⁴⁴ Ibid.

²⁴⁵ Ibid.

²⁴⁶ Ibid.

²⁴⁷ Brook Baker, ‘Investors’ IP Rights Unbound: The Danger of Investment Clauses to Access to Medicines’, *Equilibri*, GESPAM, 24 April 2013, <http://www.equilibri.net/nuovo/articolo/investors%E2%80%99-ip-rights-unbound-danger-investment-clauses-access-medicines>

holders already have multiple forms of enforcement including private lawsuits, border seizures, criminal prosecution, and state-state dispute resolution.²⁴⁸

In March 2014, UNITAID published its full report upon the *Trans-Pacific Partnership*, highlighting implications for access to medicines and public health.²⁴⁹

The report singled out the proposed Investment Chapter for extensive criticism: ‘The proposal of the USA on investment demonstrates a high degree of similarity to the investment chapter in the *North American Free Trade Agreement* (NAFTA), which has been criticized for restrictions on the regulation of corporations and the grant of broad-ranging rights which, inter alia, permit investors to seek compensation for domestic rules that they claim undermine their investments.’²⁵⁰

UNITAID identifies the overly-broad definition of investment as a problem in its analysis of the *Trans-Pacific Partnership*:

The investment chapter starts with Article 12.2 which defines the terms used in the chapter. Key terms include ‘investment’, ‘investor’ and ‘covered investment’. ‘Investment’ is defined broadly, going well beyond the ‘bricks and mortar’ definition of property and covering any asset owned or controlled directly or indirectly by an investor, whose characteristics include a ‘commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk’. The definition also includes a non-exhaustive list of the forms such investments may take, including intellectual property rights,

²⁴⁸ Ibid.

²⁴⁹ UNITAID, *The Trans-Pacific Partnership: Implications for Access to Medicines and Public Health*, Geneva: World Health Organization, 2014, http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf

²⁵⁰ Ibid., 10.

licences and permits, as well as debt securities and loans, futures, options and other derivatives. The effect of such a broad definition of ‘investment’ would be that parties will be required to protect all such forms of investment within their territories; failure to do so would lay them open to the risk of a dispute by the affected investor. Intellectual property rights are specified as a form of investment under Article 12.2(g), and this covers all forms of intellectual property rights. Article 12.2(g) also includes, in brackets, the words ‘which are conferred pursuant to domestic laws of each Party’. It is unclear whether the text in brackets would significantly affect the definition, since intellectual property rights are in fact conferred under domestic laws. The definition of ‘investor’ is similarly expansive—merely ‘attempting’ to make an investment by a concrete action suffices to qualify one as an investor.²⁵¹

This analysis highlights how the *Trans-Pacific Partnership* will protect a panoply of foreign investments.

The report highlighted three main areas of concern about the impact of the Trans-Pacific Partnership’s investment chapter upon public health.

First, UNITAID noted that ‘the provisions of the proposed investment chapter of the TPPA provide expansive rights and privileges to foreign investors, with the obligation on governments to provide protection of such rights’.²⁵² UNITAID warned: ‘The limitation on “performance requirements” can prevent governments from imposing conditions on the conduct of foreign companies, even when those conditions are imposed in the interest of protecting public health and promoting access to medicines.’²⁵³ UNITAID illustrated its

²⁵¹ UNITAID, *The Trans-Pacific Partnership: Implications for Access to Medicines and Public Health*, Geneva: World Health Organization, 2014, http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf, 86.

²⁵² Ibid., 10.

²⁵³ Ibid., 10.

point: ‘For example, it may be a contravention of the proposed TPPA provisions if a government were to require that a foreign pharmaceutical company should ensure a domestic supply (whether through import or production) of a minimum quantity of active pharmaceutical ingredients.’²⁵⁴

Second, UNITAID worried that ‘the proposed investment chapter combines strong investors’ rights and a broad scope of protection with an investor-state dispute settlement mechanism, which provides the “teeth” for enforcement of obligations.’²⁵⁵ UNITAID warned: ‘The investor-state dispute settlement, however, would allow for the possibility that investors could sue a government with respect to intellectual property and regulatory issues pertaining to medicines.’²⁵⁶ UNITAID expands upon its analysis:

As already noted above, intellectual property rights are defined as investments within the investment chapter of the TPPA, thus implying that a government measure that affects the intellectual property holdings of investors may be considered an ‘expropriation’ or a withholding of ‘fair and equitable treatment’. The disputes over tobacco packaging regulations focus on the investor’s claim that its trademarks have been infringed. In the context of access to medicines, defining investment as including intellectual property rights would raise concerns about the ability of governments to implement and use the range of TRIPS flexibilities, many of which could be seen as limitations or restrictions of the exclusive rights granted under a patent. Although Article 12.12(5) states that the use of compulsory licensing does not constitute an expropriation where the compulsory licence is granted ‘in accordance with the TRIPS Agreement’, this may still leave room for investor corporations to challenge the compulsory licence using the ISDS on the grounds that it does not comply with TRIPS. [164] Article 12.12(5) also has text, in brackets, specifying that ‘the revocation, limitation, or creation of intellectual

²⁵⁴ Ibid., 10.

²⁵⁵ Ibid., 10.

²⁵⁶ Ibid., 10.

property rights’ would not be considered expropriation when consistent with the intellectual property chapter of the TPPA. Even if this text were to be accepted, this exemption might be of only limited effect since the proposed text of the intellectual property chapter of the TPPA leaves little room for revocation or limitation of intellectual property rights.²⁵⁷

UNITAID noted that ‘only WTO members (i.e. governments) may challenge each other for non-compliance with TRIPS or any other WTO agreements’.²⁵⁸ The organisation was worried that ‘the ISDS would allow for the possibility that an investor could sue a government on the grounds that the use of compulsory licensing (or another TRIPS flexibility) is in violation of both the provisions of the investment chapter (because of adverse effects on investment) and the provisions of the TRIPS Agreement.’²⁵⁹ UNITAID warns: ‘Such a course of action would effectively create a TRIPS-plus or WTO-plus forum in which corporations could challenge governments on the implementation of the TRIPS Agreement on the grounds of its effect on investors’ rights.’²⁶⁰

Third, UNITAID observed that ‘it is important to note that the jurisdiction of arbitration tribunals is defined by the provisions of the relevant investment treaty’.²⁶¹ UNITAID commented: ‘Typically, these provisions do not impose obligations on the arbitrators to take into account in their decision-making the constitutional obligations of governments or even human rights considerations.’²⁶²

²⁵⁷ Ibid., 89.

²⁵⁸ Ibid., 89.

²⁵⁹ Ibid., 89.

²⁶⁰ Ibid., 89.

²⁶¹ Ibid. 10.

²⁶² Ibid. 10.

In conclusion, UNITAID warns that the investment chapter of the *Trans-Pacific Partnership* could have a chilling effect on government regulations:

A key lesson that can be learned from the rising numbers of investor-state disputes with exorbitant compensation awards is that they may have a ‘chilling effect’ on government regulations. Regardless of the robustness of the legal basis of investor challenges, the risk of legal suits on the interpretations of strong investor rights, coupled with the ability of private international arbitration tribunals to award large compensation amounts, may now cause governments to be cautious when making policy or law that affects investor rights. This situation can expose governments to vast liabilities, since investor-state tribunals can have enormous discretion in awarding compensation amounts, which is a serious concern for developing countries with limited resources, particularly where this may mean the diversion of budgetary resources from meeting public interest and public health needs in the country.²⁶³

Belinda O’Donnell has expressed similar concerns in 2016, writing for the Harvard T.H. Chan School of Public Health.²⁶⁴ She observed: ‘The fight to make antiretroviral therapy accessible was not an easy one, and as a result, international norms around intellectual property, trade, and global health should be consistently moving towards greater flexibility.’²⁶⁵ O’Donnell said: ‘That does not appear to be the case with the TPP.’²⁶⁶ She suggested: ‘The anxieties aggravated by the signing of the *Trans-Pacific Partnership* 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

²⁶³ Ibid.

²⁶⁴ Belinda O’Donnell, ‘HIV and the TPP’, Harvard T.H. Chan School of Public Health, 24 February 2016, <http://aids.harvard.edu/hiv-and-the-tpp/>

²⁶⁵ Ibid.

²⁶⁶ Ibid.

requirement that these drugs are made accessible to those that depend on them for their wellbeing or survival?’ In her view, ‘When considering the TPP from a global health perspective, it is essential to ask if the agreement has managed to strike that balance.’²⁶⁷

United States Representative Raul M. Grijalva – co-chair of the Congressional Progressive Caucus, and Peter Maybarduk – have been concerned about the implications of the *Trans-Pacific Partnership* for access to essential medicines.²⁶⁸ Grijalva and Maybarduk warn that: ‘Trade agreements have become a favorite tool for corporations and their lobbyists to get what they want when Congress -or any country's deliberative body - rejects their arguments.’²⁶⁹ The pair emphasized:

According to the Sunlight Foundation, pharmaceutical company lobbying reports mentioned TPP 251 times in a recent four-year period, far more than any other industry. That money has paid off: the U.S. Trade Representative seems to be taking Big Pharma's line. Doctors Without Borders calls TPP the ‘worst trade deal ever’ for access to medicines. The Vatican, the American Medical Association and AARP, among many other organizations, have raised serious concerns about the damage it would certainly do to public health.²⁷⁰

The pair commented: ‘The TPP is a bad deal for taxpayers, for doctors and for everyone who believes in corporate transparency’.²⁷¹ The United States Congressman and the expert on

²⁶⁷ Ibid.

²⁶⁸ Representative Raul Grijalva and Peter Maybarduk, ‘the Trans-Pacific Partnership is terrible for Public Health’, *The Huffington Post*, 8 April 2014, http://www.huffingtonpost.com/raul-m-grijalva/the-trans-pacific-partner_b_5111792.html

²⁶⁹ Ibid.

²⁷⁰ Ibid.

²⁷¹ Ibid.

access to medicines warned: ‘If rammed through Congress via fast-track trade authority, which doesn't allow Congress to offer any amendments, it will lead to lost jobs and lost lives.’²⁷²

D. The Final Text

The final text of the Investment Chapter of the *Trans-Pacific Partnership* still contemplates intellectual property owners being able to invoke investor-state dispute settlement. The definition of ‘investment’ specifically includes intellectual property rights.

Professor Brook Baker remains concerned that the Investment Chapter grants additional and exceptional enforcement powers to intellectual property rights-holders.²⁷³ He comments:

The TPP’s Investment Chapter greatly expands the enforcement rights of foreign pharmaceutical companies, creating substantial risks to countries’ ability to set IP-related policy and to render IP decisions. The Investment Chapter unequivocally defines IP rights as “investments.” It prohibits the following: (1) discrimination against foreign IP investors, (2) unfair and inequitable treatment, and (3) indirect expropriation. More pointedly, it allows ISDS claims directly against governments before unreviewable three-person arbitration panels, even when judicial remedies have not been exhausted or when companies have lost on appeal. Foreign investors can bring ISDS claims that domestic investors cannot. Moreover, companies might claim—correctly or not—a lack of fair and equitable treatment that undermines their well-grounded expectations of profit with respect to many health-related regulatory and judicial decisions, including the following: denials or revocations of pharmaceutical

²⁷² Ibid.

²⁷³ Brook Baker, ‘Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere’ (2016) 13 (3) *Public Library of Science Medicine* 13(3): e1001970. doi:10.1371/journal.pmed.1001970

patents; granting of compulsory licenses; denials or restrictions on marketing rights; refusals to list excessively priced, IP protected products for reimbursement; decisions to establish price controls; and required disclosure of clinical trial data. Foreign companies might claim indirect expropriation following changes in regulatory environments, including changes designed to promote public health.²⁷⁴

Baker predicts: ‘TPP member states can expect an avalanche of IP-related claims from disappointed pharmaceutical companies that think their legitimate expectations of future profits have been thwarted by foreign governments’ IP decisions or policies.’²⁷⁵

The final text of the Investment Chapter of the *Trans-Pacific Partnership* does contain some specific language upon access to essential medicines. Article 9.7 deals with expropriation and compensation. Article 9.7.5 provides: ‘This Article shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights in accordance with the *TRIPS Agreement*, or to the revocation, limitation or creation of intellectual property rights, to the extent that the issuance, revocation, limitation or creation is consistent with Chapter 18 (Intellectual Property) and the *TRIPS Agreement*.’²⁷⁶

Article 9.9 of the Investment Chapter contains some exemptions. Article 9.9.3 provides: ‘(a) Nothing in paragraph 2 shall be construed to prevent a Party from conditioning the receipt or continued receipt of an advantage, in connection with an investment of an investor of a Party or of a non-Party in its territory, on compliance with a requirement to locate production, supply a service, train or employ workers, construct or expand particular facilities, or carry out

²⁷⁴ Ibid.

²⁷⁵ Ibid.

²⁷⁶ Article 9.7.5 of the *Trans-Pacific Partnership* <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

research and development, in its territory. (b) Paragraphs 1(f), 1(h) and 1(i) shall not apply: (i) if a Party authorises use of an intellectual property right in accordance with Article 31 of the *TRIPS Agreement*, or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the *TRIPS Agreement*; or (ii) if the requirement is imposed or the commitment or undertaking is enforced by a court, administrative tribunal or competition authority to remedy a practice determined after judicial or administrative process to be anticompetitive under the Party's competition laws.²⁷⁷

Article 9.11 deals with non-conforming measures. Article 9.11.5 provides '(a) Article 9.4 (National Treatment) shall not apply to any measure that falls within an exception to, or derogation from, the obligations which are imposed by: (i) Article 18.A.9 (General Provisions National Treatment); or (ii) Article 3 of the TRIPS Agreement, if the exception or derogation relates to matters not addressed by Chapter 18 (Intellectual Property). (b) Article 9.5 (Most-Favoured-Nation Treatment) shall not apply to any measure that falls within Article 5 of the TRIPS Agreement, or an exception to, or derogation from, the obligations which are imposed by: (i) Article 18.A.9 (General Provisions National Treatment); or (ii) Article 4 of the *TRIPS Agreement*.'²⁷⁸

Such exceptions or limitations are expressed in quite convoluted language. There could be much future debate and disputation over the meaning and scope of such provisions.

²⁷⁷ Article 9.9.3 of the *Trans-Pacific Partnership* <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

²⁷⁸ Article 9.11.5 of the *Trans-Pacific Partnership* <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

In addition to some express language dealing with access to essential medicines, there is more general language in respect of exceptions to investor-state dispute settlement in respect of public health. Article 9.15 provides: ‘Nothing in this Chapter shall be construed to prevent a Party from adopting, maintaining or enforcing any measure otherwise consistent with this Chapter that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental, health or other regulatory objectives.’²⁷⁹ There will obviously a lot of debate over the scope of such exceptions. The history of international trade law has been that such provisions have been read down in a limited fashion.

²⁷⁹ Article 9.15 of the *Trans-Pacific Partnership* <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>

5. The Health ‘Transparency’ Annex

In 2015, WikiLeaks revealed a draft ‘Transparency for Health’ Annex of the *Trans-Pacific Partnership*.²⁸⁰ Dr Deborah Gleeson of La Trobe University observed that the Annex is ‘clearly intended to cater to the interests of the pharmaceutical industry’.²⁸¹ In her view, the deal did not nothing to promote high-quality healthcare or free trade. Professor Jane Kelsey of the University of Auckland commented that ‘this “transparency” Annex seeks to erode the processes and decisions of agencies that decide which medicines and medical devices to subsidise with public money and by how much.’²⁸² She highlighted the significant implications of the regime for New Zealand’s Pharmaceutical Management Agency (Pharmac). Likewise, Peter Maybarduk of Public Citizen was concerned that the pact could expose Medicare in the United States to attacks by pharmaceutical companies.²⁸³ He was also concerned that the agreement would ‘limit Congress’ ability to enact policy reforms that would reduce prescription drug costs for Americans.’²⁸⁴

²⁸⁰ WikiLeaks, ‘‘Transparency for Health’ Annex of the *Trans-Pacific Partnership*’, 10 June 2015, <https://wikileaks.org/tpp/healthcare/>

²⁸¹ Deborah Gleeson, ‘The Trans Pacific Partnership’s Healthcare Transparency Annex: Commentary on the Leaked TPP Transparency Chapter Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices Dated December 17, 2014 and released by WikiLeaks in June 2015’, WikiLeaks, 10 June 2015, <https://wikileaks.org/tpp/healthcare/Analysis-Dr-Deborah-Gleeson/page-1.html>

²⁸² Jane Kelsey, ‘The Trans-Pacific Partnership Agreement: Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices’, WikiLeaks 10 June 2015, <https://wikileaks.org/tpp/healthcare/Analysis-Professor-Jane-Kelsey/page-1.html>

²⁸³ Peter Maybarduk, ‘Latest TPP Leak Raises Burning Questions About Implications for U.S. Health Care System’, *Public Citizen*, 10 June 2015, <https://wikileaks.org/tpp/healthcare/Statement-Public-Citizen/page-1.html>

²⁸⁴ Ibid.

Dr Deborah Gleeson has provided an analysis of the final ‘Healthcare Transparency Annex’ of the *Trans-Pacific Partnership*.²⁸⁵ She comments:

The intent of Annex 26-A of the *Trans Pacific Partnership Agreement* (TPP) is to discipline national pricing and reimbursement schemes for pharmaceutical products and medical devices. While the language of the Annex is framed around principles of transparency and fairness, the objectives of the pharmaceutical and medical device industries clearly go much further than this. The ultimate objective of the industry is expanded market access at monopoly prices dictated by industry: the target is mechanisms that impact on both market access and prices. The Annex was intended to achieve this objective through greater disclosure of information, greater industry participation, and ultimately more leverage for the industry in decision making regarding pricing, reimbursement and other decisions that impact on market share, such as the range of therapeutic indications for which a product is subsidised.²⁸⁶

In her view, the language of the Annex was watered down through successive revisions during the negotiations over the *Trans-Pacific Partnership*.

Professor Brook Baker was disturbed by the final text of the Transparency Chapter on Pharmaceuticals and Medical Devices, arguing that it increased the industry’s role in medical

²⁸⁵ Deborah Gleeson, ‘Preliminary Analysis of the Final TPP Healthcare Transparency Annex: Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices’, Latrobe University, 12 December 2015, <http://infojustice.org/wp-content/uploads/2015/12/Gleeson-Preliminary-Analysis-Transparency-Annex-12-Dec-2015-1.pdf>

²⁸⁶ Ibid.

reimbursement listings.²⁸⁷ He commented: ‘In the Transparency Chapter Annex addressing transparency and procedural fairness for pharmaceutical products and medical devices, companies are given multiple opportunities to intercede in decisions to list products for reimbursement’.²⁸⁸ Baker observed that ‘these interventions could result in more listings of higher-priced medicines even in the absence of convincing evidence of added therapeutic value’.²⁸⁹ He warned: ‘Under the Pharmaceutical Product and Medical Device Transparency Annex, companies will have multiple chances to influence pharmaceutical/medical-device listing decisions, to scrutinize resulting decisions, and to challenge decisions previously rendered’.²⁹⁰ Baker feared: ‘These multiple inputs can result in more listings, higher prices, and higher administrative costs for affected countries’.²⁹¹ He commented: ‘The Transparency Chapter also gives other countries direct opportunities to complain about individual listing decisions, patterns and practices of decisions, and decision-making criteria and processes.’²⁹²

Summing up, Professor Brook Baker found: ‘IP maximization in the TPP will harm access to more affordable medicines in both the US and its trading partners’.²⁹³ He stressed: ‘Policy space on both sides of the Pacific will be reduced while opportunities for excessive pricing

²⁸⁷ Brook Baker, ‘Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere’ (2016) 13 (3) *Public Library of Science Medicine* 13(3): e1001970. doi:10.1371/journal.pmed.1001970

²⁸⁸ Ibid.

²⁸⁹ Ibid.

²⁹⁰ Ibid.

²⁹¹ Ibid.

²⁹² Ibid.

²⁹³ Ibid.

will increase dramatically with predictable adverse consequence for the right to health.’²⁹⁴ Professor Brook Baker observed: ‘Armed with knowledge about the details of the TPP’s anti-access provisions, there is still time for health advocates to convince the US Congress and TPP partners that the TPP’s monopoly-enhancing measures must be rejected.’²⁹⁵

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. The Health Annex provides procedural rights to private health companies in respect of government decision-making. The Competition Chapter does little to protect patients, consumers, and citizens in respect of the pricing of medical and pharmaceutical products. The *Trans-Pacific Partnership* provides for inadequate protection in respect of access to essential medicines.

The World Health Organization has been conscious of the challenge posed by mega-regional agreements such as the *Trans-Pacific Partnership* to global public health. Addressing the UN Economic and Social Council, Dr Margaret Chan was concerned about the impact of private

²⁹⁴ Ibid.

²⁹⁵ Ibid.

stakeholders upon public health.²⁹⁶ She warned: ‘The 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.’²⁹⁷ Chan observed: In 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’.²⁹⁸ She worried: ‘The vital role of government in protecting the public interest is diminished.’²⁹⁹ Chan commented: ‘In one especially alarming trend, provisions for the settlement of investor-state disputes are being used to handcuff governments and restrict their policy space’.³⁰⁰ She concluded: ‘When private economic operators have more say over domestic affairs than the policies of a sovereign government, we need to be concerned.’³⁰¹

In May 2014, Dr Margaret Chan reiterated such concerns in an address to the Sixty-Seventh World Health Assembly.³⁰² She observed: ‘International trade has many consequences for health, both positive and negative’.³⁰³ Chan was worried: ‘One particularly disturbing trend is the use of foreign investment agreements to handcuff governments and restrict their policy

²⁹⁶ Margaret Chan, ‘The Changing Development Landscape: What Will It Mean for Specialized Agencies in a Post-2015 Era with Focus on Sustainable Development’, UN Economic and Social Council, 25 February 2014, <http://www.who.int/dg/speeches/2014/economic-social-council/en/>

²⁹⁷ Ibid.

²⁹⁸ Ibid.

²⁹⁹ Ibid.

³⁰⁰ Ibid.

³⁰¹ Ibid.

³⁰² 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, <http://www.who.int/dg/speeches/2014/wha-19052014/en/>

³⁰³ Ibid.

space.’³⁰⁴ She noted: ‘Some Member States have expressed concern that trade agreements currently under negotiation could significantly reduce access to affordable generic medicines.’³⁰⁵ She observed: ‘If 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?’³⁰⁶

In a speech to Georgetown University in Washington DC on the 30th September 2015, Dr Margaret Chan expressed concern about the threat posed by corporate power to public health.³⁰⁷ The speech took place just before the conclusion of the negotiations to the *Trans-Pacific Partnership* in Atlanta. Chan observed: ‘The newer threats to health also lie beyond the traditional domain of sovereign nations accustomed to governing what happens in their territories’.³⁰⁸ Chan noted: ‘In a world of radically increased interdependence, all are transboundary threats.’³⁰⁹ She noted: ‘Some multinational corporations can be another transboundary threat’.³¹⁰ Chan warned that mechanisms for settling investor-state disputes are being used to sue governments for public health policies. Chan stressed: ‘What is at stake

³⁰⁴ Ibid.

³⁰⁵ Ibid.

³⁰⁶ Ibid.

³⁰⁷ Margaret Chan, ‘Governance: Global Health’s 21st Century Challenge’, Global Futures Initiative, Georgetown University, Washington DC, USA, 30 September 2015, <http://www.who.int/dg/speeches/2015/georgetown-university-lecture/en/>

³⁰⁸ Ibid.

³⁰⁹ Ibid.

³¹⁰ Ibid.

here is nothing less than the sovereign right of a nation to enact legislation that protects its citizens from harm.³¹¹

In a speech the following month, in October 2015, Dr Margaret Chan highlighted her concerns about trade and public health at a joint technical symposium on public health, intellectual property, and TRIPS at 20.³¹² She focused upon 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 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.³¹³

Chan said that access to essential medicines raised larger issues in respect of equality, fairness and development. She posed the question: 'For public health, 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?'³¹⁴ Chan stressed: 'The overarching objective of the agenda

³¹¹ Ibid.

³¹² 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, <http://who.int/dg/speeches/2015/intellectual-property-trips/en/>

³¹³ Ibid.

³¹⁴ Ibid.

for sustainable development is to put the world's poor and vulnerable populations first, not last.³¹⁵ She called for the fair and equitable interpretation and implementation of trade agreements affecting intellectual property and public health.

³¹⁵ Ibid.