

Negotiating Tactics, Tradeoffs, and Intellectual Property Politics:
Chile and Malaysia in the Trans-Pacific Partnership

Submitted for the Degree of Doctor of Philosophy

by

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Abbreviations

ASEAN	Association of Southeast Asian Nations
CPTPP	Comprehensive and Progressive Trans-Pacific Partnership
GNI	Gross National Income
IP	intellectual property
ISDS	Investor-State Dispute Settlement
RCEP	Regional Comprehensive Economic Partnership
TPP	Trans-Pacific Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UMICs	upper middle-income countries
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Abstract

Decisions on tradeoffs in trade negotiations, or decisions made to procure a win-set for a country, do not occur in a silo – rather they occur in a complex interacting web of political-economic factors. This is especially applicable to pharmaceutical intellectual property (IP), where countries often have to consider tradeoffs between public health, commercial interests, public security, and market access, and where there is notable historical controversy. When a 12-year period of exclusivity for biologics, basically a long monopoly period for a new (expensive) class of medications engineered from living organisms, was proposed by the United States in the Trans-Pacific Partnership (TPP), negotiating parties of differing income levels were reluctant and/or opposed to incorporating these IP provisions. Where there is a deadlock, the opposing side may offer market access or other benefits to force a concession. A number of political-economic factors may play into this, including previous relationships between the two nations, the formation of a coalition, and power dynamic. And while scholarly literature has described the diminishing hegemony of the United States, examining this power dynamic in the context of the TPP and associated negotiation tactics, and in particular as regards two upper middle-income countries (UMICs), Chile, and Malaysia, fills a gap in literature on trade-related IP. A couple of political-economic factors make this case study significant; including that UMICs, despite their higher GNI per capita, cannot often sustainably afford the price tags attached to biologic drugs, and that they may have established more diversified economic dependence, reducing the need for concessions in some areas solely for market access to the United States or membership of the TPP. Drawing upon the testimonials of trade negotiators, government officials, and civil society, this thesis analyses tactics utilised by UMIC negotiators when faced with biologics tradeoffs, and formulates lessons for other developing countries.

(300 words)

Chapter 1

The mega-regional trade agreement, upper middle-income countries, and intellectual property politics: an introduction

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I. Introduction

This thesis concerns the decisions of Chilean and Malaysian negotiators in considering tradeoffs for biologics market exclusivity. It is focused on biologics negotiations specifically because it was publicly known that there was a negotiation deadlock on this issue in particular. Where there is a deadlock, the opposing side may offer market access or other benefits to force a concession. A number of political-economic factors may play into this, including previous relationships between the two nations, the formation of a coalition, and power

dynamic. In other words, this thesis is centred on the prowess, predilections, and psyche of these negotiators, i.e. their negotiating capacity, the mandates given to them, and whether, in the face of U.S. demands on biologics exclusivity, those mandates were easily changed, and for what those mandates were changed. In considering this, I will examine what domestic and international political economy factors influenced their decision-making on intellectual property.

The decisions of trade negotiators are influenced by a number of political and economic factors, including the entrenchment of a particular economic ideology or tradition, pressure from industry players, and geopolitical strategic considerations, such as security.¹ These decisions are negotiated in the context of tradeoffs – for example, if we gain market access into the United States for agricultural produce, what is expected of us in terms of purchases of American military equipment, or less tangible tradeoffs, such as, we would like to be invited to the next G7 summit and position ourselves as middle powers – would making more concessions in this trade agreement to achieve this particular non-monetary goal be worth the ire of domestic stakeholders? Understanding why negotiators make decisions cannot occur without a political-economy lens through which to analyse their decision-making processes.

In order to understand what political-economic factors affected the negotiations, it would first be necessary to define what ‘political economy’ is. A basic definition, as posited by Drazen, is that political economy ‘is concerned with how politics will affect economic choices in a society’² and goes on to elaborate that politics in this is defined as the study of power and authority, i.e. the ability of an individual or group to achieve outcomes which reflect his objectives.³ Power, on the other hand, is defined by Weber as ‘the probability that an actor in a social relationship will be in a position to carry out his own will despite resistance, regardless of the basis on which this probability rests.’⁴ In order to assess this probability, Drazen suggests the asking of several questions, including ‘how do individuals, classes, or groups within a larger society gain power or authority to attempt to have the societal choice reflect their preferred course of action’.⁵ Susan Strange cautions that the international political economy is multidimensional, and that players are not ‘motivated by precise and singular goals’ and that it is *structural power*⁶ that decides outcomes,⁷ notably security, production, finance, knowledge, but also the

¹ Wendy L Hansen and Thomas J Prusa, ‘The Economics and Politics of Trade Policy: An Empirical Analysis of ITC Decision Making’ (2002) 5(2) *Review of International Economics* 230-245; Rosalie L Tung, ‘U.S.-China Trade Negotiations: Practices, Procedures and Outcomes’ (1982) 13(2) *Journal of International Business Studies* 25; Jacob Wood, ‘An Industrial Sector Analysis of the Factors Influencing FTA Negotiation Outcomes’ (2017) 18(4) *Global Business Review* 895-910

² Allan Drazen, *Political Economy in Macroeconomics* (Princeton University Press 2000) 5

³ *Ibid*

⁴ Max Weber, *The Theory of Social and Economic Organization* (The Free Press 1947) 152

⁵ Drazen (n 2) 6

⁶ Discussed further in Section VI below.

⁷ Susan Strange, ‘The Persistent Myth of Lost Hegemony’ (1987) 41(4) *International Organization* 551-574, 553

values of a particular set of actors.⁸ Strange's structural power will be discussed further in Section VI of this Chapter, but in consideration of the above, for the purposes of this thesis, political economy will be taken to mean the way power and authority affects outcomes in an economic process – in this case, the Trans-Pacific Partnership. Political economy tradeoffs, to expand, would relate to the particular concessions resulting from the shifts in power and authority amongst different stakeholders involved in the negotiations.

When I emerged onto the international trade scene as a registered civil society stakeholder and greenhorn to the TPP negotiations, I was struck by the sheer enormity of it all – the hundreds of negotiators, security barring entry to the negotiating venue (the SkyCity Casino and Hotels in Auckland, New Zealand), and everywhere you looked in restaurants and cafes near the negotiating venue, side meetings between negotiators and stakeholders. Today, as a marginally more seasoned international trade scholar, the feeling of enormity still resonates, but less so as regards to the visuals of the TPP negotiations, but rather as pertains to the TPP as an agreement and the legal, historical, and political space it inhabits.

The TPP is historically situated in a global trade order that has seen the perceived failure of multilateral trade negotiations at the World Trade Organization, a failure precipitated by the lack of consensus and coordinated developing country opposition to developed country standards. While initially committed to a multilateral approach to trade, as the decades passed, developed countries became increasingly aware that the standards they wanted would not be easily obtained at the multilateral level, but rather would be more easily negotiated in more intimate trade settings, i.e. bilateral trade agreements and regional trade agreements.

Among these standards were intellectual property (IP) standards, including a minimum 20-year patent term established in the 1994 agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Since then, intellectual property standards that go above and beyond what was contained in TRIPS (i.e. TRIPS-plus standards) have been demanded of developing countries.

However, IP standards were only one type of non-tariff standard that developed countries were seeking through trade agreements. Pursuant to the Kennedy round of negotiations held in Geneva from 1963-1967, a realisation had emerged among developed countries that the full benefits gained from the elimination of tariffs would be circumvented if nontariff barriers

⁸ Christopher May, 'Strange Fruit: Susan Strange's Theory of Structural Power in the International Political Economy' (1996) 10(2) *Global Society* 167-189, 174

were not addressed.⁹ These began with antidumping measures and regulations on exchange rate manipulations, and today in the TPP include sanitary and phytosanitary measures, advertising restrictions as a technical barrier to trade, government procurement favouring domestic companies, financial services, and TRIPS plus intellectual property. The TPP, however, does not only seek high standards; it seeks the harmonisation of these high standards over a large geographical region. Thus, due to the unlikelihood of these being advanced through WTO negotiations, the plurilateral, mega-regional,¹⁰ agreements known as the TPP and TTIP were birthed.

In the face of these standards and the requirement of extensive beyond-the-border regulatory harmonisation, the question is, how would the middle-income countries or emerging markets in the TPP i.e. the so-called 'developing countries', react? Some insights may be drawn from the GATT and TRIPS negotiations. At the beginning of the GATT negotiations, developing countries were mostly passive participants, and simply did not have the capacity to contribute to trade norms.¹¹ The dynamic was therefore characterised by the industrialised West as the rule maker and developing countries as rule takers. In the mid 1970s, there was a perception that the distribution of capabilities was shifting in favour of developing countries, and for a short moment in time, they were able to table and advance their demands.¹² Throughout time, this changed again as the early 80s saw a global economic recession, and developing countries were once again beholden to developed countries.¹³ More recently, emerging markets including the BRICS countries have seen their powers grow in global governance and international policymaking,¹⁴ although some authors question their power due to a lack of cohesion relative to high income nations.¹⁵

Power dynamics further changed with the juxtaposition of the AIDS crisis¹⁶ and organised international civil society (before the finalisation of the TRIPS agreement) in the 1990s,

⁹ Robert E Baldwin, *Nontariff Distortions of International Trade* (The Brookings Institution 1971) 2

¹⁰ See section III(b)(ii) below for definition and elaboration of 'deep integration' – but basically, a characteristic describing the tendency of today's plurilateral and bilateral agreements no longer being about traditional trade matters, but rather beyond-the-border measures.

¹¹ Nor was it necessarily in their interests to adopt TRIPS-compatible norms. As Gervais comments, these states benefit from obtaining IP 'as inexpensively as possible' in parallel with economic development. Daniel J Gervais, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford University Press 2014) 39

¹² Susan K Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (State University of New York Press 1998) 31

¹³ *Ibid* 32

¹⁴ Mattias Vom Hau, 'How the BRICS Exert Influence in the Global Politics of Development' *E-International Politics* (24 October 2017) < <https://www.e-ir.info/2017/10/24/how-the-brics-exert-influence-in-the-global-politics-of-development/> > accessed 1 October 2019

¹⁵ Deepak Nayyar, 'BRICS, Developing Countries, and Global Governance' (2016) 37(4) *Third World Quarterly* 575-591, 586

¹⁶ The AIDS crisis began to be visible in New York in the early 1980s, with drastically increasing infections through that decade. By 1989, AIDS accounted for a 'very large proportion of total mortality among young men and women in New York City in 1989'. Albert R Jonsen and Jeff Stryker (eds), *The Social Impact of AIDS in the United States* (National Academy of Sciences 1993) 246. HIV also grew by epidemic proportions in Africa at this time, increasing the international imperative to act. William W Fisher and Cyril P Rigamonti, 'The South Africa AIDS Controversy: A Case Study in Patent Law and Policy' *The Law and Business of Patents* (10 February 2005) < <https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf> > accessed 6 November 2019

resulting in increased attention and controversy around trade-related IP and patent systems. Largely before then, to quote Parthasarathy, they had been 'technical and esoteric domains operating far from public view, of real interest only to those who seek to gain an exclusive right to commercialise their inventions'.¹⁷ During this time period, patents were increasingly seen as a public health matter of grave consequence, although some countries such as Colombia and Brazil had much earlier taken note of overpricing and the possible impact of extended IP rights.¹⁸ TRIPS negotiators were boosted with support from organised international civil society, and when TRIPS was finalised, the U.S., i.e. the principal demandeur of maximalist intellectual property rights in trade, were disappointed.¹⁹ While they had successfully established an agreement for harmonisation of IP rules globally, the U.S. had wanted higher standards.

The question is, what do countries give up when they agree to higher intellectual property standards, or when they agree to harmonise IP standards with developed nations? While there have been a number of scholarly articles on developing country negotiating tactics, there hasn't been much of a focus on the tradeoffs that are made in exchange for IP standards.

IP is not negotiated in a silo, but instead is negotiated in the context of other factors, for example market access, promises of foreign direct investment in domestic research and development firms, or perceived technology transfer gains.²⁰ Tradeoffs may also occur externally to the trade agreement being negotiated – for example Colombia's intentions to issue a compulsory license for a cancer drug was met with a threat to reduce funding for Paz Colombia, the country's peace initiative.²¹ These are referred to as political economy tradeoffs. In the context of the TPP, market access tradeoffs, or 'compromises', were prominently mentioned in the press in regard to biologic medicines exclusivity by Mexican, Australian, and New Zealand negotiators.²²

It is for this reason, combined with the fact that biologics exclusivity resulted in a number of deadlocks, its relative novelty in trade agreements, and the fact that it was subject to at least three official bilateral (US-MY), (US-CL), and (US-VN) decisions in the TPP text, make it a

¹⁷ Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe* (University of Chicago Press 2017) 2

¹⁸ Constantine Vaitsos, 'Patents Revisited: Their Function in Developing Countries' (1972) 9(1) *The Journal of Development Studies* 71-97, 87-89; Andrea Koury Menescal, 'Those Behind the TRIPS Agreement: The Influence of the ICC and the AIPPI on International Intellectual Property Decisions' (2005) 2 *Intellectual Property Quarterly* 155-182

¹⁹ Graham Dutfield and Uma Suthersanen, *Global intellectual property law* (Edward Elgar Publishing Limited 2008) 37

²⁰ Meir Perez Pugatch, *The international political economy of intellectual property rights* (Edward Elgar Publishing 2004) 57

²¹ Andrew Goldman and Zack Struver, 'Senator Orrin Hatch, USTR Pressure Colombia over Imatinib Compulsory License' *Knowledge Ecology International* (10 May 2016) < <https://www.keionline.org/23082> > accessed 25 September 2019

²² Peter Clark, 'Chile and Peru balk at TPPs treatment of intellectual property' *iPolitics* (Atlanta, 4 October 2015) < <http://ipolitics.ca/2015/10/04/tpp-heads-to-the-finish-line-as-deal-appears-imminent-pc/> > Accessed 8 March 2018

compelling choice for case study on intellectual property political economy tradeoffs. Crucially, I am focusing on the responses and negotiations of two upper middle-income TPP countries, Chile and Malaysia, for several similarities and differences that I describe in more detail below.

II. Research question

The conglomeration of factors characterising the TPP, i.e. its intentions on deep integration, its massive combined GDP, the unique positions of upper middle-income country participants, and other factors discussed in brief above, and in more detail below, led me to consider a number of questions, with the main research question being: “*How do upper middle-income countries strategise for, respond to, and engineer and justify political economy tradeoffs to maximalist intellectual property provisions that they may not necessarily agree to?*” and following from that, “what intrinsic and extrinsic factors influenced negotiator decision making processes?”

These questions can be broken down to numerous specific sub-questions, including, but not limited to, the following: Due to established market access deals with all TPP countries, was Chile in a stronger position? Was it able to demand more and concede less? Are the countries equally matched in negotiating capacity? Was the deep integration objective a core reason for participation in TPP negotiations? Did domestic industrial development in biologics and/or biosimilars influence the decisions of the negotiators? If not, what did? Did the novelty of biologics, both as an IP provision in trade agreements and as a public health commodity, change political economy tradeoffs? Were the countries seen as potential points where more maximalist IP could be spread within their own regions? These questions will guide my fieldwork, and frame my findings on IP political economy tradeoffs by upper middle-income countries.

III. Continued relevance of the TPP

At time of writing, the TPP no longer exists in the form discussed in this thesis. It has morphed in membership and content pursuant to the U.S. exit, and now has been signed by the remaining 11 countries in the form of the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP). The following subsections describe why the TPP is still relevant for scholarship.

a) The TPP: essential characteristics

The TPP is a plurilateral²³ mega-regional agreement containing 30 chapters; four addressing traditional matters of trade, for example goods and services, with the other chapters delving into, among other topics, government procurement, e-commerce, intellectual property, sanitary and phytosanitary measures, labour, environment, and regulatory coherence. In specific, the agreement specifically seeks the streamlining of product supply chains so that products aren't faced with different regulations in different countries, the adoption of TRIPS-plus intellectual property, non-discriminatory access to federal government procurement contracts,²⁴ and to ensure that disputes are arbitrated via certain tribunals, among many other beyond-the border rules.

The TPP has its roots in the Trans-Pacific Strategic Economic Partnership (TPSEP) signed in 2005 by a group of countries – New Zealand, Singapore, Chile, and Brunei - called the Pacific Four or the P4.²⁵ According to the agreement text, the agreement was intended to, among other objectives, form a strategic partnership within the Asia-Pacific region, establish a predictable commercial framework for planning and investment, promote intellectual property rights, and provide a catalyst for broader cooperation at international forums.²⁶

The United States was not invited to be a part of the agreement until 2008, but when it did, it rapidly became the rulemaker. The TPP was a crucial part of Obama's 'pivot to Asia' policy, a policy designed to establish an organised trade presence in Asia and curb the rise of China.²⁷ The TPP is a manifestation of a contest of powers. Historically, assertions of global dominance would have manifested at the start of the 20th century and certainly at many moments before as catastrophic violent war.²⁸ Today, this has morphed into machinations focused on economic domination. Mearsheimer states:

[T]he great powers that shape the international system fear each other and compete for power as a result. Indeed, their ultimate aim is to gain a position of dominant power over others, because having dominant power is the best means to ensure one's own survival.²⁹

²³ Plurilateral agreements are defined as agreements between 3 or more countries on specific issues, whether within or external to the WTO system. Michitaka Nakatomi, 'Plurilateral Agreements: A Viable alternative to the World Trade Organization?' (2013) ADBI Working Paper 439, Asian Development Bank Institute <http://www.adbi.org/working-paper/2013/10/24/5914_plurilateral_agreements_alternative_wto/> accessed 22 April 2017, 2

²⁴ Olayinka Bandele, *Emerging Disciplines on Government Procurement in Trade Agreements* (The Commonwealth Secretariat 2016) <<http://thecommonwealth.org/sites/default/files/inline/GovernmentProcurementTPP1008.pdf>> accessed 3 June 2019, 3

²⁵ Gary N Horlick, 'Trans-Pacific Partnership' (2016) 11(4) *Global Trade and Customs Journal* 149-152

²⁶ TPSEP parties, *Trans-Pacific Strategic Economic Partnership* (Ministry of Foreign Affairs and Trade 2005) <<https://www.mfat.govt.nz/assets/securedfiles/FTAs-agreements-in-force/P4/Full-text-of-P4-agreement.pdf>> accessed 22 April 2017

²⁷ Michael J Green, 'The Legacy of Obama's 'Pivot' to Asia' *Foreign Policy* (3 September 2016) <<http://foreignpolicy.com/2016/09/03/the-legacy-of-obamas-pivot-to-asia/>> accessed 2 May 2017

²⁸ Yuval Noah Harari describes the historical shift in the occurrence of war in global domination, i.e. from an era where there was 'temporary absence of war' to the 'implausibility of war'. Yuval Noah Harari, *Homo Deus* (Vintage 2017) 18

²⁹ John J Mearsheimer, *The tragedy of great power politics* (Norton 2014) xv

While Mearsheimer talks about this in context of great power politics and violent war, his thoughts apply equally to great powers asserting economic dominance, and in the case of the TPP, it would be the administration of new regulatory norms over a large geographical space, to the exclusion of (and perhaps detriment of) another great power. In July 2013, Japan made the decision to join the TPP, bringing the tally of negotiating countries to twelve³⁰ and meaning that there were now two superpowers intent on two objectives: harmonising new global standards, and on containing China's power.³¹

On Japan's geopolitical interests, Tabuchi elaborates:

Japan also sees a leadership role in the partnership as a way to return to center stage after being eclipsed in the region by the rise of China, which many in Tokyo view as jeopardizing Japan's economic interests and security. China, which is pursuing its own bilateral and multilateral trade agreements in the region, is unlikely to join the agreement soon because of the concessions on state-owned enterprises, intellectual property and labor that the pact would require. That has, in effect, made the partnership a vehicle of sorts for the United States, and now Japan, to counter China's influence.³²

So while the TPP was intended to be a 'living agreement',³³ meaning countries would be able to join the finalised agreement, and that specific provisions could be revised periodically to suit changing trade trends, the superpowers knew that in order for China to join, they would have to bring their standards up to the TPP standards. Given China's affinity for state-led corporations and its approach to intellectual property, this is an unlikely occurrence in the near future. This in turn provided Japan and the U.S. the regulatory space to set up the Asia-Pacific trade order.

Backer stated that while each negotiating country had its own agenda in the TPP, the United States' and Japan's agenda was 'particularly strategic' because they were not only looking to obtain access to each other's markets – they were also both looking 'to further political and regulatory objectives at the international level'.³⁴ In fact, Bown states that the tariff issues were less important – introducing rules on perceived non-tariff barriers was the key driver of the agreement.³⁵ Others state that maximalist intellectual property was the 'core negotiating

³⁰ Alphabetically, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam.

³¹ William H Cooper and Mark E Manyin, *Japan joins the Trans-Pacific Partnership: what are the implications?* (Congressional Research Service 2013) <<https://fas.org/sgp/crs/row/R42676.pdf>> accessed 3 June 2019, 1

³² Hiroko Tabuchi, 'Japan moves to enter talks on Pacific trade' *The New York Times* (Tokyo, 15 March 2013) <<http://www.nytimes.com/2013/03/16/world/asia/japan-aims-to-join-trans-pacific-partnership-talks.html>> accessed 23 April 2017

³³ Cooper and Manyin (n 31) 3

³⁴ Larry Catá Backer, 'The Trans-Pacific Partnership: Japan, China, the U.S., and the Emerging Shape of a New Regulatory World Trade Order' (2014) 13 *Washington University Global Studies Law Review* 49-81, 65

³⁵ Chad P Bown, 'Mega-Regional Trade Agreements and the Future of the WTO' (2017) 8(1) *Global Policy* 107-112, 108; Non-tariff barriers are bureaucratic or legal issues that could involve hindrances to trade. This could include quotas, import licensing systems, sanitary regulations, prohibitions, etc. (WTO, 2017)

objective' of the U.S.³⁶ In other words, it can be gleaned that market access and reduction of tariffs was not the core focus. Rather, the TPP seeks to establish a 'gold standard' of global economic rules,³⁷ reduce or eliminate beyond-the-border and non-tariff barriers, including regulatory measures and domestic policies, and harmonise these across a large regional area.³⁸ In that sense, it is more of an instrument of 'integrated economic regulation' rather than a trade agreement per se.³⁹

Critics state that the TPP 'will handcuff our ability to set regulations in key areas like finance, industry, the environment, public procurement and fostering programs to create jobs at home'⁴⁰ and that the TPP would stifle and restrict access to generic medicines.⁴¹ The Peterson Institute for International Economics assessed the impact as generally positive, although noted that the U.S. was to benefit the most with an increase of annual real incomes by \$131 billion.⁴² The Peterson Institute also, however, noted some costs of some negotiating outcomes to the developing country participants, for example that Vietnam was likely to face costs to produce fabrics that would be greater than tariff savings.⁴³

Nineteen formal rounds of TPP negotiations were held from 2010-2013, hosted in TPP countries globally, with the first occurring in Melbourne, Australia from 15-19 March 2010, and the final formal round occurring in Bandar Seri Begawan, Brunei, from 23-30 August 2013.⁴⁴ I attended four formal rounds,⁴⁵ participating as a registered stakeholder in three formal negotiator-stakeholder engagement sessions, presenting to negotiators on the inability of states to rely on public health exceptions at the investor state dispute settlement (ISDS) tribunals, data exclusivity, and the intellectual property and Malaysian disease burden more

³⁶ Carlos Correa, Frederick Abbott, and Peter Drahos, *Emerging markets and the world patent order: the forces of change* (Edward Elgar Publishing 2013) 8

³⁷ Gordon Isfeld, 'Forget NAFTA, the TPP is the New 'Gold Standard' of Global Trade' *Financial Post* (Ottawa, 12 October 2015) <<http://business.financialpost.com/news/economy/forget-nafta-the-tpp-is-the-new-gold-standard-of-global-trade>> accessed 24 April 2017

³⁸ Reeve T Bull, Neysun A Mahboubi, Richard B Stewart, and Jonathan B Weiner, 'New Approaches to International Regulatory Cooperation: The Challenge of TTIP, TPP, and Mega-Regional Trade Agreements' (2015) 78(1) *Law & Contemporary Problems* 1-30, 4

³⁹ Backer (n 34) 50

⁴⁰ Raul Burbano, Kristen Beifus, and Manuel Pérez-Rocha, 'Facing the Threat of the Trans-Pacific Treaty' *The Tyee* (8 March 2013) <<https://thetyee.ca/Opinion/2013/03/08/Trans-Pacific-Treaty-Threat/>> accessed 23 April 2017

⁴¹ Brook K Baker, 'Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere' (2016) 13(3) *PLoS Medicine* e1001970

⁴² Peter A Petri and Michael G Plummer, 'The Economic Effects of the TPP: New Estimates' in Kimberly Ann Elliott, Caroline Freund, Anna Gelper, Cullen S Hendrix, Gary Clyde Hufbauer, Barbara Kotschwar, Theodore H Moran, Tyler Moran, Lindsay Oldenski, Sarah Oliver, Peter A Petri, and Michael G Plummer (eds), *Assessing the Trans-Pacific Partnership, Volume 1* (Peterson Institute for International Economics, 2016) <<https://piie.com/system/files/documents/piieb16-1.pdf>> accessed 23 April 2017, 6

⁴³ Kimberly Ann Elliott, Caroline Freund, Anna Gelper, Cullen S Hendrix, Gary Clyde Hufbauer, Barbara Kotschwar, Theodore H Moran, Tyler Moran, Lindsay Oldenski, Sarah Oliver, Peter A Petri, and Michael G Plummer, *Assessing the Trans-Pacific Partnership, Volume 1* (Peterson Institute for International Economics, 2016) <<https://piie.com/system/files/documents/piieb16-1.pdf>> accessed 23 April 2017, 72

⁴⁴ USTR (Office of the United States Trade Representative), 'Joint Press Statement TPP Ministerial Meeting Bandar Seri Begawan, Brunei Darussalam' Office of the United States Trade Representative' (August 2013) <<https://ustr.gov/Joint-Press-Statement-TPP-Ministerial-Brunei>> accessed 26 April 2017

⁴⁵ Auckland (4th round, December 2010), Singapore (6th round, March 2011), Kota Kinabalu (18th round, July 2013), Brunei (19th round, August 2013)

generally. Formal stakeholder engagement consisted of presentations to negotiators in a lecture-style format,⁴⁶ discussions at designated booths, and a joint briefing by Chief Negotiators to civil society, industry, and other stakeholders, after which stakeholders could ask questions of Chief Negotiators of their choice. Depending on the specifications of the host country, stakeholders were allocated 7-15 minutes to deliver their thoughts to negotiators.⁴⁷

Stakeholder engagement was not available at all negotiation rounds, and where available, were considered to be insufficient.⁴⁸ On 4 February 2013, a letter was sent to the U.S. Chief Negotiator asking for reforms to the stakeholder negotiation process, including Chief Negotiator briefings at the beginning and end of negotiations instead of just the end, and a minimum of 15 minutes for stakeholder presentations.⁴⁹ At the same time, 'cleared advisers' from U.S. industry were given access to full texts.⁵⁰ MPs from certain countries were given access to texts, but made to sign non-disclosure agreements lasting a number of years.⁵¹

This transparency imbalance was criticised by civil society, academics, and other stakeholders who were only involved when it was 'too late for their criticisms to actually improve the deal itself'⁵² and said that the lack of transparency was an 'attack on democratic governance'.⁵³ Gary Horlick, a former U.S. trade negotiator, commented that it was the least transparent negotiations he had ever seen.⁵⁴ Proponents, on the other hand, stated that the secrecy was a strategic necessity to ensure governments' objectives were not revealed.⁵⁵ This can only be related back to the substance of the TPP – in that it contains standards of domestic, sub-regional, and international policy regulation at unprecedented levels – and that secrecy was necessary to ensure its completion.

⁴⁶ USTR, 'Direct Stakeholder Engagement' *Office of the United States Trade Representative* (2013) <<https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/direct-stakeholder-engagement>> accessed 26 April 2017

⁴⁷ Krista Cox, '19th round of TPP negotiations: reduced engagement for 'stakeholder engagement' day. Knowledge Ecology International' Knowledge Ecology International (27 August 2013) <<http://keionline.org/node/1791>> accessed 27 September 2019

⁴⁸ The Council of Canadians, 'Canada setting new global standard for TPP secrecy' *The Council of Canadians* (27 June 2014) Available from: <https://canadians.org/media/canada-setting-new-global-standard-tpp-secrecy>> accessed 26 April 2017

⁴⁹ Public Citizen, 'U.S. Civil Society Letter to U.S. Chief Negotiator Barbara Weisel: U.S. Civil Society Organizations Call for Transparency and Stakeholder Engagement in Trans-Pacific Partnership (TPP) Negotiations' *Public Citizen* (4 February 2013) <<http://www.citizen.org/civ-society-letter-to-ustr-february-2013>> accessed 26 April 2017

⁵⁰ William New, 'Confidential USTR emails show close industry involvement in TPP negotiations' *Intellectual Property Watch* (5 June 2015) <<https://www.ip-watch.org/2015/06/05/confidential-ustr-emails-show-close-industry-involvement-in-tpp-negotiations/>> accessed 29 April 2017

⁵¹ Lenore Taylor, 'Australian MPs Allowed to See Top-Secret Trade Deal Text But Can't Reveal Contents for Four Years' *The Guardian* (2 June 2015) <<https://www.theguardian.com/business/2015/jun/02/australian-mps-allowed-to-see-top-secret-trade-deal-text-on-condition-of-confidentiality>> accessed 27 September 2019

⁵² Charles M Rosloff, 'What TPP Missed: Meaningful Transparency' *Wikimedia* (11 February 2016) <<https://blog.wikimedia.org/2016/02/11/tpp-missed-meaningful-transparency/>> accessed 29 April 2017

⁵³ Lori Wallach, 'A Stealth Attack on Democratic Governance' *The American Prospect* (13 March 2012) <<http://prospect.org/article/stealth-attack-democratic-governance>> accessed 29 April 2017

⁵⁴ *Ibid*

⁵⁵ Simon Lester, 'The TPP Trade Talks: Forget Secrecy, Let's Talk Substance' *Huffpost* (21 August 2013) <<http://www.huffingtonpost.com/simon-lester/the-tpp-trade-talks-forget-secrecy-lets-talk-substance>> accessed 18 July 2017

b) Context of the current state of the TPP

As aforementioned, the TPP evolved into the CPTPP and was signed by the remaining 11 countries on 8 March 2018.⁵⁶ The following paragraphs summarise how the agreement changed from the TPP into the CPTPP, beginning with the close of formal negotiation rounds of the TPP.

After the close of formal negotiation rounds of the TPP, numerous meetings were held between trade ministers and country chief negotiators to tie up loose ends and agree final concessions. Pursuant to this, on 4th February 2016, the agreement was signed.⁵⁷ It would have then been subject to a two-year waiting period, during which the countries would amend domestic laws to comply with the TPP. Following this, the so-called 'certification process' would have taken place as proposed by the Bipartisan Congressional Trade Priorities Act of 2014.⁵⁸ This process would entail verification that measures taken by TPP partners to incorporate new standards in domestic law satisfy the standards of the U.S. Congress. If countries did not satisfy the U.S. understanding of its obligations under the agreement, the U.S. could have refused to bring the agreement into force.⁵⁹ If there are shortcomings in the domestic law, the TPP partner would have then been consulted and been required to take measures to comply.⁶⁰

The outcome of the U.S. elections meant that certification - and for most TPP countries - ratification, would not occur in the expected timeframe. In his first week in office, in January 2017, U.S. President Donald Trump disavowed the TPP via executive order,⁶¹ fulfilling promises made during his campaign. These promises were couched in rhetoric that denounced foreign countries, and bore the mark of protectionism that has not been seen in the U.S. trade agenda for some time. In Pennsylvania, for example, he called foreign currency manipulators 'cheaters', claimed that the TPP would put the interests of foreign countries above the U.S.'s, force American workers to compete with Vietnamese workers, and that all in all, the TPP would be the 'deathblow of American manufacturing'.⁶²

⁵⁶ Tim McDonald, 'Asia-Pacific Trade Deal Signed by 11 Nations' *BBC News* (8 March 2018) <<https://www.bbc.co.uk/news/business-43326314>> accessed 1 October 2019

⁵⁷ Don Lee, 'Signing of Trans-Pacific Trade Deal Opens up Tough Battle in U.S.' *Los Angeles Times* (4 February 2016) <<http://www.latimes.com/business/la-fi-pacific-trade-agreement-signed-20160204-story.html>> accessed 1 May 2017

⁵⁸ United States Congress, H.R.3830 – Bipartisan Congressional Trade Priorities Act of 2014 <<https://www.congress.gov/bills/113/3830>> accessed 6 November 2019

⁵⁹ Rebecca Merrett, 'US Trade Officials Say It's Their Way or the Highway on TPP' *CIO* (18 August 2014) <https://www.cio.com.au/article/552602/us_trade_officials_say_it_their_way_highway_tpp/> accessed 6 November 2019

⁶⁰ International Trade Administration, 'Free Trade Agreement Compliance' *International Trade Administration* (November 2007) <<http://trade.gov/fta/compliance.asp>> accessed 1 May 2017

⁶¹ BBC News, 'Trump Executive Order Pulls Out of TPP Trade Deal' *BBC News* (24 January 2017) <<https://www.bbc.co.uk/news/world-us-canada-38721056>> accessed 2 October 2019

⁶² CBSN, 'Donald Trump says he'd pull U.S. out of Trans-Pacific Partnership' CBSN (28 June 2016) <<https://www.youtube.com/watch?v=Qvp1EaMdCXc&t=6s>> accessed 1 May 2017

One critic stated that Trump's decision was 'not the loss of global economic gain. It is the loss of global economic direction'.⁶³ As time passed it became clear that the U.S. plan for global economic direction was rooted in addressing trade deficits through trade wars⁶⁴ and the redrafting of NAFTA.⁶⁵ Whatever it was, at the very least, the withdrawal of the United States from the helm of a trade agreement intended to introduce the new global standard of beyond-the-border rules opened possibilities up for removal of certain contentious provisions. So, while textually it remained an American agreement, there was now room for manoeuvre.

While Japanese prime minister Shinzo Abe had initially stated that the TPP 'has no meaning' without the U.S.,⁶⁶ post-inauguration Japan changed their tune, stating that they were prepared 'to carry TPP forward in essentially the same form it was in when Trump killed it', with Deputy Prime Minister Taro Aso stating that discussions on an 11-member TPP (TPP-11) would be taken forward.⁶⁷ One reporter stated that this inclination was 'geopolitical icing' on the cake for Japan, i.e. that given the Regional Comprehensive Economic Partnership's (RCEP)⁶⁸ lower standards, Japan could see the agreement as a way to 'limit China's ability to dominate economic relations with its neighbours'.⁶⁹

Other countries expressed dismay at the U.S. exit, but kept avenues open to cooperate on TPP-11. Australia openly said that TPP continued to be in their national interest, despite the U.S. pullout.⁷⁰ The Malaysian trade minister Mustapa Mohamed said in March 2017, "It is still an open question; there was a meeting held in Chile last week and another one coming up in May in Vietnam. We will continue to exchange views because the main motivation is to get access to the American market."⁷¹ In January 2017, the Chilean Minister of Foreign Affairs

⁶³ John Edwards, 'What's Next After the US Withdrawal From the TPP?' *Al-Jazeera* (26 January 2017)

<<http://www.aljazeera.com/indepth/opinion/2017/01/withdrawal-tpp-170126092759229.html>> accessed 23 April 2017

⁶⁴ Ben Bartenstein, 'Bremmer Says U.S.-China Trade War Getting "Considerably Worse"' *Bloomberg* (30 September 2019) <<https://www.bloomberg.com/news/articles/2019-09-30/bremmer-says-u-s-china-trade-war-getting-considerably-worse>> accessed 2 October 2019

⁶⁵ Richard Partington, 'Nafta: What Is It and Why Is Trump Trying to Renegotiate?' *The Guardian* (30 August 2018) <<https://www.theguardian.com/us-news/2018/aug/30/nafta-what-is-it-why-is-trump-trying-to-renegotiate>> accessed 3 October 2019

⁶⁶ Robin Harding, 'TPP 'Has No Meaning' Without US, Says Shinzo Abe' *Financial Times* (22 November 2016) <<https://www.ft.com/content/59972c38-b058-11e6-a37c-f4a01f1b0fa1>> accessed 1 May 2017

⁶⁷ Robbie Gramer, 'Japan wants to revive the Trans Pacific Partnership even without the U.S.' *Foreign Policy* (24 April 2017) <<http://foreignpolicy.com/2017/04/24/japan-wants-to-revive-trans-pacific-partnership-even-without-united-states-asia-trade-agreements/>> accessed 25 April 2017

⁶⁸ The RCEP is a proposed plurilateral FTA between the ten member states of the Association of Southeast Asian Nations (ASEAN), i.e. Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, Vietnam, and its five FTA partners (China, Japan, South Korea, Australia, and New Zealand)

⁶⁹ Ibid

⁷⁰ Jenny Leonard, 'Australian PM Says U.S. Had 'Right' To Pull Out of TPP; Pence Promotes 'America First' *Inside U.S. Trade* (22 April 2017) <<https://insidetrade.com/daily-news/australian-pm-says-us-had-right-pull-out-tpp-pence-promotes-america-first-bilaterals>> accessed 2 May 2017

⁷¹ Bernama, 'Mustapa: Malaysia Remains Open on TPP' *The Malay Mail Online* (23 March 2017) <<http://www.themalaymailonline.com/malaysia/article/mustapa-malaysia-remains-open-on-tpp>> accessed 25 April 2017

Heraldo Muñoz said that the Chilean TPP project was cancelled.⁷² A few months later in April, however, pursuant to a meeting of trade officials in Viña del Mar, Chile, Muñoz seemed more optimistic, stating, ‘the Asia-Pacific region is ready to lead the new age of globalization in the 21st century by continuing the pluralistic approach to trade envisioned in the TPP, even though the accord no longer exists as we knew it.’⁷³ These provide a glimpse into the motivations on TPP countries – that while they are universally disappointed at the exit of the United States, their motivations with the TPP were different.⁷⁴ For Malaysia, an exporter of automotive and electrical parts, market access was the main objective. Chile, who had trade agreements in place with all TPP members, saw the TPP as a vehicle to wider rule integration.

As time passed, while the ultimate form of the TPP was unknown, i.e. whether in the form of a TPP-11 or TPP-5 agreement,⁷⁵ there was little doubt of the seepage of the standards in the agreement into other trade agreements. Mitchell and Voon comment:

Ratification by the remaining TPP countries may thus provide an internal and external political signal - that is, to both domestic constituencies and international actors - of the perceived value of trade liberalisation and foreign investment in promoting national and global welfare, with the conceivable potential to influence the next steps of other TPP countries, if not the United States... Even if the TPP is not renegotiated and never enters into force, its successful negotiation and signature are likely to have important and lasting implications for international economic law and broader policy issues.⁷⁶

Crucially, TPP provisions resulted in the amendment of existing agreements, for example the amendment of the Singapore-Australia preferential trade agreement to include TPP standards.⁷⁷ Even before the birth of TPP-11 or CPTPP, Vietnam has planned on legal reform based on TPP to over 30 legislative instruments.⁷⁸ And as NAFTA renegotiation began, the USTR borrowed language from the TPP to modernise NAFTA into what is now known as the

⁷² Valentina González, ‘Canciller Heraldo Muñoz Anuncia Que Con Salida de EEUU del TPP Proyecto Se Cancela en Chile (Chancellor Heraldo Muñoz Announces that With the Exit of the United States, the TPP Project in Chile is Cancelled)’ *Biobio Chile* (23 January 2017) <<http://www.biobiochile.cl/noticias/nacional/chile/2017/01/23/canciller-heraldo-munoz-reconoce-que-con-salida-de-eeuu-del-tpp-proyecto-se-cancela-en-chile.shtml>> accessed 2 May 2017

⁷³ Heraldo Muñoz, ‘Trade After the Trans-Pacific Partnership’ *The New York Times* (3 April 2017) <<https://www.nytimes.com/2017/04/03/opinion/trade-after-the-trans-pacific-partnership.html>> accessed 3 October 2019

⁷⁴ Sachiko Aoki, ‘Differing Motives Complicate ‘TPP-11’’ *bilaterals.org* (2 May 2017) <<http://www.bilaterals.org/?differing-motives-complicate-tpp>> accessed 4 May 2017

⁷⁵ The Japan Times, ‘Japan Pitches Idea of Five-Nation TPP’ *The Japan Times* (4 May 2017) <<http://www.japantimes.co.jp/news/2017/05/04/business/japan-trying-sell-idea-tpp-four-nations-sources/#.WQuGq1KZP0F>> accessed 5 May 2017

⁷⁶ Andrew D Mitchell and Tania Voon, ‘Foreword: The Continuing Relevance of the Trans-Pacific Partnership’ (2016) 17(2) *Melbourne Journal of International Law* i-vi, iii-iv <<http://law.unimelb.edu.au/data/assets/pdffile/0008/2214476/00cForeword.pdf>> accessed 2 May 2017

⁷⁷ *Ibid* v

⁷⁸ Nguyen Kieu Giang, ‘The TPP is Changing Vietnam’s Economy, No Matter What Trump Does’ *Bloomberg* (28 November 2016) <<https://www.bloomberg.com/news/articles/2016-11-28/the-tpp-is-changing-vietnam-s-economy-no-matter-what-trump-does>> accessed 23 April 2017

U.S.-Mexico-Canada (USMCA) trade agreement,⁷⁹ including the provision on biologics.⁸⁰

In addition to the fact that countries went ahead with TPP-style reforms despite American withdrawal, TPP-11 remained significant because of how the U.S. exit shaped geopolitics and the new world trade order. The TPP was openly described as a 'dramatic geopolitical and economic bulwark against China'.⁸¹ Born from the U.S. exit was a real opportunity for China to assert itself in the Asia-Pacific region. While not the subject of this thesis, the role of the TPP in geopolitics meant the TPP was/is a significant historical process catalysing changes on the global scale.

As aforementioned, in March 2018, the remaining 11 countries signed the agreement, now tagged the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP). While the agreement suspended 22 articles, one scholar insists that these automatically snap back into place when the United States rejoins,⁸² presumably under a subsequent administration.

On this note, documentation of the TPP is salient due to its significance in regard to, and contextualised to, (i) the failure of the Doha round of talks, historical pharmaceutical IP, and the need of powerful states to advance maximalist IP through different forums; (ii) the agenda of the powerful states to create a new world trade order via 'deep integration'; and (iii) the response and role of the upper middle-income states in world trade politics. These are detailed below.

(i) TPP in context of the 'failure' of Doha

In the mid 1980s, the industrialised countries (US and the European Communities) and the industries pressuring them were feeling increasingly frustrated by what they saw as the toothlessness of the World Intellectual Property Organisation (WIPO) in the harmonisation and enforcement of intellectual property worldwide. Due to this, in 1986 at the start of the Uruguay WTO multilateral trade round negotiations, there was a shift from WIPO to the World Trade Organisation (WTO) which they saw as the best forum to establish global minimum standards of intellectual property. In 1987, the U.S. Trade Representative (USTR) upon the instruction

⁷⁹ Heng Wang, 'The Future of Deep Trade Agreements: The Convergence of the TPP (and CPTPP) and CETA?' (2019) 53(2) *Journal of World Trade* 317-342, 319

⁸⁰ Jack Caporal, 'Biologics Protection, Canada's Patent Utility Regime Among PhRMA's NAFTA Priorities' *Inside U.S. Trade* (16 June 2017) <<https://insidetrade.com/daily-news/biologics-protection-canadas-patent-utility-regime-among-phrmas-nafta-priorities>> accessed 30 June 2017

⁸¹ Jane Kelsey, quoting Mitt Romney, 'US-China relations and the geopolitics of the Trans Pacific Partnership Agreement (TPPA)' *Global Research* (11 November 2013) <<http://www.globalresearch.ca/us-china-relations-and-the-geopolitics-of-the-trans-pacific-partnership-agreement-tppa/5357504>> accessed 2 May 2017

⁸² Tom Chodor, 'The Rise and Fall and Rise of the Trans-Pacific Partnership: 21st Century Trade Politics Through a New Constitutionalist Lens' (2019) 26(2) *Review of International Political Economy* 232-255, 233

of the then-President Ronald Reagan, developed quantitative estimates of U.S. trade distortions resulting from insufficient intellectual property protection.⁸³ The results were published in 1988, showing unverified industry-estimated aggregate losses of US\$23.8 billion worldwide due to 'inadequate intellectual property protection'.⁸⁴

In 1994, out of the Uruguay round, the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement was created, and then on WTO member countries were expected to adhere to these minimum standards.⁸⁵ Anything over and beyond these standards were known as TRIPS Plus standards.

Behind the scenes, however, at the nexus of civil society concerns of maximalist intellectual property and industrialised countries' concerns of the 'pirating' of knowledge,⁸⁶ tensions were bubbling. TRIPS was not the best case scenario for the industrialised West,⁸⁷ and they set an agenda in place for the prescription and harmonisation of TRIPS Plus standards. At the same time, industrialised countries were becoming acutely aware of resistance from developing countries and civil society groups and the possibility of the WTO possibly not being the best forum for them to advance TRIPS Plus standards. Through this process, developing countries had become increasingly concerned of the effect of the agreement of the standards on their other political interests, for example the advancement of public health.⁸⁸

The next round of WTO negotiations, the Doha Development Round, commenced in November 2001 and was intended to cover a broad developmental agenda.⁸⁹ The developing countries were looking forward to achieving large market access gains for agriculture and textiles, while central to the EU's agenda were the so-called 'Singapore issues' of government procurement, trade facilitation (customs issues), trade and investment, and trade and competition.⁹⁰

⁸³ Frank Emmert, 'Intellectual Property in the Uruguay Round – Negotiating Strategies of the Western Industrialised Countries' (1990) 11(4) Michigan Journal of International Law 1317-1399, 1324

⁸⁴ USITC (United States International Trade Commission), Foreign Protection of Intellectual Property Rights and the Effect on U.S. Industry and Trade: A Report to the United States Trade Representative (USITC Washington, D. C. 1988) 4-2 <<https://www.usitc.gov/publications/332/pub2065.pdf>> Accessed 27 February 2018

⁸⁵ Laurence R Helfer, 'Regime Shifting in the International Intellectual Property System' (2009) 7(1) Perspectives on Politics 39-44, 39

⁸⁶ Emmert (n 83) 1319

⁸⁷ Dutfield and Suthersanen (n 19) 37

⁸⁸ Christopher May and Susan K Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers 2006) 176

⁸⁹ Dilip K Das, 'A Kiss of Life for the Withering Doha Round of the Multilateral Trade Negotiations?' (2008) 37(2) Global Economic Review 293-310

⁹⁰ Kevin P Gallagher, 'Understanding Developing Country Resistance to the Doha Round' (2007) 15(1) Review of International Political Economy 62-85, 73; Andreas Falke, 'EU-USA Trade Relations in the Doha Development Round: Market Access Versus a Post-Modern Trade Policy Agenda' (2005) 10 European Foreign Affairs Review 339-357, 346

At this stage, however, developing countries did not come to the negotiations to be yes-men. There were very large disagreements concerning, among other things, intellectual property, agriculture, and the protection of domestic service suppliers.⁹¹ Gallagher contends that despite this, the developing countries knew that they would be giving up generous amounts of development sovereignty as part of a grand bargain to gain access to OECD markets.⁹² This knowledge did not mean, however, that developing countries would necessarily and uniformly lower the resistance. As negotiations progressed, it became evident to the U.S. and the EU that they would have difficulties advancing their interests due to the resourceful and organised resistance brought by civil society,⁹³ widely diverse negotiating objectives, the lack of enthusiasm towards TRIPS from developing countries, and the structure of the WTO agreements being non-conducive to radical revisions of existing texts.⁹⁴

The 'egregiously problem-prone' negotiations broke down in the space of two years,⁹⁵ and a sense of disappointment – although to varying degrees for different countries - emanated from both the developed and developing world. The Bush administration post-9/11 was hoping that 'a successful conclusion to the Doha talks would send a strong signal of cooperation within the international community', and approached the talks with market access as the prime goal.⁹⁶ The EU on the other hand, was more focused on the post-modern trade agenda, including the streamlining of rules on investment, e-commerce, and labour standards.⁹⁷ And while some developing countries claimed that the Doha round negatively affected their economies, numerous economic estimates attest that net benefits to developed countries were up to the 100-billion-dollar mark.⁹⁸

Even before the Doha negotiations had broken down, the U.S. was rapidly signing bilateral free trade agreements.⁹⁹ The U.S. had gone into the Doha Round with a sense of disappointment about TRIPS over WTOs enforcement of intellectual property, and the breakdown of Doha to fix their concerns and advance maximalist rules was the final nail in the coffin, and resulted in a 'regime shift' to bilateral and regional agreements, where they could

⁹¹ Gary Clyde Hufbauer, 'Liberalisation in Services Trade' in Kimberly Ann Elliott, Caroline Freund, Anna Gelpern, Cullen S Hendrix, Gary Clyde Hufbauer, Barbara Kotschwar, Theodore H Moran, Tyler Moran, Lindsay Oldenski, Sarah Oliver, Peter A Petri, and Michael G Plummer (eds), *Assessing the Trans-Pacific Partnership, Volume 1* (Peterson Institute for International Economics, 2016) < <https://piie.com/system/files/documents/piieb16-1.pdf> > accessed 23 April 2017, 82

⁹² Gallagher (n 90) 67

⁹³ Das (n 89) 300

⁹⁴ Duffield and Suthersanen (n 19) 39

⁹⁵ Das (n 89) 294

⁹⁶ Falke (n 90) 350-351

⁹⁷ Ibid 346

⁹⁸ Gallagher (n 90) 73

⁹⁹ Das (n 89) 296

'more easily leverage their economic and political clout'.¹⁰⁰ In the words of TPP proponents Petri and Plummer:

[M]egaregional agreements—offer a way forward. They can include a sufficient number and range of partners to limit the costs of trade diversion and to have an impact on global rules. Yet their membership can be small enough to reach compromises on difficult issues.¹⁰¹

Helfer describes the principal objective of regime shifting as the 'the creation of legal rules in one forum as an intermediate strategy for later incorporating those rules into other institutions and treaties'.¹⁰² The TPP is at its very essence an agreement for a countries over a wide region to adopt maximalist IP standards and other non-tariff rules, and is designed so that through the passage of time other countries will be able to join and agree to those standards and subsequent revisions of these standards.¹⁰³ For this reason, as Laïdi opines, the TPP and the TTIP are instruments that will 'kill the WTO' and that the WTO will 'cease to be the place where trade standards are negotiated'.¹⁰⁴ In December 2017 a WTO Ministerial was held in Buenos Aires, discussing matters of e-commerce and attracting corporate lobbyists,¹⁰⁵ but otherwise the WTO has faced numerous pressures to reduce its mandate, including recent U.S. obstruction on the appointment of new judges to WTO's appellate body.¹⁰⁶

The TPP, as a far-reaching mega-regional, is therefore historically situated in decades and decades of evolution of trade-related intellectual property politics and the evolution of the global trading order, with great economic powers driving maximalist IP and other standards as global norms. Further study on political economy tradeoffs and the unique situation and motivations of the upper middle-income countries, while in no way can comprehensively diagnose the future of international trade and IP, will help situate the TPP in this historical account in terms of the negotiating dynamics between upper-middle income countries and the United States, and document the agreement as it advances (or fails) in the form of the TPP-11.

¹⁰⁰ Helfer (n 85) 41

¹⁰¹ Petri and Plummer (n 42) 4

¹⁰² Helfer (n 85) 40

¹⁰³ For example, the biologics exclusivity clause in the TPP requires revision after 10 years. (Trans-Pacific Partnership, Article 18.52.3)

¹⁰⁴ Zaki Laïdi, 'Trade Deals Show Power Politics is Back' *Financial Times* (31 March 2013) <<https://www.ft.com/content/e2aae9f4-9254-11e2-851f-00144feabdc0>> accessed 23 April 2017

¹⁰⁵ Deborah James, *State of Play in the WTO Toward the 11th Ministerial in Argentina* (Centre for Economic and Policy Research, 2017) <<http://cepr.net/publications/op-eds-columns/state-of-play-in-the-wto-toward-the-11th-ministerial-in-argentina>> accessed 30 June 2017

¹⁰⁶ Keith Johnson, 'How Trump May Finally Kill the WTO' *Foreign Policy* (9 December 2019) <<https://foreignpolicy.com/2019/12/09/trump-may-kill-wto-finally-appellate-body-world-trade-organization/>> accessed 17 December 2019

(ii) The TPP and ‘deep integration’: the new political economy of trade

The TPP is also still relevant because of where it is historically situated in the political economy of international trade. Historically, the political economy of trade has been explained in light of the elimination of tariffs. It has been explained in terms of abundant products or factors supporting the removal of tariffs, or protectionist approaches for new industries.¹⁰⁷ A change in trade policy eras was precipitated by a greater focus on nontariff distortions in trade agreements, i.e. behind the border policy measures, regulatory measures, or practices that result of distortions of trade,¹⁰⁸ for example, manipulations in real currency exchange rates, import quotas, or intellectual property policies.

Negotiators began to ask, as Krugman states: ‘Why not demand that countries match us, not only in what they do at the border, but in internal policies?’¹⁰⁹ This began in the 1970s after the WTO Kennedy Round of negotiations, where industrialised countries began tabling proposals as to what they considered were reasonable standards to be adopted by all WTO members to prevent nontariff trade distortions. The attempt to harmonise rules to large numbers of countries with varied developmental levels, as aforementioned, met with disagreement and failure of the negotiation rounds to complete. Today, as represented in the TPP, the rules intended to remove nontariff barriers have evolved and become ever more far-reaching, insofar as to constitute ‘a process of economic integration that erodes differences in national economic policies and regulations and renders them more compatible for economic exchange’, i.e. deep integration.¹¹⁰ From the beginning of the TPP negotiations, it was evident that especially in regard to the Latin American TPP countries, there was already favourable access to the US market, and at least for this region, the tariff was not at the top of the agenda.¹¹¹

Since history has shown that deep integration per U.S. standards cannot occur in the WTO setting, industrialised nations have now, with the TPP and TTIP, sought to harmonise and standardise them among select regions via these plurilateral agreements. According to Kim,

¹⁰⁷ Lisa L Martin, *The Oxford handbook of the political economy of international trade* (Oxford University Press 2015) 5-7

¹⁰⁸ Wendy Takacs, ‘Nontariff Measures’ in Kenneth A Reinert and Ramkishan S Rajan (eds), *The Princeton Encyclopedia of the World Economy* (Princeton University Press 2009) 843

¹⁰⁹ Paul Krugman, ‘What Should Trade Negotiators Negotiate About?’ (1997) XXXV *Journal of International Economics* 113-120, 133 <<https://econrsa.org/wkshops/tradepolicy/session2day1-whatshouldtradenegotiatorsnegotiateabout.pdf>> accessed 2 May 2017

¹¹⁰ Soo Yeon Kim, ‘Deep Integration and Regional Trade Agreements’ in Lisa L Martin (ed), *The Oxford Handbook of the Political Economy of International Trade* (Oxford University Press 2015) 360-361

¹¹¹ Juan Felipe López Aymes, ‘México and the TPP: A Critical View on Diversification and Intellectual Property’ (2017) 4 Bandung Journal of the Global South 1-23, 4

it is deep integration, and not preferential market access due to the elimination of tariffs, that is the hallmark of the modern regional trade agreement (RTA).¹¹²

Given that the character of these agreements has changed, one wonders whether there is a corresponding change in the nature of tradeoffs. Fernández and Portes take this query further and ask whether it changes the behaviour of states,¹¹³ and ‘insofar as the RTA does alter future incentives and behaviour, how does it change the expectations of all parties involved?’¹¹⁴ Duina and Morano-Foadi discuss RTAs that exhibit more institutionalism, i.e. RTAs that are marked by rich legislative measures, robust administration, and established judicial mechanisms, such as MERCOSUR.¹¹⁵ The authors further stress that RTAs are not ‘isolated or insulated exercises’, but rather that they evolve according to domestic political agenda and shape institutional outcomes.¹¹⁶ These agreements not only involve more political commitment, but also financial and technical resources to integrate the rules therein. The literature suggests that even the finalization of an ordinary trade agreement leads to uncertainty about the costs of compliance.¹¹⁷ In a deep integration plurilateral agreement, given the need for strong multidisciplinary technical and regulatory capacity, it may well be that this is magnified.

To illustrate, deep integration regional trade agreements (RTAs) are often supported by industries producing parts and components, i.e. intermediate goods, and their movement across and beyond borders would generate nontariff costs borne from domestic regulation. Kim states that their success in generating profits and gaining from economies of scale relies not only on reducing these costs, but also, that they have ‘stable expectations regarding these regulations’.¹¹⁸ In essence, the industrialised West expects regulatory homogeneity from developing countries in these agreements, and the decisions that developing country negotiators make in these agreements could be contingent on something as tangible as access to a market as large as the U.S. or domestic industries’ concerns about non-discriminatory beyond border regulations, or something as intangible as a promise to increase technology transfer, or that the agreement will improve the credibility of domestic policies

¹¹² Kim (n 110) 360

¹¹³ The behaviour of negotiating states should be distinguished from the behaviour of individual negotiators. U.S. negotiators have been described as ‘fundamentally forceful and pragmatic. Individual negotiators may be genial, or moralistic, or pushy, but ultimately all share a businesslike concern to achieve results in the shortest time.’ USIP (United States Institute for Peace), *U.S. negotiating behaviour*. (USIP 2002) <<https://www.usip.org/sites/default/files/sr94.pdf>> accessed 1 June 2017. This does not seem to have changed.

¹¹⁴ Raquel Fernández and Jonathan Portes, ‘Returns to Regionalism: An Analysis of Nontraditional Gains from Regional Trade Agreements (1998) 12(2) *The World Bank Economic Review* 197-220, 200

¹¹⁵ Francesco Duina and Sonia Morano-Foadi, ‘Introduction: The Institutionalisation of Regional Trade Agreements Worldwide: New Dynamics and Future Scenarios’ (2011) 17(5) *European Law Journal* 561-567

¹¹⁶ *Ibid* 564

¹¹⁷ B Peter Rosendorff, ‘Domestic Politics and International Disputes’ in Lisa L Martin (ed), *The Oxford Handbook of the Political Economy of International Trade* (Oxford University Press 2015) 140

¹¹⁸ Kim (n 110) 367

(therefore increase negotiating leverage with other negotiating partners).¹¹⁹ Furthermore, a state in late development (for example upper middle-income countries like Chile or Malaysia) may find that they have more leverage (compared to lower middle-income countries) in these agreements due to a combination of factors including income levels, industrial capabilities, and moderate to high levels of technological capacity. Manger and Shadlen discuss:

[T]rade needs to be understood in the context of broader constellations of economic policies, and that scholars need to keep in mind the overarching commonalities with regard to the role of the state in late development.¹²⁰

It is also worth remembering that while homogenous standards are expected of these states, these countries are not homogenous, and so while commonalities that drive states to make similar tradeoffs are important, so are the differences. Krugman illustrates: 'Nations may legitimately have different ideas about what is a reasonable standard... even nations that share the same values will typically choose different standards if they have different incomes.'¹²¹ The inverse is also true: that countries with same incomes will typically choose different standards if they have different values. Basically, negotiating decisions are multifactorial, and what countries choose in terms of standards would depend on their values and the histories that have determined those values.

Similarly, in terms of intellectual property, the decision for countries to agree to TRIPS Plus standards occurs in the context of 'compromises'¹²² i.e. political economy tradeoffs. Muzaka emphasizes that 'contests over IPR cannot be considered in isolation' and refers to broader developments that may have an impact on these processes.¹²³ As mentioned in Section IV of this chapter, in the TPP, market access tradeoffs were particularly visible in the context of exclusivity for biologic medicines. There may have been other forms of tradeoffs. Pugatch observes that decisions not to grant IP rights to foreigners are contingent on that countries' access to foreign markets,¹²⁴ i.e. the ability of its domestic firms to purchase alternative IP products, and that the country may be forced to accept maximalist IP in the face of a threat of trade retaliation.¹²⁵

¹¹⁹ Fernández and Portes (n 114) 203-206

¹²⁰ Mark S. Manger and Kenneth C Shadlen, 'Trade and Development', in Lisa L Martin (ed), *The Oxford Handbook of the Political Economy of International Trade* (Oxford University Press 2015) 475

¹²¹ Krugman (n 109) 116

¹²² Reuters in Atlanta, 'TPP trade deadlock: Pacific countries near deal after biotech breakthrough' *The Guardian* (5 October 2015) <<http://www.theguardian.com/business/2015/oct/04/tpp-trans-pacific-partnership-pacific-countries-pharmaceuticals>> accessed 29 December 2015

¹²³ Valbona Muzaka, *The Politics of Intellectual Property Rights and Access to Medicines* (Palgrave Macmillan 2011) 5

¹²⁴ Pugatch (n 20) 50

¹²⁵ Pugatch (n 20) 66

In any case, with increasingly maximalist IP, and other rules in these deep integration mega-regional agreements, the global trade order is changing. Hamilton posits:

In Washington's view, successful TPP and TTIP negotiations might create momentum that could in fact push Doha forward. In addition, if TPP and TTIP partners went even further and codified and aligned their existing free trade agreements with all others with whom they have such free trade agreements, such a step would be a major boost to the global trading order.¹²⁶

While the TTIP never to fruition, and the TPP eventually became the CPTPP and suspended biologics exclusivity, the rules negotiated in these agreements, as Kwakwa explains, are likely to go on from there to be introduced in North-South bilateral agreements, where the negotiating dynamic is different and developing countries 'in all likelihood, have less leverage than they would have in the multilateral setting'.¹²⁷ The Asian Development Bank concurred, saying that the diversity of the members could result in the plurilateral agreement disintegrating and the rules therein instead reappearing as 'loosely-tied bilateral deals'.¹²⁸

The TPP and the TTIP is attempting the gradual adoption of EU-US rules as the basic norms and the core of new global standards in trade,¹²⁹ and the effective diminution of any chance of an equal arena for the Global South.

(iii) The response and role of the upper middle-income states in world trade politics

Middle-income country trade gains in response to maximalist intellectual property have historically occurred in an environment of coercion. Evidence of resistance to maximalist intellectual property is aplenty, particularly from Brazil and India, and there is agreement that there were 'inducements' to accede to TRIPS.¹³⁰ Middle-income countries were concerned about the development costs of TRIPS - not only the costs of longer medicines monopolies, but also the costs of drafting new laws, enhancing administrative capacities, and strengthening enforcement mechanisms.¹³¹ As the TRIPS negotiations progressed, it became increasingly clear to Western industrialised nations that they would have to make concessions on agriculture and textiles.¹³² Combined with the threat that developing countries would lose

¹²⁶ Daniel S Hamilton, 'America's Mega-Regional Trade Diplomacy: Comparing TPP and TTIP' (2014) 49(1) *The International Spectator* 81-97, 84

¹²⁷ Edward Kwakwa, 'Reflections on "Development," "Developing countries" and the "Progressive development" of International Trade and intellectual Property Law' (2011-2012) 40(1-3) *Denver Journal of International Law & Policy* 221-236, 221

¹²⁸ Shamim Adam, 'TPP Trade Pact Risks Degenerating into Bilateral Deals, ADB Says' *Bloomberg* (24 October 2013) <<https://www.bloomberg.com/news/articles/2013-10-24/tpp-trade-pact-risks-degenerating-into-bilateral-deals-adb-says>> accessed 7 April 2017

¹²⁹ Hamilton (n 126) 84-85

¹³⁰ Poppy S Winanti and Alisdair R Young, 'Complying with Unwelcome Rules: Developing Countries and the TRIPS Agreement' (2009) 2(52) *Indian Journal of International Economic Law* 52-79, 58

¹³¹ Winanti and Young (n 130) 58

¹³² Emmert (n 83) 1325

access to the U.S. and EU markets previously negotiated under GATT, developing countries reluctantly agreed to the agreement.¹³³ They were given transition periods to become TRIPS compliant.

In international trade literature, developing countries have been traditionally seen as part of the same bloc, i.e. the bloc that is concerned about maximalist intellectual property because of philosophical, social, developmental, or economic priorities.¹³⁴ The industrialised nations, on the other hand, are homogeneously characterised as countries which seek higher standards of intellectual property in order to minimise trade losses and provide an incentive for innovation. The reality is much more complex, in that upper middle-income countries are in a unique position, and behave differently from their lesser-developed bloc-mates.

In specific, they are countries aspiring to become developed countries and thus are seen as easier targets for maximalist IP, but at the same time are seen as conduits for greater harmonisation of maximalist IP due to several reasons: their recent experience of being lesser-developed, sufficient income levels and IP capacity, their geographical proximity to lower middle-income countries, established political relationships with the lesser developed, and may have sufficient indigenous technological and industrial capabilities to generate IP, and therefore be less inhibited in terms of stronger IP.¹³⁵ I suggest that given the deep integration characteristic of the TPP, the upper middle-income role and distinction is more evident, and this research will seek to elucidate the distinction and provide, from an upper middle-income country perspective, lessons for lesser-developed countries seeking to engage in, or already commencing, trade negotiations. This brief explanation allows me now to segue into why Chile and Malaysia will be used as illustrative examples of how different upper-middle income countries make political economy tradeoffs.

IV. Chile and Malaysia: illustrating upper middle-income country approaches in trade negotiations

Chile, a Latin American presidential constitutional republic and former Spanish colony of 18 million people stretching over 6000 kilometers of South America's western coastline, could not

¹³³ Winanti and Young (n 130) 58

¹³⁴ Patricia L Judd, 'Toward a TRIPS Truce' (2011) 32 Michigan Journal of International Law 613-662, 636

¹³⁵ Lall notes that as income rises in developing countries, the intensity of patenting falls as countries build local capabilities. Kim expands on this with the example of Korea, whereby it was only after the development of local capacity and R&D expenditure did IPRs become more relevant to Korean firms. Hence generators of IP would be more inclined towards accepting higher standards of IP. Sanjaya Lall, *Indicators of the relative importance of IPRs in developing countries*. (International Centre for Trade and Sustainable Development (ICTSD) & United Nations Conference on Trade and Development (UNCTAD) 2003) 5 <<http://www.ictsd.org/sites/default/files/research/2008/06/cslall.pdf> > accessed 25 June 2017

seem more different from Malaysia, a majority Muslim constitutional monarchy and Commonwealth country of 32 million people situated in the centre of Southeast Asia.¹³⁶ They have vastly different historical backstories, with Chile achieving independence from the Spanish in 1818s, undergoing an economic crisis in 1982, and following that, consolidation of market-oriented reforms and trade liberalisation. In 2003, Chile signed the U.S.-Chile FTA, eliminating tariffs for 90% of U.S. agricultural products and adopting TRIPS-plus provisions.¹³⁷

British Malaya, as it was loosely termed from the 19th century through to the formation of the Malayan Union in 1946, was an agriculture- and mineral-rich land, and in the year 1900 saw influxes of Chinese and Indian immigration for tin mining and rubber plantations.¹³⁸ After independence from the British in 1957, it was for many decades protectionist for the purpose of import-substituting industrialisation (ISI).¹³⁹ In the mid-1970s to early-1980s, it had a boom in revenue due to petroleum exports,¹⁴⁰ but was still wary of United States interests. In 2006 negotiations began for a U.S.-Malaysia FTA, with the then-U.S. Trade Representative stating that Malaysia was at the 'forefront of economic dynamism' in Asia,¹⁴¹ but by 2007 negotiations had broken down due to disagreements on government procurement, intellectual property, and economic impact of tariff elimination.¹⁴² Malaysia has only relatively recently signed multiple bilateral trade agreements.

The countries (chosen out of 4 upper-middle income TPP countries) also, however, have a number of unifying similarities, and it is the combination of these similarities and differences that will make an illuminating narrative, and are key to their negotiations and/or losses or gains on biologic medicines.¹⁴³ These include income levels, similar negotiating expertise, alliances on IP, and specific TPP biologics negotiating events, and are elaborated upon below.

¹³⁶ Department of Statistics, Malaysia, 'Current Population Estimates, Malaysia, 2014-2016' 2016 <<https://www.dosm.gov.my/v1/index.php?r=column/cthemByCat&cat=155&bulid=OWIxdEVoYIJCS0hUZzJyRUcvZEYxZz09&menuid=L0pheU43NWJwRWVVSZkiWdzQ4TihUUT09>> accessed 30 May 2017

¹³⁷ G Gabriel Zorogastua, 'Peru's too expensive – I'll Get my Cheese from Chile: The Agricultural Market Access Provisions of the U.S.-Chile FTA and the U.S.-Peru FTA' (2007) 16(2) *Journal of Transnational Law and Policy* 337-359, 339

¹³⁸ Francis Loh Kok Wah, *Beyond the Tin Mines: Coolies, Squatters and New Villagers in the Kinta Valley, Malaysia, c. 1880-1980* (Oxford University Press 1988) 9

¹³⁹ Protectionism to allow infant industries to mature without competition from established foreign competitors. Rokiah Alavi, *Industrialisation in Malaysia: import substitution and infant industry performance* (Routledge 1996) xii

¹⁴⁰ John H Drabble, *An Economic History of Malaysia, c. 1800-1990* (Macmillan Press Ltd 2000) 199

¹⁴¹ USTR (The Office of the United States Trade Representative), 'United States, Malaysia Announce Intention to Negotiate Free Trade Agreement' USTR (8 March 2006) <http://www.sice.oas.org/TPD/USA_MYS/Negotiations/BeginFTA_e.pdf> accessed 4 November 2019

¹⁴² Michael F Martin, 'The Proposed U.S.-Malaysia Free Trade Agreement' (Congressional Research Service, 26 January 2009) <<https://apps.dtic.mil/dtic/tr/fulltext/u2/a500370.pdf>> accessed 4 November 2019

¹⁴³ Interestingly, there has been a comparison of Chile's and Malaysia's approaches to financial stability in the TPP – with both countries seeking to preserve regulatory space in regard to capital account regulations, with the authors noting that for Malaysia, the agreement that most limited their policy space was with Japan, and for Chile, it was the U.S.-Chile FTA that created a similar restricted policy space. The authors also noted that both Malaysia and Chile made compromises, albeit retaining some control to respond to financial crises. Ricardo Ffrench-Davis, Kevin P Gallagher, Mah-Hui Lim, and Katherine Soverel, 'Financial Stability and the Trans-Pacific Partnership: Lessons from Chile and Malaysia' (2015) 6(4) *Global Policy* 330-342, 339-340

Grounds for Comparison

For ease of reference, the grounds are set out numerically below and substantiated further.

Similarities

- 1) Income levels & negotiating capacity
- 2) Human development levels & negotiating capacity
- 3) Alliances on IP in the TPP, specifically on U.S.-proposed provisions
- 4) Approaches at the WTO – close to big economies, and allied with regional partners
- 5) Experience/familiarity in making concessions to U.S. demands. Both countries accepted data exclusivity as a result of U.S. pressure/negotiations/agreements
- 6) Governmental focus and interest in biopharmaceutical innovation, and domestic manufacturing capacities

Differences

- 7) Chile having pre-existing bilateral trade agreements with all TPP countries, therefore established market access deals.
- 8) Chile already having 5 years of market exclusivity on biologics.
- 9) Chile being in a stronger economic position and implications on concessions.

1. Similar income levels as an indicator of similar negotiating capacity

Among the four upper-middle-income TPP countries, Chile and Malaysia are the closest in terms of GDP, GNI per capita, and real GDP growth.¹⁴⁴ Country income levels lend relevance to several phenomena in the international trade environment, including how countries negotiate (power dynamics), what commitments they are subject to, eligibility for trade expertise funding, negotiating capacity, and administrative capacity of the state and domestic implementing actors.¹⁴⁵

How countries behave in trade negotiations is often dependent on economic prowess, because it indicates not only what products they can bring to the table, but also what aid or

¹⁴⁴ World Bank, 'Malaysia' (2017) < <http://www.worldbank.org/en/country/malaysia> > accessed 30 May 2017

¹⁴⁵ Meredith Kolsky Lewis, 'The Trans-Pacific Partnership Agreement and Development' in Tania Voon (ed), *Trade liberalisation and international cooperation: a legal analysis of the Trans-Pacific Partnership Agreement* (Edward Elgar Publishing Limited 2013) 34-38; Helen V Milner, 'The Political Economy of International Trade' (1999) 2 *Annual Reviews of Political Science* 91-114, 102

technical assistance they can withhold or withdraw. The U.S., for example, is seen as a 'heavy-handed hegemon'¹⁴⁶ in international trade, and often resorts to a number of bullying or threat tactics, including threats against ambassadors¹⁴⁷, withdrawal of foreign aid and technical assistance, putting pressure on capitals, and including countries in their intellectual property naughty list, the Special 301 Priority Watch List.¹⁴⁸

Jawara and Kwa describe the 'bullying hierarchy' in more detail:

While both developed and developing countries participate in the sophisticated political games played by different blocs to try to get what they want at the WTO, the Quad (Canada, European Communities, Japan, Luxembourg, Sweden, USA) and other developed countries, being the most powerful players by far, are firmly entrenched at the top of the bullying hierarchy. Their much greater political and economic muscle means they are better placed to call the shots, and to issue threats and promises where necessary to further their interests.¹⁴⁹

The authors then described upper-middle income (and a handful of lower middle income) countries as being next in the hierarchy, but with a game that is more complex, reflecting a balance of interests between appearing friendly with the major powers and reaping the benefits of strategic alliances with least developed countries. On their role, the authors state: One of the main bargaining chips they can offer in this process is the influence they can exert on other developing countries, particularly through regional and other groupings.¹⁵⁰

Least developed countries, historically have had limited participation in trade, with Hoekman and Kostecki commenting on the GATT agreement as 'primarily of relevance to OECD countries. Developing countries did not participate fully.'¹⁵¹ While the authors did not state expressly that this was due to a lack of negotiating capacity, others have noted weak domestic institutions and human capacity as a key factor to this lack of participation.¹⁵² In the 1990s, emphasis on trade-related technical expertise to least developed countries (LDCs) emerged and was funded by developed nations. That is to say, there is a nexus between country incomes and negotiating expertise, albeit an imprecise one, as arguably some Indian and

¹⁴⁶ Tony Porter, 'The United States in International Trade Politics: Liberal Leader or Heavy-Handed Hegemon' in Dominic Kelly and Wyn Grant (eds), *The Politics of International Trade in the Twenty-First Century: Actors, Issues and Regional Dynamics* (Palgrave MacMillan 2005) 218

¹⁴⁷ Fatoumata Jawara and Aileen Kwa, *Behind the Scenes at the WTO: The Real World of International Trade Negotiations: The Lessons of Cancun* (Zed Books Ltd, 2004) 151

¹⁴⁸ *Ibid* 150-151

¹⁴⁹ *Ibid* 149

¹⁵⁰ *Ibid*

¹⁵¹ Bernard Hoekman and Michel Kostecki, *The political economy of the world trading system* (Oxford University Press 2001) 385

¹⁵² J Michael Finger and Philip Schuler, 'Implementation of Uruguay Round Commitments: the Development Challenge' (2000) 23(4) *The World Economy* 511-525, 511 <<http://onlinelibrary.wiley.com/doi/10.1111/1467-9701.00287/abstract>> accessed 16 February 2017)

Brazilian negotiators are better skilled than high income country negotiators. While the strength of this nexus has not been conclusively established in academic literature, it is an accepted truth in the international trade scene that countries of similar incomes exhibit similar negotiating expertise, and that expertise is central to effective trade gains.

In a 2010 study, Jones et al. describe the threats and intimidation that small state negotiators face, and that these threats 'severely constrains their perceived ability to negotiate successfully and their determination to persist'.¹⁵³ The authors also describe how small states are constrained in their ability to design and deploy negotiating strategies.

This lack of participation, and a lack of gains from international trade negotiations has also been documented in the access to medicines sphere, with Drahos suggesting four lessons for developing countries to learn for increased efficacy in negotiations.¹⁵⁴ These include the need for developing countries to prepare strategies to realise negotiating gains, and to be wary of 'negotiating fatigue' resulting from developed countries bearing down and renegotiating issues repeatedly in order to break the weaker party down.

This is not to say, however, that developing countries cannot win negotiating gains against a stronger power. Developing countries can and have won gains against developed countries via a multitude of different tactics, including tradeoffs, coalition-building, and agenda-setting, among others. However, this is dependent on negotiating capacity. Singh elaborates:

[D]eveloping countries can "win" only through clever combinations of knowledge, flexibility and daring... Negotiation environments, in particular, can be directly derived from particular power configurations of the global economy and determine the negotiating 'rules of the game' and the availability of alternatives to the developing world.¹⁵⁵

In the 1990s, it became obvious at least in the multilateral trading sphere that developing countries were ill equipped to negotiate to their best interests. In 1996, a WTO ministerial event was held in Singapore, where ministers of trade discussed and agreed upon a Plan of Action to end the marginalisation of LDCs in trade, and elucidate funding streams for trade-related technical expertise programmes for LDCs.¹⁵⁶

¹⁵³ Emily Jones, Carolyn Deere-Birkbeck, and Ngaire Woods, *Manoeuvring at the Margins: Constraints Faced by Small States in International Trade Negotiations* (Commonwealth Secretariat 2010) xv

¹⁵⁴ Peter Drahos, 'Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines' (2007) 28 *Liverpool Law Review* 11-39, 11

¹⁵⁵ J P Singh, 'Weak Powers and Globalism: The Impact of Plurality on Weak-Strong Negotiations in the International Economy' (2000) 5 *International Negotiation* 449-484, 450

¹⁵⁶ Hoekman and Kostecky (n 151) 398-399

Today these programmes are carried out by the WTO and are funded by major donors such as Norway, Sweden, and the United Kingdom.¹⁵⁷ According to a survey conducted by the WTO on these international support measures among least developed countries, financial constraints mean that they are often unable to access information available in their countries' public administration, they were not able to understand questions in the survey, and inadequate human resources.¹⁵⁸ Upper middle-income countries are precluded from receiving trade-related technical assistance from this fund.

Negotiating countries with similar incomes often choose similar standards, even if they have different values.¹⁵⁹ In the context of this PhD, this nexus between country income and negotiating capacity and negotiating behaviours is salient because I seek to document how different countries of similar income, developmental level, and negotiating capacity responded to demands that they did not necessarily agree with. This will provide useful lessons for other middle-income countries.

In my view, a comparison with a high-income TPP country would have lent a different narrative – i.e. how different financial prowess and political dynamic affects how different countries negotiate, but this has already been documented numerous times elsewhere.¹⁶⁰ In addition, the example of one upper middle-income country simply would not capture unique regional histories that affect trade negotiations. It is also for that reason that I did not select two countries in the same region. A choice of Chile and Mexico, for example, would simply be another study on trade in Latin America.¹⁶¹

IP capacity is a different thing altogether. Even in the TRIPS negotiations, neither the chief negotiators from the GATT contracting parties nor Ambassador Anell and the members of the GATT Secretariat assigned to the TRIPS negotiations were intellectual property experts.¹⁶²

¹⁵⁷ WTO (World Trade Organization), *Fifth Global Review of Aid for Trade: Reducing Trade Costs for Inclusive, Sustainable Growth* (WTO 2015) 111 <https://www.wto.org/english/tratop_e/devel_e/a4t_e/global_review15prog_e/5qr_review_e.pdf> accessed 4 November 2019

¹⁵⁸ UNDESA (United Nations Department of Economic and Social Affairs/Committee for Development Policy), *Survey on International Support Measures Specific to the Least Developed Countries (LDCs) related to WTO Provision and Preferential Market Access: Responses by LDCs* (UNDESA 2012) 3-4 <<http://esango.un.org/ldcportal/documents/10179/15001/Summary%20%26%20Analysis%20LDCs.pdf?version=1.1&t=1349984705000>> accessed 15 February 2017

¹⁵⁹ Krugman (n 109) 116

¹⁶⁰ Emmert (n 83); Helen V Milner and B Peter Rosendorff, 'Democratic Politics and International Trade Negotiations: Elections and Divided Government as Constraints on Trade Liberalisation' (1997) 41(1) *Journal of Conflict Resolution* 117-146

¹⁶¹ Zorogastua (n 137); Johanna Von Braun, *The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements* (Routledge 2012); Kakali Mukhopadhyay, Paul J Thomassin, Debesh Chakraborty, 'Economic Impact of Freer Trade in Latin America and the Caribbean: a GTAP Analysis' (2012) 49(2) *Latin American Journal of Economics* 147-183

¹⁶² Jacques J Gorlin, *An Analysis of the Trade-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement* (Intellectual Property Institute, 1999) 6

However, given different geographical regions, and different political systems, cultures, and historical backstories, I wish to further substantiate the choice by comparing human development levels of the two countries.

2. Human development levels

The first Human Development Report, released in 1990, introduced the Human Development Index (HDI) as an alternative to looking at development from solely an ‘expansion of income and wealth’ perspective¹⁶³ and aims to capture a broader characterisation of development by looking at education, inequality, trade, and employment, among other things.¹⁶⁴ In the context of this PhD, consideration of HDI may reveal certain meaningful differences pertaining to the stake of the country in intellectual property and access to medicines, and/or their capacity to negotiate on intellectual property at the level of trade negotiations.

Among the four upper middle-income countries in the TPP, Chile and Malaysia have the highest ranked HDI, although the margin of difference in rank and HDI is larger between Chile and Malaysia as compared to Malaysia and Mexico.

The below table presents the human development index and corresponding global ranking of the upper middle-income countries in the TPP:

Figure 1: Human Development Index (Source: UNDP)

Country (alphabetical order)	HDI	Rank	Expected years of schooling (years)	Population with at least some secondary education (% aged 25 and above)	Exports & Imports (% of GDP)
Chile	0.832	42	15.2	74.8	65.5
Malaysia	0.779	62	12.7	68.2	154.1
Mexico	0.756	74	13.1	58.0	64.2
Peru	0.734	84	13.1	61.1	48.8

Malaysia has the least expected years of schooling, but the second highest percentage of population with at least some secondary education. Chile ranked highest out of the four countries with respect to most indicators pertaining to education. While this cannot be

¹⁶³ UNDP (United Nations Development Programme), *Human Development Report 1990* (UNDP 1990) <<http://hdr.undp.org/sites/default/files/reports/219/hdr1990encompletenostats.pdf>> accessed 4 November 2019

¹⁶⁴ Martin Ravallion, ‘Troubling Tradeoffs in the Human Development Index’ (2012) 99(2) *Journal of Development Economics* 201–209

conclusively linked to negotiating capacity, other studies assist in illustrating value of human capital in these countries. Beine et al. conducted an empirical analysis of data, including emigration rates by educational and skill level, factoring for credit constraints on education, and found that both Chile and Malaysia are undergoing a 'beneficial brain drain', meaning that emigration rates are having a 'positive impact on gross human capital formation', and that this may foster investment in education at home.¹⁶⁵ However, according to this economic model, Chile's human capital formation gains more from skilled migration prospects as compared to Malaysia.

Malaysia also differs to the other countries in terms of exports & imports as a percentage of GDP, which is often used as a general indicator of openness to foreign trade,¹⁶⁶ and is an indicator of higher human development. It also indicates the dependence of domestic producers and consumers on foreign supply relative to GDP.¹⁶⁷ The International Chamber of Commerce looks at openness to trade in greater depth, and ranks Chile and Malaysia both in the 'above average openness' category, with Peru and Mexico in the 'average openness' category, as tabulated below.

Category	Country (alphabetical order)	Rank	Score
Above average openness	Chile	29	4.1
	Malaysia	33	4.0
Average openness	Mexico	54	3.1
	Peru	40	3.8

Table 1: Openness to trade of upper-middle income TPP countries (Source: ICC, 2015, p. 11)

Chile has double the number of bilateral trade agreements in force compared to Malaysia, with 15 bilateral trade agreements. In total, Chile has 21 free trade agreements, whereas Malaysia has 13. Out of Malaysia's 13 free trade agreements, 7 are bilateral.¹⁶⁸ These lead me to the question: how does trade openness influence concessions? Will a country that is hungrier for an FTA make more concessions that it is not ready for?

¹⁶⁵ Michel Beine, Frédéric Docquier, and Hillel Rapoport, 'Brain Drain and Human Capital Formation in Developing Countries: Winners and Losers' (2008) 118 *The Economic Journal* 631-652, 644-645 <<http://econweb.umd.edu/~Lafortune/puc-readings/BeineDocquierRapoport2008.pdf>> accessed 15 February 2017

¹⁶⁶ World Bank, 'World Development Indicators 2015' (2015) <<https://blogs.worldbank.org/opendata/release-world-development-indicators015>> accessed 30 May 2017

¹⁶⁷ UNDP (United Nations Development Programme), *Exports and imports (% of GDP)* (2017) <<http://hdr.undp.org/en/indicators/133206>> accessed 30 May 2017

¹⁶⁸ SICE, 'Information on Chile: trade agreements in force' (2017) <<http://www.sice.oas.org/cty/index/CHL/CHLAgreementse.asp#PartialPrefs>> accessed 30 May 2017; MITI (Ministry of International Trade and Industry), 'Malaysia's Free Trade Agreements' (2017) <<http://fta.miti.gov.my/index.php/pages/view/4?mid=23>> accessed 30 May 2017

FTA hunger, as was demonstrated in the case of the North American Free Trade Agreement (NAFTA), was mainly because of Mexico's intention to improve the credibility of its domestic policies rather than market access targets.¹⁶⁹ As a result of FTA hunger, Mexico significantly reduced tariffs in exchange for only partially reduced tariffs, and deregulated investment and supplemental agreements.¹⁷⁰ Turkey similarly made deep concessions, simply in order to avoid economic marginalisation from not being included in a regional trade bloc.¹⁷¹

Trade openness, however, does not automatically equate to desperation to sign an FTA. A country with high export & import figures may feel that it has sufficient or adequate openness to grow its economy, and may not feel the need to make major concessions for an FTA that would only give it marginal benefits. On the other hand, Milner describes how openness to trade changes domestic preferences in that it increases the number of supporters of free trade.¹⁷² This would in turn provide more room for concessions.

3. Allied on intellectual property

As leaked TPP texts came to the fore, it became clear that alliances among developing countries and occasionally alliances between developing countries and select developed countries were being formed. In the IP text, Chile and Malaysia were allied on, among other things, trademark protection for scents (Article QQ.C.1) (TPP IP group country negotiators, ¹⁷³ recordal of trademark licenses as a condition to join infringement proceedings (Article QQ.C.10), geographic indications (QQ.D.5), and the issue of the denial of patents solely due to the fact that the product did not result in increased efficacy (QQ.E.1). Importantly, Chile and Malaysia were part of an alliance of five countries (New Zealand, Canada, Singapore, Chile, and Malaysia) in proposing pre- and/or post-patent grant opposition procedures (QQ.E.4).¹⁷⁴

Kolsky Lewis discusses these alliances in the TPP negotiations, and says that while the TPP environment was less favourable to developing country participants as compared to the WTO,

¹⁶⁹ Paola Conconi and Carlo Perroni, 'Conditional versus Unconditional Trade Concessions for Developing Countries' (2012) 45(2) *The Canadian Journal of Economics* 613-631, 615

¹⁷⁰ Mine Eder, 'Deeper Concessions and Rising Barriers to Entry: New Regionalism for Turkey and Mexico' (2001) 36(3) *Studies in Comparative International Development* 29-57, 32

¹⁷¹ *Ibid* 31

¹⁷² Milner (n 145) 108

¹⁷³ TPP IP Group Country Negotiators, *Trans-Pacific Partnership Agreement: Intellectual Property [rights] Chapter: Consolidated text* (30 August 2013) <<https://wikileaks.org/tpp/static/pdf/Wikileaks-secret-TPP-treaty-IP-chapter.pdf>> accessed 14 February 2017

¹⁷⁴ *ibid*

it was likely to be more favourable as compared to bilaterals with developed countries, where they would have less bargaining leverage as compared to the multilateral setting.¹⁷⁵

For the purposes of this project, given that by the final release of the IP chapter all bracketed text had been removed and it is not apparent whether alliances were formed on biologics exclusivity, it would be interesting and novel to document whether alliance-forming was one of the strategies employed in addition to or in lieu of a market access tradeoff.¹⁷⁶

4. Position at the WTO – closeness to developed countries and established alliances with regional developing country partners

Chile has been described as a favourite of the big economies, and has persuaded other Latin American countries to agree to positions demanded by the big economies. Similarly, while traditionally Malaysia has been a strong leader of developing countries and impervious to threats from industrialised nations, from 2003 onwards demonstrated their agreeability to industrialised nation proposals, and even persuaded African countries to agree.¹⁷⁷

This matters for the main reason that the TPP is at its core a deep integration agreement. As discussed above, the rule makers in the TPP (i.e. U.S. and Japan) want to establish new global norms. In addition, upper middle-income countries and lesser-developed countries (LDCs) have a 'development proximity' in that they understand the technical needs of LDCs and are seen as models for the next stage of development.¹⁷⁸ In order for new rules to be accepted as the norm, industrialised nations need not only developing country practitioners of their rules, but also for those developing countries to be advocates of those rules to lesser developed countries.

Political closeness (which in turn often comes hand in hand with some form of economic interdependence) can affect domestic trade choices. For example, countries with military cooperation trade more with each other, opening up the possibility of more trade concessions. Adding to this equation is that a country with military dependence on another country means that there is a position of dominance, increasing the likelihood of concessions. An example of

¹⁷⁵ Meredith Kolsky Lewis, 'The Trans-Pacific Partnership Agreement and Development' in Tania Voon (ed), *Trade liberalisation and international cooperation: a legal analysis of the Trans-Pacific Partnership Agreement* (Edward Elgar Publishing Limited 2013) 39; Kwakwa (n 127) 229

¹⁷⁶ Chile also negotiated Annex 18-B pertaining to biologics exclusivity, which was not given to any other negotiating country. It is unclear at this point whether additional concessions were made.

¹⁷⁷ Jawara and Kwa (n 147) 165

¹⁷⁸ Dorotea Lopez and Felipe Muñoz, 'Challenges for Middle-Income Countries to Play an Active Role in Trade: The Case of Chile' World Trade Organization (2013)

<<https://www.wto.org/english/tratope/devele/a4te/globalreview13proge/aftresumesnontechiqueschilee.pdf>> accessed 16 May 2017

this has been documented in regard to the Colombia-U.S. FTA, which Healey describes as being an FTA rooted in security motives¹⁷⁹ as opposed to general developmental goals, and keeps Colombia dependent on U.S. military aid.¹⁸⁰ Milner also describes the effect of previous trade relationships on current trade choices, in that if previous trade has cultivated a pacific relationship between two countries, it is likely that further liberalisation will be stimulated.¹⁸¹ Following on from this train of thought, it would be necessary, therefore, to determine whether Chile's previous negotiations with the U.S. brought on a pacific relationship that contributed to Chile's proclivity towards the TPP, and whether Malaysia being at loggerheads with the U.S. in the U.S.-Malaysia bilateral FTA negotiations in 2006 dictated a more cautious approach, and therefore less concessions.

5. Experience with IP concessions as a result of U.S. demands

Previous experience with U.S. IP demands in trade is something that both Chile and Malaysia have in common. Chile agreed to data exclusivity via the Chile-U.S. bilateral trade agreement in 2003.¹⁸² Malaysia, on the other hand, was asked to accept data exclusivity in the negotiations for the Malaysia-U.S. bilateral agreement in 2006, but given that negotiations broke down and the agreement was never concluded, data exclusivity was not accepted at that point of time.

In 2010, however, Malaysia was put on the US Trade Representative's Special 301 Priority Watch List (PWL) for failing to include data exclusivity in its laws. One year after being including in the PWL, Malaysia adopted and implemented data exclusivity for pharmaceuticals via a government directive.¹⁸³ In 2012, Malaysia was removed off the PWL, and US Trade Representative Ron Kirk in his Special 301 Report specifically mentioned data exclusivity as one of the key reasons for removing Malaysia off the PWL.¹⁸⁴ Chile, on the other hand, continues to be included in the Special 301 PWL due to 'longstanding IPR issues' on patent-data linkage,¹⁸⁵ and may suggest either disagreement with the U.S. on implementation, or a

¹⁷⁹ Declan Healey, 'The U.S.-Colombia Free Trade Agreement – A Historical Placement of the FTA' (PhD Thesis, College of Liberal Arts & Social Sciences, DePaul University 2010) 5 <<http://via.library.depaul.edu/etd/10>> accessed 7 November 2019; This is not an isolated phenomenon. Trade concessions have occurred in the context of increased or decreased military aid, and entire regional trade agreements have been deemed as military alliances in addition to market access instruments. Kathy Powers, 'Regional Trade Agreements as Military Alliances' (2004) 30(4) *International Interactions* 373-395

¹⁸⁰ Joanne Gowa, *Allies, Adversaries, and International Trade* (Princeton University Press 1994)

¹⁸¹ Milner (n 145) 110

¹⁸² Carlos Correa, 'Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines' (2004) 36 *Case Western Reserve of International Law* 79-94, 84

¹⁸³ National Pharmaceutical Control Bureau (BPFK), *Government Directive No. 2 of 2011, issued under Regulation 29 of the Control of Drugs and Cosmetic Regulations 1984* (2011) (Revised 2006)

¹⁸⁴ Ron Kirk, *2012 Special 301 Report* (Office of the USTR 2012)

<<https://ustr.gov/sites/default/files/2012%20Special%20301%20Report0.pdf>> accessed 31 May 2017

¹⁸⁵ Michael D G Froman, *2015 Special 301 Report* (2015)<<https://ustr.gov/sites/default/files/2015-Special-301-Report-FINAL.pdf>> accessed 31 May 2017

disregard of the 'aggressive unilateralism' of the Special 301 list.¹⁸⁶

It is unclear at this stage how previous experience with U.S. negotiators could have influenced concessions. Theoretically, learning from previous negotiations would've better prepared developing country negotiators to anticipate U.S. demands and respond by creating issue-linkages and alliances. This theory assumes that learning from previous experience has passed completely from trade negotiations of one era to another, or that the trade negotiation authority had a predefined idea of a win-set and corresponding strategy.

Zeng, detailing American coercive diplomacy in trade,¹⁸⁷ states that discussions on most-favoured nation status during the U.S.-China bilateral trade negotiation process in the 1990s brought 'virtually no discernible change in Beijing's policies',¹⁸⁸ and that threats to use the Special 301 was met with strong Chinese resistance. On IP protection, at three different incidences did the U.S. threaten China with trade sanctions if they did not occur, but at all three times last-minute agreements were achieved, with the 1996 sanctions withdrawn without any concessions from China.¹⁸⁹ This suggests some unit-level learning, but with China having enormous economic prowess, it may have been easier to leverage their resources and deny American demands on IP.

6. Domestic biopharmaceutical and biosimilar industries – political commitment and manufacturing capacity

Weatherall states:

A states' interests in framing domestic IP law will depend on a variety of factors: its development status, *the level of indigenous research and innovation, the local mix of industries* (a country with a strong export industry in education, for example, may have an interest in copyright exceptions for educational uses), and other issues such as the health status of the population (a country suffering an AIDS or other pandemic, for example, may wish to make use of flexibilities in patent law to reduce the cost of, and increase access to, essential medicines).¹⁹⁰ [Emphasis added].

¹⁸⁶ Jagdish Bhagwati, 'Departures from Multilateralism: Regionalism and Aggressive Unilateralism' (1990) 100 *The Economic Journal* 1304-1317

¹⁸⁷ Ka Zeng, *Trade threats, trade wars: bargaining, retaliation, and American coercive diplomacy* (The University of Michigan Press 2003) 92

¹⁸⁸ David M Lampton, 'Ending the MFN Battle' (1997) 4(2) *NBR Research* (National Bureau of Asian Research) 7-14, 7

¹⁸⁹ Zeng (n 187) 169

¹⁹⁰ Kim Weatherall, 'The TPP as a Case Study of Changing Dynamics for Intellectual Property Negotiations' in Tania Voon (ed), *Trade liberalisation and international cooperation: a legal analysis of the Trans-Pacific Partnership Agreement* (Edward Elgar Publishing Limited 2013) 51

Basically, trade preferences change based on domestic actors, i.e. whether import competition or the opening of markets abroad would affect their incomes.¹⁹¹ Applying this to the biologics or biosimilar industries in Malaysia and Chile, a country with a burgeoning biosimilar industry, established innovation of biosimilars, or even political plans towards investing in biosimilars may be more inclined towards insisting for an exception for biologics exclusivity.

Governmental agencies in charge of development and investment in Chile and Malaysia have both emphasised the strategic value of biotechnological or biosimilar drugs, and provides incentives for biotechnological companies to invest in their countries.¹⁹² CORFO, the Chilean Economic Development Agency, who works towards ‘transforming Chile into a global innovation and entrepreneurial hub’, has stated that they view the biotechnological industry as of strategic value to Chile, and so facilitate the incorporation of biomedical companies that seek to transfer technology and install manufacturing capacity in Chile.¹⁹³

Malaysian interest in biotechnology was noticed by U.S. stakeholders as early as 2006, when the Biotechnology Innovation Organization (BIO), the world’s largest trade agency focused on biotechnology based in Washington, D. C., in lauding the commencement of bilateral U.S.-Malaysia negotiations, noted that Malaysia was an ‘important market with a strong interest in developing in biotechnology industry’.¹⁹⁴ CORFO’s parallel agency in Malaysia, MIDA (Malaysian Investment Development Agency) on its website notes the ‘huge potential demand globally’ and provides for ‘pioneer status’ or ‘investments tax allowance incentives’ for companies manufacturing pharmaceuticals, biopharmaceuticals, nutraceuticals¹⁹⁵, microbials and probiotics.¹⁹⁶ It is unclear, however, whether these policies are tailored towards attracting originator biotechnology companies, or whether they benefit domestic biosimilar producers.

In terms of biosimilar manufacturing capacity, Malaysia has two companies producing biosimilars, InnoBio and Biocon, with the latter focusing solely on the production of recombinant insulin. Innobio is financed by the Malaysian government and is equipped with

¹⁹¹ Milner (n 145) 95

¹⁹² Asilfa, ‘Nuevos Medicamentos Biotecnológicos o Biosimilares: ¿Es El Costo un Desafío al Acceso? (New Biotechnological or Biosimilar Medicines: is the Cost a Challenge to Access?)’ *Al Día* (May 2015) <<http://asilfa.cl/ASILFACHILE/wp-content/filesmf/1431524981NEWSASILFAMAYO.pdf>> accessed 20 February 2017

¹⁹³ CORFO (Chilean Economic Development Agency), *About Corfo* (2015) <<http://www.english.corfo.cl>> accessed 9 February 2017; Asilfa (n 192)

¹⁹⁴ BIO (Biotechnology Innovation Organisation), ‘BIO President Jim Greenwood Welcomes U.S. FTA Negotiations with Malaysia’ *BIO* (8 March 2006) <<https://www.bio.org/media/press-release/bio-president-jim-greenwood-welcomes-us-fta-negotiations-malaysia>> accessed 31 May 2017

¹⁹⁵ Nutraceuticals are pharmaceutical-grade standardised nutritional supplements.

¹⁹⁶ MIDA (Malaysian Investment Development Authority), ‘Pharmaceuticals’ MIDA (2015) <<http://www.mida.gov.my/home/pharmaceuticals/posts/>> accessed 10 February 2017

bioreactors that can be run 15-18 times a year, and has thus far produced 7 biosimilar components for the Indian and Korean markets. They are also working with Cuban entities for the production of novel antibodies. These two companies are the two main biomedicine companies, although Malaysia has had an established small-molecule medicine generic pharmaceutical industry for some time. It is unclear, however, as to the extent of engagement these companies had with trade negotiators on pharmaceutical IP.

While there are Santiago-based companies providing laboratory testing of biosimilar products,¹⁹⁷ Chile does not have the capacity at present to produce biosimilars despite the government being very keen on developing a commercialised biosimilars market.¹⁹⁸ Similarly to Malaysia, Chile has a growing domestic small-molecule pharmaceutical industry, with an estimated growth rate of 11.3% per year.¹⁹⁹

The state of the domestic industry in both countries is salient for the reason that in the development stages, these industries rely on lower IP regimes in order to reverse engineer products and to develop indigenous technological and industrial capacity. It is only when there is indigenous capacity and intensity of effort to generate IP that IP becomes beneficial for these industries.²⁰⁰ Given the political commitment towards biotechnological development in both countries, it would be intriguing to discover in my research whether this eventually was a factor contributing to negotiating outcomes.

Among other TPP countries that were at loggerheads with the U.S. over biologics exclusivity, Australia has a blooming biomedical industry, with biomedical exports earning more than cars and wine, and domestic companies aiming to produce novel treatments in the near future.²⁰¹ One of these domestic companies, Mesoblast, has several novel stem cell treatments in the pipeline, and has recently received backing from an American company.²⁰² In addition to this, towards the end of 2016, the Turnbull government launched a \$500 million Biomedical

¹⁹⁷ SGS, 'Servicios de Pruebas de Biosimilares (Biosimilar Testing Services)' (2017) <<http://www.sgs.cl/es-ES/Life-Sciences/Laboratory-Services/Biosimilar-Testing-Services.aspx>> accessed 20 February 2017

¹⁹⁸ Email from Alexis Aceituno, Faculty of Pharmacy, Universidad de Valparaíso, to author (2 March 2017)

¹⁹⁹ PR Newswire, 'Despite Its Limited Size, Chile's Pharmaceutical Market Offers Growing Opportunity for Drug Industry' *PR Newswire* (22 September 2014) <<http://www.prnewswire.com/news-releases/despite-its-limited-size-chiles-pharmaceutical-market-offers-growing-opportunity-for-drug-industry-276015141.html>> accessed 31 May 2017

²⁰⁰ Lall (n 135); Linsu Kim, *Technology transfer & intellectual property rights*. Geneva: International Centre for Trade and Sustainable Development (ICTSD) & United Nations Conference on Trade and Development (UNCTAD) 2003) 5-13 <<http://www.ictsd.org/sites/default/files/research/2008/06/ckskim.pdf>> accessed 25 June 2017

²⁰¹ Mark Metherell, 'Australian Biomedical Industry Blooming' *The Sydney Morning Herald* (8 September 2012) <<http://www.smh.com.au/federal-politics/australian-biomedical-industry-blooming-20120907-25jbi.html>> accessed 20 February 2017

²⁰² Brian Robins, 'Local Stem Cell Biotech Mesoblast Wins Key U.S. Investor Backing' *The Sydney Morning Herald* (23 December 2016) <<http://www.smh.com.au/business/innovation/local-stem-cell-biotech-mesoblast-wins-key-us-investor-backing-20161222-gth19y.html>> accessed 20 February 2017

Translation Fund to stimulate development of biomedical products from the laboratory into the final product stages.²⁰³

Despite Australia's prospects in the production of novel biologics, Australia was a key opponent of the U.S. proposals for extended biologics market exclusivity, as they would not go beyond 5 years of exclusivity. Because of this, they were on the receiving end of vitriol from U.S. Senator Orrin Hatch, who said they wanted to 'steal U.S. patents' for biologics.²⁰⁴ In Atlanta, the pivotal round for the conclusion of TPP negotiations, the then-Trade Minister Andrew Robb told U.S. magazine *Inside Trade* that they were close to a compromise on biologics. So despite biomedical developments back home, limited biologics exclusivity still became a sticking point for Australia, possibly due to pressures from local public health groups.²⁰⁵

While a comparison with Australia would also be interesting because it would help elucidate why some developed countries object to maximalist IP for pharmaceuticals despite having the wealth and industrial background that is usually consistent with maximalist IP, this would not assist my objective in providing an illustrative documentation of how economies intending to become high income deal with demands from IP maximalist countries.

7. Pre-existing exclusivity for biologics

In the Chile-U.S. FTA which entered into force on 1 January 2004, Chile entered into commitments related to the protection of undisclosed data in a way which would prevent regulatory agencies from marketing a generic product in reliance of the originator's data.²⁰⁶

The relevant article states:

Article 17.10: Measures related to certain regulated products

1. If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical

²⁰³ Ministers and Assistant Ministers for the Department of Industry, Innovation and Science, '\$500 Million Fund Will Help Build Australia's Biomedical Industry of the Future' (13 December 2016) <<http://www.minister.industry.gov.au/ministers/hunt/media-releases/500-million-fund-will-help-build-australias-biomedical-industry-future>> accessed 20 February 2017

²⁰⁴ Michael Vincent, 'TPP: Australia wants to steal US medicine patents, Senator Orrin Hatch Says' *ABC News* (14 July 2016) <<http://www.abc.net.au/news/2016-07-15/orrin-hatch-accuses-australia-of-using-tpp-to-steal-patents/7629740>> accessed 20 February 2017

²⁰⁵ Gabrielle Chan, 'Andrew Robb: Australia and U.S. Close to Drug Patent Compromise for TPP Deal' *The Guardian* (4 October 2015) <<https://www.theguardian.com/australia-news/2015/oct/04/andrew-robb-australia-and-us-close-to-drug-patent-compromise-for-tpp-deal>> accessed 20 February 2017

²⁰⁶ Jose Luis Cárdenas Tomazic, 'El Uso de la Información No Divulgada y el Linkage en el TLC con EE.UU.: ¿A Qué Realmente Se Obligó el Estado de Chile y Cómo Ha Cumplido?' (The use of Undisclosed Information and Linkage in the FTA With the U.S.: What Did the State of Chile Agree to and How Did it Comply?) (2011) 1(2) *Revista de Derecho Económico Internacional* 4-24 <<http://dei.itam.mx/archivos/articulo2/Cardenas.pdf>> accessed 21 February 2017

entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information *to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information*. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. Each Party shall protect such information against disclosure except where necessary to protect the public. [Emphasis added].

This article is market exclusivity, meaning that generic companies may rely on data from the originator company to produce the generic copy and register it within the stipulated time, but that they may not market it during the stipulated time.

Chile includes the TPP biologics market exclusivity within this definition, so their key position may have been to ensure that U.S. negotiators in the TPP did not go beyond 5 years. Malaysia may have been in a weaker position, due to the fact that its exclusivity provision was data exclusivity as opposed to market exclusivity, and it was not applied to all products, but rather discretionarily applied. The distinction is significant because in the case of data exclusivity, the generic company is not able to rely on originator company data to register their product, meaning that that may only register the product after the 5-year period is over.

Effectively, because market approval would take longer, data exclusivity provides for a longer monopoly period. The distinction is described in more detail in Section III below, but it remains to be seen whether this consideration was at all material in the context of the negotiations. Malaysian negotiators repeatedly stated the TPP final provisions meant that it was 'status quo' for biologics when compared to Malaysian law,²⁰⁷ presumably meaning that they operated on the assumption they would not have to amend their law pursuant to TPP finalisation, and that 5 years data exclusivity was the same as 5-8 years market exclusivity in the TPP.

8. Economic vulnerability

Fears of recessions and economic instability have resulted in developing countries agreeing to concessions or entirely new negotiation rounds.²⁰⁸ In addition, bad economic trends often result in political leaders overturning any remaining protectionist policies, and embracing more

²⁰⁷ Fifi Rahman, 'Maximalist Machinations in the TPP: An Illustration with Biologics' *Policies for Equitable Access to Health* (31 March 2016) <<http://www.peah.it/2016/03/maximalist-machinations-in-the-tpp-an-illustration-with-biologics/>> accessed 27 March 2017

²⁰⁸ Jawara and Kwa (n 147) 272

liberalisation in order to further integrate into the global economy, as seen in the 1980s debt crises.²⁰⁹

A fall in commodities prices, depleted foreign exchange reserves, and the 1MDB scandal, resulted in a financial credibility crisis, leaving Malaysia in an economically frail position.²¹⁰ While it has a current account surplus, as opposed to Chile which has a current account deficit, slowing economic growth and reliance on credit places it in a vulnerable position within the region. The 1MDB scandal, marked by the siphoning of funds from a sovereign wealth fund to the Prime Minister's personal bank account and towards funding, among other things, the Wolf of Wall Street movie, has been said to have eroded external financial confidence in Malaysian markets, and at the time was seen as an omen for a ratings downgrade.²¹¹

Despite the current account deficit, however, Chile has been described as having low levels of economic vulnerability.²¹² Despite this, in 2017, a reduction in copper exports as a result of domestic strikes, and rising unemployment, indicates some weaknesses that Chilean negotiators could have foreseen and acted to rectify – whether correctly or erroneously – via the TPP. I will seek to elucidate these questions during fieldwork.

This difference between the two countries lends depth to the comparison between the two – that while upper middle-income countries share many similarities in negotiating prowess, numerous other factors influence trade outcomes and tradeoffs that they may make.

V. Relevance of a focus on biologics

a) Why a focus on biologics?

Biologics are complex therapies synthesised from living things, for example plant or animal cells, or viruses. They are different from small molecule drugs which are produced through chemical synthesis, have well-defined molecular structures, and are generally relatively stable. Biologics, on the other hand, have complex, heterogenous structures, and are very sensitive to environmental conditions such as light or and temperature. These factors translate

²⁰⁹ Milner (n 145) 99; Susan K Sell, 'Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice' (1995) 49(2) *International Organization* 315-349, 320

²¹⁰ David Pilling, 'Malaysia's Economic Frailty is All Too Familiar' *Financial Times* (2 September 2015) <<https://www.ft.com/content/96d3f610-50bb-11e5-8642-453585f2cfcf>> accessed 14 February 2017

²¹¹ Leslie Shaffer, 'Why Malaysia's 1MDB Scandal is Denting Growth' *CNBC* (28 January 2016) <<http://www.cnbc.com/2016/01/28/malysias-1mdb-scandal-denting-growth-oxford-economics.html>> accessed 21 February 2017

²¹² Victor Petersen Zañartu, '¿Qué Tan Vulnerable está Chile Ante un Shock Externo? (How Vulnerable is Chile to an External Shock?)' *Pulso* (28 August 2013) <<http://s2.pulso.cl/wp-content/uploads/2013/08/1809075.pdf>> accessed 14 February 2017

into the fact that even if a minor variation in manufacturing technique is made, clinical outcomes may be drastically different.²¹³ Most are created via recombinant DNA technology, although experiments are being done to produce biologics via total chemical synthesis.²¹⁴ In an era where molecular individualised medicine is replacing the one-size-fits-all medicine, the medicines innovation landscape is changing.²¹⁵ As part of this changing innovation landscape, biologics have seen an increasing market share over the years.

Heled elaborates:

They are large in size, sensitive to environmental changes (both during production and afterwards), and expensive to develop and manufacture. But in their complexity lies their advantage: unparalleled effectiveness in the treatment of serious, and sometimes previously untreatable, ailments that renders biologics, in many cases, nothing short of wonder drugs.²¹⁶

This unparalleled effectiveness is reflected in market trends. In 2006, only one of the top-ten drugs on the market was biologic. By 2015, seven out of the top-ten selling drugs were biologic, accounting for \$67.2 billion in revenue.²¹⁷ In the projected top-ten selling drugs in 2017, all but one were biologic, accounting for \$70.2 billion in revenue.²¹⁸ Brown also predicted the launch of a number of new biologics in 2017, including Roche's Ocrevus (multiple sclerosis) and Sanofi's Dupilumab (atopic dermatitis), with projected revenues of \$4.1 billion each.²¹⁹ In 2016 alone, the FDA approved 12 new biologics and 3 biosimilars, including for cancer, muscular dystrophy and rheumatoid arthritis.²²⁰ The Pharmaceutical Research Manufacturers of America (PhRMA) states that American companies are using biological process to research 907 medicines and vaccines targeting more than 100 diseases.²²¹ The exponential growth and domination of biologic drugs is expected to continue, with the global market potential of biologics to reach \$250 billion globally by 2020.²²²

In addition to a rapidly increasing market share, trends have shown that the top 25-selling

²¹³ Shein-Chung Chow, *Biosimilars: Design and Analysis of Follow-on Biologics* (CRC Press 2014) 4

²¹⁴ Linda C Hsieh-Wilson and Matthew E Griffin, 'Improving Biologic Drugs via Total Chemical Synthesis' (2013) 342 *Science* 1332-1333, 1332 <<http://science.sciencemag.org/content/342/6164/1332>> accessed 1 March 2017

²¹⁵ Graham Dufield, 'Healthcare Innovation, Personalisation and the Patent System: Where is the Public Interest?' in Harikesh Bahadur Singh, Alok Jha, and Chetan Keswani, *Intellectual property issues in biotechnology* (CAB International 2016) 165-176, 166

²¹⁶ Yaniv Heled, 'Biologics, Biosimilars and Other Idiosyncrasies', in Bryan Mercurio and Daria Kim (eds), *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options* (Routledge 2017) 47-67, 48

²¹⁷ Brady Huggett, 'America's Drug Problem' (2016) 34(12) *Nature Biotechnology* 1231-1241, 1232

²¹⁸ Amy Brown, *EP Vantage 2017 preview* (Evaluate Group Ltd 2016) 5 <<http://info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf>> accessed 1 March 2017

²¹⁹ *ibid* 8

²²⁰ Chris Morrison, 'Fresh from the Biotech Pipeline – 2016' (2017) 35(2) *Nature Biotechnology* 108-112, 110

²²¹ PhRMA (Pharmaceutical Research and Manufacturers of America), *Medicines in Development: Biologics* (PhRMA 2013) <<http://phrma-docs.phrma.org/sites/default/files/pdf/biologics2013.pdf>> accessed 1 March 2017

²²² Sarah Rickwood and Stefano Di Biase, Searching for Terra Firma in the Biosimilars and Non-Original Biologics Market: insights for the Coming Decade of Change (IMS Health 2013) 3

biologics have undergone 'aggressively increased prices regardless of years on the market or indication'.²²³ This raises important questions in terms of patient access, and whether negotiators considered these factors during the negotiation on biologics tradeoffs. In Section VI of this Chapter, I draw upon Sell's observations that 'unit-level learning' leads negotiators to redefine their interests.²²⁴ This leads to a reciprocal change in behaviour from negotiators on the opposing side.²²⁵ and simultaneously resulting in negotiators from the opposing side changing their behaviour. Basically, in the case of biologics negotiations, were negotiators informed by biomedicine market data, whether international or domestic, and if not, what were their main considerations? And, how did this modify their behaviour?

In any case, the surge in biologic medicines, motivated by research environments that are increasingly tailored to individual biomarkers and genes,²²⁶ has brought a corresponding response in terms of intellectual property governing biologics and regulatory pathways for biosimilar drugs.²²⁷

The manufacture of biologic drugs is expensive, requiring significant upfront investment on human and infrastructural capacity. Production is highly complex, as the final biopharmaceutical product is highly sensitive to external factors such as temperature, growth conditions, and the conditions during storage and transport.²²⁸ Some have claimed that manufacturing a new drug generally costs \$2.6 billion dollars, however this figure includes cost of capital and does not take into account public research grants or subsidies.²²⁹ It has been estimated that follow-on biologics or biosimilars take 8-10 years to develop, costing between US\$100-200 million.²³⁰ The cost of creating a biosimilar is significantly higher than producing a generic of a small molecule drug, estimated to cost from US\$2-3 million.²³¹

Relatively recently, there has been a flurry of interest around biosimilars as governments struggled to afford originator biologic prices, and at the same time realised the investment and

²²³ Huggett (n 217) 1234

²²⁴ Sell (n 12) 6

²²⁵ *ibid*

²²⁶ Dutfield (n 215) 166

²²⁷ Biosimilars are defined as similar, but non-identical pharmaceuticals to the pioneer reference product. The complexity of biologic cells and processes mean that it is impossible to create a generic for a biologic product. Thus the products are called biosimilars or follow-on biologics.

²²⁸ Paul J Declerck, 'Biologics and Biosimilars: A Review of the Science and its Implications' (2012) 1(1) *Generics and Biosimilars Initiative Journal* 13-16, 13

²²⁹ Jerry Avorn, 'The \$2.6 Billion Pill: Methodologic and Policy Considerations' (2015) 372(2) *New England Journal of Medicine* 1877-1879, 1878 <<http://www.nejm.org/doi/pdf/10.1056/NEJMp1500848>> accessed 16 March 2017

²³⁰ Federal Trade Commission, *Emerging health care issues: follow-on biologic drug competition*. (Federal Trade Commission 2009) <<https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>> accessed 5 March 2017, iii

²³¹ Andrew Fischer Bourgoïn and Beth Nuskey, *An outlook on U.S. biosimilar competition* (Thomson Reuters 2013) 9 <<https://healthtrustpg.com/biosimilars/pdf/thomson-reuters.pdf>> accessed 4 November 2019

economic potential of commercialising production of biosimilars.²³² In addition, a number of countries have successfully substituted novel biologic medicines with biosimilars. For example, following government policy incentivising doctors to substitute, in Norway, the biosimilar infliximab has reached 92.9% of market share.²³³ Country medicines regulators have also embraced biosimilars, stating that treatment-naïve patients may be started on biosimilars, and that those already on treatment may be switched to biosimilars under physician supervision.²³⁴

Global sales of biosimilars are expected to reach US\$25 billion by 2020, with an estimated annual compound growth rate of 7.7%,²³⁵ and the American and EU markets have in the past year approved substitutions of key originator biologics with biosimilars, including replacing genetically engineered insulin analogue Lantus with biosimilar Basaglar, and Zarxio being approved as a substitute for Neupogen, to treat neutropenia in cancer patients and acute myeloid leukemia, among other indications.²³⁶ At the closing of 2016, there were 12 pending biosimilar applications for the European market, including applications for biosimilars of pegfilgrastim (for patients undergoing chemotherapy) and trastuzumab (breast cancer).²³⁷

The entry of biosimilars into the market, the corresponding reduction of revenue to originators, may precipitate a stronger intellectual property response²³⁸ in the form of increased exclusivities. Heled, however, comments that the primary rationale for these exclusivities has been to compensate product developers for what they see as insufficient incentivisation

²³² MIDA (Malaysian Investment Development Authority), 'Pharmaceuticals' MIDA (2015) <<http://www.mida.gov.my/home/pharmaceuticals/posts/>> accessed 10 February 2017

²³³ Anna Rose Welch, 'The Norwegian Biosimilar Phenomenon: from Biosimilar to Biogeneric' *Biosimilar Development* (26 July 2016) <<https://www.biosimilardevelopment.com/doc/the-norwegian-biosimilar-phenomenon-from-biosimilar-to-biogeneric-0001>> accessed 23 March 2017

²³⁴ Christoph Baumgärtel, 'Austrian Medicines Authority Positive Towards Biosimilar Interchangeability' (2017) 6 GaBi Journal <<http://gabi-journal.net/austrian-medicines-authority-positive-towards-biosimilar-interchangeability.html>> accessed 24 March 2017

²³⁵ iGate Research, *Global Biosimilars Market and Forecast (By Product Type, Applications, Country Wise and Companies) to 2021 and Biosimilars Approved and Pipeline Analysis* (iGate Research 2016) <<http://www.marketreportsonline.com/504244.html>> accessed 16 March 2017

²³⁶ CVSHealth, *2017 Standard Formulary List of Removals and Updates*, CVSHealth (2016) <<http://investors.cvshealth.com/~media/Files/C/ CVS-IR-v3/documents/02-aug-2016/2017-standard-formulary-list-of-removals-and-updates.pdf>> accessed 16 March 2017; Zosia Chustecka, 'First Biosimilar Approved in US: Filgrastim-sndz (Zarxio)' *Medscape* (6 March 2015) <<http://www.medscape.com/viewarticle/841021>> accessed 16 March 2017

²³⁷ Jacob F Siegel and Irena Royzman, 'Biosimilars in Europe: 2016 Year in Review and What's Ahead' *Biologics Blog* (4 January 2017) <<https://www.biologicsblog.com/biosimilars-europe-2016-year-review-whats-ahead/>> accessed 27 February 2017

²³⁸ Pharmaceutical intellectual property is, to a large extent, born of the free market. That is to say, in addition to developing as a response to market changes, intellectual property also responds to ethical and philosophical discussions, and legal developments. (Parthasarathy n 17) Cohen and Boyer's 1973 discovery of recombinant DNA is considered to be the foundation of modern biotechnology. Eugene Russo, 'Learning How to Manipulate DNA's Double Helix has Fueled Job Growth in Biotechnology During the Past 50 Years, says Eugene Russo' (2003) 421 *Nature* 456-457, 457 <<https://www.nature.com/naturejobs/2003/030123/pdf/nj6921-456a.pdf>> accessed 30 June 2017; Only 7 years later, biologics intellectual property was prominently discussed in the 1980 case of *Diamond v Chakrabarty*, concerning the patentability of a genetically engineered microorganism designed to break up oil particles. The court ruled that the microorganism was a product of human ingenuity 'having a distinctive name, character [and] use' per *Hartranft v Wiegmann*, 121 U.S. 609, 121 U.S. 615 (1887) and was therefore patentable. Today, there is an expanding rate of new patent applications for novel gene and protein discoveries. Pritom Chowdhury, Sangeeta Borchetia, and Tanoy Bandyopadhyay, 'Changing Paradigm for Intellectual Property Rights Protection in Drug Discovery Research: Where India Stands' in Harikesh B Singh, Alok Jha, and Chetan Keswani (eds), *Intellectual Property Issues in Biotechnology* (CAB International 2016) 233

provided by the patent system.²³⁹ That is to say, product developers say that more time is needed to recoup R&D costs and generate rewards for innovation, as studies taken after the patent filing can effectively reduce the patent term from 20 years to single digits.²⁴⁰ The U.S. Federal Trade Commission has refuted this, stating that 'pioneer biologic drugs are covered by more and varied patents, including manufacturing and technology platform patents, than small-molecule branded products' and that contentions of unpatentability of pioneer biologics are backed by very little data.²⁴¹ In addition, Kinch states that clinical development times for biologics are generally shorter compared to small-molecule drugs, averaging 7.4 years.²⁴² Assuming that clinical development runs from the first patent, the company would have 12.6 years of patent protection.

Proponents of long data and market exclusivity provisions argue further, that under 7-year and 10-year market exclusivity periods, even if the pioneer biologic retains substantial market share after biosimilar entry, that biologic would fail to recover the average costs of development, manufacturing, promotion, and the cost of capital.²⁴³ Grabowski et al. state that this would only be possible in 12.9-16.2 years, justifying a market exclusivity period of 12 years. It is this period that U.S. negotiators sought, and as Heled mentions, was intended to 'set minimum standards for the regulation of biologics and biosimilars globally.'²⁴⁴ Biologics exclusivity in the context of the TPP is discussed further in Section c below.

b) Relevance of biologics to upper-middle income countries

Upper-middle income countries are in a unique position economically and demographically. From an economic standpoint, these countries are relatively wealthy; however they exist at the crossroads of economic development, aging, and non-communicable disease (NCD).²⁴⁵ That is to say, these countries have longer life expectancies when compared to lesser-developed countries, and that NCDs disproportionately affect older people, presenting countries with important social policy, budgetary, and political questions. Upper middle-income countries are also the key targets for maximalist intellectual property, presenting governments with unique budgetary and health prioritisation challenges.

²³⁹ Heled (n 216) 64-65

²⁴⁰ Henry Grabowski, Genia Long, and Richard Mortimer, 'Data Exclusivity for Biologics' (2011) 10 *Nature Reviews Drug Discovery* 15-16, 15

²⁴¹ Federal Trade Commission (n 230) vi

²⁴² Michael S Kinch, 'An Overview of FDA-Approved Biologics Medicines' (2014) 20(4) *Drug Discovery Today* 393-398, 395

²⁴³ Grabowski et al. (n 240) 15

²⁴⁴ Heled (n 216) 62

²⁴⁵ Laura N Gitlin and Patricio Fuentes, 'The Republic of Chile: An Upper Middle-Income Country at the Crossroads of Economic Development and Aging' (2012) 52(3) *Gerontologist* 297-305

From a disease burden perspective, causes of death in upper middle-income countries are more similar to high-income countries rather than lower-middle income countries, that is, focused more on non-communicable diseases. For example, the top three causes of death for the United States and Australia (high income countries) are ischemic heart disease, cardiovascular diseases, and Alzheimer's disease.²⁴⁶ The corresponding causes in Chile and Malaysia (upper-middle income countries) are ischemic heart disease, cardiovascular diseases, and lower respiratory diseases. Lung, stomach, and colorectal cancers round up higher- and upper middle-income countries.²⁴⁷ Whereas lower middle-income countries have diseases like tuberculosis (Indonesia), cirrhosis from Hepatitis C (Egypt), diarrheal diseases (Nigeria, Guatemala), and protein energy malnutrition (Guatemala) as part of their top ten causes of deaths.²⁴⁸

Dutfield explains:

[T]he disease profiles of many developing countries are becoming more similar to those of the developed countries. This is not just because wealthier people anywhere in the world live longer than the poor, and diseases that tend to affect the elderly most are broadly similar everywhere: non-communicable ones such as cancer, cardio-vascular diseases, Alzheimer's, etc. It is also because there is a certain amount of uniformity in the lifestyles including diets of people having similar levels of income and purchasing power wherever they happen to live. This means disease affecting people are becoming more and more the same wherever they live. This prospect for industry of the global similarity of disease profiles and life expectancies with their attendant market and economies of scale opportunities appears to be quite new.²⁴⁹

The increasing similarity to developed nation disease trends results in an increasing dependence on biologic drugs. These drugs are exorbitantly priced, and even developed countries have pushed for biosimilar substitution to ease pressures on national health budgets.

Di Biase elaborates:

As governments in emerging markets extend health coverage, and as the *disease profile shifts*, they will push for lower prices and gravitate toward non-original biologics, making life more difficult for originators. Phamerging country governments are adopting increasingly

²⁴⁶ Institute of Health Metrics and Evaluation, *United States* (2015) <<http://www.healthdata.org/united-states>> accessed 27 March 2017

²⁴⁷ Institute of Health Metrics and Evaluation, *Chile* (2015) <<http://www.healthdata.org/chile>> accessed 27 March 2017

²⁴⁸ Institute of Health Metrics and Evaluation, *Nigeria* (2015) <<http://www.healthdata.org/nigeria>> accessed 27 March 2017

²⁴⁹ Dutfield (n 215) 165-176

protectionist stances, favoring non-original biologics, particularly in BRICs. The desire to develop local industry initiatives will continue to shape government policies in BRICs and beyond.²⁵⁰ (Emphasis added)

Di Biase's comment on 'phamerging' country governments responding in an increasingly protectionist way may relate to TPP countries' strenuous objections to exclusivities for biologics. This of course is to be explored further. Given extortionate prices for biologics and the predicted IP harmonisation push on biologics, the response of upper-middle income countries may not be so different from that of high-income countries, i.e. facilitating the entry of biosimilars the moment patents expire.²⁵¹

Several other factors also may have influenced the significance of biologics and biosimilars to the decision-making of Chile and Malaysia in the TPP negotiations, for example, government and physician commitment to interchangeability of biologics and biosimilars, and potential of local biosimilars industry. Heled suggests that TPP countries agreeing to the vague and flexible biologics exclusivity term in the TPP could have been a reflection of high-income signatories' views that they were not as vulnerable to biosimilars competition from the developing countries at present market and regulatory conditions.²⁵² Arguably, however, the end result for biologics in the TPP could have also been a result of 'negotiating fatigue'²⁵³ or political economy tradeoffs.

c) TPP Biologics Provisions

Under Article 18.50.1(a) on marketing approval of pharmaceutical products, the TPP restricts the ability of third persons to market their product based on undisclosed test or other data for at least 5 years. This means that the undisclosed data is only exclusive for the purposes of market approval, and therefore does not prohibit reliance on the data for development of the relevant pharmaceutical product.

Article 18.50: Protection of Undisclosed Test or Other Data

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the

²⁵⁰ Stefano Di Biase, 'Searching for Terra Firma in the Biosimilars and Non-Original Biologics Market: Insights for the Coming Decade of Change' *Pharma Forum* (6 February 2014) <<http://pharmaphorum.com/views-and-analysis/searching-for-terra-firma-in-the-biosimilars-and-non-original-biologics-market-insights-for-the-coming-decade-of-change/>> accessed 27 March 2017

²⁵¹ Welch (n 233)

²⁵² Heled (n 216) 61

²⁵³ Drahos (n 154) 11

consent of the person that previously submitted such information, to market the same or a similar product on the basis of:

- (i) that information; or
- (ii) the marketing approval granted to the person that submitted such information, for at least five years⁵³ from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

Specifically in regard to biologics, the TPP text states in Article 18.52.1(a) that a party may provide effective market protection by utilising Article 18.50.1(a) as stated above with Article 18.50.3 (protections on TRIPS and public health) for at least 8 years from the date of marketing approval, or (b) 5 years market exclusivity provided there are 'other measures' in place and that market circumstances also contribute to effective market protection. Therefore, 5 years exclusivity would only be able to apply if there is a comparable market outcome.²⁵⁴

Article 18.52: Biologics

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

'Other measures' is not defined in the text. The text has been criticised as ambiguous and vague,²⁵⁵ resulting in different interpretations of the text. While Malaysia, Chile, New Zealand, and Australia officials have all said that the TPP results in 'status quo' data exclusivity provisions, i.e. that they would not have to change their preexisting laws, U.S. Senators and negotiators have stated that it is 8 years market exclusivity. Probir Mehta, USTR Deputy

²⁵⁴ Public Citizen, 'Analysis: Ambiguity Leads to Fallacy: Biologics Exclusivity in the Trans-Pacific Partnership' *Public Citizen* (2015) <<https://www.citizen.org/documents/tpp-biologics-exclusivity-memo-november-2015.pdf>> accessed 5 March 2017

²⁵⁵ *ibid*; Jeff Overley, 'TPP Leaves Leeway on Biologics Exclusivity' *Law 360* (5 November 2015) <<https://www.law360.com/articles/723618/tpp-leaves-leeway-on-biologics-exclusivity>> accessed 5 March 2017

Assistant for the Office of Intellectual Property and Innovation and U.S. TPP Chief Intellectual Property negotiator stated: ‘anyone who interprets option B as requiring only five years of biologics exclusivity is misreading the text of the agreement.’²⁵⁶

Footnote 53 in the TPP text clarifies:

For greater certainty, a Party may limit the period of protection under paragraph 1 to five years, and the period of protection under Article 18.52.1(a) (Biologics) to eight years.

As to what constitutes a ‘comparable market outcome’, the TPP is entirely silent. This may mean that had the TPP gone forward, the definition may have been left to trade tribunals via investor-state dispute settlement (ISDS), or it may have been clarified by the U.S. Congress at the certification stage.²⁵⁷ Others have speculated that the ‘comparable market outcome’ would include patents and regulatory efforts,²⁵⁸ possibly meaning that market exclusivity is less restrictive than data exclusivity for registration purposes per se.

Heled discusses this lack of a clear definition, and how the provision does not describe how ‘market outcomes’ may be quantified and measured, if at all.²⁵⁹ He further states, that the provision seemingly blurs the lines between ‘*de jure* standards of protection of biologics and *de facto* outcomes of such protection’. Given that the TPP provides that the biologics provision should be reviewed after 10 years,²⁶⁰ the vague wording of the provision may reflect a corresponding lack of clarity as to market effects of exclusivity and biosimilar competition in TPP countries, or alternatively may simply have been settled for as a minimum standard, i.e. that so long as *some* biologics exclusivity was achieved, it could be expanded upon later.

Discussions around the TPP negotiations also reflected a conflation of the terms ‘data exclusivity’ and ‘market exclusivity’. Crucially, the biologics provision prohibits the use of data to market a follow-on biologic, but not to register one. Grabowski et al. explain that ‘data exclusivity is one factor contributing to market exclusivity — the period of time during which a therapy is the only marketed version of that molecule — but not the only determinant.’²⁶¹ Basically, a biosimilar would only be able to enter the market after the expiry of patents, data

²⁵⁶ Public Citizen (n 254)

²⁵⁷ The certification stage would have taken place at the end of the two-year ratification period. During the ratification period, countries amend domestic law to comply with the final TPP agreement. Certification is a legally binding compliance obligation, and if domestic approval processes and alteration of domestic laws does not satisfy U.S. expectations, the U.S. President may withhold formal written notification of certification. (See TPP No Certification. [Accessed 27 March 2017] Available from: <http://tpnocertification.org/certification-at-a-glance/>)

²⁵⁸ Overlay (n 255)

²⁵⁹ Heled (n 216) 61

²⁶⁰ Trans-Pacific Partnership agreement, Article 18.52.3

²⁶¹ Grabowski et al. (n 240) 15

exclusivity, and market exclusivity.²⁶² This interchangeability of terms may or may not have been significant – country officials continued to use the term ‘data exclusivity’ post-TPP signing.²⁶³

A market exclusivity provision is arguably better than a data exclusivity provision applied to registration of a product, as a biosimilars manufacturer could rely on originator data to market their biosimilar. In both Chile and Malaysia, however, 5 years data exclusivity was already in place, raising questions as to whether the TPP establishes a 5+3 years of data and market exclusivity (8 years of market exclusivity), instead of the ‘status quo’ amount of exclusivity claimed by Australian, Chilean, and Malaysian negotiators.²⁶⁴ Given these considerations, further exploration is needed on negotiator understanding of U.S. demands and whether this may have influenced resulting tradeoffs.

In any case, the pharmaceutical industry and its proponents reacted with dismay to the finalisation of 5-8 years of market exclusivity for biologics with pro-Pharma Republican U.S. Senator Orrin Hatch stating that “There are ways of doing it – they’ll just have to do it”²⁶⁵ and “We have to come up with a methodology where they agree to 12 years”.²⁶⁶

As early as July 2015 countries were deadlocked on biologics, with countries meeting in Maui to resolve these differences, but coming to no agreement.²⁶⁷ It appears, however, that some countries may have come to agreement on biologics earlier. Malaysia, for example, in a side letter dated 4 February 2016 to the U.S. Trade Representative Michael Froman, stated that it had come to agreement on biologics, and Froman responded his confirmation of this agreement.²⁶⁸

IP political-economy tradeoffs were particularly visible with the biologics provision, given the

²⁶² Ronald A Rader, ‘An Analysis of the U.S. Biosimilars Development Pipeline and Likely Market Evolution’ (2013) 11(6)s *Bioprocess International* 16-23, 18 <<http://www.biopharma.com/biosimilars/pipeline.pdf>> accessed 27 March 2017

²⁶³ Joseph Sipalan, ‘Minister: Malaysia firm on five-year data protection of biologics under TPP’ *The Malay Mail Online* (12 November 2015) <<http://www.themalaymailonline.com/malaysia/article/minister-malaysia-firm-on-five-year-data-protection-of-biologics-under-tpp>> accessed 30 June 2017

²⁶⁴ Tomás Lagomarsino G., ‘TPP y el Precio de Medicamentos en Chile (TPP and the cost of medicines in Chile)’ *El Mostrador* (9 June 2016) <<http://www.elmostrador.cl/noticias/opinion/2016/06/09/tpp-y-el-precio-de-los-medicamentos-en-chile/>> accessed 5 February 2017; Rahman (n 207)

²⁶⁵ Vicki Needham, ‘Hatch: TPP Deal Can Get Done in Lame-Duck Session’ *The Hill* (14 June 2016) <<http://thehill.com/policy/finance/296034-hatch-pacific-deal-gets-done-in-the-lame-duck-session>> accessed 26 March 2017

²⁶⁶ Jenny Leonard, ‘Hatch: Biologics Commitments from TPP Countries Would Not Require Side Letters’ *Inside U.S. Trade* (8 September 2016) <<https://insidetrade.com/daily-news/hatch-biologics-commitments-tpp-countries-would-not-require-side-letters>> accessed 27 March 2017

²⁶⁷ Patterson Belknap, ‘Exclusivity Period of Biologics Remains a Hurdle in Trans-Pacific Partnership Talks’ *Biologics Blog* (26 August 2015) <<https://www.biologicsblog.com/exclusivity-period-biologics-remains-hurdle-trans-pacific-partnership-talks/>> accessed 1 March 2017

²⁶⁸ Mustapa Mohamed and Michael Froman, ‘US-MY Letter Exchange re Articles 18.41 .50 and .52.’ U.S. Trade Representative (4 February 2016) <<https://ustr.gov/sites/default/files/TPP-Final-Text-US-MY-Letter-Exchange-re-Articles-18-41-50-and-52.pdf>> accessed 26 March 2017

biologics ‘deadlock’ at the final negotiation round in Atlanta, Georgia,²⁶⁹ leading to the conclusion of the negotiations being delayed due to lack of consensus. The Australian press included demands to know what Australia ‘has horse-traded in other chapters of the agreement’ to get an acceptable outcome on biologics.²⁷⁰ Market access for dairy was mentioned as being the key tradeoff for biologics exclusivity for New Zealand (‘once biologics is in the bag, and not before then, the dairy saga can end’)²⁷¹ whereas the Mexican Minister for Economy stated that he could not reveal details of the *compromise* on biologics “until everyone has signed up and we are all on the same page”.²⁷² [Emphasis added.]

The media visibility of the deadlock on biologics provides a useful starting point for interviews with Chilean and Malaysian negotiators. Interview domains will focus not only on predetermined mandates and the influence of unit-level learning on negotiating outcomes, but also on the novelty of biologics within trade agreements and whether these impacted negotiating power differentials, i.e. whether or not negotiators were aware of factors that could influence the biologics exclusivity decision: for example domestic biosimilars industrial prospects, patient group concerns and cancer burdens, and possible economic gains from protection of domestic industries.

d) Future IP around biologics and relevance for international trade

No one could have predicted the sheer expansion of the biotechnology industry since *Diamond v Chakrabarty* (1980), which famously decreed that patents were to include ‘anything under the sun that is made by man’, and allowed the patentability of a single bacterium containing multiple plasmids capable of degrading different hydrocarbon compounds during an oil spill.²⁷³ *Chakrabarty* was interpreted broadly by the U.S. Patent and Trademark Office (PTO), and issued patents on plants. A patent on a genetically engineered oyster had been rejected, but in 1987, the court deemed that this decision was erroneous because there was no evidence that the said oysters ‘occur naturally without the intervention of man’.²⁷⁴ Soon after the decision, the PTO Commissioner issued a memo allowing patents on all ‘non-

²⁶⁹ Dan Stanton, ‘TPP: Five Years Data Protection for Biologics in US-Asia Trade Deal’ *BioPharma-Reporter* (5 October 2015) <<http://www.biopharma-reporter.com/Markets-Regulations/TPP-Five-years-data-protection-for-biologics-in-US-Asia-trade-deal>> accessed 29 December 2015

²⁷⁰ Ruth Lopert, ‘Why Biologics Were such a Big Deal in the Trans-Pacific Partnership’ *The Conversation* (6 October 2015) <<http://theconversation.com/why-biologics-were-such-a-big-deal-in-the-trans-pacific-partnership-48595>> accessed 29 December 2015

²⁷¹ Clark (n 22)

²⁷² *Ibid*

²⁷³ Douglas Robinson and Nina Medlock, ‘*Diamond v Chakrabarty*: a Retrospective on 25 years of Biotech Patents’ (2005) 17(10) *Intellectual Property & Technology Law Journal* 12-15, 12

²⁷⁴ *Ibid*, citing *Ex Parte Allen* (1987)

naturally occurring non-human multicellular living organisms.²⁷⁵ This was the beginning of intellectual property applicable to biologics.

Thirty years later, biologics IP has only grown more complex. Firstly, the biotechnology industry believes that international standards of patentability are fragmented, and that some form of harmonisation is necessary to ensure legal and commercial certainty.²⁷⁶ Secondly, given the resource-intensive nature of biologics production, many multinational companies are producing both original biologics and biosimilars. This complicates the role of IP in biomedicine because companies want to increase the monopolies applicable to their originator products while at the same time ensuring a market for their biosimilars.²⁷⁷ This may mean there will be an increasing focus on non-patent intellectual property. Thirdly, the future of biologics IP is increasingly punctuated with ethical questions, but also with questions of secrecy. For example, there has been a proposal for the deposit of cell lines as a condition of marketing authorization²⁷⁸ – which could be controversial in future reiterations of IP harmonization on biologics. The European Patent Office in particular has acknowledged the distributive effects of biotechnology patents on farmers, scientists, and patients, and in consideration of this, increased their patentability standards.²⁷⁹

As aforementioned, TPP provisions were likely to have been meant to set global minimum standards for the regulation of biologics and biosimilars.²⁸⁰ This means that establishing biologics exclusivity in trade would be the starting point for further maximalist IP on these drugs. Given that the U.S. will continue to be ‘the world’s principal demandeur’ for maximalist IP,²⁸¹ it was not unrealistic to foresee the U.S. demanding biologics exclusivity via bilateral deals as preferred by the Trump administration. Indeed these manifested in the reincarnation of the North American Free Trade Agreement (NAFTA), dubbed the USMCA.²⁸² This is concerning for the reason that in a bilateral setting, developing countries are weaker as they are unable to form coalitions on similar matters, among other things, and this creates more disparate power dynamics.²⁸³

²⁷⁵ Parthasarathy (n 17) 82

²⁷⁶ Molly Jamison, Patent Harmonisation in Biotechnology: Towards International Reconciliation of the Gene Patent Debate’ (2015) 15(2) *Chicago Journal of International Law* 688-720, 690-710

²⁷⁷ Kenneth Neil Cukier, ‘Navigating the Future(s) of Biotech Intellectual Property’ (2006) 24(3) *Nature Biotechnology* 249-251, 249

²⁷⁸ Lisa Diependaele, Julian Cockbain, and Sigrid Sterckx, ‘Similar or the Same? Why Biosimilars are Not the Solution’ (2018) 46 *The Journal of Law, Medicine & Ethics* 776-790, 789

²⁷⁹ Only 28% of all biotechnology applications received by the EPO are granted. Battistelli, 2010, cited in Parthasarathy (n 17) 184-186

²⁸⁰ Heled (n 216) 62

²⁸¹ Raquel Artecona and Rosine M Plank-Brumback, Access to Medicines and Incentives for Innovation: the Balance Struck in the Trans-Pacific Partnership on Intellectual Property (Patent and Data Exclusivity) Protection for Pharmaceutical Products (United Nations, ECLAC Office in Washington, D.C., 2016) 9

²⁸² See analysis below, Chapter VI, I(c)

²⁸³ Jawara and Kwa (n 147)

In 2017 it was surmised that regardless of the U.S. exit, as mentioned in Section II above, ongoing talks and a potential U.S. re-entry into the agreement with a new (Democratic) presidency in 2020 could potentially mean that these global minimum standards could still be a reality,²⁸⁴ however as USMCA talks progressed into 2019, and drug pricing debates continued to rage in the United States, it became clear that advancing biologics intellectual property in trade agreements was increasingly difficult.²⁸⁵ Indeed, at the conclusion of the USMCA in 2019, biologics intellectual property standards did not make the final text, and U.S. Trade Representative Robert Lighthizer said, “We conceded on biologics.”²⁸⁶

The starting point of biologics market exclusivity could eventually open up the global pharmaceutical paradigm to include harmonised gene patents, narrow bolar exemptions, ‘patent dance’ dispute resolution discussed below,²⁸⁷ special protection certificates like in EU law, and exclusivity specifically for paediatric formulations.

Gene patents in particular could pose complex conundrums for scientists, national regulators, negotiators, and policymakers alike. At the very basis of these conundrums is, essentially, as geneticist and oncologist Siddhartha Mukherjee discussed in a podcast with neuroscientist and philosopher Sam Harris: ‘Why is a BRCA gene mutation any different from your nose? It is part of your body... sure, these tools are borrowed from the microbiological world, but they were refined and changed and programmed and reprogrammed by individual scientists’.²⁸⁸ Biomedicine today is characterised by products that specifically target certain genes. Scientists can isolate specific strands or segments of DNA, extract mitochondrial RNA and create it in DNA form, i.e. creating what is known as complementary DNA (cDNA).²⁸⁹ These in turn will be used in creating biologic wonderdrugs. In the case of *Myriad Genetics*, concerning the patenting of the isolated strands of BRCA1 and BRCA2 genes, the U.S. Supreme Court ruled unanimously that isolated human genes were unpatentable, but that cDNA could.²⁹⁰ Given the failure to patent these in the U.S., a proposal to include them in future trade agreements would be unlikely to proceed without intense domestic and

²⁸⁴ Nyshka Chandran, ‘After U.S. Drops TPP, China Joins Member States in Trade Talks’ *CNBC* (14 March 2017) <<http://www.cnbc.com/2017/03/14/china-south-korea-join-tpo-members-in-trade-talks.html>> accessed 27 March 2017

²⁸⁵ See Wallach (n 891)

²⁸⁶ CBS News, ‘Transcript: Robert Lighthizer on “Face the Nation,” December 15, 2019’ *Face The Nation* (15 December 2019) <<https://www.cbsnews.com/news/transcript-robert-lighthizer-on-face-the-nation-december-15-2019/>> accessed 24 December 2019

²⁸⁷ Kanikaram Satyanarayana and Sadhana Srivastava, ‘Access to Healthcare through Biosimilars’ in Harikesh B Singh, Alok Jha, and Chetan Keswani (eds), *Intellectual Property Issues in Biotechnology* (CAB International 2016) 199

²⁸⁸ Sam Harris, ‘Waking Up With Sam Harris #77 - The Moral Complexity of Genetics (with Siddhartha Mukherjee)’ (2017) <<https://www.youtube.com/watch?v=H2-8wthSGy0>> accessed 1 June 2017

²⁸⁹ Ryan Leal, ‘The Next Step in Gene Patents: *Association for Molecular Pathology v Myriad Genetics*’ (2014) 24(2) *DePaul Journal of Art, Technology, and Intellectual Property Law* 403-424; 413

²⁹⁰ Parthasarathy (n 17) 170

international scrutiny.

The U.S. ‘patent dance’ on the other hand, is a dispute resolution mechanism that delays the introduction of a biosimilar by providing cumbersome procedural requirements – beginning with the biosimilar applicant providing manufacturing details to the manufacturer of the reference product (the originator). This would be followed by the originator providing a list of patents which it believes is being infringed by the biosimilar application. Pursuant to this, the biosimilar applicant must respond to the patent list and respond legally and factually as to why the originator’s patents are invalid. The originator company would then be given 60 days to respond, after which both parties would be able to negotiate within the space of 15 days to come to an agreement as to which patents would be subject to an infringement action.²⁹¹

Narrow bolar exemptions are a current concern in Europe for the production of biosimilars. Because of the variability of biosimilars, clinical trials are necessary to ensure clinical efficacy and safety of the biosimilar, so a narrow bolar exemption would prevent the necessary clinical trials to occur, thus delaying the entry of a biosimilar. However, given that the same multinational companies that produce innovator biologics sometimes make biosimilars, it is unclear whether broad bolar exemptions would be a negotiating objective in future trade agreements.

Regardless of the form of the IP measure, given the trajectory of the world trade order and intellectual property politics, maximalist IP will continue to respond to legal, philosophical, and economic developments, and these will be done most visibly in the context of trade agreements. Trade agreements allow these provisions to be subject to maximum enforceability, with trade sanctions and investor-state dispute settlement as primary tools to respond to infringement. Given current and accelerating biomedical global domination, pharmaceutical IP will promulgate accordingly.

VI. Theoretical considerations: structural power, game theory, and deadlock theory

As mentioned earlier in this chapter, the research project primarily seeks to answer the question of how upper middle-income countries respond to, and negotiate for, political economy tradeoffs to maximalist intellectual property.²⁹² At the genesis of this question are a

²⁹¹ Satyanarayana and Srivastava (n 287) 199

²⁹² Singh explains that developing countries have used a host of negotiating tactics effectively, including building coalitions, using issue-linkages and creating bargaining alternatives. Singh (n 155) 449-451

myriad of other questions: whether negotiators had a predetermined mandate, what unit-level learning influenced this mandate, what strategic imperatives formed the structure of concessions or political economy tradeoffs, whether there was a deadlock, and how negotiators and government officials responded to those tradeoffs. In that sense, it draws from some game theory, in that there is 'not only goal-oriented behaviour and mutual gains, but also rational decisions and conscious coordination'.²⁹³

It is impossible to examine tradeoffs and how it affects international trade law without drawing upon literature on international trade politics and international political economy. Hence this PhD draws upon international relations and international negotiations theory, and well as literature on international political economy to examine progressions through the negotiations and how that progression affects tradeoffs on intellectual property provisions. In that sense, this thesis contributes to the need for a 'joint discipline' bridging the gap between international law (international trade law in the context of this PhD) and international relations, as argued by other authors.²⁹⁴ Slaughter et al. describe how international lawyers have relied on international relations theory, i.e. notably to (1) diagnose international policy problems and formulate solutions to them; (2) to explain the function and structure of particular legal institutions; and (3) to examine and reconceptualise particular institutions or international law generally.²⁹⁵

The topic of this thesis centres around the progression of trade-related IP within plurilateral 'deep integration' trade agreements,²⁹⁶ that is to say, trade agreements that no longer deal only with trade, but seek to influence beyond-the-border domestic regulation in matters outside of trade. With the decline in influence of the WTO,²⁹⁷ preferential trade agreements have been the key 'institutions' or vehicles through which nations seek enforceable trade-related rules. Trade law alone cannot explain a deadlock in intellectual property negotiations, or tradeoffs made in that context. Thus this thesis draws upon international relations as well as theory around power in the international political economy literature to help rationalise changes in international trade-related intellectual property law.

²⁹³ Holger Janusch, 'The Breakdown of International Negotiations: Social Conflicts, Audience Costs, and Reputation in Two-Level Games' (2016) 21(3) *International Negotiation* 495-520, 500

²⁹⁴ Anne-Marie Slaughter, Andrew S. Tulumello, and Stepan Wood, 'International Law and International Relations Theory: A New Generation of Interdisciplinary Scholarship' (1998) 92(3) *American Journal of International Law* 367-397; Kenneth W. Abbott, 'Modern International Relations Theory: A Prospectus for International Lawyers' (1989) 14 *Yale Journal of International Law* 335-411

²⁹⁵ Slaughter, Tulumello, and Wood (n 294) 373

²⁹⁶ Kim (n 110) 360-361

²⁹⁷ Itai Agur, 'The US Trade Deficit, the Decline of the WTO and the Rise of Regionalism' (2007) EUI Working Paper ECO 2017/17 < <https://cadmus.eui.eu/bitstream/handle/1814/7104/ECO-2007-17.pdf?sequence=3&isAllowed=y> > accessed 20 August 2019; Sheng Bin and Gao Jiang, 'TPP vs WTO: Stepping Stone or Stumbling Block?' (2016) 6(3) *Journal of WTO and China* 60-77

Putnam's two-level game theory formed the basis of my theoretical approach, although as the thesis progressed, it became clear that this alone was insufficient, and that Susan Strange's theories on structural power, as well as theories around coalitions and deadlocks were relevant and necessary for analysis. This is elaborated further in Chapter 6 of this thesis.

Putnam's game theory is as follows:

The politics of many international negotiations can usefully be conceived as a two-level game. At the national level, domestic groups pursue their interests by pressuring the government to adopt favourable policies, and politicians seek power by constructing coalitions among those groups. At the international level, national governments seek to maximise their own ability to satisfy domestic pressures, while minimising the adverse consequences of foreign developments.²⁹⁸

Contextualised to the subject matter of this thesis, at the national level, non-government health coalitions, domestic pharmaceutical industries, and chambers of commerce, were pursuing their interests via multiple modes of discourse with government negotiators. For analytical ease, Putnam calls this Level II.²⁹⁹ Informed by the interests of these stakeholders, negotiating governments at the international level face a balancing exercise between domestic interests and mitigating possible negative consequences arising from foreign developments, for example, U.S. insistence on 12 years of market exclusivity for biologic medicines. This bargaining between negotiators is called Level I.³⁰⁰

The theory is elaborated further in terms of 'win-sets' i.e. a set of objectives that each negotiating government would consider a win. For example, a U.S. TPP win-set would include 12-years of market exclusivity for biologics (per domestic commercial pressures and domestic laws), and less concessions on hotly contested agricultural tariffs. A Malaysian win-set could include the minimum number of years of biologics market exclusivity possible and market access to the United States. A Chilean win-set could similarly include a minimum number of years of biologics market exclusivity, with other market access demands.

Janusch,³⁰¹ drawing upon both Putnam and Schelling states that 'a smaller win-set can be a bargaining advantage at Level I (Schelling conjecture), because the smaller the win-set, the more credibly governments can refer to their tied hands at Level II to receive more concessions at Level I'.³⁰² Von Braun elaborated further on the notion of 'tied hands' in the

²⁹⁸ Robert D Putnam, 'Diplomacy and Domestic Politics: The Logic of Two-Level Games' (1988) 42(3) *International Organization* 427-460, 434

²⁹⁹ *ibid* 436

³⁰⁰ *ibid* 436

³⁰¹ Janusch (n 293) 501

³⁰² Putnam (n 298); Thomas C Schelling, *The Strategy of Conflict* (Harvard University Press 1960)

context of the US-Peru and US-Colombia trade negotiations, i.e. that the U.S. negotiators were operating 'within the realms of a strict negotiation mandate' and had very little negotiation slack.³⁰³ According to the Schelling conjecture, this means that they would have more bargaining power. Von Braun also noted that in addition to less negotiating slack, the U.S. negotiators 'were negotiating on the back of a more powerful economy',³⁰⁴ further increasing their bargaining power.

Depending on whether the U.S. considered the final agreed exclusivity period of 5 years to be a negotiation breakdown, Janusch's introduction of social conflicts³⁰⁵ into Putnam's two-level game theory may be relevant as well to frame this thesis. Social conflicts, for example negotiators citing audience costs caused by the salience of the issue to the public, or reputation costs, better explains why negotiations fail.³⁰⁶

In exploring political economy tradeoffs and concessions, it would be essential to understand domestic politics leading to different negotiating outcomes or trajectories.³⁰⁷ Putnam states that to do this, a theory must be formulated about the power and the preferences of the major actors at Level II.³⁰⁸ My hypothesis is that Chile, having established market access deals with all countries in the TPP, and working on the back of a stronger economy compared to Malaysia, had more power and thus conceded less. As to negotiating preferences, there is less clarity, and I hope to address this gap through fieldwork.

Game theory alone is insufficient to understand the complexities within these negotiations and the resulting tradeoffs. Notably, as elaborated by Susan Strange:

[R]epresentations of Game Theory habitually deal with situations in which the 'players' are engaged in one game at a time; in which the players are limited to two, or some quite small number, and in which the game is played in vacuo and the players are motivated by precise and singular goals. These situations *are the very opposite of the reality of international political economy*, in which the players (including 'bit players') are engaged simultaneously in a whole series of bargaining games, some domestic and some international, and are motivated by a *complex and shifting tapestry* of interacting, sometimes contradictory, motivations.³⁰⁹
[Emphasis added.]

³⁰³ von Braun (n 161) 125

³⁰⁴ *ibid*

³⁰⁵ Janusch (n 298) 504-506

³⁰⁶ *Ibid* 516

³⁰⁷ Manger and Shadlen (n 120) 475

³⁰⁸ Putnam (n 298) 442

³⁰⁹ Strange (n 7) 553

To understand this complex and shifting tapestry, I use a methodology set out in the next section designed to specifically identify points of conflict and other significant points during the negotiations, and the precipitants, or causes, of these events. But the methodology alone is insufficient to understanding political economy tradeoffs. The nature of power in these negotiations must be elaborated, and where there is this complexity, structural power as defined by Strange is relevant. Notably, Strange states:

In this new great game of states, structural power decides outcomes (both positive and negative) much more than relational power does... Structural power is the power to choose and to shape the structures of the global political economy within which other states, their political institutions, their economic enterprises, and (not least) their professional people have to operate.³¹⁰

Strange then describes structural power as lying with the person or group who is able to exercise control over other people's security from violence, the person or group who can control the system of production of goods, those who are able to control the system of finance, and those who have the most influence over knowledge.³¹¹ Based on these it would undoubtedly be that the United States, the rulemaker in the TPP, would undoubtedly have structural power in the negotiations – and would easily obtain outcomes. We know that the outcomes in biologics negotiations were not per the United States' expectations – the question is how do we explain it?

There are additional considerations in Strange's theories. Notably, as Christopher May explains, in an analysis of Strange's work:

It is structural power that determines the relationship, or bargain, between authority and market. Market solutions cannot play a major role in the way in which a political economy functions *unless they are allowed to do so* by the actor that wields economic power and possesses authority.³¹² [Emphasis added]

Does this mean, therefore, that when Malaysia, Chile, and partners in the TPP pushed against U.S. demands in the TPP, that they only obtained the outcomes they wanted because they were allowed to by the United States? Additional considerations are relevant. In the case of biologics and concerns about medicine prices, Strange's writings on values in the international political economy (IPE) may be relevant. May explains:

³¹⁰ Ibid 565

³¹¹ Ibid 565

³¹² May (n 8) 174

Strange's aim is make IPE value sensitive; recognising where values are being ordered and traded off, and the history of such decisions and bargains. It is also necessary to understand how and when the ordering of values informs analysis.³¹³

Notably, a fifth structure suggested by Strange may be relevant – notably the structure of welfare, elaborated specifically with the example of threats to human life and contentment, and the idea that these should be avoided, alleviated, or compensated.³¹⁴ This is particularly relevant to the issue at hand, but it still raises further questions about whether the first four elements of structural power (security, production, finance, and knowledge) can and was tempered by the fifth structure. Christopher May states that while Strange is 'explicitly concerned with producing an explanatory theory, she remains sceptical of to the possibility of an all-embracing, all-explanatory theory of international political economy',³¹⁵ and that she doesn't directly analyse the dynamics of authoritative, technological, and market shifts that influence structural power.³¹⁶ And while it is not the object of this thesis either to provide an all-explanatory theory, drawing on these different complementary and contrasting sources may help illustrate why decisions were made the way they were.

A paper by Haugaard may help expand on Strange's theory. Notably, he states:

Power over of the pre-modern kind, as described by Machiavelli and Schitt, is usually zero-sum. To the extent to which A prevails over B, B loses... In the episodic moment that A exercises power over B, structures are reproduced that constitute the democratic game, which gives both the actors the dispositional power to replay. Structural reproduction entails the possibility of B exercising power over A at a different future episodic moment.³¹⁷

Caporaso, writing earlier than Strange, on the other hand characterises structural power as a 'higher power order because it involves the ability to manipulate the choices, capabilities, alliance opportunities, and payoffs that actors may utilise'.³¹⁸ In analysing these, we can say that while structural power per Strange belongs to the United States, a number of factors per Caporaso and Haugaard can reproduce and amend these structures, enabling an apparently weaker party to exercise power over the structurally stronger party.

Several other theoretical writings help underpin my research questions. First and foremost, that negotiations always involve reciprocal concessions. There is general agreement that this

³¹³ May (n 8) 174

³¹⁴ May (n 8) 174-175

³¹⁵ May (n 8) 172

³¹⁶ May (n 8) 185

³¹⁷ Mark Haugaard, 'Rethinking the Four Dimensions of Power: Domination and Empowerment' (2012) 5(1) *Journal of Political Power* 33-54, 37-38

³¹⁸ James A Caporaso, 'Introduction to the Special Issue of *International Organization* on Dependence and Dependency in the Global System' (1978) 32(1) *International Organization* 1-12, 4

is almost always in terms of access to the home market.³¹⁹ But this is not always the case. Reciprocal concessions may be in the form of vague promises to ensure increased technology transfer, or even perceived supply-chain benefits from rule harmonisation. They may also be in the form of threats to withdraw existing support, for example foreign aid or military support.³²⁰ Basically, negotiators may agree on concessions in one area in return for a 'package deal' of gains in all or some other issue areas.³²¹

Putnam describes a situation where Level II partners may initially oppose oil price decontrol as a policy issue, but may be able to switch their vote and agree on concessions if the chief negotiator could broker a deal to deliver more jobs.³²² So while this does not alter the Level II actor's preferences, it creates a policy option that was previously beyond the Level II actor's domestic control. Putnam calls this particular type of issue linkage '*synergistic linkage*'.³²³ Through this PhD, I hope to identify where possible synergistic linkages were, and whether those linkages were finalised into political economy tradeoffs.

In addition to identifying synergistic linkages, completeness would dictate that it would be necessary to identify what unit-level learning the negotiators had participated in (from either the Level I or Level II actors) that influenced how states approached issues in particular negotiations. Sell states that negotiators choices are not preordained,³²⁴ and that unit-level learning can lead states 'to redefine their interests'.³²⁵

VII. Research methodology

From a methodological standpoint, empirical data gained from fieldwork interviews with negotiators, government officials advising negotiators, and civil society stakeholders were be subjected to a turning points analysis as proposed by Crump and Druckman.³²⁶

Interviews were based on a topic guide seen in Annex C of this thesis – with domains on:

- 1) Country approach to TPP negotiations (ideological/historical/politico-economic)
- 2) Unit-level learning
- 3) Turning points

³¹⁹ Lisa L. Martin, *The Oxford Handbook of the Political Economy of International Trade* (Oxford University Press 2015) 10; J. Michael Finger, 'Implementing the Uruguay Round agreements: problems for developing countries' (2001) 24(9) *The World Economy* 1097-1108, 1099

³²⁰ Jawara and Kwa (n 147) 150-151

³²¹ Valbona Muzaka, 'Linkages, Contests and Overlaps in the Global Intellectual Property Rights Regime' (2010) 17(4) *European Journal of International Relations* 755-776, 761

³²² Putnam (n 298) 446-447

³²³ Putnam (n 298) 448

³²⁴ Sell (n 12) 6

³²⁵ *ibid* 14

³²⁶ Larry Crump and Daniel Druckman, 'Turning Points in Multilateral Trade Negotiations on Intellectual Property' (2012) 17(1) *International Negotiation* 9, 9

Negotiators in particular were asked all questions and subquestions under each domain. Some stakeholders had not attended negotiations but had conducted advocacy with local politicians and attended post-negotiation briefings by negotiators, so questions under the 'country approach to TPP negotiations' domain such as 'What were your key negotiating aims' were less relevant, but questions under the unit-level learning domain, such as 'can you tell about your engagement with negotiators' and 'how would you characterise your relationship' was more relevant. The variance in the questioning was managed by way of writing up a profile of the interviewee beforehand – and crossing out questions which likely had less relevance. To plot a chronology of key turning points, the question of 'Do you remember when you first found out that the U.S. were asking for 12 years of market exclusivity for biologics? What were your thoughts?' under the turning points domain was most relevant. All negotiators and former negotiators were asked this question. On the other hand, for questions directed to Pedro Roffe, for example, who is an expert in the history of Chilean trade and intellectual property but had not attended the negotiations, only the first domain was relevant.

The turning points analysis as proposed by Crump and Druckman³²⁷ essentially involved plotting a detailed chronology of events using 'turning points' and 'departures' – in other words, identifying where substantive issues arise and finding out what were the precipitants or causes. I rely predominantly on what negotiators and government advisors identified as the most important negotiation rounds for disputes and disagreements on biologics negotiations, and how they characterise those departures. Once a list of departures are plotted, precipitants, or causes of those departures will be plotted out using the process model shown in Figure 2 below.

Crump and Druckman established a detailed chronology of events occurring during the TRIPS agreement negotiations, for example listing that in October 2001, the WTO chair was unable to secure a compromise between two sides, and in November 2001, a representative of Mexico was appointed to mediate the TRIPS/health issue.³²⁸ From this chronology, precipitants of departures, consequences of those departures, and outcomes are identified, and this renders useful lessons about the negotiation process and effective negotiator behaviour.³²⁹

Crump and Druckman clarify as follows:

³²⁷ Ibid 9

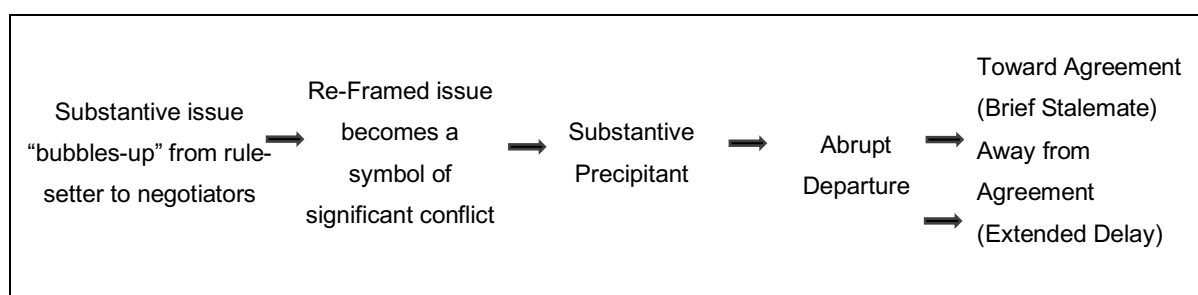
³²⁸ Ibid 25

³²⁹ Ibid 9

By identifying departures during the negotiation process, the analysis highlights the critical moments that move the process from impasse to agreement. By discovering the precipitants of those departures, the analysis distinguishes from external and internal causes of departures. By tracing the consequences of the departures, the analysis extends the path from prior to posterior events on the way to outcomes.³³⁰

Following Crump and Druckman’s example, departures will be extracted from interviews – for example, if an interviewer said disagreements occurred at a negotiation round in Salt Lake City, that would be plotted as a departure and be numbered based on chronological order. This methodology will also enable me to logically and methodically identify the precipitants or causes of issues arising in the negotiations. The following process model³³¹ applies:

Figure 2: Process Model Linking Departures to Precipitants



Process models specifically linked to findings from interviews can be seen in Figures 5 and 6 in Chapter 5 of this thesis. At the initial stage of this PhD, I predicted that the Singapore round of negotiations was bound to feature in this chronology, as it was at this round that rumours of 12 years of biologics exclusivity was most prominent, events leading up to the Malaysia-U.S. side letter on biologics exclusivity, and the trade representative meeting in Maui in August 2015 that rendered no agreement, among other notable events where departures were clear. Before this research, while I had theories about what caused departures, for example concerns about drug prices and access to medicines, these were not evidence-based. Interviews with negotiators and other stakeholders in attendance at negotiating rounds helped elucidate the significance or non-significance of departures, eventually yielding, as shown in Chapter 5 of this thesis, that four negotiation rounds were especially significant on this issue.

As departures are plotted and tradeoffs become clearer, theories on power, deadlocks, and coalitions may be useful to help explain why negotiators behaved in a certain way. Notably, when there is a deadlock, negotiators on both sides may opt for vague and/or ambiguous

³³⁰ Ibid 11

³³¹ Larry Crump and Daniel Druckman, 'Turning Points and International Environments: Multilateral Negotiations in the GATT and WTO' (2016) 21 International Negotiation 1-42, 32

language that may satisfy both parties,³³² or they could employ a number of tools to break deadlock, including coalition building, unofficial channels (such as meeting at an informal venue – Camp David is an example, or on the golf course a la Obama),³³³ or via ‘shuttle mediation’.³³⁴ In essence, the tools contained in Crump and Druckman’s turning points framework will be analysed in the context of theoretical considerations in Section VI above.

VIII. Organisation of the thesis

By drawing on two-level game theory, elucidating the deep integration characteristic of the TPP, explaining the importance of biologics, and historically situating TPP IP in the larger pharmaceutical intellectual property politics picture, this chapter demonstrates the salience of an examination of political economy tradeoffs in trade-related intellectual property, particularly as regards the TPP, as a norm-setting agreement. I point out how IP is never negotiated in isolation, but rather in the context of concessions, and that these concessions may not necessarily be in the form of market access, but also in the form of vague promises, for example, that the trade agreement would create more jobs, or a perception that longer monopolies on biologics can increase technology transfer.

I also consider what factors influence negotiator decision-making, i.e. whether there was a predetermined mandate, whether negotiating positions changed, what unit-level learning influenced these changes, the existence of upper middle-income country alliances, what domestic pressures influenced decision-making on biologics, and what tactics negotiators used when confronted with tradeoffs. UMICs are in a unique position as regards trade negotiations of this magnitude and reach – they aspire to be developed nations, and thus are more susceptible to accepting developed country standards, but at the same time exist in a less generous fiscal space where they must take into account budgetary health constraints and developing domestic industries. At the same time, they serve as conduits towards wider harmonisation of norms among developing countries, due to their special position or ‘development proximity’ to lesser developed countries and positions within regional alliances (ASEAN, MERCOSUR) that could prove as launching pads for newly adopted norms. This is contextualised to the industrialised nation belief that the WTO is no longer the forum for the harmonisation of norms – at least not at the level the industrialised nations believe is fair and equitable.

³³² Gorlin (n 162) 15

³³³ David Nakamura, ‘In Hawaii, Obama Golfs with Malaysian Prime Minister Najib Razak’ *The Washington Post* (24 December 2014) <https://www.washingtonpost.com/news/post-politics/wp/2014/12/24/in-hawaii-obama-golfs-with-malaysian-prime-minister-najib-razak/>> accessed 23 October 2019

³³⁴ Peter Harris and Ben Reilly (eds), *Democracy and Deep-Rooted Conflict: Options for Negotiators* (International IDEA 1998) 103

This thesis is divided into five chapters organised thematically. This chapter provides a backdrop for the problem at hand: the sheer enormity and norm-setting nature of the TPP, and the perceived obsolescence of the WTO as a forum for furthering maximalist intellectual property. The chapter engages with the idea of capacity, domestic influences, and strategy of upper middle-income country negotiators, highlighting their unique positions as conduits of norm change and influences to lesser-developed nations. The main focus of the chapter is to introduce the main question: i.e. how do upper middle-income countries strategise for, respond to, and engineer and justify political economy tradeoffs to maximalist intellectual property provisions that they may not necessarily agree to? Framing this notion is several agential factors – that stronger economies enable negotiators to make less tradeoffs, that domestic stakeholders play a strong role in changing a predetermined win-set, if any, and that decisions at Level I that may not necessarily be accepted at Level II and vice versa may be justified with strategy suggesting that one's hands are tied.

Chapter 2 is focused on the role of the industrialised nation in pharmaceutical intellectual property, introducing a historical overview of the convergence of hegemonic power, corporate rulemaking, and international diplomatic institutions. It then segues into the emergence of North-South IP disputes and disagreements, and chronologically details how these deadlocks led to industrialised nations moving away from the WTO as a fundamental norm-making agency.

Chapters 3 and 4 consider current trade policies and salient historical events that may lend context to Chile and Malaysia's decisions and negotiating outcomes in the TPP, answering questions on domestic factors that influenced negotiating win-sets, the level of unit-level learning gained from previous trade engagement, and whether the novelty of biologics IP was in any way a factor for negotiating decisions.

Chapter 5 synthesises the findings from fieldwork and the literature review. It is here that I hope to provide my most original contribution: what political economy tradeoffs were made, and whether lessons from this thesis can predict what role upper middle-income countries should play in the face of maximalist intellectual property in the near future.

Chapter 6 contains analysis on the findings, including a discussion on how negotiation tactics modify asymmetry in negotiations and how the changing global philosophy on access to medicines may alter how trade-related pharmaceutical IP in the future. The chapter details my theoretical contribution, i.e. 'common precedent' and how negotiators can effectively rely on

it, and from a practical standpoint, provides recommendations for developing countries entering similar trade negotiations.

Chapter Two: Politics of Intellectual Property and Pharmaceuticals: An Historical Overview

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I. Introduction

The history of international intellectual property (IP) politics has been characterised by the imposition of developed country intellectual property standards on developing countries, threats, the shifting or opening of trade forums when there is too much developing country resistance, and political economy tradeoffs. It is grounded in an aspiration of a harmonised supranational intellectual property code extending pharmaceutical industry monopolies as long as is viable. It is also grounded on the idea that so long as developing countries want access to U.S. (or European) markets, or even for less tangible goals, like them wanting to be seen as part of an established trade diplomacy with the most powerful country on earth, it is possible to keep asking for more maximalist intellectual property. The history of intellectual property as a tool for incentivising innovation is a long one; in a 1922 hearing to revise patent laws, one William Dodge cited the patent system as a way to serve national security, that it would do so long as it continues to be the engine of America's progress, that it was the 'best incentive', and that compulsory licenses 'posed uncertainties for innovation and the economy'.³³⁵ The historical development since this time is beyond the scope of this thesis, but it is notable that the arguments for intellectual property today, as can be seen in the following paragraphs, continue to be defined along these lines. For the purposes of this thesis, the account of the history of pharmaceutical IP begins with the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) system, which was the starting point for global enforceability of pharmaceutical IP.

³³⁵ William Dodge (1922), quoted in Parthasarathy (n 17) 34

II. Where it began: the Uruguay round

The Uruguay round marked the beginning of the intellectual property moving into the realm of international trade. To quote Taubman, it was 'a turning point for multilateral governance and a catalyst for transformation of law, policy, and international relations in IP'.³³⁶ The U.S. was irked by the fact that many countries did not provide patents for pharmaceutical products, and that its attempts to advance intellectual property during the 1973-1979 Tokyo Round of GATT negotiations were unsuccessful.³³⁷ According to Dinwoodie and Dreyfuss, it was activities after this Round, including coordinated lobbying by U.S. industry, that paved the way for inclusion of intellectual property into the Uruguay Round.³³⁸

The U.S. approach to the Uruguay round was strongly motivated by domestic policy. The 1984 U.S. Trade and Tariff Act, had the central message that access to U.S. markets would be contingent on other markets not only opening their markets to U.S. foreign direct investment and U.S. high technology products, but also to introduce and implement new forms of IP protection.³³⁹ A 1988 report by the U.S. International Trade Commission compiled industry data and found that U.S. companies lost between \$43-61 billion due to foreign infringement or insufficient coverage of intellectual property rights. This further bolstered their international IP approach and became an oft-quoted argument for expanding IP into the international trade regime.³⁴⁰

At the same time, there was a growing dissatisfaction with the pre-existing trading system, the GATT. For a long time the GATT had been a platform favouring developed nations, and one that marginalised lesser-developed countries.³⁴¹ But leading up to the Uruguay Round, there was a sea change in how developing countries viewed the role of trade in economic and social development, largely spurred by success stories of export-oriented policies of East Asian 'tiger' economies and Chile, and a debt crisis that paralysed domestic economies.³⁴² As a consequence, in the words of Otten, 'there was a growing kernel of developing countries

³³⁶ Antony Taubman, 'Thematic Review: Negotiating 'Trade-Related Aspects' of Intellectual Property Rights' in Jayashree Watal and Antony Taubman, *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (World Trade Organization 2015) 15

³³⁷ John H Jackson and Alan O Sykes, 'Introduction and Overview' in John H Jackson and Alan O Sykes (eds), *Implementing the Uruguay Round* (Oxford University Press, 1997)

³³⁸ Graeme B Dinwoodie and Rochelle C Dreyfuss, *A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime* (Oxford University Press 2012)

³³⁹ Raphael Kaplinsky, 'Industrial and Intellectual Property Rights in the Uruguay Round and Beyond' (1989) 25(3) *Journal of Development Studies* 373

³⁴⁰ USITC (n 84)

³⁴¹ Hoekman and Kostecki (n 151) 385

³⁴² Hoekman and Kostecki (n 151) 391; Adrian Otten, 'The TRIPS Negotiations: An Overview' in Jayashree Watal and Antony Taubman, *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (World Trade Organization, 2015) 74-75

committed to a major strengthening of the multilateral trading system from the outset'.³⁴³ The developing countries had also attempted a reform of the Paris Convention on IP to ensure them the maximum liberty to enact IP laws according to their developmental levels and emphasising 'the economic inequalities between nations'. This 1977 attempt for more 'balanced' IP was viewed as too radical by developed nations, and thus failed.³⁴⁴ While this was an unprecedented pushback by developing countries, this merely showed to developing countries that 'balance' was not something the developed countries were interested in, and to the developed countries, that there was a necessity to cement IP rules within the trade regime as soon as possible. These factors combined provided a fertile ground for pushing the agenda on IP into the international trading system and IP concessions for developing countries.

The Uruguay Round was launched on 20 September 1986 in Punta del Este, Uruguay. The Punta del Este Ministerial Declaration directed negotiators to 'promote effective and adequate protection of intellectual property rights'.³⁴⁵ It also said, although in light of the results of the negotiations, more as a diplomatic nod to developing country interests rather than as a non-negotiable guiding principle, that developed countries shall not seek or require that less developed countries make concessions that were 'inconsistent with the latter's development, financial and trade needs'.³⁴⁶ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that was born of the Uruguay Round resulted in enforceable supranational intellectual property code that went beyond developing countries' needs,³⁴⁷ and was the most significant starting point for the expansion of trade-related IP. Indeed, the TRIPS Agreement was 'one of the Round's most enduring accomplishments'.³⁴⁸

The Agreement came to pass with strategic lobbying by the U.S., European, and Japanese pharmaceutical industries, including working closely with developed country negotiators, GATT, and WIPO Secretariats during the course of the Uruguay Round negotiations to ensure their interests were included in final texts, and sending delegates from the Intellectual Property Committee (IPC) for various lobbying missions, including to emerging markets like Singapore, prior to the Uruguay Round starting.³⁴⁹ The IPC, consisting of up to fourteen corporations including Merck, Monsanto, and Pfizer, had direct access to the office of the U.S. Trade Representative through the Advisory Committee for Trade Negotiations, and they had also

³⁴³ Adrian Otten, 'The TRIPS Negotiations: an Overview' in Jayashree Watal and Antony Taubman, *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (World Trade Organization, 2015) 75

³⁴⁴ Dinwoodie and Dreyfuss (n 338) 28

³⁴⁵ GATT-Punta del Este Declaration (20 September 1986) <<http://www.sice.oas.org/trade/Puntae.asp>> Accessed 8 February 2018

³⁴⁶ *ibid*

³⁴⁷ Peter K Yu, 'Currents and Crosscurrents in the International Intellectual Property Regime' (2004) 38 *Loyola L.A. Law Review* 323

³⁴⁸ Clayton K Yeutter, USTR, quoted in Gorlin (n 162)

³⁴⁹ Dinwoodie and Dreyfuss (n 338) 33; Gorlin (n 162) 1

mobilised actors in the EU and Japan, constituting a 'cohesive working group, ready to supply Northern diplomats with statistics, theoretical arguments, framing devices, etc'.³⁵⁰

Also prior to the Uruguay Round beginning, the U.S. had entered into a number of bilateral trade agreements that included intellectual provisions. These were strategic decisions to normalise the language of 'trade-related IP' in international trade circles, and by the time the Uruguay Round was launched, according to Carolyn Deere, 'the idea that intellectual property protection was 'trade-related' had firmly taken hold'.³⁵¹

Despite this, IP negotiations moved extremely slowly during the first four years (1986-1989) of the Uruguay Round negotiations. This was for two reasons – negotiations progressed based on previous IP work in the GATT, meaning that negotiators were working from a very limited IP viewpoint, and that many participants – notably developing country participants – felt that WIPO was still the 'normal' forum for IP and they wanted to avoid prejudicing them.³⁵² So while there was general acceptance of 'trade-related' IP, countries for some time were still treading with caution.

Approaching the mid-term review of the negotiations, various forms of pressure had been exerted upon developing countries, resulting in developing countries agreeing to discuss norms and standards for IP at the April 1989 meeting in Geneva, a meeting intended to complete the mid-term review.³⁵³

In January of the fifth year of the Uruguay Round (1990), industrialised countries began tabling legal texts on IP and by spring of that year these texts had become more comprehensive, with texts drafted by developed nations (United States, EC, Switzerland, Japan) and a group of developing countries (Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe).³⁵⁴ The first composite IP text was issued by the GATT Secretariat in June 1990.³⁵⁵

On 23 July 1990, the Chairman of the TRIPS working group, Lars Anell of Sweden, reported on the Status of Work in the Negotiating Group and attributed the progress in the text to

³⁵⁰ Dinwoodie and Dreyfuss (n 338) 33

³⁵¹ Carolyn Deere, *The Implementation Game: the TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford Scholarship Online 2009)

³⁵² Daniel Gervais and Vera Nicholas-Gervais, 'Intellectual Property in the Multilateral Agreement on Investment' (1999) 2(2) *The Journal of World Intellectual Property Rights* 257

³⁵³ Biswajit Dhar and C. Niranjana Rao, 'Dunkel Draft on TRIPS: Complete Denial of Developing Countries' Interests' (1992) 27 *Economic and Political Weekly* 275

³⁵⁴ Gorlin (n 162) 2

³⁵⁵ *Ibid*

informal consultations that had been held up to then.³⁵⁶ The report shows what language had been agreed to at that moment in time (unbracketed text) and that which had yet to be agreed upon (bracketed text). At this point, it had yet to be agreed whether patents would be either 'available' or 'granted', whether they would be provided for 'any inventions' in 'all fields of technology', and whether they would be granted for pharmaceutical processes.³⁵⁷ Also yet to be agreed was whether inventions contrary to public health would be excluded from patentability.³⁵⁸

The informal discussions continued, and when the Chairman reported on the Status of Work again in September 1990, he noted that developing countries had expressed concern at 'the tendency to treat intellectual property as a purely commercial issue' and that there was 'insufficient attention paid to the national policy objectives of developing countries'.³⁵⁹

The TRIPS negotiating group met formally on a number of dates after that, including the 10th and 21st of September and the 8th and 15th of October, with numerous informal consultations in between. In a note by the GATT Secretariat dated 8 October 1990, reference was made to the continuing 'major divergences' between developed and developing nations.³⁶⁰ In the same document, developing countries reminded all participants of the Punta del Este declaration, emphasising that less-developed parties should not be required to make concessions inconsistent with their development needs.³⁶¹

This sentiment did not change throughout the negotiations, with the entire negotiations on pharmaceutical IP being drawn along North-South lines, resulting in significant tensions.³⁶² Furthermore, because it was originally intended for the Uruguay Round negotiations to come to a close in December 1990, considerable pressure was placed upon developing countries to agree to the consolidated texts. However when the draft final text authored by the GATT Director-General Arthur Dunkel (hereinafter the 'Dunkel Draft') was tabled, it became clear that negotiations would continue into 1991 due to continuing tensions between developed and developing countries.³⁶³ While the U.S. pharmaceutical industry expressed strong

³⁵⁶ GATT Secretariat, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Status of Work in the Negotiating Group: Chairman's Report to the GNG (23 July 1990) MTN.GNG/NG11/W/76, 1 < https://www.wto.org/gatt_docs/English/SULPDF/92090135.pdf> accessed 29 November 2019

³⁵⁷ Ibid 29

³⁵⁸ Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Status of Work in the Negotiating Group: Chairman's Report to the GNG (23 July 1990) MTN.GNG/NG11/W/76, 30

³⁵⁹ GATT Secretariat, Press Bulletin: Negotiations Intensify as Groups Get Down to Detailed Drafting (9 October 1990) NUR 041, 5 < <http://sul-derivatives.stanford.edu/derivative?CSNID=91520164&mediaType=application/pdf>> Accessed 2 March 2018

³⁶⁰ GATT Secretariat, Meeting of Negotiating Group of 10-21 September 1990 (8 October 1990) MTN.GNG/NG11/25, 2

³⁶¹ Ibid

³⁶² Gorlin (n 162) 6-7

³⁶³ Gorlin (n 162) 5; Biswajit Dhar and C. Niranjana Rao, 'Dunkel Draft on TRIPS: Complete Denial of Developing Countries' Interests' (1992) 27 Economic and Political Weekly 275

dissatisfaction with the Dunkel Draft for not providing monopolies for products still in the pipeline, developing countries struggled with the fact that the text did not at all reflect what the Punta del Este Declaration promised.³⁶⁴ Thirteen Latin American countries continued to say that patent protection for pharmaceuticals was not necessary.³⁶⁵ The Dunkel Draft was described as being a 'total sell-out to the U.S. position'³⁶⁶ and a 'complete denial of developing country interests'.³⁶⁷ Due to this impasse, negotiations were 'officially' dissolved, but in reality continued into the new year.

The new year galvanised increasing threats and coercion by the U.S. upon developing countries. This included threats against ambassadors, withdrawal of special trade preferences, and including countries in the Special 301 Priority Watch List.³⁶⁸ As these threats came to a climax, as Dinwoodie and Dreyfuss describe, 'developing countries begun to look at the emerging TRIPS agreement as the lesser of two evils'.³⁶⁹

While developing countries continued to disagree in principle on broad patent terminology including patents for processes and patents 'in all fields of technology', economic threats meant that developing countries would make the IP concessions. It was the last issue to be resolved prior to the tabling of the final Dunkel draft agreement in December 1991,³⁷⁰ and as expected, the reaction to the final agreement was muted as it was presented as an 'up or down' draft, meaning that countries could vote yes or no but had limited space for changing text.³⁷¹ A reflection of economic threats, most countries had expressed a 'general willingness' to move forward beyond IP to market access and services.³⁷²

The TRIPS agreement was signed on 15 April 1994 in Marrakech, and countries were given different dates for application of the agreement, with developing countries having to apply TRIPS by 1 January 2000. Despite securing globally enforceable pharmaceutical patent standards, the American pharmaceutical industry was not happy. They had managed to

³⁶⁴ Williams, 'Bio-piracy' under new fire, *Financial Times*, 30 Nov 1993, at 6, cited in Amy S Dwyer, 'Trade-Related Aspects of Intellectual Property Rights' in Terence P Stewart (ed), *The GATT Uruguay Round: a Negotiating History (1986-1994): Volume IV: The End Game (Part I)* (Kluwer 1999)

³⁶⁵ *ibid*

³⁶⁶ J. M., 'GATT, the Dunkel Draft and India' (1992) 27 *Economic and Political Weekly* 140

³⁶⁷ Dhar and Rao (n 353)

³⁶⁸ Jawara and Kwa (n 147) 151

³⁶⁹ Michael L Doane, 'TRIPS and International Intellectual Property Protection in an Age of Advancing Technology' (1994) 9(2) *American University International Law Review* 465, cited in Dinwoodie and Dreyfuss (n 338) 33

³⁷⁰ Adrian Otten, Director, Intellectual Property Division, WTO, 'The Implications of the Results of the Uruguay Round for the Protection of Pharmaceutical Inventions' (Presentation at the Annual International Forum on the Latin-American Pharmaceutical Industry (ALIFAR), 12 May 1994), cited in Gorlin (n 162) 21

Mogens Peter Carl, Director-General of DG Trade, 'The TRIPS Agreement 10 Years Later' (Speech at the International Conference on the 10th Anniversary of the WTO TRIPS Agreement, Brussels, 23 June 2004) <<http://trade.ec.europa.eu/doclib/docs/2004/june/tradoc117772.pdf>> accessed 29 May 2011

³⁷¹ Terence P Stewart (ed), *The GATT Uruguay Round: A Negotiating History (1986-1994): Volume IV: The End Game (Part I)* (Kluwer 1999) 2284

³⁷² *ibid*

secure higher intellectual property standards through bilateral trade agreements and the use of the Special 301 watch lists, and they were disappointed not only at the lower standards in TRIPS but also at the transition periods allotted to developing countries.³⁷³

III. The 'failure' of the Doha round

The politics of pharmaceutical IP in the WTO must be seen in the light of wider non-pharmaceutical sector negotiations. The total domination of developed countries, the blocking of developing country proposals, and the unbalanced outcomes in the Uruguay Round led to developing countries feeling marginalised.³⁷⁴ The next round of negotiations was due to be launched at the biannual WTO ministerial conference in Seattle in 1999, but disagreements with developing countries, as well as massive street protests by civil society, led to a 'spectacular launch-failure'.³⁷⁵ The launch failure led a crisis of legitimacy in the WTO, and increased pressure to include developing countries in the decision-making process.³⁷⁶

From then on, leading towards what would be the Doha Round, developing countries quickly learned the value of strategic alliances.³⁷⁷ Brazil, for example, came to the Doha Round seeking major gains on agriculture, and knew it needed to build an alliance with India to be seen as credible by other developing nations.³⁷⁸ Sector-specific negotiations in 2000 allowed developing countries to reach out to each other and establish alliances.³⁷⁹ When the WTO Doha Round of negotiations launched in November 2001, major alliances were in formation, including the Core Group of developing countries resisting the so called 'Singapore issues' i.e. transparency of government procurement, trade facilitation, trade and investment, and trade and competition (hereinafter 'the Core Group').

Officially called the Doha Development Round, it contained a broad development agenda intended to address economic inequalities in the Global South. While the EU joined the Doha Round enthusiastically and with the core position that the Singapore issues were conducive to development, the United States were less enthusiastic; they did not foresee economic gains

³⁷³ *ibid*

³⁷⁴ Kristin Hopewell, 'Different Paths to Power: The Rise of Brazil, India and China at the World Trade Organization' (2015) 22 *Review of International Political Economy* 311, 316

³⁷⁵ Joseph Francois, Hans van Meijl and Frank van Tongeren, 'Trade Liberalization in the Doha Development Round.' (2005) 20 *Economic Policy* 350, 351; Hopewell (n 374) 316

³⁷⁶ Hopewell (n 374) 316

³⁷⁷ *Ibid* 321

³⁷⁸ *ibid* 322

³⁷⁹ Francois, van Meijl, and van Tongeren (n 375) 354

from the Doha Round and their support for the Round was mainly grounded in geostrategic considerations post-9/11.³⁸⁰

The Doha Round was characterised with recurrent North-South conflict, including 'walkouts from negotiating sessions and heated rhetoric concerning the very purpose of free trade talks'.³⁸¹ Throughout the negotiations, leading up to the next scheduled WTO ministerial conference in Cancun, it became clear that there were 'new constellations of power' involving the merging markets of China, India, and Brazil, and that these challenged the hegemony of the United States and the multilateralist role of the European Union.³⁸² India played a leading role in mobilising the Core Group in insisting that the Singapore issues could not be grouped together as a negotiating concession.³⁸³ This was a key factor that led to the breakdown at the Cancun ministerial.

Unique characteristics of these three countries created a powerful new dynamic at the WTO. Brazil saw itself as a potential leader of developing country interests, representing growing economic power, but also being relatable in terms of social indicators such as poverty and access to affordable medication, and thus saw itself as uniquely positioned to bridge North-South chasms.³⁸⁴ India, while less inclined to take a leadership role, was a powerful alliance builder, whereas China utilised its sheer economic might. This new power dynamic meant, and still means, that it is not possible to conclude any deal at the WTO without these three countries.³⁸⁵

In the first quarter of 2001, Zimbabwe through its ambassador Boniface Chidyausiku chaired the WTO TRIPS Council, and emphasised that 'the WTO could not longer ignore the access to medicines issue', and he requested a special TRIPS Council session on access to medicines in April 2001.³⁸⁶ Discussions during this meeting, and subsequent TRIPS Council meetings in July and September of that same year, are what planted the seeds for what would grow into the most pressing intellectual property issue for the Doha Development agenda, much to the consternation of the United States.³⁸⁷ In October 2001, Stuart Harbinson, the

³⁸⁰ Alasdair R Young, 'Transatlantic Intransigence in the Doha Round: Domestic Politics and the Difficulty of Compromise' in Amrita Narlikar (ed), *Deadlocks in Multilateral Negotiations* (Cambridge 2010) 138, citing Guy de Jonquières testimony, 6 May 2008; Anders Ahnlied and Ole Elgström, 'Challenging the European Union: The Rising Powers and the USA in the Doha Round' (2014) 20 *Contemporary Politics* 77, 81

³⁸¹ Arthur Daemrich, 'The Evolving Basis for Legitimacy of the World Trade Organization: Dispute Settlement and the Rebalancing of Global Interests' (2011) Harvard Business School Working Paper 12-041, 1 <<http://www.hbs.edu/faculty/Publication%20Files/12-041.pdf>> accessed 9 February 2018

³⁸² Anders Ahnlied and Ole Elgström, 'Challenging the European Union: The Rising Powers and the USA in the Doha Round' (2014) 20 *Contemporary Politics* 77, 77

³⁸³ Amrita Narlikar and Diana Tussie, 'The G20 at the Cancun Ministerial: Developing Countries and Their Evolving Coalitions in the WTO' (2004) 27 *The World Economy* 947, 950

³⁸⁴ Hopewell (n 374) 316-318

³⁸⁵ *ibid* 318

³⁸⁶ Crump and Druckman (n 326) 23

³⁸⁷ Susan K Sell, 'Intellectual Property and the Doha Development Agenda' (2006) 6(2) *Global Social Policy* 147

Chair of WTO General Council, who had a key role in establishing the WTO agenda, submitted to the WTO Ministerial Conference in Doha a single text on TRIPS and Public Health with two options – one preferred by developing countries and the other by developed countries.³⁸⁸ The U.S. then attempted to divide the developing country coalition. This was followed up by Brazil strategically threatening to reopen the entire Doha agenda if the developing country text was not adopted. Harbinson and Mike Moore, the WTO Director-General, seeking to avoid this, unsuccessfully tried to mediate a compromise.³⁸⁹ Evident in this process for the developing countries was the ‘intellectual property fundamentalism’ exhibited by the developed countries; i.e. that the only way to achieve development was to adopt developed country standards.³⁹⁰ Developing countries viewed IP differently, i.e. as only one component that could be part of a development strategy.

In November 2001, largely due to the efforts of developing countries who were concerned about access to medicines, the Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO at the 2001 Doha Ministerial Conference. It clarified that countries had the right to determine what constituted a national emergency or circumstances of extreme urgency when issuing a compulsory licences, and urged the WTO TRIPS Council to look into solutions pertaining to the fact that countries with limited manufacturing capacity had difficulties utilising compulsory licences.³⁹¹

The next biannual WTO conference in Cancun in 2003 was intended to be an important milestone for the Doha Round of negotiations. 146 member countries of the WTO attended. The U.S. and the EU had put forward a joint proposal on agriculture that they thought might meet the developing countries halfway.³⁹² Agriculture had long since been the most protected sector in international trade and both the U.S. and the EU were extremely defensive throughout the Doha Round due to the extensive support both countries provided to domestic farmers.³⁹³ Developing countries were not satisfied with the joint proposal. In Cancun, the Core Group led by India succeeded in forcing the Singapore issues off the negotiating table. In addition, Brazil, India, and South Africa led the charge on negotiating outcomes pertaining to intellectual property and access to medicines.³⁹⁴

³⁸⁸ Crump and Druckman (n 326) 24

³⁸⁹ *ibid*

³⁹⁰ Graham Dutfield, ‘The US and Europe are ‘Intellectual Property Fundamentalists’’ SciDevNet (11 March 2005) <<https://www.scidev.net/global/health/opinion/the-us-and-europe-are-intellectual-property-funda.html>> accessed 27 February 2018

³⁹¹ WTO, Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2

³⁹² Hopewell (n 374) 318; Daemmrlich (n 381)

³⁹³ Alasdair R Young, ‘Transatlantic Intransigence in the Doha Round: Domestic Politics and the Difficulty of Compromise’ in Amrita Narlikar (ed), *Deadlocks in Multilateral Negotiations* (Cambridge 2010) 131; Cody A Thacker, ‘Agricultural Trade Liberalisation in the Doha Round: the Search for a Modalities Draft’ (2005) 33 *Georgia Journal of International & Comparative Law* 721, 723

³⁹⁴ Hopewell (n 374) 324

Instead, the Cancun Ministerial was dominated by an insurmountable stalemate on agricultural subsidies, intellectual property, the Singapore issues, and capital controls. In the wake of the 1997 Asian financial crisis, investors had rapidly pulled out of a number of countries including Malaysia and Korea, resulting in stock market crashes and recessions.³⁹⁵ The stalemate meant that there was a 'recalibration of North-South relations in WTO negotiations'.³⁹⁶ The extent to and ease of which a smaller group of developed countries could dictate norms to the whole of the WTO was changing. It moved further away the traditional duopoly of the U.S. and the EU, although these countries are still very much needed for the successful conclusion of WTO negotiations.³⁹⁷ This new reality resulted in developed countries shifting to different trade forums. Since the Doha Round stalemate, more than 300 Preferential Trade Agreements (PTAs) and over 500 Free Trade Agreements (FTAs) have been signed.³⁹⁸

IV. Forum 'shifting' in intellectual property regimes

When developed countries are unable to score the wins they want from developing countries, they 'shift' their demands to bilateral or preferential trade agreements (PTAs) where the power imbalance is higher. In the words of Hartman: '[W]hen a multilateral trade system does not respond to a nation's needs, PTAs becomes the path of least resistance'.³⁹⁹ According to Gathii and Ho, forum shifting focuses on 'destabilising existing understandings' in one forum by establishing new norms in another.⁴⁰⁰ These norms are almost always in favour of intellectual property owners. Especially in regional preferential trade agreements, these new norms are adopted uniformly by all negotiating countries, further isolating norms that the developed world deems outdated. But because there has been a proliferation of forum shifting, there are a plethora of divergent rules, actors, and values.⁴⁰¹ Intellectual property lawmaking post-Doha, therefore, occurs predominantly through bilateral and regional trade agreements.

In intellectual property, forum shifting has been triggered especially when developing countries effectively veto developed country demands. In 1986, a group of developing countries led by Brazil successfully criticised WIPO's Treaty on Intellectual Property in Respect of Integrated Circuits.⁴⁰² Demandeurs of relevant provisions then shifted forums to the WTO and integrated

³⁹⁵ Daemrich (n 381)

³⁹⁶ Aileen Kwa, *Power Politics in the WTO* (Focus on the Global South, 2003) 26

³⁹⁷ Alasdair R Young, 'Transatlantic Intransigence in the Doha Round: Domestic Politics and the Difficulty of Compromise' in Amrita Narlikar (ed), *Deadlocks in Multilateral Negotiations* (Cambridge 2010)

³⁹⁸ Stephen W Hartman, 'The WTO, the Doha Round Impasse, PTAs, and FTAs/RTAs' (2013) 27(5) *The International Trade Journal* 411

³⁹⁹ *Ibid* 427

⁴⁰⁰ James Gathii and Cynthia Ho, 'Regime Shifting of IP Lawmaking and Enforcement from the WTO to the International Investment Regime' (2017) 18 *Minnesota Journal of Law, Science, and Technology* 427, 429

⁴⁰¹ Peter K Yu, 'International Enclosure, the Regime Complex, and Intellectual Property Schizophrenia' (2007) 2007(1) *Michigan State Law Review* 1, 16

⁴⁰² Peter Drahos, 'Developing Countries and International Intellectual Property Standard-Setting' (2002) 5(5) *The Journal of World Intellectual Property* 765

these provisions into TRIPS. Drahos calls the shifting of IP from WIPO to the Uruguay Round ‘one of the greatest forum shifts in the second part of the twentieth century’.⁴⁰³

As regards IP, the TPP is not only another notch in the forum shifting process, but also testament to the declining strategic relevance of the WTO and WIPO to the United States.⁴⁰⁴

V. TRIPS plus – maximalist IP through bilateral and regional agreements

TRIPS was not to the satisfaction of developed country pharmaceutical industries. Forum shifting, as aforementioned, enabled the United States to achieve measures beyond TRIPS (TRIPS-plus) in bilateral and regional trade agreements. Underlying their efforts was a mandate contained in domestic law: that a principal negotiating objective of the United States would be to ensure that intellectual property provisions in any trade agreement entered into by the United States ‘reflect a standard of protection similar to that found in United States law’.⁴⁰⁵

Data exclusivity, or the protection of undisclosed information concerning the safety of a pharmaceutical that utilizes a new chemical entity, was and continues to be one of the key IP provisions that the U.S. includes in their trade agreements. It is one of the principal means for the pharmaceutical industry to block generic competition, as it serves to delay generic companies from relying on the originator companies’ test data in their own applications for regulatory and/or marketing approval of similar products.⁴⁰⁶ The United States has had a 5-year data exclusivity term in their law since 1984, when the Hatch-Waxman Act was enacted, and thus sought to ensure that its trading partners incorporated the same standards.⁴⁰⁷

The 1994 North American Free Trade Agreement (NAFTA) between the U.S., Canada, and Mexico, was the first trade agreement to adopt data exclusivity as a condition for marketing approval, with conditions that disclosure would only be permissible ‘to protect the public’ or where other steps have been taken to prevent ‘unfair commercial use’.⁴⁰⁸ A period of 7 years passed before it would be included in another agreement, owing to initial hopes that it would

⁴⁰³ Peter Drahos, ‘China, the TPP, and Intellectual Property’ (2016) 47(1) IIC – International Review of Intellectual Property and Competition Law 1, 3

⁴⁰⁴ *ibid*

⁴⁰⁵ 19 U.S. Code § 4201 Trade Negotiating Objectives 5(A)(i)(II)

⁴⁰⁶ Lisa Diependaele, Julian Cockbain, and Sigrid Sterckx, ‘Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity’ (2017) 17 Developing World Bioethics 11

⁴⁰⁷ Drug Competition and Patent Term Restoration Act (Hatch-Waxman Act) 21 U.S.C. Sect. 355(c)(3)(E)(ii) (1984)

⁴⁰⁸ North American Free Trade Agreement (NAFTA) (1994), Article 1711(5) < <https://www.nafta-sec-alena.org/Home/Texts-of-the-Agreement/North-American-Free-Trade-Agreement?mvid=1&secid=b6e715c1-ec07-4c96-b18e-d762b2ebe511#A1711> > Accessed 7 March 2018

have been included in the Doha Round of WTO negotiations. When this failed, the U.S. negotiated a bilateral FTA with Jordan, and in December 2001, Jordan became the first country to agree to TRIPS plus rules through a U.S. FTA.⁴⁰⁹ These provisions included data exclusivity and patent linkage - a mechanism to ensure a product's patent status is reported to pharmaceutical regulatory authorities.

In 2003, the U.S. negotiated an FTA with Chile and successfully included data exclusivity as a condition for marketing approval, with additional text specifying that Chile would 'maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product'.⁴¹⁰ This wording would serve as the negotiating template for data exclusivity in future U.S. FTAs, and is seen in Australian, Bahraini, Moroccan, and Korean FTAs with the U.S.⁴¹¹ The Moroccan and Bahraini U.S. FTAs went slightly further, stating that a presentation of any new clinical information would attract an additional three years of data exclusivity.⁴¹²

The Hatch-Waxman Act also provides for patent term adjustments if the 'issue of an original patent is delayed' due to failures at the Patent and Trademark Office.⁴¹³ This language was modified in the U.S. FTAs, specifying that the patent term adjustment was to 'compensate for unreasonable delays that occur in granting the patent' and that an 'unreasonable delay' was a delay in the issuance of the patent of more than four years from the date of filing or two years after a request for the examination of the patent application has been made.⁴¹⁴ This language is also found in all U.S. FTAs since then.

The U.S. approach to biologics can be traced back to the 1980 case of *Chakrabarty* discussed in Chapter 1 of this thesis. It was when the Supreme Court of the United States took the case that the patenting of life forms became 'a legal issue of public importance' due to the myriad of moral questions juxtaposing themselves with the interests of the emerging biotechnology industry. Notably, in the words of Parthasarathy: '[T]he patentability of life forms would influence business strategies and likely change the shape of the emerging industry overall'.⁴¹⁵ Finally, it was decided that all 'nonnaturally occurring non-human multicellular living

⁴⁰⁹ Rohit Malpani, 'All Costs, No Benefits: How the US-Jordan Free Trade Agreement Affects Access to Medicines' (2009) 6 *Journal of Generic Medicines* 206

⁴¹⁰ Chile-United States Free Trade Agreement, Article 17.10(1)

⁴¹¹ Diependaele, Cockbain, and Sterckx (n 406) 14; Horacio Rangel-Ortiz, 'Patent and Trademark Rights in Commercial Agreements entered by the United States with Latin American Nations in the First Decade of the Twenty-First Century: Divide et Vincas' in Gustavo Ghidini, Rudolph J. R. Peritz, and Marco Ricolfi, *TRIPS and Developing Countries: Towards a New IP World Order* (Edward Elgar 2014) 79

⁴¹² Carsten Fink and Patrick Reichenmiller, 'Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements' in Richard Newfarmer (ed), *Trade, Doha, and Development: A Window Into the Issues* (The World Bank 2006) 291

⁴¹³ 35 U.S. Code § 154(b) Contents and Term of Patent; Provisional Rights

⁴¹⁴ Bahrain-U.S. Free Trade Agreement, Article 14.8(6)

⁴¹⁵ <https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/assetuploadfile2116293.pdf> Accessed 7 March 2018

⁴¹⁵ Parthasarathy (n 17) 82

organisms' should be patented.⁴¹⁶ For some time the U.S. tried to incorporate the patenting of life forms, and in 2006 successfully included it in the Morocco-U.S. FTA.⁴¹⁷ This continues to be the strongest language on life forms and patents in any U.S. FTA.⁴¹⁸ However, as time progressed, the United States realised that patents on biologic material were problematic – because of the complexity of the molecules more time was being spent developing the drug after the first patent filing, the inability in some cases to satisfy patentability criteria,⁴¹⁹ and in addition to that, they became concerned about administrative challenges to biologics patents.⁴²⁰

Responding to this realisation, and market trends showing that the biggest grossing drugs were biologic, the originator biotechnology industry set into motion to incorporate biologics market exclusivity within national, and then, international intellectual property law. In American law, biologics market exclusivity is provided in the 2009 Biologics Price Competition and Innovation Act (BPCIA) which prohibits the market approval of a biosimilar 'until the date that is 12 years after the date on which the reference product was first licensed'.⁴²¹

The negotiation of biologics exclusivity during the TPP saw those who wanted the minimum number of years of exclusivity for biologics against those that wanted 8 or 12 years. The result, a vague provision providing for 8 years exclusivity, or 5 years exclusivity with other measures that provided a 'comparable market outcome', was a compromise reached after multiple deadlocked rounds. A Chilean TPP negotiator interviewed for this PhD expressed that it was a good thing that the language was vague, and that it was the only compromise that could be agreed upon. The negotiator stated:

[I]n the text, there is a lot of wording that could be subject to interpretation. We do wanted to make sure that we had some interpretive tools within the chapter that would tip the balance in one way or another, and that's why one of the very complex things that we achieved was incorporating the objectives and principles of the TRIPS agreement here, as well as some flexibilities for HIV, malaria and tuberculosis, because there we were thinking that even though we are drafting obligations here, there is a higher interest on public policy regarding public health or social security or national interest, when comparing it to intellectual property it needs to be on a higher level. I don't know if I can explain myself even more, but that's why you have those provisions. We understood that in order to have an agreement, there was necessarily the

⁴¹⁶ *ibid*

⁴¹⁷ Morocco-U.S. Free Trade Agreement 2006, Article 15.9(2)

⁴¹⁸ Fink and Reichenmiller (n 393) 290 TRIPS

⁴¹⁹ Matthew T Latimer, 'Patenting Inventions Arising from Biological Research' (2005) 6 *Genome Biology* 203

⁴²⁰ Terry G Mahn, 'Biologic Patents are Under Attack' *Law360* (New York, 29 June 2016) <<https://www.fr.com/wp-content/uploads/2016/06/Biologic-Patents-Are-Under-Attack.pdf>> accessed 7 March 2018

⁴²¹ Biologics Price Competition and Innovation Act 2009, § 7002 (k)(7)(A)

language that was kind of ambiguous and drafting that was kind of ambiguous. Because you kind of need to be on a middle ground.⁴²²

Vague language as a compromise in deadlocked negotiations has been seen elsewhere in trade-related IP, for example in the negotiation on exhaustion in the TRIPS agreement, which pitted countries that wanted silence on the issue (mostly developed countries) against countries who wanted their own exhaustion regimes. According to Gorlin, 'once a consensus was developed not to address exhaustion in TRIPS, the negotiators paid scant attention to the actual wording of the final language'.⁴²³

The above shows not only that the U.S. will continue to be the principal demandeur of TRIPS plus provisions, but also that these provisions are based on domestic law, that will morph with market realities, and they will continue to overwhelmingly favour IP owners.

VI. Political economy tradeoffs

Political economy factors underlie IP concessions. This ranges from international relations considerations such as who a country's biggest trading partner is, to internal policy such as wanting to map oneself as a future intellectual property shaper, to the perceived benefits from the optics of being seen as allies with a world superpower, or the need to avoid trade sanctions. Hudson and Marquette describe political economy analysis as being concerned with the 'interaction of political and economic processes in a society: the distribution of power and wealth between different groups and individuals, and the processes that create, sustain and transform these relationships over time'.⁴²⁴ The authors also place emphasis on ideas and how ideas that, among other things, underpin legitimate forms of rule and guide domestic interests, help explain why actors often act 'against their own obvious economic self-interest'.⁴²⁵ Notably, they ask readers to consider that they are not 'actors' but *people*, which lends an additional layer of complexity to political economy considerations.⁴²⁶ Collinson and others talk about how a political economy approach involves the examination of the 'nature of power in the societies concerned' and what processes 'create, sustain, and transform these relationships over time'.⁴²⁷

⁴²² Interview with M (anonymised as per request), Chilean negotiator, Santiago, Chile (17 November 2017)

⁴²³ Gorlin (n 162) 15

⁴²⁴ David Hudson and Heather Marquette, 'Mind the Gaps: What's Missing in Political Economy Analysis and Why It Matters' in Alan Whites and others (eds), *A Governance Practitioners Notebook: Alternative Ideas and Approaches* (OECD, 2015) 69-70

⁴²⁵ *Ibid* 69

⁴²⁶ *Ibid*

⁴²⁷ Sarah Collinson and others, *Power, Livelihoods and Conflict: Case Studies in Political Economy Analysis for Humanitarian Action* (Humanitarian Policy Group, 2003) 10

In an analysis of international IP, Shadlen and others find that it is membership of the WTO and bilateral pressures from the United States, particularly those on reciprocal concessions, is the main political economy factor resulting in increases of IP protection.⁴²⁸ These then go on to have deep impacts in country, including on access to medicines and perceived credibility with foreign multinationals. Due to that, in regard to pharmaceutical IP, the State through its negotiators must balance the commercial interests with public health interests. The political sensitivity of these issues makes managing tradeoffs particularly complex.⁴²⁹ Furthermore, politically sensitive issues in trade negotiations are often left to the end of negotiations, when tradeoffs between different sectors may occur, with these final negotiations often led by Chief Negotiators or Ministers who might not appreciate the full spectrum of interests involved.⁴³⁰

The political economy factors preceding TRIPS contextualises why developing countries had to accept IP standards. Dinwoodie and Dreyfuss elaborate:

Developed countries were facing significant challenges as production shifted to countries with lower labour costs. At the same time, however, global wealth was increasing and tastes were changing. Profits from creative output were becoming a potential source of foreign exchange, crucial to correcting trade imbalances in other sectors of the economy... It was no longer acceptable to the North for countries of the South to refuse to recognise intellectual property rights and take a free ride on investments in creativity – to use knowledge products without contributing to right holders' development costs through the payment of royalties.⁴³¹

When the U.S. began to pressure developing countries with trade sanctions, the choice became clear. It would be a tradeoff of more IP for no trade sanctions. In addition, developing countries were persuaded that the incorporation of these IP standards would result in the entry of large multinationals, stabilising local business and raising their reputations. Developing countries were also persuaded that associations with these multinationals would lead to joint venturing, technology transfer, and strategic alliances.⁴³²

Political economy tradeoffs can be further illustrated by the example of international exhaustion in the Uruguay Round in 1991, where least-developed country (LDC) language on international exhaustion was vigorously opposed by the United States and European industries for appearing to support international exhaustion. To break the deadlock, a tradeoff

⁴²⁸ Kenneth C Shadlen, Andrew Schrank, and Marcus J Kurtz, 'The Political Economy of Intellectual Property Protection: The Case of Software' (2005) 49 *International Studies Quarterly* 45

⁴²⁹ *Ibid* 49

⁴³⁰ Ruth Lopert and Deborah Gleeson, 'The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines' (2013) 41(1) *Journal of Law, Medicine, and Ethics* 199, 210

⁴³¹ Dinwoodie and Dreyfuss (n 338) 30-31

⁴³² Richard T Rapp and Richard P Rozek, 'Benefits and Costs of Intellectual Property Protection in Developing Countries' (1990) 24(5) *Journal of World Trade* 75

was suggested between Article 6 (international exhaustion) and Article 28 (rights conferred on patent owners), notably the removal of the word 'importing' from Article 28 (favouring LDCs) in exchange for the deletion of Article 6.⁴³³ While this particular tradeoff did not come to pass in the final text of the TRIPS Agreement, this example illustrates one type of tradeoff that may occur for pharmaceutical IP.

For others, the tradeoff is grounded in tangible goods. For New Zealand in the TPP, agreement to the biologics exclusivity clause was contingent upon there being a market access deal for dairy products.⁴³⁴ Tradeoffs are characterised by reciprocity, and not necessarily balance. While the TRIPS Agreement was overwhelmingly in favour of developed countries, detailed rules on compulsory licences were viewed as a sufficient concession for the enforcement of pharmaceutical IP.⁴³⁵ Dinwoodie and Dreyfuss opine that despite coercion and questionable market-access-for-IP tradeoffs, the TRIPS Agreement 'reflects compromise both on the economic impact of protection and on the continued relevance of broader social values... TRIPS is a product of a single moment in history and reflects the national and international policies and interests pertaining to that moment.'⁴³⁶ This sentiment in the coming chapters is extrapolated to the TPP.

⁴³³ Gorlin (n 162) 155

⁴³⁴ Clark (n 22)

⁴³⁵ Mogens Peter Carl, Director-General of DG Trade, 'The TRIPS Agreement 10 Years Later' (Speech at the International Conference on the 10th Anniversary of the WTO TRIPS Agreement, Brussels, 23 June 2004) <<http://trade.ec.europa.eu/doclib/docs/2004/june/tradoc117772.pdf>> accessed 29 May 2011

⁴³⁶ Dinwoodie and Dreyfuss (n 338) 41-42

Chapter Three

Chile: Trade Motivations, Developmental Considerations, and Its Place in Pharmaceutical IP History

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I. Introduction

The economic policy of Chile today is characterised by market openness and reciprocal international demand of its exports. Along with the EU, Singapore, and India, Chile is one of the most active users of preferential trade agreements.⁴³⁷ It is a relatively small economy with a GDP of \$247b, putting them between Singapore and Hong Kong, and its orientation towards external markets is considered the ‘motor’ of its economic growth.⁴³⁸

It has advanced much since its early approach beginning at the end of the 19th century, which was initially heavily influenced by the dominant ideology in developed countries, i.e. consolidation of power through mercantilism, which involved protectionism by the state and the development of national industries, establishing colonies, and accumulating bullion in national reserves.⁴³⁹

It was during the rule of the dictator Augusto Pinochet, following a period of hyperinflation and economic uncertainty, that Chile opened their markets. This was a decision driven and designed by the Chicago boys, a group of Chilean technocrats who had studied under Milton

⁴³⁷ Leslie Johns and Lauren Peritz, ‘The Design of Trade Agreements’ in Lisa L Martin (ed), *The Oxford Handbook of the Political Economy of International Trade* (OUP 2015) 352

⁴³⁸ Andrés Rebolledo, ‘Historia y Desafíos de la Política Comercial Chilena.1974-1994’ (Universidad Complutense de Madrid, Facultad de Ciencias Económicas y Empresariales 1996) 2

⁴³⁹ Rolf Lüders Schwarzenberg, *Crecimiento Económico de Chile: Lecciones de la Historia* (Universidad de Chile, Facultad de Ciencias Económicas y Administrativas, 2007) 13; Gordon Bannerman, ‘The Free Trade Idea’ Lisa L Martin (ed), *The Oxford Handbook of the Political Economy of International Trade* (OUP 2015) in 39

Friedman at the University of Chicago, and who went on to hold many senior positions in Pinochet's government. The policies they instituted survived long after the fall of the brutal Pinochet regime and into their transition to democracy in 1990, and the obvious economic growth occurring as a result of market openness means that a majority of Chileans to this day continue to embrace neoliberal ideologies, although tempered with social policies.⁴⁴⁰ Of late, however, there has been increasing social unrest and protests against the neoliberal model, arising from concerns about for-profit education, workers conditions, and consumer rights.⁴⁴¹ The neoliberal model saw the signing of numerous free trade agreements, and with the signing of an FTA with the United States, several maximalist intellectual property provisions were incorporated within domestic law and practice, extending monopolies for essential medicines.

As described in previous chapters, economic policies are not the sole influencing factor of trade negotiator decisions, but rather they take into account a number of considerations including developmental concerns. Chile has the highest inequality among OECD countries,⁴⁴² and while recent writings - including that of the American cognitive psychologist and linguist Steven Pinker - have denounced inequality indicators as rooted in a lump fallacy that 'if some people end up with more, others must have less', it continues to be a widely accepted indicator of less ideal socioeconomic conditions.⁴⁴³ Chilean social scientists, in line with the latter ideology, have illustrated that this socioeconomic inequality has resulted in increasing petty crime, worsening perception of insecurity, a huge disparity in costs of public and private education, resulting in educational segregation, and the existence of the private health system of better quality than the public health system and that discriminates against people in need.⁴⁴⁴ In October 2019, Chile underwent popular civil unrest due to frustrations with 'growing income inequality and a weak social safety net',⁴⁴⁵ resulting in violent rallies.

In other areas of health, while Chile has a well-established network of primary healthcare providers and a public health system financed by mandatory salary contributions to one of two insurance systems, its health budget is stretched, it has a large debt due to the import of

⁴⁴⁰ It should be noted that in recent times, neoliberal policies have come under the microscope in Chile – largely due to concerns about inequality. Lüders Schwarzenberg (n 420) 12-13; Tomás Undurraga, 'Neoliberalism in Argentina and Chile: Common Antecedents, Divergent Paths' (2015) 23(55) *Revista de Sociología e Política* 11-34

⁴⁴¹ Undurraga (n 440) 12

⁴⁴² C Morales and P Guarda, 'Chile Mejora Índices de Distribución del Ingreso, pero Continúa Siendo el Más Desigual de la Oede' *La Tercera* (Santiago, 24 November 2016) <<http://www2.latercera.com/noticia/chile-mejora-indices-distribucion-del-ingreso-continua-siendo-mas-desigual-la-ocde/>> accessed 31 May 2018

⁴⁴³ Steven Pinker, *Enlightenment Now: The Case for Reason, Science, Humanism and Progress* (Allen Lane, 2018) 98-99

⁴⁴⁴ Alfredo Rodríguez and others, 'Visible and Invisible Violence and Inequality in Neoliberal Santiago' (2014) 26(2) *Environment and Urbanization* 359-372, 366-367

⁴⁴⁵ Sebastian Boyd, 'How Chile Went From an Economic Star to an Angry Mess' *Bloomberg* (23 October 2019) <<https://www.bloomberg.com/news/articles/2019-10-23/how-chile-went-from-an-economic-star-to-an-angry-mess-quicktake>> accessed 23 October 2019

medications, and it is characterised by inequity.⁴⁴⁶

Any number of these factors could underlie the decisions made by negotiators analysed in Chapter 5 of this thesis, whether alone or in relation to each other. As I describe these factors in greater detail below, a cohesive picture should come together and contextualise why Chile made the decisions on any tradeoffs in the TPP.

II. An overview of trade and economic policy – Pinochet to present day

Chile was not always a bastion of the free market that it is today. For some time, including during the reign of Presidents Salvador Allende (1970-1973) and Frei Montalva (1964-1970) before him, statism and the protection of domestic industry was the centre of their economic policies.⁴⁴⁷ The young Salvador Allende had been involved in the 1932 socialist experiment as part of the aftermath of the military takeover by the left-wing Colonel Marmaduke Grove, and thereon devoted himself towards shaping policy to help the poor.⁴⁴⁸ Part of this involved nationalising foreign-owned firms so that profits from the sale of natural resources could be directed towards social welfare.⁴⁴⁹ Expansionary economic policy without relying on taxes resulted in increasing fiscal deficits, and Allende's government dipped into the large foreign reserves it had inherited from the previous government to finance those deficits.⁴⁵⁰ By the early 1970s, it became clear that import substitution schemes had failed.⁴⁵¹ Allende's policies resulted in declining foreign reserves, hyperinflation up to 500%, and widespread unemployment.⁴⁵²

His romantic ambitions of a peaceful transition to socialism would end in blood and bombs.⁴⁵³ In September 1973, a military junta led by General Augusto Pinochet stormed La Moneda, where Allende was holed up with key advisors. Under heavy fire, Allende transmitted his last message to the Chilean people, including the iconic phrase 'I will pay with my life for the loyalty of the people', and attributing the coup to 'foreign capital and imperialism'.⁴⁵⁴ He then committed suicide.

⁴⁴⁶ Alicia Lorena Núñez Mondaca and Chunhuei Chi, 'Equity in Out-of-Pocket Payment in Chile' (2017) 51 *Rev Saude Publica* 44

⁴⁴⁷ Manfred Wilhelmy and Roberto Durán, 'Los Principales Rasgos de la Política Exterior Chilena Entre 1973 y el 2000' (2003) XXXIII(2) *Revista de Ciencia Política* 273-286, 275

⁴⁴⁸ Richard Muir and Alan Angell, 'Commentary: Salvador Allende: His Role in Chilean Politics' (2005) 34 *International Journal of Epidemiology* 737, 737

⁴⁴⁹ *ibid* 737

⁴⁵⁰ Rodrigo Caputo and Diego Saravia, 'The Fiscal and Monetary History of Chile 1960-2010' (University of Chicago, April 2014) <<https://bfi.uchicago.edu/sites/default/files/research/MonetaryandFiscal.pdf>> accessed 24 June 2014, 5

⁴⁵¹ Lüders Schwarzenberg (n 420) 14

⁴⁵² Caputo and Saravia (n 431) 5

⁴⁵³ Paul E Sigmund, *The Overthrow of Allende and the Politics of Chile, 1964-1976* (University of Pittsburgh Press 1977)

⁴⁵⁴ *ibid* 4

The coup that ensued is normally attributed to one of two causes - the hyperinflation caused by Allende's economic policies, or the cause preferred by the right-wing camp, that there was to be a leftist coup in September 1973, and the only way to prevent that was via a preemptive coup of their own.⁴⁵⁵ Underlying these attributions were several realities – that Allende's policies were hostile to U.S. economic interests and thus the U.S. instituted an official policy to destabilise his regime.⁴⁵⁶ These sentiments are apparent in several declassified U.S. documents circa 1970, including a declassified memo dated 3 November 1970 intended for the then-U.S. National Security Advisor Henry A Kissinger. This document warned that the Allende government will 'have a profound anti-American bias and will work to extirpate U.S. influence from the country' and suggested 'carefully measured actions' to weaken the Allende government, including discouraging multilateral and third party investment in Chile.⁴⁵⁷

The American neoliberal influence however did not begin in 1970. In 1956, an academic exchange agreement was signed between the University of Chicago and the Catholic University of Chile. This resulted in a group of young Chilean economists undertaking postgraduate studies in Chicago under Arnold Harberger and Milton Friedman, who both espoused free market economic philosophies.⁴⁵⁸ These economists, which included Sergio de Castro, Rolf Lüders Schwarzenberg, and Hernán Büchi, who would all later hold Ministerial positions under the Pinochet government, were dubbed the 'Chicago Boys'. The role of the 'Chicago Boys' is inextricable from Chile's economic history – Sergio de Castro authored the Chicago Boys' economic recommendations, and but a few weeks before the coup, delivered the document to Navy Admiral José Toribio Merino, who would be part of the junta that would install Augusto Pinochet as the new head of state.⁴⁵⁹ Due to the immensity of the task, these recommendations were further substantiated with the addition of other economists within the group and compiled into one publication,⁴⁶⁰ called *El Ladrillo* ('The Brick') due to its sheer weight. It became the guiding tome of the Chicago Boys in their unprecedented rewriting of the Chilean economy. As time passed, the ideologies of the Chicago Boys – i.e. the creation of a market economy - permeated all levels of Chilean society.⁴⁶¹

⁴⁵⁵ *ibid* 9

⁴⁵⁶ *ibid* 13

⁴⁵⁷ National Security Council, Options Paper on Chile (NSSM 97, 1970)
<<https://nsarchive2.gwu.edu/NSAEBB/NSAEBB8/docs/doc24.pdf>> accessed 27 June 2018

⁴⁵⁸ Timothy David Clark, 'Rethinking Chile's "Chicago Boys": Neoliberal Technocrats or Revolutionary Vanguard?' (2017) 38(6) *Third World Quarterly* 1350

⁴⁵⁹ Tania Opazo, 'The Boys who Got to Remake an Economy' *Slate* (12 January 2016)
<<http://www.slate.com/business/2018/05/millennials-are-in-a-deep-financial-hole-compared-to-past-generations.html>>
accessed 28 May 2018

⁴⁶⁰ Centro de Estudios Públicos, "El Ladrillo": Bases de Política Económica del Gobierno Militar Chileno (Centro de Estudios Públicos, 1992)

⁴⁶¹ Clark (n 458) 1354

Clark elaborates:

[T]he Chicago Boys were much more than neoliberal technocrats: they were a revolutionary vanguard that fostered a capitalist revolution that radically transformed the material and ideological foundations of the nation.⁴⁶²

The U.S. neoliberal influence continued in the background. The influential Edwards family in Chile played a key role in strengthening the influence and acceptance of neoliberalism – they used their influence to establish the first free market think tank in Chile in 1963, the Center for Social and Economic Studies (CESEC), which allowed the Chicago Boys a place to congregate and proliferate their ideas.⁴⁶³ The Edwards Group then invited several Chicago Boys to author op-eds in their newspaper *El Mercurio*, which was the most influential conservative newspaper at that time.⁴⁶⁴ A scion of the Edwards family, the media mogul Agustín Edwards Eastman collaborated with the CIA to facilitate and prop up the coup that led to the installation of Pinochet as President.⁴⁶⁵

In the mid-1970s and early 1980s, Chile suffered the same external shocks suffered by other developing countries. The severe recession in 1975 led to 13 per cent decline in GDP.⁴⁶⁶ The Pinochet military government in the mid-1970s instituted widespread economic reform, the best known of which is the opening up of Chile to external markets, i.e. the elimination of all non-tariff barriers and a rapid reduction of tariffs.⁴⁶⁷ Andrés Rebolledo, the current Minister of Energy and former Director-General of DIRECON, the government office in charge of international economic relations and oversaw the TPP negotiations, wrote in his postgraduate dissertation that while Chile underwent a profound political, social, and economic transformation, it was the opening up of the economy which was its most ‘transcendental structural reform’.⁴⁶⁸ Following the 1982-1984 recession due to the external debt crisis, which was felt by the rest of Latin America, the Pinochet government reversed these trade reforms and increased the import tariffs to the GATT consolidated rate of 35%.⁴⁶⁹

These structural reforms did not translate into success overnight.⁴⁷⁰ In fact, free market

⁴⁶² *ibid* 1350

⁴⁶³ *ibid* 1352

⁴⁶⁴ *ibid*

⁴⁶⁵ Emily Langer, ‘Obituary: Agustín Edwards Eastman’ *The Independent* (London, 4 May 2017)

<<https://www.independent.co.uk/news/obituaries/agust-n-edwards-eastman-obituary-a7717881.html>> accessed 27 June 2018

⁴⁶⁶ Ricardo Ffrench-Davis, Patricio Leiva, and Roberto Madrid, ‘Trade Liberalisation and Growth: the Chilean Experience, 1973-89’ in Timothy M Shaw (ed), *Trade and Growth: New Dilemmas in Trade Policy* (MacMillan Press, 1993)

⁴⁶⁷ *ibid*

⁴⁶⁸ Andrés Rebolledo, ‘Historia y Desafíos de la Política Comercial Chilena.1974-1994’ (Universidad Complutense de Madrid, Facultad de Ciencias Económicas y Empresariales 1996) 3

⁴⁶⁹ *ibid* 5

⁴⁷⁰ Ffrench-Davis questions whether it was really the neoliberal foreign policy that led to economic success, and what that success meant. He commented that Chile’s economic growth was ‘multifaceted’ and that ‘The decision to embark upon liberalization should not be arrived at in a vacuum, but rather in the light of its possible effects on resource allocation and

adjustments meant that total imports 'rose significantly in relation to the level of domestic economic activity'.⁴⁷¹ Financial reforms continued into the mid-70s, with the privatisation of banks that had been nationalised under the Allende government, the abolition of price controls, financial market deregulation, and tax reform, among others.⁴⁷² Despite these efforts, growth continued to be slow up to the early- to mid-80s.⁴⁷³ According to the Chilean economist Ricardo Ffrench-Davis:

Investment was low for a number of reasons. High interest rates were an important factor, but the drop in public investment also played a significant role, as did the swift liberalization of imports (which pushed up the relative cost of imported capital goods, discouraged the domestic production of importables and sharply boosted imports of consumer goods) and the low rate of capacity utilization. Thus, employment prospects and the outlook for wage hikes were dimmed by the low level of investment and capacity utilization.⁴⁷⁴

In 1976, external debt increased as imports dominated the market and crowded out nationally produced goods.⁴⁷⁵ This required readjustment and in 1979, a new stage of macroeconomic policies was adopted that eventually achieved a fiscal surplus.⁴⁷⁶ Ffrench-Davis explains further that Chile did not show signs of economic stability until 1986, when trends showed predictability and strength with accelerated economic activity and an increase in aggregate demand.⁴⁷⁷ Chile's position was further improved by the increase in copper prices that year.

In September of 1986, the Uruguay Round of GATT negotiations commenced in Punta del Este, Uruguay, and was intended to be the most ambitious set of multilateral negotiations, established most-favoured nation rules and reduction of tariffs. The Uruguay Round concluded in 1994. Chile's positions in the Uruguay Round depended on where they were in their domestic economy; in the beginning of the negotiations, Chile's economy was improving, but by no means could one say that it had sustained economic strength. Furthermore, the Pinochet military regime's foreign strategy was 'imbued with a complex combination of "nationalism" and "realism"' that prioritised bilateral relations to the detriment of multilateralism.⁴⁷⁸ Thus Chile was heavily influenced by the problems facing its economy.⁴⁷⁹

economic growth. Reform is not an objective in and of itself, but rather as a means of achieving development with social equity.' Ffrench-Davis, Leiva, and Madrid (n 447)

⁴⁷¹ *ibid*

⁴⁷² Ricardo Ffrench-Davis, *Economic Reforms in Chile: from Dictatorship to Democracy* (University of Michigan Press 2002) 10

⁴⁷³ Ffrench-Davis, Leiva, and Madrid (n 447)

⁴⁷⁴ *ibid*

⁴⁷⁵ *ibid*

⁴⁷⁶ Ffrench-Davis (n 453) 11

⁴⁷⁷ Ffrench-Davis (n 453) 14

⁴⁷⁸ Manfred Wilhelmy and Roberto Durán, 'Los Principales Rasgos de la Política Exterior Chilena Entre 1973 y el 2000' (2003) XXXIII(2) *Revista de Ciencia Política* 273-286, 276

⁴⁷⁹ DIRECON (Dirección General de Relaciones Económicas Internacionales), *Chile: 20 Años de Negociaciones Comerciales* (DIRECON, 2009) 53

While it was willing to engage on the multilateral stage with a broad agenda in mind, it called on industrialised countries to take the lead, but at the same times focusing on its own interests in terms of improving its terms of trade.⁴⁸⁰

In the late 1980s, as the Uruguay Round of negotiations progressed, the political climate in Chile was changing. In October 1988 Chileans had voted to bring an end to the military dictatorship, in a plebiscite where Augusto Pinochet had offered to govern for another 8 years and had fully expected to win.⁴⁸¹ This set the scene for elections to take place in December 1989 and Patricio Aylwin, a socialist democrat from the Christian Democratic Party in the *Concertación* coalition, won the elections. Several factors helped this – the fact that *Concertación* coalition had managed to attract a centre right party, the *Partido Acción de Centro* (PAC), some of them previously staunch Pinochet supporters, was one of them. They also appealed to the urban and rural poor and middle class who had been disenchanted by the policies of the Pinochet government.⁴⁸²

But the changing political flavour in the late-1980s/early 1990s meant that while Chile continued to espouse a liberal and open trade policy, it had yet to form established national positions to present to the world at large.⁴⁸³ In the early nineties domestic economic conditions had changed substantially from Chile's position at the beginning of the Uruguay Round, with five years of consistent economic growth, the improvement of its terms of trade, and the fact that international interest rates had fallen significantly.⁴⁸⁴

In the early 1990s, Chile sought to undo some of the poverty and inequality that had developed under the Pinochet government by correcting some of the 'serious deficiencies of neoliberal economic policies'.⁴⁸⁵ This included restoring workers' rights and increasing social spending, while at the same time adopting measures to reduce Chile's vulnerability to external financial volatility.⁴⁸⁶ It also sought to re-establish itself in the international relations arena by repairing damaged bilateral, regional, and global relations, not just in the international trade arena, but also in terms of international human rights and good governance approaches.⁴⁸⁷ Aylwin's

⁴⁸⁰ *ibid* 53-54; Interview with Pedro Roffe, Senior Fellow, International Centre for Trade and Sustainable Development (Skype, 13 February 2018)

⁴⁸¹ Alan Angell and Benny Pollack, 'The Chilean Elections of 1989 and the Politics of the Transition to Democracy' (1990) 9(1) *Bulletin of Latin American Studies* 1-23, 1

⁴⁸² *ibid* 7

⁴⁸³ Interview with Pedro Roffe, Senior Fellow, International Centre for Trade and Sustainable Development (Skype, 13 February 2018)

⁴⁸⁴ DIRECON (n 479) 53

⁴⁸⁵ Ricardo Ffrench-Davis, 'Progresos y Retrocesos del Desarrollo Económico de Chile en los Gobiernos de la Concertación: 1990-2009' (2016) 83(1) *El Trimestre Económico* 5-34, 11

⁴⁸⁶ *ibid* 11

⁴⁸⁷ Lorena Oyarzún, 'When Trade Policy is Not Enough: Opportunities and Challenges for Chile's International Insertion' (2013) 19(2) *Journal of Iberian and Latin American Research* 268-285, 273

presidency (1990-1994) saw the promotion of multilateralism, the signing of FTAs with Canada and Mexico, and the expansion of ties with Asia, starting with Malaysia.⁴⁸⁸ This period also saw Chile's support for including services within the Uruguay Round of negotiations.⁴⁸⁹

The second *Concertación* government under President Eduardo Frei (1994-2000) saw more trade diplomacy, with business leaders following him on diplomatic TRIPS with the specific mission of attracting business.⁴⁹⁰ He participated in the first APEC summit, which would later be an important venue for Chile and its preferential trade agreement goals. It was during his reign that the WTO reflected a concern with Chile's preoccupation with regionalism rather than 'locking in these reforms through binding commitments at the multilateral level'.⁴⁹¹

The third *Concertación* government saw another socialist democrat, Ricardo Lagos (2000-2006) seek to improve regional trade ties by seeking incorporation into MERCOSUR, although it never could achieve the requisite domestic support.⁴⁹² Lagos also strengthened ties with his American counterpart, George W Bush, lauding the two countries common goals in terms of human rights and a market economy.⁴⁹³ For Lagos, the FTA was a key part of his strategy to counteract the relatively low rate of growth compared to the previous decade.⁴⁹⁴ At the same time, the United States, who had enjoyed a trade surplus with Chile for some time, had become concerned by a recent trade deficit, and sought to correct this via an FTA.⁴⁹⁵ Bush obtained fast track authority to negotiate a Chile-U.S. FTA on 1 August 2002,⁴⁹⁶ and this would eventually become the United States' first free bilateral trade agreement with a Latin American country. The agreement, with liberalised 85% of consumer and industrial products between the two nations,⁴⁹⁷ also introduced to Chile intellectual property requirements described further in Section IV of this Chapter. The business community in Chile had active participation in the U.S.-Chile FTA, with their different unions holding numerous meetings with DIRECON (Directorate for International Economic Affairs) throughout the negotiations.⁴⁹⁸

⁴⁸⁸ *ibid* 273

⁴⁸⁹ DIRECON (n 479)

⁴⁹⁰ Oyarzún (n 487) 273

⁴⁹¹ WTO (World Trade Organisation), 'Chile's Trade Regime Leads to Strong Economic Growth, but Increasing Emphasis on Regional Agreements Complicates Trade Policy' (Trade Policy Review, Geneva, 10 September 1997) <<https://www.wto.org/english/tratope/tpre/tp060e.htm>> accessed 28 June 2018

⁴⁹² Oyarzún (n 487) 274

⁴⁹³ George W Bush, 'Remarks Prior to Discussions with President Ricardo Lagos of Chile and an Exchange With Reporters' (*The American Presidency Project*, 16 April 2001) <<http://www.presidency.ucsb.edu/ws/index.php?pid=45654>> accessed 28 June 2018

⁴⁹⁴ Felipe Agüero, 'El Acuerdo de Libre Comercio Chile-Estados Unidos' (2005) 61 *Colombia Internacional* 51, 56

⁴⁹⁵ Lindsay M Faine, 'The Internationalization of Chilean Agriculture: Implications of the United States-Chile Free Trade Agreement' (2004) 13 *Minnesota Journal of Global Trade* 383, 390-91

⁴⁹⁶ United States Senate, *Roll Call Vote 107th Congress - 2nd Session* (1 August 2002) <<https://www.senate.gov/legislative/LIS/rollcallists/rollcallvotecfm.cfm?congress=107&session=2&vote=00207#top>> accessed 1 July 2018

⁴⁹⁷ 'U.S.-Chile Free Trade Agreement' (2003) 97(3) *The American Journal of International Law* 696-699, 696

⁴⁹⁸ Sonia Esmeralda Reyes Posada, *Percepción de las Organizaciones de la Sociedad Civil sobre las Negociaciones de Chile en el Escenario Internacional sobre Temas de Propiedad Intelectual* (Universidad de Chile, 2015) 34

Through this agreement, Chile experienced well-known U.S. bullying tactics – as a political economy tradeoff for making concessions on tariffs, the United States pressured Chile for their vote in favour of military intervention in Iraq at the U.N. Security Council.⁴⁹⁹ Lagos and his foreign policy advisor Heraldo Muñoz stood firm, however, and Chile voted against military intervention.⁵⁰⁰ Muñoz later became Minister of Foreign Affairs under the fourth *Concertación* government, and oversaw the negotiation of the TPP agreement. It is unclear at this point whether his previous experiences with U.S. pressure had any bearing on tradeoffs in the TPP.

The U.S.-Chile FTA was finalised on 11 December 2002 and George W Bush notified Congress of its intent to sign the FTA on 31 January 2003.⁵⁰¹ Despite Chile's no-vote on Iraq, the agreement came into force on 1 January 2004. A year later in an April 2005 meeting in Santiago with Secretary of State Condoleezza Rice, Lagos would extol the virtues of the U.S.-Chile FTA, notably an increase of trade by more than 31 per cent, more manufacturing exports and more quality employment.⁵⁰²

The fourth *Concertación* government under Michelle Bachelet (2006-2010) upheld multilateralism, regionalism, and promoted free trade, much like her predecessors. That is, all four *Concertación* democratic governments maintained free market policies. But what was different about the *Concertación* governments compared to the Pinochet dictatorship was the economic growth and an increased social spending. While per capita GDP averaged 5.1% in the 20 years between 1990 and 2009, compared to 1.3% during the Pinochet reign,⁵⁰³ at the same time the proportion of Chileans living under the poverty line fell from 40% to 15%, and quality of life for the average Chilean improved greatly.⁵⁰⁴ As political sociologist Tomás Undurraga comments: '*Concertación* did not break up with neoliberalism, but only aimed to temper it by orchestrating greater social equality'.⁵⁰⁵

Chile's economy today is thriving, with its top exports being copper, fruit, fish products, and wine, among others. It is also an exporter of pharmaceuticals, with countries like Peru importing 22% of its pharmaceuticals from Chile.⁵⁰⁶ Its top export destination is China at

⁴⁹⁹ DIRECON (n 479) 136

⁵⁰⁰ Heraldo Muñoz, *A Solitary War: A Diplomat's Chronicle of the Iraq War and Its Lessons* (Fulcrum Publishing, 2008)

⁵⁰¹ DIRECON (n 479) 136; Muñoz would later be the Minister of Foreign Affairs during the negotiations of the Trans-Pacific Partnership.

⁵⁰² Condoleezza Rice, 'Remarks to the Press with President Ricardo Lagos of Chile' (*U.S. Department of State*, 28 April 2005) <<https://2001-2009.state.gov/secretary/rm/2005/45387.htm>> accessed 28 June 2018

⁵⁰³ French-Davis (n 466)

⁵⁰⁴ Undurraga (n 421) 23

⁵⁰⁵ Undurraga (n 421) 11

⁵⁰⁶ Artecona and Plank-Brumback (n 274) 13

\$17.4B followed by the United States (\$8.86B) and Japan (\$5.19B).⁵⁰⁷ Its relationship with China has been described as the 'most solid in Latin America',⁵⁰⁸ and this is reflected in a history of diplomatic engagements post-Pinochet. Minister of Foreign Affairs Hernán Cubillos visited China in 1978 and signed technological and economic cooperation agreements which resulted in FDI exchanges in the mining industry.⁵⁰⁹ But Chile-China trade momentum and diplomatic visibility was only reached in more recent history. In November 2005, under the Presidency of Ricardo Lagos, the Chile-China FTA was signed, which quadrupled Chile's exports to China from 2005 to 2010.⁵¹⁰ In 2010, China consumed over 40% of the world's copper production, with the imports for copper ore increasing further in 2018 to 53% of the global production, which only increased Chile's value to China.⁵¹¹ Falling copper prices in recent times threatened to diminish Chile's profitability in this area, but Chile responded by increasing other exports to China. Notably, Chile topped Thailand as China's top importer of fruit.⁵¹²

Post-FTA, Chile-China relations have been more visible, demonstrated by Michelle Bachelet's attendance at the Bao forum in China at the invitation of Hu Jintao, and subsequent signing of additional bilateral cooperation agreements, including scholarships for Chinese students.⁵¹³ More recently, in November 2017, Bachelet and Chinese President Xi Jinping met in Vietnam to witness the upgrading of the Chile-China FTA.⁵¹⁴

These and other political economy factors lend context and relevance to discussions in the final chapter of this thesis. Chile's multiple FTAs signed with all TPP partners, widespread governmental endorsement of the free market model, their close relationship and economic dependence on China and copper, and previous experience with U.S. bullying tactics may help explain Chile's motivations during the TPP.

⁵⁰⁷ Observatory of Economic Complexity, 'Chile' (MIT, 24 June 2018) <<https://atlas.media.mit.edu/en/profile/country/chl/>> accessed 24 June 2018

⁵⁰⁸ Juan Carlos Gachúz, 'Chile's Political and Economic Relationship with China' (2012) 1 *Journal of Current Chinese Affairs* 133, 134

⁵⁰⁹ *ibid* 134

⁵¹⁰ *ibid* 136

⁵¹¹ Gachúz (n 489) 140; Pratih Narayanan, 'China Sets New Records for Gobbling Up the World's Commodities' *Bloomberg* (New York, 12 January 2018) <<https://www.bloomberg.com/news/articles/2018-01-12/world-s-commodity-engine-roars-to-another-record-with-xi-at-helm>> accessed 24 June 2018; 'Commodities Buzz: Global Copper Consumption Rises 4.58% This Year' India Info Online (Mumbai, 21 June 2018) <<https://www.indiaonline.com/article/capital-market-commodity-futures-mid-session-commentary/commodities-buzz-global-copper-consumption-rises-4-58-this-year-1180621002871.html>> accessed 24 June 2018

⁵¹² The Santiago Times, 'Chile Topples Thailand To Become China's Largest Fruit Supplier' *The Santiago Times* (Santiago, 2 April 2017) <<http://santiagotimes.cl/2017/04/02/chile-topples-thailand-as-chinas-largest-fruit-supplier/>> accessed 24 June 2018

⁵¹³ Ministry of Foreign Affairs of the People's Republic of China, 'Joint Press Communiqué Between the People's Republic of China and the Republic of Chile' (MoFA, 16 April 2008)

<<http://www.fmprc.gov.cn/mfaeng/wjdt665385/2649665393/t427229.shtml>> accessed 24 June 2018

⁵¹⁴ China Daily 'Xi, Bachelet witness upgrade of China-Chile FTA' *China Daily* (Da Nang, 12 November 2017) <<http://www.chinadaily.com.cn/china/2017-11/12/content34425949.htm>> accessed 29 June 2018

III. The Chilean public health system

Chile's health system is generally described as being well governed and well functioning.⁵¹⁵ Chile has in fact enjoyed increasing life expectancy above the OECD rate, and has been lauded for its effective cancer screening programs, among other things.⁵¹⁶ But as with other upper middle-income countries, it has an increasing burden of chronic non-communicable diseases. Out of pocket payments for medication is also very high, with families spending 5.4% of their total incomes to finance healthcare in addition to insurance payments.⁵¹⁷

The main characteristic of Chile's health system is a mandatory contribution of 7% from salaries into either one of two health subsystems, public health insurance called *Fondo Nacional de Salud* (Fonasa) or private health insurance from local providers (Isapres).⁵¹⁸ These operate with different rules. While both are required to adhere to certain guarantees as elaborated shortly, the Isapres have more regulatory space to amend premium amounts, types of diseases covered, and other details, resulting in inequity.⁵¹⁹ However, this does not mean Chile has universal health care – out of pocket- and co-payments are high, and for diseases not covered by either Fonasa or Isapres, patients who are unable to access the medications they need are forced to petition courts to compel the public system to respond to their needs. The following paragraphs will illustrate key developments in Chilean public health history and the current situation, to help situate the thinking of IP negotiators in the TPP.

The Pinochet government was not just neoliberal in matters of trade, but also health. In 1979, they introduced the Fonasa system which segmented the insured population into four tiers based on income category, which determines the proportion of health services is covered by the state and which has to be paid out of pocket by the individual. Group A includes indigent people and those on welfare and pensions, and they receive 100% of the benefits provided under Fonasa for free.⁵²⁰ Group B are people earning the minimum wage; they too receive 100% of the benefits (for covered illnesses). Group C are those people who earn higher than the minimum wage but not more than 1.46 times that amount, in which case Fonasa covers 75% of benefits, whereas in Group D (earning more than 1.46 times above minimum wage)

⁵¹⁵ OECD *Reviews of Public Health: Chile: a Healthier Tomorrow* (OECD, 2017) <<https://www.oecd.org/health/health-systems/OECD-Reviews-of-Public-Health-Chile-Assessment-and-recommendations.pdf>> accessed 30 June 2018

⁵¹⁶ *ibid*

⁵¹⁷ Paulina Correa-Burrows, 'Out-of-Pocket Health Care Spending by the Chronically Ill in Chile' (2012) 1 *Procedia Economics and Finance* 88, 93

⁵¹⁸ Alejandra Zúñiga Fajuri, 'Sistemas Sanitarios y Reforma AUGE en Chile' (2007) 13(2) *Acta Bioethica* 237-245, 241

⁵¹⁹ *ibid* 241

⁵²⁰ Rodolfo L B Rodriguez and Sebastian A F Avalos, 'Conflictos entre Afiliados e Isapres y entre Afiliados y Fonasa' (Universidad de Chile, Facultad de Derecho, 2004) <

<http://repositorio.uchile.cl/bitstream/handle/2250/107544/Conflictos%20entre%20afiliados%20e%20Isapres%20y%20entre%20afiliados%20y%20Fonasa.pdf?sequence=3>> accessed 29 June 2018, 40

receive 50% of benefits and have to cover the remaining costs out-of-pocket.⁵²¹ Pinochet also decentralised primary health services to municipal health authorities.⁵²²

In 1981, Pinochet's government created Isapres 'to manage the payroll contributions allocated to health care for those opting out of the state system', with the ultimate aim of having Isapres be the dominant health system in Chile.⁵²³ Basically the Isapres were created to cater to those who could afford to pay for the best quality healthcare.⁵²⁴ Isapres were completely unregulated in the first few years, resulting in exorbitant premiums.⁵²⁵ In terms of coverage, routine healthcare was covered, but not 'catastrophic diseases'.⁵²⁶ They operated on a basis of risk selection and 'cream skinning', or selecting customers based on potential profitability.⁵²⁷ Most Chileans were unable to pay, and remained under Fonasa. However the government was adamant on ensuring more Chileans joined Isapres, and so, in 1986 introduced incentives to join, including a 2% subsidy targeting middle-income populations.⁵²⁸ While this was happening, the Pinochet government was progressively reducing public health spending as a percentage of GDP, in order to force citizens into Isapres.⁵²⁹ All this occurred in the midst and in the aftermath of severe recessionary periods. The inequality that resulted contributed to the increasing discontent with the Pinochet government.

When the *Concertación* coalition won the general elections in 1989, key reforms to the healthcare system were undertaken. Public health spending increased from 2% to 3% of GDP in less than a decade.⁵³⁰ The Aylwin government then moved to regulate Isapres by creating an Isapres Superintendent body which would mediate conflicts between individuals and Isapres and produce market statistics, and secondly to ensure that Isapres could no longer unilaterally terminate contracts without justifications.⁵³¹ These reforms saw Isapres premiums drastically reduce, but since then, while the population enrolled in Isapres has remained stable, premiums have slowly and gradually increased again.⁵³² But these initial reforms did not regulate what diseases had to be covered under both Isapres and Fonasa systems and this went unaddressed by the legislature for some time.

⁵²¹ Ibid 40

⁵²² ISAPRE, ISAPRES 1981-2016: 35 Years Supporting Chile's Private Health System (Asociación de ISAPRES de Chile, 2016) 11

⁵²³ Jean-Pierre Unger and others, 'Chile's Neoliberal Health Reform: An Assessment and a Critique' (2008) 5(4) PLoS Medicine 542, 543

⁵²⁴ Alejandra Zúñiga Fajuri, 'When Constitutional Justice has the Last Word on Health Care: the Case of Chile' (2014) 44(2) International Journal of Health Services 373, 374

⁵²⁵ María Soledad Martínez-Gutiérrez and Cristóbal Cuadrado, 'Health Policy in the Concertación Era (1990-2010): Reforms the Chilean Way' (2017) 182 Social Science & Medicine 117, 119

⁵²⁶ Ibid 121

⁵²⁷ Jens Holst, Ulrich Laaser, and Jürgen Hohman, 'Chilean Health Insurance System: A Source of Inequity and Selective Social Insecurity' (2004) 12 Journal of Public Health 271

⁵²⁸ Martínez-Gutiérrez and Cuadrado (n 525) 119

⁵²⁹ Ibid 119

⁵³⁰ Ibid 119

⁵³¹ Ibid 121

⁵³² Ibid 121

The judicature in the year 2000 sought to address this issue. The Supreme Court in Santiago ruled that public health plans should cover at least 50% of what Fonasa covered in its *libre elección* ('free choice') schemes, i.e. schemes where consultation and medical attention is covered, but medications are covered by copayment.⁵³³ Due to intensive state and public pressure, later that year Isapres agreed collectively to offer additional catastrophic disease coverage.⁵³⁴ In a separate case, the Supreme Court ruled that Isapres had to cover at the least the equivalent of what public sector beneficiaries would have to pay out of pocket, which regulated the Isapres cost ceilings.⁵³⁵

In 2004, under the administration of Ricardo Lagos, health law reform was instituted in Chile via Law N° 19,966, providing for diseases for which insurance coverage would be guaranteed. It was intended to address problems of high copayments in the private health insurance system.⁵³⁶ Initially known as the AUGE, and later renamed the *Garantías Explícitas de Salud* (Explicit Health Guarantees – GES), it insured a co-payment system for listed diseases and a specified upper cap per year to cover out-of-pocket payments, including those to purchase pharmaceutical drugs.⁵³⁷ Throughout its application, most AUGE/GES claims were made for emergency ambulatory dental conditions, followed by acute respiratory infections, primary arterial hypertension, and cervico-uterine cancers.⁵³⁸ The AUGE also covers depression, although the high demand and high cost of these treatments have strained Chilean health budgets.⁵³⁹ The GES not only specifies the diseases that are covered, but also what diagnostics and treatments that are covered for certain diseases. Patients who would like different medications will have to pay out of pocket.

In 2010, judicial check and balance of Chile's health system kicked in again, with the Constitutional Court ruling that the adjustment of price plans based on risk factor tables was unconstitutional.⁵⁴⁰ This explicit right to health in the Constitution, contained in Article 19 No. 9, states: "The State protects the free and egalitarian access to actions for the promotion, protection, and recovery of the health of the individual" and that "it is the prime duty of the

⁵³³ *ibid* 122

⁵³⁴ *ibid* 122

⁵³⁵ Jens Holst, Ulrich Laaser, and Jürgen Hohman, 'Chilean Health Insurance System: a Source of Inequity and Selective Social Insecurity' (2004) 12 *Journal of Public Health* 271, 280

⁵³⁶ Martínez-Gutiérrez and Cuadrado (n 525) 122

⁵³⁷ Ramiro de Elejalde, 'Las Garantías Explícitas de Salud: un Gran Negocio para las Isapres' (*Universidad Alberto Hurtado*, 24 January 2018) <<http://fen.uahurtado.cl/2018/noticias/las-garantias-explicitas-de-salud-un-gran-negocio-para-las-isapres/>> accessed 10 June 2018

⁵³⁸ Guillermo Vergara, Natalia Dembowski, and Carlos Cruz, 'Garantías y Garantías Explícitas en Salud (GES-AUGE) en patología de Depresión en el Sistema de Salud Chileno. 10 Años de Experiencia y Aprendizaje' (2017) XXXIV(1/2) *Psiquiatría y Salud Mental* 5-20, 6

⁵³⁹ *ibid* 6

⁵⁴⁰ Rol 1710/2010 <<http://www.tribunalconstitucional.cl/expediente?rol=1710wsdefrtg>> accessed 29 June 2018; Zúñiga Fajuri (n 518) 375

State to guarantee health assistance, whether undertaken by public or private institutions”.⁵⁴¹ Some Chilean legal scholars have deemed the provision as ‘lacking in guarantees’,⁵⁴² but in recent times it has been increasingly used in judicial activism to correct deficiencies in the health system via *recursos de protección* or health protection lawsuits. In a groundbreaking 2018 decision, the Supreme Court ruled that Isapres had to cover the costs of an experimental therapy for a cancer patient, despite Isapres contending that there wasn’t enough scientific evidence.⁵⁴³

It is not just Isapres that face *recursos de protección*. The public health system, with its stretched budgets due to high and ever increasing medicine prices due to the lack of a comprehensive medicines cost containment mechanism, broad (but necessary) health guarantees under the GES, and reliance on imported medications, has quotas for treatment of certain diseases. In April 2018, in one such constitutional protection action, the Third Chamber of the Supreme Court confirmed rulings ordering Fonasa to fund treatments for Morquio disease for two patients, stating that while Fonasa’s actions corresponded to public policy, i.e. that treatment for this disease was restricted to 27 patients, that Fonasa’s actions violated the principle of equality before the law established in the Constitution.⁵⁴⁴ From a historical standpoint, Chile has not seen the right to health at the forefront of legal discourse or public interest litigation,⁵⁴⁵ but this has changed, with a 300% increase in health-related petitions at the State Defense Council from 2005-2011.⁵⁴⁶

In 2015, President Michelle Bachelet signed off on the Ricarte Soto law which provides financial coverage for specific high-cost diagnostics and treatments.⁵⁴⁷ Named after a celebrity TV and radio personality who died of lung cancer, the law now covers diagnostics and treatments for 18 high-cost diseases, including hereditary angioedema, type 1 mucopolysaccharidosis, and pancreatic cancers for all Chileans no matter what insurance system they are covered by.⁵⁴⁸

⁵⁴¹ Constitution of the Republic of Chile, Article 19 N°9

⁵⁴² Alejandra Zúñiga Fajuri, ‘El Derecho a la Vida y el Derecho a la Protección de la Salud en la Constitución: una Relación Necesaria’ (2011) 9(1) Estudios Constitucionales 37-64, 42

⁵⁴³ El Mostrador, ‘Histórica Sentencia: Corte Suprema Ordena a Isapre Consalud dar Cobertura de Tratamiento Experimental a Paciente con Cáncer’ El Mostrador (Santiago, 9 February 2018) <<http://www.elmostrador.cl/noticias/pais/2018/02/09/historica-sentencia-corte-suprema-ordena-a-isapre-consalud-dar-cobertura-de-tratamiento-experimental-a-paciente-con-cancer/>> accessed 29 June 2018

⁵⁴⁴ Alejandro Alarcón, ‘Corte Obliga a Fonasa Costear Tratamiento de Dos Afiliados con Extraña Enfermedad Crónica’ BioBioChile (Santiago, 26 April 2018) <<https://www.biobiochile.cl/noticias/nacional/chile/2018/04/26/corte-obliga-a-fonasa-costear-tratamiento-de-dos-afiliados-con-extrana-enfermedad-chronica.shtml>> accessed 17 May 2018

⁵⁴⁵ Zúñiga Fajuri (n 542) 41-42

⁵⁴⁶ Francisco Miranda Suarez, ‘Demandas por Responsabilidad Médica en Chile: Análisis de Montos, Condenas y Duración’ (2015) 7 *Revista de Derecho* 79-102

⁵⁴⁷ Law N°20.850 Sistema de Protección Financiera para Diagnósticos y Tratamientos de Alto Costo

⁵⁴⁸ The Ricarte Soto law initially covered diagnostics and treatments for 11 diseases. It was amended twice to add more conditions, with the recent tally being at 18. Decreto N47, Determina los Diagnósticos y Tratamientos de Alto Costo con Sistema de Protección Financiera de la Ley N° 20.850 (Santiago, 29 December 2017)

Medicines are supplied either by international multinational companies or domestic laboratories. Domestic laboratories produce more than 80 percent of medicines consumed in Chile.⁵⁴⁹ Medicines are procured for the public health system in large volumes by the *Central de Abastecimiento del Sistema Nacional de Servicios de Salud* (CENABAST), largely from India, China, Malaysia, and the Ukraine. This has resulted in a large public debt. According to Millaleo, 'This debt poses a difficult political problem because it reinforces the influence of foreign laboratories over the Chilean state'.⁵⁵⁰

The framework of the health system reforms instituted by the Pinochet dictatorship has remained largely intact, but tweaked by various legislative and judicial decisions. It is still, however, plagued by several key problems. Membership of Isapres have remained stable through the years, with 2011 statistics indicate that approximately 17.5% of the population are affiliated with Isapres insurance coverage,⁵⁵¹ and while the GES system has provided adequate healthcare for many conditions, even the best health plans do not cover psychiatric and chronic illnesses adequately.⁵⁵² There are high costs of medicines and out-of-pocket payments for medications, of which the government is acutely aware, and has recently tried to improve by introducing tools for pharmacies to compare medicine prices,⁵⁵³ and considering the use of compulsory licences for hepatitis C drugs, which were priced at \$36,000 per patient.⁵⁵⁴ These considerations, along with pressure from civil society groups may have influenced the decisions of TPP IP negotiators.

IV. Adoption of TRIPS domestically

The Chilean Political Constitution of 1980 recognises 'industrial ownership of invention patents', but at the time did not apply this to pharmaceutical products.⁵⁵⁵ The patentability of pharmaceuticals was first considered by the administration of Augusto Pinochet in 1984. The administration wanted to improve their diplomatic relations with the United States, and pressure from American pharmaceutical companies indicated to them that patents were a

⁵⁴⁹ Salvador Millaleo H, 'Chile: the Case of IP Opposition from Predominantly Private Interests' in Rochelle Dreyfuss and César Rodríguez-Garavito (eds), *Balancing Wealth and Health: the Battle over Intellectual Property and Access to Medicines in Latin America* (OUP 2014) 136

⁵⁵⁰ *ibid* 135

⁵⁵¹ Victor Becerril-Montekio and others, 'El Sistema de Salud de Chile' (2011) 53(Suppl. 2) *Salud Pública de México* s132-s142, s134

⁵⁵² Jens Holst, Ulrich Laaser, and Jürgen Hohman, 'Chilean Health Insurance System: a Source of Inequity and Selective Social Insecurity' (2004) 12 *Journal of Public Health* 271, 281

⁵⁵³ Sebastián Asencio, 'Gobierno Lanza Comparador de Precios de Medicamentos en Farmacias' *El Mostrador* (Santiago, 7 May 2018) <<http://www.elmostrador.cl/noticias/pais/2018/05/07/gobierno-lanza-comparador-de-precios-de-medicamentos-en-farmacias/>> accessed 1 July 2018

⁵⁵⁴ Ed Silverman, 'Chilean Health Minister Supports Use of Compulsory Licenses for Hepatitis C Drugs' STAT (12 March 2018) <<https://www.statnews.com/pharmalot/2018/03/12/chile-compulsory-licenses-hepatitis-2/>> accessed 30 June 2018

⁵⁵⁵ The Political Constitution of Chile 1980, Article 25

good way to do so.⁵⁵⁶ It wasn't until 1989, however, that Pinochet instituted Law No. 18.935, published in the Official Journal in February of the following year, which provided for the patenting of 'medicines of all kinds' contingent upon marketing authorisation in the country of origin, communication in writing within 90 days, and a request for a grant of patent within 180 days of application.⁵⁵⁷ As customary with laws in Chile, the President at the time, Augusto Pinochet, delivered a Congressional message on occasion of the promulgation of this law, noting that the Pharmaceutical Manufacturers Association (PhRMA) had condemned Chile in a submission to the USTR, and asked Congress to approve the law with urgency.⁵⁵⁸

The TRIPS agreement, a product of the GATT Uruguay Round, would substantially change Chilean IP law. As discussed above in Section II, at the beginning of the Uruguay Round, Chile was preparing to transition into a democratic government, and so did not have official positions on many topics, least of all intellectual property.⁵⁵⁹ According to Chilean intellectual property expert Pedro Roffe, however, understanding Chile's IP mindset going into the Uruguay Round requires consideration of a number of factors, including the transition of power as discussed above and the context of IP in Latin America in general, including medicines patentability on the throughout the continent, and IP decisions made in the Andean Community (of which Chile is a member).⁵⁶⁰

The TRIPS agreement, a product of the GATT Uruguay Round, changed Chilean IP law. As discussed above in Section II, at the beginning of the Uruguay Round, Chile was preparing to transition into a democratic government, and so did not have elaborated public policy on intellectual property. According to Chilean intellectual property expert Pedro Roffe, however, understanding Chile's IP mindset going into the Uruguay Round requires consideration of a number of factors, including the transition of power as discussed above and the context of IP in Latin America in general, including the patentability of medical products throughout the continent. Chile and Mexico were the first in Latin America to introduce in the early 1990s its protection. In general, the position of Chile was in line of that of a number of developing countries as expressed in the document submitted in 1990 by 12 developing countries to the

⁵⁵⁶ Millaleo H (n 549) 138

⁵⁵⁷ Law N° 18.935 Dicta Normas Sobre Propiedad Industrial, Artículo Transitorio (24 February 1990)

<<https://www.leychile.cl/Navegar?idNorma=30305>> accessed 30 June 2018

⁵⁵⁸ Augusto Pinochet, *Mensaje del Presidente de la Republica: Dicta Normas Sobre Propiedad Industrial* (Biblioteca del Congreso Nacional de Chile, 5 May 1989)

<<https://www.bcn.cl/historiadelailey/fileadmin/fileley/7332/HLD7332749a0d2dec7072ac83d52ebf0f2ff393.pdf>> accessed 30 June 2018

⁵⁵⁹ Interview with Pedro Roffe, Senior Fellow, International Centre for Trade and Sustainable Development (Skype, 13 February 2018)

⁵⁶⁰ The Andean Community is a regional body with the power to enact binding legislation; Roffe (n 540)

Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods.⁵⁶¹

Prior to the Uruguay Round (1986-1994), Latin America did not take a liberal approach to IP and a majority of countries did not provide for medicines patents. Decisions within the Andean Community indicate the restrictive flavour of the Latin American approach to IP. Decision 24, enacted in December of 1970, provides for the regimen for foreign capital, trademarks, patents, licenses, and royalties in the region, generally stating that Parties should have national bodies that can, among other duties, authorise license agreements for the exploitation of trademarks and patents, and specifying that competent bodies receiving patent and trademark applications shall evaluate the effective contribution of imported technologies by estimating its probable profits.⁵⁶² Decision 85, enacted in June 1974, restrictively defined the scope of patentability criteria, i.e. what constituted 'new', 'an invention', and 'of industrial applicability', and specified what patents should not be granted for, including plant and animal varieties and pharmaceutical products.⁵⁶³

However, in June 1990, President Patricio Aylwin introduced Law N° 19.039, which recognised pharmaceutical patents, and stated in his presidential message that the 'comprehensive modernisation of the industrial property system' was necessary for the encouragement of development and technological innovation.⁵⁶⁴ Chile therefore was the first country to recognise patentability of pharmaceuticals, followed by Mexico. Chile therefore found itself in a very difficult situation in the Uruguay Round. Developing countries were very influenced by the Andean Community's positions, including their role in promoting a revision of the Paris Convention.⁵⁶⁵ This was further buttressed by a 1975 UNCTAD report 'The International Patent System as an Instrument for National Development' which was focused on the revision of the Paris Convention to increase compatibility with the needs of developing countries.⁵⁶⁶ Either way, developing countries simply did not have the technical or resource capacity to withstand developed country pressures on TRIPS.⁵⁶⁷ The TRIPS Agreement

⁵⁶¹ GATT, *Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, and Uruguay* (MTN.GNG/N11/W/71, 14 May 1990) <<http://sul-derivatives.stanford.edu/derivative?CSNID=92100147&mediaType=application/pdf>> accessed 6 July 2018

⁵⁶² Comunidad Andina, *Decisión N° 24 de 31 de diciembre de 1970, por la que se establece el Régimen Común de Tratamiento a los Capitales Extranjeros y sobre Marcas, Patentes, Licencias y Regalías* (31 December 1970) <<http://www.wipo.int/wipolex/es/text.jsp?fileid=224179#LinkTarget350>> accessed 30 June 2018

⁵⁶³ Comunidad Andina, *Decisión N° 85 de 5 de junio de 1974 por la que se establece el Reglamento para la Aplicación de las Normas sobre Propiedad Industrial* (5 June 1974) <<http://www.wipo.int/wipolex/es/text.jsp?fileid=223988>> accessed 30 June 2018

⁵⁶⁴ Patricio Aylwin, *Mensaje Presidencial Ley N° 19.039* (Biblioteca del Congreso Nacional de Chile, 27 June 1990) <<https://webcache.googleusercontent.com/search?q=cache:K1Vj0181QowJ:https://www.bcn.cl/obtienearchivo%3Fid%3Drecursoslegales/10221.3/22982/2/DFL3PropIndustrialArt23.doc+&cd=1&hl=en&ct=clnk&gl=uk&client=safari>> accessed 1 July 2018

⁵⁶⁵ Interview with Pedro Roffe, Senior Fellow, International Centre for Trade and Sustainable Development (Skype, 13 February 2018); May and Sell (n 88) 156

⁵⁶⁶ May and Sell (n 88) 156

⁵⁶⁷ *ibid* 155

became effective on 1 January 1995 with transition periods in place for developing countries, including Chile.

Chile began to discuss the implementation of TRIPS in October 1999, and these discussions led to the enactment of Law N° 19.996, amending the abovementioned Law N° 19.039, and incorporating TRIPS requirements, including conferring a 20-year monopoly for patent holders beginning from the date of application.⁵⁶⁸ President Eduardo Frei's presidential message incorporated all the trade-related intellectual property language that developed countries had strenuously lobbied for before and throughout the Uruguay Round negotiations; he stressed that competitiveness, productivity, efficiency and profitability 'cannot be achieved without an effective system to protect efforts aimed at developing assets in the field of knowledge', stated that intellectual property was necessary to prevent trade distortions, and that intellectual property was an instrument of development but also a way to protect legitimate interests of holders of intellectual property rights.⁵⁶⁹

The Chile-U.S. FTA, a TRIPS-plus agreement, began negotiations in 2001 and entered into force on 1 January 2004. It imposed new obligations on Chile pertaining to data exclusivity, patent extensions for regulatory delay, and patent linkage, including the requirement that the granting of marketing approval to third parties must obtain consent of the patent holder.⁵⁷⁰ At the outset of the negotiations, Chile was well aware of the U.S. position on trade and TRIPS-plus provisions based not only on public and communicated views of the Trade Promotion Authority, but also knew what to expect from the Jordan-U.S. FTA which had been signed on 24 October 2000.⁵⁷¹ Also from the outset of the negotiations, Chile wanted to avoid as far as possible the inclusion of TRIPS-plus provisions because it felt that it had 'intensively advanced' in implementation of the TRIPS agreement and other IP conventions.⁵⁷² There was also some concern that further monopolies would create further inequity in the public health system.⁵⁷³

Data exclusivity attracted the most opposition. The former head of the Instituto de Salud Pública (ISP), the governmental body in charge of quality control of medicines and vaccines, the grant of marketing approval for new products, medicines audits, and disease surveillance,

⁵⁶⁸ Ignacio Gillmore Valenzuela and José Santos Ossa Rogat, 'Protección y Exclusividad de Datos de Prueba de Productos Farmacéuticos en Chile' (2017) 77 *Revista de Derecho Económico* 3-30, 9;

⁵⁶⁹ Eduardo Frei, Mensaje Presidencial Ley N° 19.996 (Biblioteca del Congreso Nacional de Chile, 4 October 1999) <<https://www.bcn.cl/historiadelaley/nc/historia-de-la-ley/5621/>> accessed 1 July 2018

⁵⁷⁰ Wael Armouti and Mohammad Nsour, 'Data Exclusivity for Pharmaceuticals in Free Trade Agreements: Models in Selected United States Free Trade Agreements' (2017) 40 *Houston Journal International Law* 105, 117

⁵⁷¹ Pedro Roffe, 'The U.S.-Chile FTA: Intellectual Property Issues' (2004) 7 *ictsd.org* 17

⁵⁷² Pedro Roffe, *Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement* (Quaker International Affairs Programme, 2004) 9

⁵⁷³ Felipe Agüero, 'El Acuerdo de Libre Comercio Chile-Estados Unidos' (2005) 61 *Colombia Internacional* 51, 58

Gonzalo Navarrete criticised the provision as being 'written solely from the economic point of view'.⁵⁷⁴ At this time, numerous stakeholders including generic medicines industry associations like ASILFA and RECALCINE lobbied against the U.S. proposal.⁵⁷⁵ Despite these efforts, concessions were made and data exclusivity was included in the final text. Chile's current exclusivity rules dictate that marketing approval for a third party product shall not be issued until the end of the exclusivity period and that protection of test data would apply to all types of preclinical studies, in vivo or in vitro, and clinical studies at any phase.⁵⁷⁶

Chile's application of linkage has for years been a sore point between themselves and the United States and is one of the core reasons that Chile is almost an annual feature in the USTR's Special 301 Priority Watch List. The ISP does not presently verify whether a patent is still pending when granting market approval to generics. While the Special 301 can scare countries into compliance, Chile's position is that it does not recognise the Special 301.⁵⁷⁷ Chile has, however, made efforts to comply with a bill presented to the Congress in 2012.⁵⁷⁸

V. Chile in the international IP system

Chile is more well known in the international IP arena for having progressive views on copyright and related rights,⁵⁷⁹ although in recent times, Chile has taken a number of progressive stances on pharmaceutical IP on the international scene.

In 2017, the TRIPS agreement was amended to provide legal certainty that poorer countries with zero or limited pharmaceutical production capacity to use flexibilities to access generic medications.⁵⁸⁰ Paulina Nazal, the Director-General of DIRECON, the government body in charge of trade negotiations and external economic affairs, celebrated the amendment, stating: 'we join the consensus on the needs of developing countries in public health. In this spirit, we had approved this amendment in 2013 because we believe that it reinforces our idea that in terms of intellectual property, countries can adopt measures to protect public health of the population.'⁵⁸¹

⁵⁷⁴ Millaleo H (n 549) 144

⁵⁷⁵ *ibid* 145

⁵⁷⁶ Ignacio Gillmore Valenzuela and José Santos Ossa Rogat, 'Protección y Exclusividad de Datos de Prueba de Productos Farmacéuticos en Chile' (2017) 77 *Revista de Derecho Económico* 3-30, 15

⁵⁷⁷ Interview with Lispeth, Chilean Trade Negotiator (Vitacura, Chile, 16 November 2017)

⁵⁷⁸ Raúl Allard Soto, 'El Acceso a los Medicamentos: Conflictos entre Derechos de Propiedad Intelectual y Protección de Salud Pública' (2015) 21(1) *Acta Bioethica* 83, 89

⁵⁷⁹ WIPO document SCCR/12/3, 2 November 2004

⁵⁸⁰ WTO, *WTO IP rules amended to ease poor countries' access to affordable medicines* (Geneva, 23 January 2017)

<<https://www.wto.org/english/newse/news17e/trip23jan17e.htm>> accessed 1 July 2018

⁵⁸¹ DIRECON, 'OMC modifica normas de propiedad intelectual para facilitar el acceso a medicamentos de primera necesidad' (DIRECON, 24 January 2017) <<https://www.direcon.gob.cl/2017/01/omc-modifica-normas-de-propiedad-intelectual-para-facilitar-el-acceso-a-medicamentos-de-primera-necesidad/>> accessed 1 July 2018

In February of 2018, Chile co-sponsored, together with Brazil, South Africa, Bolivia, and China, a document at the WTO TRIPS Council focused on intellectual property and the public interest focusing on the Bolar exemption, i.e. a provision to override certain exclusivities so that generic companies can begin relying on undisclosed data prior to patent expiration to stimulate competition and facilitate quick generics entry.⁵⁸² In its official submission on the matter, Chile emphasised that the bolar exemption allowed protected subject matter to be, among other things, manufactured and produced for the purpose of obtaining sanitary registration or authorisation, that it was necessary to 'reduce the time needed to launch generic medicines and bring them to market' and that the bolar exemption was considered part of 'the balanced intellectual property system that the country has sought to implement'.⁵⁸³

Chile has also insisted on human rights provisions being included in their free trade agreements (FTAs).⁵⁸⁴ While these stipulations are largely aspirational and expressed in preambles rather than the substantive text, this sends at least a diplomatic message about Chile's approach in trade-related IP and the consolidated of related norms.⁵⁸⁵

VI. Conclusion

Any number of these political, strategic, and developmental factors could have influenced the actions of trade negotiators in the TPP. A higher economic dependence on China versus the United States could mean that the trade negotiators were less susceptible to U.S. demands. Concerns about increasing medicine prices could have predetermined the position that certain TPP IP provisions were 'red lines'. Recent views expressed in the international IP arena could be indicative of an approach acknowledged and accepted across key agencies involved in the TPP. A long history of neoliberalism could have made an impression on negotiators in terms of their approach to market access concessions, or alternatively, made them realise that certain socialist elements may be more prudent in negotiating text. These will be analysed in the context of interviews with negotiations presented in Chapter 5 of this thesis.

⁵⁸² WTO TRIPS Council, IP/C/M/88

⁵⁸³ WTO TRIPS Council, IP/C/M/88, 57

⁵⁸⁴ Susan Ariel Aaronson, 'A Match Made in Heaven? The Wedding of Trade and Human Rights' in Lisa L Martin (ed), *The Oxford Handbook of the Political Economy of International Trade* (OUP 2015) 496

⁵⁸⁵ Pedro Roffe and Maximiliano Santa Cruz, 'Aspectos Controversiales de los Capítulos sobre Propiedad Intelectual de los Acuerdos de Libre Comercio Celebrados Principalmente por los Estados Unidos' (CEPAL 2010); Susan Ariel Aaronson, 'A Match Made in Heaven? The Wedding of Trade and Human Rights' in Lisa L Martin (ed), *The Oxford Handbook of the Political Economy of International Trade* (OUP 2015) 510

Annex: Chronological History of Economic versus Public Health and IP Developments in Chile

ECONOMIC DEVELOPMENTS		PUBLIC HEALTH/IP DEVELOPMENTS
	1942	Servicio Medico Nacional de Empleados (SERMENA) was established, creating a fund for white-collar workers to access health services.
	August 1952	The National Health Service (SNS) was created via Law N° 10,383, but did not provide universal healthcare
The first wave of students (26 individuals) were sent to Chicago to study economics under Milton Friedman, funded by the United States Agency for International Development (USAID). A subgroup of these individuals became the Chicago Boys.	1955-1964	
Salvador Allende was elected President via general elections.	4 September 1970	
	31 December 1970	Decision 24 of the Andean Community declared a regime on foreign investment, patents, trademarks, licensing, and royalties.
The final recommendation of the Chicago Boys, dubbed El Ladrillo, was given to Navy Admiral José Toribio Merino.	Late August/Early September 1973	
Chilean coup d'état, resulting in the suicide of Salvador Allende and subsequent assumption of power by General Augusto Pinochet	11 September 1973	
	5 June 1974	Decision 58 of the Andean Community establishes regulations for the application of intellectual property norms
	3 August 1979	El Fondo Nacional de Salud (FONASA) or Chile's national health fund, was established via Decree Law N° 2763
	11 September 1980	New Chilean Constitution was created via referendum, explicitly providing for the right to

		health as a constitutional guarantee, whether via the State or private entities.
Chilean banking crisis brought on by radical neoliberal reforms, including departure from free floating exchange rates. This results in massive unemployment levels and the GDP falling by 14.3%.	1982	
The Uruguay Round of GATT negotiations began	1986	
Chileans voted via plebiscite to end the rule of Pinochet's military government.	October 1988	
Chile's return to democracy. Elections were held, and Patricio Aylwin, a socialist democrat from the <i>Concertación</i> coalition was elected President.	December 1989	
	1991	Chile joined the Paris Convention.
	1993-1994	The ISAPRE association no longer excludes the treatment of certain high-cost diseases from their plans.
Ricardo Lagos won the presidential runoff election by 51.3% of the vote to become the President of Chile.	January 2000	
Chile-U.S. FTA comes into force	1 January 2004	
	25 August 2004	The Regime of Explicit Health Guarantees (initially known as AUGE) was promulgated via Law N° 19,966, specifying the diseases for which insurance schemes are mandated to provide coverage.
Brunei, Chile, New Zealand, and Singapore sign the Trans-Pacific Strategic Economic Partnership (TPSEP)	July-August 2005	
12 countries, including Chile and Malaysia, sign the Trans-Pacific Partnership agreement	4 February 2016	
	9 March 2018	The Minister of Health in Resolution 399, declared that for public health reasons and due to the high cost of sofosbuvir for hepatitis C, that a compulsory licence was justified.

Chapter Four

Malaysia: Socio-Economic Development, International Trade Diplomacy, and Relations with the United States

Chapter Four	I Introduction	109
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	IV U.S.-Malaysian diplomatic relations	117
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I. Introduction

Like the previous chapter, this chapter seeks to detail the political, economic, and social background of Malaysia with the end objective of elucidating Malaysia's decision-making on intellectual property tradeoffs in the TPP. While Malaysia is an relatively open economy, unlike Chile it did not embrace a ideological approach to neoliberalism, but rather pragmatically adopted trademark neoliberal policies alongside interventionist policies.⁵⁸⁶ Malaysian politics have also been marked by rhetoric rejecting 'Western imperialism' during the first period of the leadership of Mahathir Mohamad,⁵⁸⁷ and similar rhetoric was echoed by civil society during the TPP negotiations, who claimed that the TPP was a new form of colonisation.⁵⁸⁸ During the TPP negotiations, however, Malaysia repeatedly emphasised the value of being able to access to U.S. markets, particularly for automobile parts and textiles.⁵⁸⁹ Was tariff reduction as pertains the U.S. market perceived to be an adequate tradeoff for accepting more intellectual property? Or was Malaysia's recent experience with a HIV epidemic and overriding patents still an overriding factor? The following paragraphs seek to make this clearer.

⁵⁸⁶ Bonn Juego, 'The Institutions of Authoritarian Neoliberalism in Malaysia: A Critical Review of the Development Agendas under the Regimes of Mahathir, Abdullah, and Najib' (2018) 11(1) *Austrian Journal of South-East Asian Studies* 53-79

⁵⁸⁷ Mohd Azizuddin Mohd Sani, 'Mahathir Mohamad as a Cultural Relativist: Mahathirism on Human Rights' (Conference Paper presented at the 17th Biennial Conference of the Asian Studies Association of Australia in Melbourne, 1-3 July 2008) <<http://artsonline.monash.edu.au/mai/files/2012/07/mohdazizuddinmohdsani.pdf>> accessed 14 November 2018

⁵⁸⁸ Free Malaysia Today, 'Malaysia Tidak Dijajah Amerika, Kuasa Besar Kerana TPPA – Najib (Malaysia will not be Colonised by America, Major Powers due to TPPA)' *Free Malaysia Today* (Kuala Lumpur, 26 January 2016) <<https://www.freemalaysiatoday.com/category/bahasa/2016/01/26/malaysia-tidak-dijajah-amerika-kuasa-besar-kerana-tppa-najib/>> accessed 14 November 2018

⁵⁸⁹ The Star, 'Malaysia to Gain US\$200bil by Joining TPPA' *The Star Online* (Kuala Lumpur, 4 December 2015) <<https://www.thestar.com.my/business/business-news/2015/12/04/pwc-msia-to-gain-from-tppa/>> accessed 14 November 2018; Mergawati Zulfakar, 'Explaining the Trans-Pacific Partnership' *The Star Online* (Kuala Lumpur, 13 July 2013) <<https://www.thestar.com.my/business/business-news/2013/07/13/explaining-the-transpacific-partnership/>> accessed 14 November 2018

II. Socio-economic development in Malaysia

Similar to Chile, Malaysia's economy experimented with import substituting industrialisation (ISI) efforts.⁵⁹⁰ For Malaysia, this occurred in the first decade after independence from the British in 1957, but through time Malaysia's policies underwent significant diversification to become the export-oriented upper-middle income economy that it is today.⁵⁹¹

Malaysia's domestic economic strategy is characterised along ethnic lines – Malaysia's Economic Planning Unit under the purview of the Prime Minister describes how in the 1970s, the *bumiputera* (ethnic Malays and other indigenous populations) lacked specialised skills and managerial capabilities 'to participate effectively in modern economic sectors', meanwhile Malaysians of Chinese and Indian descent dominated the business sector.⁵⁹² A New Economic Policy (NEP 1970-1990) was launched, and included policies such as building industrial communities for ethnic Malays and increasing *bumiputera* equity shareholding, providing housing discounts for ethnic Malays, modernising rural areas, and boosting *bumiputera* participation in the private sector, university enrolment quotas for *bumiputera*, including *bumiputera*-only educational scholarships.⁵⁹³ While overall poverty reduced, and *bumiputera* equity increased (albeit relatively marginally), *bumiputera* populations continue to be economically marginalised, and this has been attributed to the 'dependency syndrome' – i.e. the inclination to wait and accept assistance from government.⁵⁹⁴ *Bumiputera* policies continue to be strong red lines within international trade agreements, including the TPP.

In February of 1982, Prime Minister Mahathir Mohamad, who is widely acknowledged to be the architect of Malaysia's economic and industrial success, introduced the 'Look East' policy which established Japan as the model for industrial development and became the cornerstone of Malaysia-Japan relations.⁵⁹⁵ This policy resulted in a drive toward Japanese investment in Malaysia and heavy industrialisation. At about the same time, Mahathir⁵⁹⁶ announced a 'Buy British Last' campaign – and throughout his rule he presented a very 'visible and firm stand against the kinds of Western manipulations he had always resented'.⁵⁹⁷ Mahathir also dreamed of building massive internationally-recognised conglomerates à la Japan, and from

⁵⁹⁰ Kwame Sundaram Jomo, *Growth and Structural Change in the Malaysian Economy* (Palgrave MacMillian 1990) 53

⁵⁹¹ *ibid*

⁵⁹² Economic Planning Unit, *Malaysia's Development Philosophy and the Affirmative Action* (Government of Malaysia, 2016) 3

⁵⁹³ Khairiah Salwa Mokhtar, Chan Ai Reen, and Paramjit Singh Jamir Singh, 'The New Economic Policy (1970-1990) in Malaysia: The Economic and Political Perspectives' (2013) 1(1) *GSTF International Journal on Media & Communications* 12, 13

⁵⁹⁴ *Ibid*

⁵⁹⁵ Fumitaka Furuoka, 'Malaysia-Japan Relations under the Mahathir Administration: Case Studies of the 'Look East' Policy and Japanese Investment in Malaysia' (2007) 47(3) *Asian Survey* 505-519, 508

⁵⁹⁶ Malay names are patronymic and thus individuals are referred to by their first names.

⁵⁹⁷ Khoo Boo Teik, *Paradoxes of Mahathirism: An Intellectual Biography of Mahathir Mohamad* (Oxford University Press 1995) 57

this vision Petronas,⁵⁹⁸ the multinational oil and gas conglomerate was formed. Japan was not the only country in the Far East that became a model for Malaysian industry. Industrialisation in Malaysia was driven by the state-owned Heavy Industries Corporation of Malaysia (HICOM), modelled after South Korea's Heavy and Chemical Industries.⁵⁹⁹ He continued to emphasise other policies to advance industrialisation, including fostering close links between the financial and industrial sectors.⁶⁰⁰

Malaysia suffered heavily during the 1997 Asian financial crisis, losing an estimated \$60 billion in market value from July 1997 to August 1998.⁶⁰¹ In September 1998, Malaysia applied capital control measures to restrict the free flow of monies in or out of the nation's capital account – which is widely attributed as the cause of Malaysia's recovery.⁶⁰² Malaysia's economy has continued to grow through the decades, and has in recent years shown resilience despite external shocks. The IMF in its 2018 assessment of the country stated that Malaysia was on-track toward achieving high income status, but needed to improve female labour force participation, improve the regulatory framework for investment, and improve the quality of education, among other things.⁶⁰³

While the word 'neoliberal' was somewhat a taboo during Mahathir's administration, a number of policies were aligned with the so-called Washington Consensus, which is touted as being the primary delivery mechanism of neoliberal hegemony worldwide.⁶⁰⁴ Measures installed by Mahathir included reforms to make the investment regime more attractive for foreign direct investment, and the privatisation of services such as power, healthcare services, and water supply.⁶⁰⁵ Thus Khoo comments that Malaysia was 'systematically interventionist *and* neoliberal', but selectively so.⁶⁰⁶ Mahathir also emphasised the importance of free trade to Malaysia's economy, but emphasised economic imperatives as a key objective, rather than ideological and political objectives within free trade agreements.⁶⁰⁷

⁵⁹⁸ Petronas is most recognised today through its sponsorship of the Mercedes Formula 1 team, but also through multi-billion dollar investments overseas. Elffie Chew, Natalie Obiko Pearson, and Kevin Orland, 'Petronas Nears Deal to Invest in \$31 Billion Canada Project' (*Bloomberg*, 31 May 2018) <<https://www.bloomberg.com/news/articles/2018-05-31/petronas-said-near-investment-in-31-billion-Ing-canada-project>> accessed 12 November 2018

⁵⁹⁹ Edmund Terence Gomez, 'The Rise and Fall of Capital: Corporate Malaysia in Historical Perspective' (2009) 39(3) *Journal of Contemporary Asia* 345-381, 358

⁶⁰⁰ *ibid* 349

⁶⁰¹ Simon Johnson and Todd Mitton, 'Cronyism and Capital Controls: Evidence from Malaysia' (2003) 67 *Journal of Financial Economics* 351-382

⁶⁰² *ibid*

⁶⁰³ International Monetary Fund, 'Malaysia: Staff Report for the 2018 Article IV Consultation' (*IMF*, 7 March 2018) <<https://www.imf.org/en/Publications/CR/Issues/2018/03/07/Malaysia-2018-Article-IV-Consultation-Press-Release-Staff-Report-and-Statement-by-the-45677>> accessed 3 November 2018

⁶⁰⁴ Eric Sheppard and Helga Leitner, 'Quo vadis neoliberalism? The remaking of global capitalist governance after the Washington Consensus' (2010) 41(2) *Geoforum* 185-194; Mark Beeson and Iyanatul Islam, 'Neoliberalism and East Asia: Resisting the Washington Consensus' (2005) 41(2) *The Journal of Development Studies* 197-219

⁶⁰⁵ Boo Teik Khoo, 'Social movements and the crisis of neoliberalism in Malaysia and Thailand' (*IDE Discussion Paper*, 2010) 7-8

⁶⁰⁶ *ibid*

⁶⁰⁷ *Juego* (n 586) 58

Mahathirism is roundly credited with Malaysia's economic and social development, although the prominent Malaysian economist KS Jomo characterises Mahathir's economic legacy as a 'checkered record of bold experiments, false starts, partial successes, and narrow escapes' and that while the cumulative effect of his policies were 'not an unmitigated disaster', Malaysia's development would have been better without multi-billion ringgit losses due to speculative activities on the pound sterling, cronyism and expensive projects, and the handling of corporate debt.⁶⁰⁸

According to the United Nations Development Programme, Malaysia is rated as having 'very high human development' – with high life expectancy, high mean years of schooling, and a GNI per capita that has risen from \$10,170 PPP in 1990 to \$20,443 PPP in 2010 to \$26,107 PPP in 2017.⁶⁰⁹ Malaysia ranks 62nd out of 160 countries in the Gender Inequality Index, with 78.9 per cent of adult women having reached at least a secondary level of education compared to 81.3 per cent of their male counterparts.⁶¹⁰

Malaysia has seen a consistent rise of health expenditure as a percentage of GDP – in 2000 this figure was 2.43% versus 4% in 2015.⁶¹¹ Malaysia has a heavily subsidised public health system, and is ranked 29th in the world for healthcare efficiency i.e. the cost of health care relative to incomes, above the UK and Germany.⁶¹² It is also reliant on generic medicines, with 84.7% of brand name medicine requests being substituted with generics.⁶¹³ Malaysia has used TRIPS flexibilities, notably government use licences, to override pharmaceutical patents and ensure accessibility to generics. The first of these times was in 2004 when pursuant to protracted price negotiations with GlaxoSmithKline and Bristol-Myers Squibb, Malaysia issued a government use licence for HIV drugs, reducing prices by up to 81% and enabling Malaysia to increase treatment coverage during a concentrated HIV epidemic caused by injecting drug use.⁶¹⁴ More recently, after similarly lengthy negotiations with pharmaceutical company

⁶⁰⁸ Kwame Sundaram Jomo, 'Mahathir's Economic Legacy' (*Kyoto Review of Southeast Asia*, October 2003) <<https://kyotoreview.org/issue-4/mahathirs-economic-legacy/>> accessed 14 November 2018

⁶⁰⁹ United Nations Development Programme, 'Briefing Note for Countries on the 2018 Statistical Update: Malaysia' (UNDP, 2018) <<http://hdr.undp.org/sites/all/themes/hdrtheme/country-notes/MYS.pdf>> accessed 3 November 2018

⁶¹⁰ *ibid*

⁶¹¹ World Bank, 'Current Health Expenditure (% of GDP)' (*World Bank*) <<https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=MY>> accessed 12 November 2018

⁶¹² Lee J Miller and Wei Lu, 'These are the Economies with the Most (and Least) Efficient Health Care' (*Bloomberg*, 19 September 2018) <<https://www.bloomberg.com/news/articles/2018-09-19/u-s-near-bottom-of-health-index-hong-kong-and-singapore-at-top>> accessed 3 November 2018

⁶¹³ Chee Ping Chong, Mohamed Azmi Hassali, Mohd Baidi Bahari, and Asrul Akmal Shafie, 'Generic Medicine Substitution Practices among Community Pharmacists: A Nationwide Study from Malaysia' (2011) 19(1) *Journal of Public Health* 81-90

⁶¹⁴ WHO (World Health Organization), 'Access to Affordable Medicines for HIV/AIDS and Hepatitis: The Intellectual Property Rights Context' (*World Health Organisation* 2014) <<http://apps.searo.who.int/PDSDOCS/B5144.pdf>> accessed 12 November 2018

Gilead, and amidst financial constraints in the health budget, Malaysia issued a government use licence for the Hepatitis C drug sofosbuvir.⁶¹⁵

III. Malaysia and international trade diplomacy

Malaysia's first bilateral investment treaty was with the Netherlands, coming into force in September 1972, and was primarily aimed at promoting the development of international shipping services.⁶¹⁶ While it participated in a number of bilateral investment treaties subsequent to this, its involvement in the multilateral trading system was more muted. Malaysia joined the multilateral trading system in 1957, but for several decades its role in the GATT was minimal. The launch of the Uruguay Round of GATT negotiations in the mid-1980s, however, saw a 'notable turnaround' in how Malaysia engaged in the international trade world given a realisation of growing importance of export-oriented manufacturing for Malaysia's economy.⁶¹⁷ At the Ministerial launching the round in Punta del Este in 1986, the Minister of International Trade and Industry, Tengku Razaleigh Hamzah, delivered a speech emphasising the support for the Round and the importance of exports to Malaysia's economy, but notably said that 'rule-making for the international trading system be the imposition of the interests of the strong at the expense of the weak',⁶¹⁸ indicating that while their active participation was not up to that point prominent, that they had observed machinations of the hegemonic powers and were in agreement with other developing countries.

The next Ministerial statement was delivered in 1988 by the new Minister of Trade and Industry, the formidable Rafidah Aziz, who stated in no uncertain terms how Malaysia felt about the state of play in the negotiations, particularly in regard to negotiations on tropical products, stating that:

[T]here still seems to be massive mental blocks in the way of compromise and goodwill. We have continually urged the large players to display the necessary flexibility, and to not allow narrow parochialism to constitute a barrier to the greater liberalisation of

⁶¹⁵ Fifa Rahman (ed), *At the Edge of a Miracle: The Hepatitis C Virus (HCV) Epidemic in Malaysia* (Malaysian AIDS Council: Kuala Lumpur 2017)

⁶¹⁶ Agreement on Economic Co-operation between the Kingdom of the Netherlands and Malaysia (15 June 1971) <<http://investmentpolicyhub.unctad.org/IIA/country/127/treaty/2470>> accessed 31 October 2018

⁶¹⁷ Prema-Chandra Athukorala, 'Trade Policy in Malaysia: Liberalisation Process, Structure of Protection, and Reform Agenda' (2005) 22(1) ASEAN Economic Bulletin 19, 30

⁶¹⁸ GATT, 'Malaysia: Statement by H.E. Tengku Razaleigh Hamzah, Minister of Trade and Industry, at the Meeting of the GATT Contracting Parties at Ministerial Level, 15-19 September 1986, Punta del Este, Uruguay' Doc MIN(86)/ST/37 (17 September 1986) 1

world trade. It appears to me that some players not only ask for too much and offer too little, but in effect say too much and do nothing.⁶¹⁹

At this stage Malaysia was insistent at the lowering of barriers for agriculture in the short term, but when the United States stated that they preferred gradual long-term reforms, Minister Rafidah stated 'we have moved back to square one.' She also warned of Malaysia's plans in the negotiations: 'we did not come here to make speeches. We also want to be listened to.'⁶²⁰

Malaysia formed a strong alliance with the other four main ASEAN economies of Singapore, Indonesia, Thailand, and the Philippines in the Uruguay Round market access negotiations, and at the Ministerial in Brussels in 1990 issued a paean for developing countries to take responsibility for the 'tragic state of affairs' in the economies of developing countries and urged them to address a lack of leadership in promulgating 'prudent economic policies', while urging major powers to 'give and take' on agriculture.⁶²¹

At the closing of the Uruguay Round in Marrakesh, Rafidah Aziz lauded the conclusion as an 'important milestone in international economic cooperation', although stating strong opposition to the insistence of major economies to include 'extraneous issues' such as labour. She also noted a tradeoff Malaysia made – that despite already having very high foreign presence in the financial services sector, Malaysia liberalised services even further in this area.⁶²²

In the late-90s the WTO was gearing up for another round of multilateral negotiations. In the lead up to the Seattle Ministerial in 1999, Malaysia gained experience of forming alliances or bargaining coalitions, an important tactic in trade negotiations. Instead of supporting launching a new round of WTO negotiations, together with other developing countries Malaysia joined the Group of 15 (G15), and the Like-Minded Group (LMG) led by India, Pakistan, and Egypt – which held the position that there were still implementation concerns resulting from the Uruguay Round.⁶²³ The G15/LMG submitted detailed proposals that would provide more distributive power to the Global South, and were against the inclusion of the so-called 'Singapore issues' on the agenda, including investment rules and transparency in government procurements.⁶²⁴

⁶¹⁹ GATT, 'Malaysia: Statement by Ms. Datin Paduka Rafidah Aziz, Minister of Trade and Industry' Doc MTN.TNC/MIN(88)/ST/68 (7 December 1988)

⁶²⁰ *ibid* 3

⁶²¹ GATT, 'Malaysia: Statement by H.E. Dato' Seri Rafidah Aziz, Minister of International Trade and Industry' Doc MTN.TNC/MIN(90)/ST/35 (5 December 1990)

⁶²² Multilateral Trade Negotiations: The Uruguay Round, 'Malaysia: Statement by Dato' Seri Rafidah Aziz: Minister of International Trade and Industry' Doc MTN.TNC/MIN(94)/ST/41 (13 April 1994)

⁶²³ Athukorala (n 617) 31

⁶²⁴ *ibid*

Malaysia's active involvement with developing country issues is further illustrated through the Ezulwini Statement, a statement agreed to amongst the Heads of State of Botswana, Lesotho, Gambia, Ghana, Malawi, Malaysia, Mozambique, Namibia, Nigeria, Sierra Leone, South Africa, Sudan, Uganda, Zambia and Zimbabwe who met in Swaziland in August 2003 to express their concerns about the 'domination of one group of countries over the others', stating further that rich and powerful countries preferred to act unilaterally and 'dominate their economic partners through one-sided bilateral agreements'.⁶²⁵ The document, presented to the WTO by the Malaysian Minister of Foreign Affairs, emphasised:

If the developing world is expected to participate in trade liberalization, developed countries must open their own markets fully. Intellectual property rights should not be applied equally between countries at different stages of development. Social (health) factors must be given full consideration in the application of IPR.⁶²⁶

In an interview for this PhD, that Foreign Minister Syed Hamid Albar spoke about the sentiment behind the statement, extolling the virtues of trade as 'the only way to get ourselves out of poverty and improve our standard of living', but that 'the playing field was not level' and was 'always in favour of the developed countries'. Albar also spoke about the importance of coalition building on the Ezulwini Statement, saying that 'individually, we don't (didn't) have the strength' and that without 'playing the numbers game, we would continue to be bullied'.⁶²⁷

This marks an important point in assessing Malaysia's negotiating capacity. The formation of coalitions is considered a major variable that influence negotiation processes and outcomes, and is one of the tools that can break deadlocks.⁶²⁸ Coalitions of weaker parties bound by a common interest are particularly useful in an asymmetrical negotiating relationship, and has been seen by example in the Cairns Group in the GATT negotiations, where a middle power (Australia) and developing countries such as Colombia, Indonesia, and Malaysia developed enough of a collective weight to be considered a 'third force' in the GATT negotiations.⁶²⁹

⁶²⁵ World Trade Organisation, Ezulwini Statement on a Just Regime in Global Trade through Smart Partnership Dialogue: Communication from Malaysia (12 September 2003) WT/MIN(03)/16, 3

⁶²⁶ *ibid*

⁶²⁷ Interview with Syed Hamid Albar (Kuala Lumpur, 18 December 2018)

⁶²⁸ Christophe Dupont, 'Negotiation as Coalition Building' (1996) 1(1) *International Negotiation* 47-64, 47; Harris and Reilly (n 334) 103

⁶²⁹ Richard A Higgott and Andrew Fenton Cooper, 'Middle Power Leadership and Coalition Building: Australia, the Cairns Group, and the Uruguay Round of Trade Negotiations' (1990) 44(4) *International Organization* 589-632, 604

Despite the statement against ‘one-sided bilateral agreements’, in the early 2000s, Malaysia too had been bitten by the preferential trade agreement bug affecting East Asia.⁶³⁰ Bilaterals were a contemporary approach resulting from trends elsewhere, and were seen as not just economic tools, but also as mechanisms to foster closer ties. When Abdullah Badawi took over as Prime Minister in 2003, he emphasised capitalism with an ‘Islamic flavour’ and sought to improve human capital to ensure Malaysia’s competitiveness in the global market through projecting Malaysia’s image as peaceful, stable, democratic, and as working actively to combat corruption.⁶³¹ This, Bonn Juego dubbed a ‘thin icing on a largely neoliberal capitalist cake’.⁶³² During Badawi’s administration Malaysia’s first bilateral preferential trade agreements with Japan (2005) and Pakistan (2007) were signed, and negotiations with New Zealand were commenced.

Figure 3: Bilateral Trade Agreements - Malaysia

Contracting Party	Date of Agreement	Date of Entry into Force
Japan	13 December 2005	13 July 2006
Pakistan	8 November 2007	1 January 2008
New Zealand	30 May 2009	1 August 2010
Chile	13 November 2010	25 February 2012
India	18 February 2011	1 July 2011
Australia	30 March 2012	1 January 2013
Turkey	17 April 2014	1 August 2015

At the time the Japan-Malaysia FTA was signed, Japan was one of Malaysia’s top trading partners, and this continues to this day.⁶³³ Within the Japan-Malaysia FTA were clear experiences with tradeoffs in a bilateral deal – Malaysia wanted tariffs eliminated on plywood but this was not granted, on the other hand despite Japanese steelmakers opposed market opening for steel, the deal provided for phased tariff elimination.⁶³⁴ A number of political economy considerations arose before negotiations began – notably the technological inferiority of Malaysian car parts and the implications for tariff removal on automobiles.⁶³⁵

Malaysia’s experience in trade negotiations and negotiating tactics were tested in the U.S.-Malaysia FTA negotiations which commenced in June 2006. Among U.S. demands were tariff

⁶³⁰ Mark S Manger, ‘The Economic Logic of Asian Preferential Trade Agreements: The Role of Intra-Industry Trade’ (2014) 14 *Journal of East Asian Studies* 151-184, 151

⁶³¹ Muhammad Ali, ‘Malaysia’s Islam Hadhari and the Role of the Nation-State in International Relations’ in Deina Abdelkader, Nassef M. Adiong, and Raffaele Mauriello (eds), *Islam and International Relations* (Palgrave MacMillan 2016) 207

⁶³² Juego (n 586) 63

⁶³³ Daniel Workman, ‘Malaysia’s Top Trading Partners’ (*World’s Top Exports*, 7 March 2018) <<http://www.worldstopexports.com/malaysias-top-import-partners/>> accessed 3 November 2018

⁶³⁴ Manger (n 630)

⁶³⁵ *ibid*

cuts for 561 manufactured goods,⁶³⁶ that Malaysia would open up government procurement to U.S. bidders, and that Malaysia would adopt data exclusivity in pharmaceutical IP. Government procurement was a point of contention from the beginning, with the then-Minister of International Trade and Industry signalling that they would only have ‘non-binding’ discussions on the matter.⁶³⁷ On intellectual property, U.S. Ambassador LaFleur peddled the standard line on pharmaceutical IP – that it would result in increased foreign direct investment.⁶³⁸ Malaysia was reluctant to accept U.S. demands to restrict the use of compulsory licences, but agreed on a 5 year data exclusivity term for new pharmaceutical products, provided that the period run from the same data as given in the origin country.⁶³⁹

IV. U.S.-Malaysian diplomatic relations

U.S.-Malaysian diplomatic relations have been characterised as ‘deeply ambivalent’.⁶⁴⁰ Both are strategically important to each other – Malaysian imports are the 15th highest imports by country for the United States,⁶⁴¹ and Malaysia is key to the United States for both the geopolitical interests of restraining China’s influence, and furthering economic interests in the region.⁶⁴² Recent years have also seen strong gains in Malaysia-U.S. trade due to increasing U.S. demand for manufactured goods.⁶⁴³ Malaysia has been the recipient of U.S. foreign aid, but this is constrained to military education and anti-terrorism support in marginal and reducing amounts over time,⁶⁴⁴ so by and large diplomatic relations between the two are untethered to foreign aid.

Political stances on the Middle East and opinions coming out of the 1997 Asian financial crisis saw the worst of bilateral tensions between Malaysia and the United States – Prime Minister Mahathir Mohamad attributed the crisis to stock market manipulations by George Soros, a key ally of the Clintons, whereas the Clinton administration (1996-2000) attributed the crisis to the

⁶³⁶ Bernama, ‘Malaysia-US FTA at Technical Stage, says Rafidah’ (*Bilaterals.org*, 8 May 2007) < <http://bilaterals.org/?malaysia-us-fta-at-technical-stage>> accessed 3 November 2018

⁶³⁷ Bernama, ‘Msia-US FTA: ‘We’re Open to Non-Binding Talks’ (*Bilaterals.org*, 1 October 2008) <<http://bilaterals.org/?msia-us-fta-we-re-open-to-non>> accessed 3 November 2018

⁶³⁸ Ambassador Christopher LaFleur, quoted in Robert Galantucci, ‘Data Protection in a U.S.-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Drug Manufacturers’ (2007) 17 *Fordham Intellectual Property, Media, and Entertainment Law Journal* 1083, 1086

⁶³⁹ *New Straits Times*, ‘FTA: Malaysia Imposes Terms on Data Exclusivity for US Pharmaceuticals’ (*Bilaterals.org*, 20 April 2007) <<http://bilaterals.org/?fta-malaysia-imposes-terms-on-data>> accessed 3 November 2018

⁶⁴⁰ Sandra Smeltzer, ‘A Malaysia-United States Free Trade Agreement: Malaysian Media and Domestic Resistance’ (2009) 50(1) *Asia Pacific Viewpoint* 13-23, 14

⁶⁴¹ U.S. Census Bureau, ‘Top Trading Partners – September 2018’ (*U.S. Census Bureau*, September 2018) < <https://www.census.gov/foreign-trade/statistics/highlights/top/top1809yr.html>> accessed 13 November 2018

⁶⁴² Smeltzer (n 640) 13

⁶⁴³ MATRADE, ‘Malaysia External Trade Statistics: Trade Performance for the Year of 2014 and the Month of December 2014’ (*MATRADE*, 20 December 2014) < <http://www.miti.gov.my/miti/resources/fileupload/Press%20Release%20Dec%202014%20EN.pdf>> accessed 13 November 2018

⁶⁴⁴ Michael F Martin, ‘U.S.-Malaysia Relations: Implications of the 2008 Elections’ (Congressional Research Service, 3 April 2008) < <https://file.wikileaks.org/file/crs/RL33878.pdf>> accessed 1 November 2018

lack of transparency in business dealings, cronyism, and structural weaknesses in Asian economies.⁶⁴⁵ Relations worsened even further when Mahathir sacked his deputy, Anwar Ibrahim, over allegations of corruption and sodomy, in 1998. When Anwar was convicted of sodomy, the U.S. Department of State issued a statement that the judgment 'cast serious doubt on the impartiality and independence of the Malaysian judiciary'.⁶⁴⁶ In addition to these tensions, the United States' pro-Israel stance and Mahathir's anti-Semitic comments became a sticking point which led to Mahathir being 'personally rebuked' by George W Bush in 2003.⁶⁴⁷

When negotiations for the Malaysia-U.S. FTA commenced in 2006, the new Prime Minister Abdullah Badawi emphasised the economic importance of the United States to Malaysia, but a myriad of tensions continued to arise. These tensions were multipronged and arose in relation to trade and non-trade issues. Tensions about the war in Iraq and Palestine continued to arise.⁶⁴⁸ Malaysia experienced U.S. hegemony in these negotiations on intellectual property matters, transparency in government procurement, and Malaysia's affirmative action policies. During the trade negotiations, a number of political and ideological conflicts threatened to derail the negotiations. These included disagreements about the war in Iraq, the U.S. approach to Palestine, and a particular deal between Malaysia and Iran to help develop Iranian gas fields. This deal resulted in significant conflict, with the then-Chairman of the House Committee on Foreign Affairs calling the deal 'abhorrent', and sending a letter to the U.S. Trade Representative asking for the suspension of the U.S.-Malaysia FTA negotiations until the Iranian deal was called off.⁶⁴⁹

Malaysia responded strongly:

Malaysia reiterates that the FTA negotiations cannot be held hostage to any political demand, and cannot be conducted under such threats. Malaysia is also ready to suspend negotiations if the situation warrants it.⁶⁵⁰

Negotiations broke down in 2008 amidst numerous disagreements. The 2008 U.S. elections and a reassessment of U.S. needs are widely attributed as the main cause of why this agreement did not come to fruition. Statements by Deputy Prime Minister Najib Razak, however, hinted as to disagreements and the power imbalance inherent in any negotiation

⁶⁴⁵ Pamela Sodhy, 'U.S.-Malaysian Relations during the Bush Administration: The Political, Economic, and Security Aspects' (2003) 25(3) *Contemporary Southeast Asia* 363-386, 364

⁶⁴⁶ Richard Boucher, 'Malaysia -- Verdict Against Former Deputy Prime Minister Anwar Ibrahim' *U.S. Department of State* (8 August 2000) <<https://1997-2001.state.gov/www/briefings/statements/2000/ps000808a.html>> accessed 13 November 2018

⁶⁴⁷ Alex Spillius, 'Bush Rebuke for Mahathir' *The Telegraph* (21 October 2003) <<https://www.telegraph.co.uk/news/worldnews/asia/malaysia/1444743/Bush-rebuke-for-Mahathir.html>> accessed 13 November 2018

⁶⁴⁸ Smeltzer (n 640) 14

⁶⁴⁹ Martin (n 644) 21-22

⁶⁵⁰ *ibid*

with the United States: "I hope they (the US) will see that what the world actually needs is not more assistance but a free trade regime that is fair and just," he said.⁶⁵¹

A turning point in Malaysia-U.S. relations arose out of the September 11 tragedy. Amid an outpouring of sympathy from ordinary Malaysians, Mahathir phoned the U.S. embassy in Kuala Lumpur the moment he found out with condolences, and arranged for increased security at the U.S. embassy.⁶⁵² This was followed by George W Bush phoning Mahathir to thank him for his anti-terrorism efforts, and U.S. Assistant Secretary of State James Kelly dubbing Malaysia 'a beacon of stability' in the region, a moment which Sodhy calls 'a significant shift in U.S. policy towards Malaysia'.⁶⁵³

The TPP was negotiated during the administrations of Najib Razak (2009-2018) and Barack Obama (2009-2017). The Obama administration saw Malaysia-U.S. relations grow even warmer. The TPP negotiations provided both Prime Minister Najib Razak and President Obama the opportunity to liaise on multiple occasions and build a closeness unprecedented in Malaysian history, and each time emphasising economic cooperation and the TPP. In 2011, the second year of TPP negotiation, the two met in the sidelines of the ASEAN Summit in Bali and emphasised the expansion of trade and investment linkages. Obama emphasised the strong bilateral relationship between the two and commended Najib's 'great leadership' in boosting the economy.⁶⁵⁴

In 2014, the two were spotted golfing at a Marine Corps Golf Course in Hawaii. Criticised for ignoring flash floods occurring in Malaysia, Najib emphasised that the golf session was in order to 'establish diplomatic ties'.⁶⁵⁵ The two met again in Kuala Lumpur in 2015, the first visit to Malaysia by a U.S. leader in over 50 years, to discuss the TPP. In a joint press conference, Najib sang the TPP's praises – that it would increase trade and investment, and that it would ensure that 'TPP countries (are) able to create more wealth, more innovation, and set new standards in terms of things like environment and labour'.⁶⁵⁶ In his comments, Obama noted that bilateral relations had strengthened on a number of fronts, trade being a significant

⁶⁵¹ Bernama, 'US Wants to Hold Back FTA Talks with Malaysia for a While' (Bilaterals.org, 26 November 2008) <<http://bilaterals.org/?us-wants-to-hold-back-fta-talks>> accessed 3 November 2018

⁶⁵² Sodhy (n 645) 367

⁶⁵³ *ibid*

⁶⁵⁴ The White House, *Remarks by President Obama and Prime Minister Najib of Malaysia before Bilateral Meeting* (Bali, 18 November 2011) <<https://obamawhitehouse.archives.gov/the-press-office/2011/11/18/remarks-president-obama-and-prime-minister-najib-malaysia-bilateral-meet>> accessed 13 November 2018

⁶⁵⁵ The Star Online, 'Golf Game with Obama for Diplomatic Relations, Says Najib' *The Star Online* (Kota Bharu, 27 December 2014) <<https://www.thestar.com.my/news/nation/2014/12/27/najib-gold-obama>> accessed 15 November 2018

⁶⁵⁶ The White House, *Remarks by President Obama and Prime Minister Najib of Malaysia After Bilateral Meeting* (Kuala Lumpur, 20 November 2015) <<https://obamawhitehouse.archives.gov/the-press-office/2015/11/20/remarks-president-obama-and-prime-minister-najib-malaysia-after>> accessed 13 November 2018

factor, but also counterterrorism and maritime disputes in the South China Sea, a major source of dispute between the U.S. and China.⁶⁵⁷

The U.S. Trade Representative, Michael Froman, too made a number of TRIPS to Malaysia toward the end of the negotiations, and in a forum held in Kuala Lumpur in May 2015 emphasised how the TPP was aligned with Malaysia's own objectives:

For a country like Malaysia, there is much to be gained... particularly in helping Malaysia achieve what it has set out to do on its own for its objectives to become an advanced country by 2020, to grow its per capita income to a significantly higher income, and that's why it's been so important to have Malaysia as a founding member of the TPP. To be sitting at the table helping to shape the rules of the road for this region.⁶⁵⁸

The pally relationship of the two countries rendered little doubt that Malaysia would sign the Trans-Pacific Partnership. The rhetoric had shifted – this period saw little to no mention of the litany of United States military actions or their pro-Israel stance, and from the United States, with the exception of recommendations in Malaysia's 2013 Universal Periodic Review, there was reduced commentary on human rights violations committed in Malaysia. On many points of view in the TPP, at least outwardly, there seemed to be an alignment of values. Per Zaki Laïdi, 'trade liberalisation in a globalised world no longer refers simply to competition between economies, but between social systems.'⁶⁵⁹ In the situation where there was ostensible alignment, and perhaps a certain desperation to be associated and engaged with the United States, would more tradeoffs be made?

V. Malaysia and trade-related IP

While many factors influence tradeoffs, Malaysia's historical relationship with trade-related IP, particularly as regards pharmaceuticals, may have influenced Malaysia's approach to IP negotiations in the TPP. Malaysia is a net importer of intellectual property, with foreign patent holders accounting for more than 80% of annual patent applications.⁶⁶⁰ Domestic patent registration too has remained stable, at the average rate of 1267 applications per year since 2009.⁶⁶¹

⁶⁵⁷ *ibid*

⁶⁵⁸ Michael Froman, 'US: TPP to Greatly Benefit Malaysia' *KiniTV* (7 May 2015) <<https://www.youtube.com/watch?v=Yfqmhfk--Us>> accessed 14 October 2018

⁶⁵⁹ Zaki Laïdi, 'How Trade Became Geopolitics' (2008) 25(2) *World Policy Journal* 55-61, 56

⁶⁶⁰ Intellectual Property Corporation of Malaysia, *MyIPO Statistical Booklet 2017* (2017) 11

<<https://drive.google.com/file/d/1s3p-6wCBGXB8s9BwrBKMNUKqj-hiGiT/view>> accessed 11 November 2018

⁶⁶¹ *ibid*

Malaysian patent law today is governed by the Patents Act 1983, which came into effect in 1986. Prior to 1986, Malaysia's patent system operated based on patents that were registered in the United Kingdom.⁶⁶² The undue cost and burden of applying for patents in the UK was seen as prohibitive for Malaysian inventors and small industries by the then-Minister of International Trade and Industry, Mahathir Mohamad, who prompted the idea of a more cohesive domestic patent law.⁶⁶³ In the background to this, the United States had placed significant pressure on the Malaysian government to enact the 1983 Act, including threatening revocation of Malaysia's Generalised System of Preferences duty-free status.⁶⁶⁴ At that time, the U.S. Trade Representative had also had contact with the Malaysian government in other fields of intellectual property, notably on copyright matters. Uphoff notes that the Malaysian government was 'very responsive' to American requests, and began taking on the language of intellectual property for innovation and foreign investment.⁶⁶⁵ In the lead up to the 1983 Patent Law, WIPO, together with consultants from Sweden and the United States, sent a delegation to Malaysia to provide advice to the government.⁶⁶⁶ The result was a patent law which was essentially a WIPO/United States template. Reforms resulting from this Patent Act saw Malaysia removed from the USTR's Special 301 Watchlist in 1991.⁶⁶⁷

On 23 June 1988, Malaysia deposited its instruments of accession to the Paris Convention for the Protection of Industrial Property, a Convention which enables patent holders to use their first filing dates as effective filing dates in other contracting states,⁶⁶⁸ and establishes guidelines for national patent legislation.⁶⁶⁹ Upon its formal accession to the Convention in October 1990, Malaysia implemented a series of reforms to facilitate the recognition of patents granted in certain major patent offices, including those of the United States and the European Patent Office. These reforms meant that patents granted in these offices could forego substantive patent examination.⁶⁷⁰

It is unclear what Malaysia's role had been in the efforts to reform the Paris Convention in the mid-70s through to mid-80s. These reforms were centred around the idea that, among others,

⁶⁶² Lim Heng Gee, 'Patent Ownership in Malaysia – a Comparative Legal Analysis of the Patents Act 1983' (PhD thesis, Queen Mary 1996)

⁶⁶³ *ibid* 52

⁶⁶⁴ Dylan A MacLeod, 'U.S. Trade Pressure and the Developing Intellectual Property Law of Thailand, Malaysia, and Indonesia' (1992) 26 *University of British Columbia Law Review* 343-374, 364

⁶⁶⁵ Elisabeth Uphoff, *Intellectual Property and US Relations with Indonesia, Malaysia, Singapore, and Thailand* (Cornell University Press 2018) 22

⁶⁶⁶ Lim (n 662) 52

⁶⁶⁷ MacLeod (n 664) 370

⁶⁶⁸ WIPO (World Intellectual Property Organization), *Paris Notification No. 120: Paris Convention for the Protection of Industrial Property: Accession by Malaysia* (24 June 1988) <<https://www.wipo.int/treaties/en/notifications/paris/treatyparis120.html>> accessed 20 January 2019

⁶⁶⁹ Sell (n 12) 108

⁶⁷⁰ Lim Heng Gee, Ida Madieha Azmi and Rokiah Alavi, 'Reforms towards Intellectual Property-Based Economic Development in Malaysia' (2009) 12(4) *The Journal of World Intellectual Property* 317-337, 326

that patents were restrictive to technology transfer from the North to South and that their main function was to assist profit maximisation for multinationals,⁶⁷¹ and was led by India and the Andean Group of Countries. A key proposed reform was Article 5(A) which would provide for the issuance of 'non-voluntary' licences⁶⁷² – an instrument which Malaysia has used a number of times since then. Malaysia is not present in any of the documentation of the WIPO diplomatic conferences for the revision of the Paris Convention in Nairobi in 1981⁶⁷³ – signalling that her role was muted, or that IP awareness only arose beyond this date.

MacLeod noted in a 1992 article that Malaysia generally responds to U.S. pressure more readily compared to its northern neighbour Thailand, likely due to its dependent trade relationship with the U.S.⁶⁷⁴ This experience with the United States prepared Malaysian negotiators for the upcoming TRIPS negotiations in 1994, with Judge Umi Kalthum Majid, Malaysia's lead TRIPS negotiator noting in a 2015 account of her experiences that Malaysia had been under immense pressure from the United States to enter to bilateral agreements on IP, and as a result she had made observations to the Malaysian government on the impact of trade-related IP, particularly on issues on sovereignty vis-à-vis the United States.⁶⁷⁵ Majid was also made aware of developed country strategies, including drawing out negotiations into the early morning, wearing opponents down so that they would agree to anything – and Majid was determined not to horse-trade Malaysia's positions.⁶⁷⁶ Despite being told internally that Malaysia would not have the ability to make a difference to the negotiations, Malaysia continued to play a strong role in pushing through exceptions and protections.⁶⁷⁷

In an interview conducted for this PhD, however, while Majid confirmed that the U.S. had made threats towards Malaysian companies in the event of non-compliance, and that she 'fought tooth and nail against the American position on the TRIPS agreement', she acknowledged that she bore full responsibility of negotiating for Malaysia, with zero support from IP academics or experts.⁶⁷⁸ This was despite an Intellectual Property Division having been established under the Ministry of Domestic Trade in October 1990.⁶⁷⁹

⁶⁷¹ Constantine Vaitsos, 'Patents Revisited: their Function in Developing Countries' (1972) 9(1) *Journal of Development Studies* 71-97, 83

⁶⁷² Sell (n 12) 121

⁶⁷³ WIPO, Diplomatic Conference on the Revision of the Paris Convention (30 September 1981) Document PR/DC/24; WIPO, Diplomatic Conference on the Revision of the Paris Convention (23 December 1983) Document PR/SM/6

⁶⁷⁴ MacLeod (n 664) 344

⁶⁷⁵ Umi K. B. A. Majid, 'Negotiating for Malaysia' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (World Trade Organisation 2015) 276

⁶⁷⁶ *ibid* 277

⁶⁷⁷ *ibid* 279

⁶⁷⁸ Interview with Malaysia's former TRIPS negotiator (Putrajaya, 20 December 2018)

⁶⁷⁹ Intellectual Property Corporation of Malaysia (MyIPO), 'About Us' <<http://www.myipo.gov.my/en/about/>> accessed 24 January 2019

Leading up to the TRIPS negotiations, in October of 1993, Sak Cheng Lum, the then-Senator and Parliamentary Secretary of the Ministry of Domestic Trade and Consumer Affairs, stated in Hansard that the demands encapsulated under the upcoming TRIPS agreement would 'almost totally' be met if Malaysia adhered to the Paris Convention.⁶⁸⁰ The next time TRIPS was mentioned in Parliament it would be in July of 1996, with Sak's successor Tan Chai Ho mentioning it in the context of the newly enacted Industrial Designs Act as 'creating jobs' and 'facilitating technology transfer'.⁶⁸¹

Along with other developing countries, Malaysia was required to make amendments within domestic law by 1 January 2000. These manifested in the Patents (Amendment) Act 2000, which incorporated, among other TRIPS provisions, the 20-year patent term.⁶⁸² In the meantime, in the mid-90s the HIV epidemic had exploded in Malaysia with an estimated 7000 new infections annually.⁶⁸³ By the early 2000s, the situation budget-wise was untenable given the scale of the epidemic and the cost of the patented medicines. After protracted negotiations, in November 2002 the Malaysian government issued a government use licence, a form of TRIPS flexibilities, to override patents on several key HIV drugs.⁶⁸⁴ As a result, Malaysia could procure generic drugs at the cost of US\$45 monthly versus US\$261 monthly per patient.⁶⁸⁵ While this was not specifically cited for Malaysia's inclusion in the USTRs Special 301 Priority Watch Lists (PWL), described elsewhere in this thesis as the USTRs IP 'naughty list', Malaysia faced heavy intimidation from the United States for the issuance of this licence.⁶⁸⁶ It should be noted, however, that despite this intimidation, Malaysia issued another compulsory licence in 2016 to override the patent for sofosbuvir, a hepatitis C drug. This too attracted threat and intimidation tactics, including meetings between the originator pharmaceutical company and the Minister of Foreign Affairs at the World Economic Forum in Davos in 2017, follow-up meetings at the Malaysian Embassy in Washington, D.C., and a flurry of letters between the USTR and the Malaysian government.⁶⁸⁷

⁶⁸⁰ Sak Cheng Lum, in House of Representatives, Malaysia 'Penyata Rasmi Parliamen (Parliamentary Debates)' (19 October 1993) 6735 < <https://www.parlimen.gov.my/hansard-dewan-rakyat.html?uweb=dr&> accessed 26 January 2019

⁶⁸¹ Tan Chai Ho, in House of Representatives, Malaysia 'Penyata Rasmi Parliamen (Parliamentary Debates)' (23 July 1996) 25 < <https://www.parlimen.gov.my/hansard-dewan-rakyat.html?uweb=dr&> accessed 26 January 2019

⁶⁸² Patents (Amendment) Act 2000 (Laws of Malaysia Act A1088), s 5

⁶⁸³ Adeeba Kamarulzaman, 'Taking Stock of Two Decades of the HIV/AIDS Epidemic in Malaysia' (2005) 60(1) *Medical Journal of Malaysia* 1-4, 1

⁶⁸⁴ Martin Khor, 'Tackling AIDS with Generic Drugs' *The Star Online* (6 December 2004) < <https://www.thestar.com.my/opinion/letters/2004/12/06/tackling-aids-with-generic-drugs/> accessed 15 November 2018

⁶⁸⁵ *Ibid*

⁶⁸⁶ WHO (n 614) 5

⁶⁸⁷ James Love, 'Communications between Gilead and USTR regarding Malaysia Compulsory License on HCV Patents, 2017 to May 2018' *Knowledge Economy International* (28 November 2018) <<https://www.keionline.org/29257>> accessed 24 January 2019

In 2005, the United States was gearing up for bilateral trade negotiations with Malaysia. That year, their Special 301 report made their intentions clear on data exclusivity for pharmaceuticals and patent linkage:

Malaysia has enacted neither protection for confidential test data nor a coordination mechanism between the health authorities and patent office to prevent unauthorized registrations of patent-infringing products. The United States will work with Malaysia to make progress on these pressing IPR issues through the Trade and Investment Framework Agreement (TIFA) discussions, and we hope to see continued progress from the Government of Malaysia in the near future.⁶⁸⁸

In a 2006 roundtable between representatives of the Malaysian and U.S. governments, preparing them for the upcoming FTA negotiations, Malaysia was given a clear picture of U.S. expectations: that the United States expected that the FTA provisions would reflect a standard of protection similar to U.S. law and that Malaysia would provide 'strong protection for new and emerging technologies.'⁶⁸⁹ Also in 2006, Malaysia signed an FTA incorporating intellectual property measures, including a provision that a patent was not to be rejected solely on the basis that the subject matter was a microorganism, provisions on 'unfair competition', and the formation of a Subcommittee on Intellectual Property to monitor enforcement of IP under the agreement, among other matters.⁶⁹⁰ At least one Malaysian official underwent a research fellowship at WIPO sponsored by the Japanese government on the harmonisation of IP systems that year.⁶⁹¹

In March 2006, negotiations began on the U.S.-Malaysia FTA⁶⁹² and as expected, the U.S. demanded that Malaysia accept both data exclusivity and patent linkage, and restrict the ability for Malaysia to issue future compulsory licences. As discussed above in Section III of this Chapter, negotiations broke down in 2008, and thus Malaysia did not enact data exclusivity laws at that time. The U.S. Government continued to work closely with Malaysia, funding a training program for 23 Malaysian officials conducted by the U.S. Patent and Trademark Office (USPTO) in 2008.⁶⁹³

⁶⁸⁸ U.S. Trade Representative, '2005 Special 301 Report' USTR (29 April 2005) <<https://ustr.gov/archive/assets/DocumentLibrary/ReportsPublications/2005/2005Special301/assetuploadfile1957636.pdf>> accessed 15 November 2018

⁶⁸⁹ Christopher LaFleur, Ambassador, 'U.S.-Malaysia Intellectual Property Rights Roundtable' (*Wikileaks*, 2 May 2006) <<https://wikileaks.org/plusd/cables/06KUALALUMPUR794a.html>> accessed 1 November 2018

⁶⁹⁰ 'Agreement between the Government of Malaysia and the Government of Japan for an Economic Partnership' (2006) <<http://fta.miti.gov.my/miti-fta/resources/auto%20download%20images/55894af110378.pdf>> accessed 26 January 2019

⁶⁹¹ WIPO, 'Research by Long-Term Fellows Supported by Japan FIT/IP' WIPO <<https://www.wipo.int/cooperation/en/fundsintrust/japanfitipaspac/pubsresearch.html>> accessed 26 January 2019

⁶⁹² Bilaterals.org, 'M'sia, US Launch FTA Negotiations' (*Bernama*, 8 March 2006) <<https://www.bilaterals.org/?m-sia-us-launch-fta-negotiations>> accessed 26 January 2019

⁶⁹³ Robert Rapson, Deputy Chief of Mission, 'Special 301 Review: Malaysia' (*Wikileaks*, 10 March 2009) <<https://wikileaks.org/plusd/cables/09KUALALUMPUR177a.html>> accessed 1 November 2018

The U.S. was dogged in its pursuit of data exclusivity in Malaysian law. In 2010, Malaysia was once again put on the US Trade Representative's Special 301 Priority Watch List for failing to include data exclusivity in its laws. Malaysia was also quizzed on its failure to adopt data exclusivity at the 2010 WTO Trade Policy Review – where Malaysia assured Member States that it intended to implement test data protection but that it simply had not decided the mechanism for doing so.⁶⁹⁴

One year after being included in the PWL, Malaysia adopted and implemented data exclusivity for pharmaceuticals via a government directive.⁶⁹⁵ In 2012, Malaysia was removed off the PWL, and US Trade Representative Ron Kirk in his Special 301 Report specifically mentioned data exclusivity as one of the key reasons for removing Malaysia off the PWL.⁶⁹⁶ Malaysia's experience with U.S. *modus operandi* as concerns maximalist IP and the Special 301 shows a certain deference to this type of 'aggressive unilateralism'.⁶⁹⁷ This is contrasted with Chile which 'does not recognise the validity of the 301 List'.⁶⁹⁸

Aside from its issuances of compulsory licenses, Malaysia does not often lead discussions on pharmaceutical IP at multilateral fora. At the WTO TRIPS Council, which monitors application of the TRIPS agreement and relevant flexibilities, Malaysia's presence is generally muted. Its most recent intervention pertained to complaints that countries have violated the spirit of trade law, and Malaysia voted together with other developing countries in supporting a continued moratorium of the rule being applied to intellectual property, and stated that its position was 'well-known'.⁶⁹⁹ The U.S.-based nonprofit Knowledge Ecology International commented on this provision as representing 'a stealth attack on WTO members' sovereign right to use TRIPS flexibilities such as compulsory licensing to safeguard health and promote access to medicines for all'.⁷⁰⁰

The Malaysian negotiation team was led by J Jayasiri, a negotiator of 35 years' experience in government and with a background in Southeast Asian studies, and who was a negotiator for

⁶⁹⁴ World Trade Organisation (WTO), *Trade Policy Review: Malaysia* (19 March 2010), WT/TPR/M/225/Add.1, 9

⁶⁹⁵ National Pharmaceutical Control Bureau (BPFK). 2011. Government Directive No. 2 of 2011, issued under Regulation 29 of the Control of Drugs and Cosmetic Regulations 1984 (Revised 2006)

⁶⁹⁶ Ron Kirk, *2012 Special 301 Report* (Office of the USTR 2012)

<https://ustr.gov/sites/default/files/2012%20Special%20301%20Report0.pdf> accessed 31 May 2017

⁶⁹⁷ Bhagwati (n 179)

⁶⁹⁸ Joaquin Larrondo, 'Chile no Reconoce Validez de "Lista Negra" de Piratería de EE.UU. (Chile Does Not Recognise the Validity of the United States Piracy Blacklist)' *Emol Nacional* (1 May 2013)

<https://www.emol.com/noticias/nacional/2013/05/01/596379/chile-no-reconoce-la-validez-de-la-lista-negra-de-pirateria-de-eeuu.html> accessed 15 November 2018

⁶⁹⁹ WTO TRIPS Council, 'Minutes of Meeting' IP/C/M/80/Add.1 (22 February 2016) 38

https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=227007,225274&CurrentCatalogueIdIndex=0&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True accessed 21 November 2019

⁷⁰⁰ Thiru Balasubramaniam, '17 WTO Members (Brazil, China, India, Russia) submit draft Ministerial Decision on Non-Violation and Situation Complaints' (*Knowledge Ecology International*, 12 August 2015) <<https://www.keionline.org/22863>> accessed 11 November 2018

Malaysia in the Uruguay Round as well as numerous multilateral and bilateral trade negotiations. While there is no documented evidence of Jayasiri's approach going into the negotiations as pertains to intellectual property specifically, he stated that he went into the negotiations with a 'tight mandate', understanding that government procurement and affirmative action policies would be negotiated, and that he went into the negotiations 'with the knowledge that we can negotiate flexibilities so that we will have sufficient policy space to continue with some of these very sensitive policy issues'.⁷⁰¹ In the same presentation he emphasised the importance of access to the preferential markets of the U.S., Canada, Peru and Mexico, and that 'those who join the club later will always have to pay a higher price,'⁷⁰² indicating at least that the political imperative was that market access was the ultimate aim and the costs of not joining were larger than incidental costs of other deep integration provisions.

VI. Conclusion

This chapter suggests a certain uncomfortable familiarity with U.S. demands on intellectual property – but one that could've possibly influenced how Malaysia approached demands on biologics IP in the TPP. It also shows, however, that Malaysia's Health Ministry views compulsory licenses as essential tools for access to medicines – and the first round of intimidation from the United States did not deter them from issuing a second compulsory license in 2016. Whether these views were communicated to trade negotiators, and whether they were meaningfully integrated into country positions will be discussed further in the following chapter.

Malaysia lacked the historical ideological endorsement of neoliberal trade policies central to Chile – whether by political leaders or the general public. In Chapter 3 of this thesis we saw the then-President of Chile Eduardo Frei issue a presidential message on the occasion of the incorporation of TRIPS measures, extolling the measures as necessary for competitiveness, productivity, and the prevention of trade distortions.⁷⁰³ Also in the same chapter, the redesign of Chile's economy by postgraduates educated under Milton Friedman, the guru of modern economic neoliberalism, was described as being the foundation of Chile's economic approach beginning from the Pinochet regime.

⁷⁰¹ Bursa Marketplace, 'Invest Malaysia 2016 | The Capital Market Conversation | TPP Track: A Game Changer' (18 April 2016) comments by J Jayasiri, Malaysian Chief Negotiator for the TPP <<https://www.youtube.com/watch?v=jrxS19YKMK>> Accessed 14 October 2018

⁷⁰² Ibid

⁷⁰³ Eduardo Frei, Mensaje Presidencial Ley N° 19.996 (Biblioteca del Congreso Nacional de Chile, 4 October 1999) <<https://www.bcn.cl/historiadelailey/nc/historia-de-la-ley/5621/>> accessed 1 July 2018

This did not mean that Malaysia rejected neoliberal or U.S. policies outright, despite generally having a relationship of distrust towards neocolonialism via legislation. As aforementioned, in the early 90s politicians representing the Ministry of Domestic Trade, while not at the level of a head of state, too extolled the virtues of the TRIPS agreement. Given that the Malaysian TRIPS negotiator stated that she did not receive any technical support on IP, it may be that while the early 90s was not where comprehensive IP awareness came about, it could have been its origin.

The 2000s saw negotiations of bilateral FTAs with Japan and the United States, both of which contained IP provisions not previously existing in Malaysian law. Malaysia's 'Look East' policies, as well as opposition to U.S. insistence on government procurement transparency in the FTA, combined with critique of U.S. policies in the Middle East, saw the Japan FTA signed and the U.S. FTA floundering and unfinished. Considering Malaysia's role in the Ezulwini Statement in GATT negotiations, Malaysia's experiences of asymmetry in negotiations occurred both in bilateral and multilateral negotiations. So while in terms of absolute numbers of signed trade agreements compared to Chile, these experiences could have increased Malaysia's negotiating capacity and negotiating efficiency when it came to the TPP. The 2000s also saw Malaysian IP officials undergo training with the U.S. Patent and Trademark Offices, and training with WIPO funded by Japan, while at the same time, a HIV epidemic saw Malaysia issuing government use licenses and withstanding expected U.S. pressure. This changed beginning 2012 onwards, with Malaysia crumbling under the pressure of being included in the Priority Watch List, a blossoming friendship between President Obama and Prime Minister Najib, and respected neoliberal thinktanks defending longer patent terms as having 'no negative impact'.⁷⁰⁴

The non-conclusion of a U.S. FTA rendered Malaysia keen to access U.S. markets in the TPP. Examining these political economic factors in light of Malaysia's keenness towards accessing U.S. markets for a number of key commodities in the TPP will be a key focus in the following Chapter. In considering political economy tradeoffs, it is important to consider what frameworks, precedents,⁷⁰⁵ or red lines negotiators were given entering the negotiations and how these were modified over time.

⁷⁰⁴ Ram Anand, 'Ideas: Fear of Intellectual Property Rights Insulting to Malaysians' *Malay Mail* (22 August 2016) < <https://www.malaymail.com/news/malaysia/2016/08/22/ideas-fear-of-intellectual-property-rights-insulting-to-malaysians/1189129> > accessed 27 January 2019

⁷⁰⁵ Precedents, defined as past behaviours or events that guide or dictate present positions, have been seen, for example, in EU negotiations on financial services, where a Chilean counterpart was advised to incorporate European standards as they were less lenient than American standards, and so when coming up against the United States in a future agreement, they would be able to rely on previous incorporation of EU standards as precedent of what they would not go beyond. Larry Crump, 'Toward a Theory of Negotiation Precedent' (2016) 32(2) *Negotiation Journal* 85-102, 87

These make for an interesting dynamic – divergent domestic interests, experience of power asymmetries in trade, political prioritisation of public health despite external pressures, fragmented and late-developing IP awareness, a historical distrust of the United States and this morphing into an endearment of the United States and some of its policies by certain sectors in more recent years, complemented by the target of U.S. market access, are some of the key political economic factors that will be analysed in considering tradeoffs in the conclusion to this thesis.

Chapter Five

Results and Findings: Political Economy Tradeoffs, Negotiation Theory, and Trade-Related Intellectual Property

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I. Introduction: negotiation theory and relevancy to political economy tradeoffs

In the process of considering binding commitments on the international stage, it is imperative that the decision and the associated tradeoffs be 'sustainable in light of the dynamic incentives that the country faces vis-à-vis its trading partners as well as its domestic agents'.⁷⁰⁶ In other words, were the concessions 'worth it'. In Chapter 1 of this thesis I drew upon Putnam's game theory⁷⁰⁷ to understand the machinations at Level I (international negotiations) and Level II (discussions with domestic stakeholders) to help understand how the negotiators in the TPP arrived at tradeoffs, or indeed whether they made any tradeoffs at all vis-à-vis biologics. This

⁷⁰⁶ Conconi and Perroni (n 169) 615

⁷⁰⁷ Putnam (n 298) 434

requires a consideration of what both Malaysia and Chile, and indeed the United States, would have considered ‘win-sets’, and what tradeoffs were impediments to those win-sets. For example, a Malaysian win-set could include the minimum number of years of market exclusivity on biologics, transparency in government procurement (discussed further below), and market access to the United States. Political scientist Holger Janusch drew on Putnam, and said that the smaller the win-set, the more credibly governments can refer to their tied hands at Level II to receive more concessions at Level I.⁷⁰⁸

Thinking about political economy tradeoffs or concessions involves understanding the character of the negotiations themselves, negotiating objectives in the pre-negotiation environment, the experience or negotiating capacity of the parties involved, power and resource asymmetries, and whether concessions were made in the aftermath of deadlocks. Game theory alone cannot adequately explain these occurrences. Throughout this chapter, I contextualise my findings with a number of other theories, summarised in the following paragraphs.

Understanding what Chile, Malaysia, and the United States considered win-sets requires a consideration of what they expected as they approached the negotiations from a political economy standpoint, i.e. what gains they expected, what red lines they would not cross, and what was negotiable and could be reasonably traded or conceded in return for a major gain. A useful consideration at this point would also be to consider whether ‘moral largesse’⁷⁰⁹ of the developed countries, as described by J P Singh, was something that Chile and Malaysia would be willing to concede for in exchange for some exclusivity on biologics. In past trade agreements many a developing nation has made concessions for ‘moral largesse’, such as trade capacity-building assistance or foreign aid, rather than real tariff reductions.⁷¹⁰ In the case of Malaysia and Chile, upper middle-income countries and arguably more difficult to classify as a ‘developing country’ in terms of need for trade assistance, for example, may have been offered different kinds of moral largesse – for example perceived credibility gleaned from political mileage from being in a plurilateral agreement with the United States. Section II(a) of this Chapter unpacks political economy accounts surrounding the TPP in the three countries – and from this I extracted key tangible and less-tangible expectations of each country in terms of their perceived gains.

⁷⁰⁸ Janusch (n 293) 501

⁷⁰⁹ ‘Moral largesse’ generally consists of offers of trade assistance, training, foreign aid, or other items with less direct economic ramifications, in contrast with market access concessions or tariff reductions.

⁷¹⁰ J P Singh, ‘Development Objectives and Trade Negotiations: Moralistic Foreign Policy or Negotiated Trade Concessions’ (2010) 15 *International Negotiation* 367-389, 371

Also in this Section, we see an illustration of how a country who is less economically dependent on the demandeur can afford to give up less concessions. This draws upon ‘asymmetric interdependence’ theory, where an actor who profits less can be less cooperative because the harms of non-cooperation are less, and thus can force greater concessions from the opposing side.⁷¹¹ In this case, Chile was not seeking major economic gains for the United States due to previously established trade agreements, and thus entered the agreement in a strong position. Circumstances where an actor can afford to be less cooperative because they profit less increases the likelihood of a country not having to make a tradeoff on a particular issue.⁷¹²

The biologics issue in the TPP saw the creation of a coalition. Coalition theory plays a dominant role in asymmetrical plurilateral agreements. The main function of coalitions, as Dupont describes, is to ‘facilitate the attainment of outcomes through increased power’.⁷¹³ They are also one of the tools to break deadlocks, in addition to, et al, discussions through unofficial channels, and ‘shuttle mediation’ i.e. bilateral discussions to define each parties’ needs.⁷¹⁴ There are a number of factors that determine the success of any particular coalition, including the ‘ideological distance’⁷¹⁵ of the individual members within the coalition – whether they had similar material interests domestically and whether there were positive socialisation dynamics⁷¹⁶ – and indeed, the roles of those individuals within that coalition, i.e. whether they were in a leadership position as ‘drivers’, or ‘benevolent neutrals’ in favour of consensus but playing a more passive role in negotiations, or whether they were ‘defenders’ – who have focused preoccupations and play a more active role in ensuring the conflict is resolved in accordance with their interests.⁷¹⁷ The strength or weakness of a coalition could be the material difference between multiple tradeoffs for the issue in question or none at all. The formation and operation of biologics coalition and its influence on the resulting tradeoffs are discussed in detail in Section II(c) of this Chapter. These negotiation theories are seen throughout this Chapter and help contextualise the eventual conclusion of what tradeoffs were made (Section II(d)) and how these findings can help developing countries. (Section III).

⁷¹¹ Robert O Keohane and Joseph S Nye, *Power and Interdependence: World Politics in Transition* (Little, Brown 1977)

⁷¹² *ibid*

⁷¹³ Dupont (n 628) 49

⁷¹⁴ Harris and Reilly (n 334) 103

⁷¹⁵ Dupont (n 628) 55

⁷¹⁶ Basically, where the individual negotiators got along well. J P Singh, ‘Coalitions, Developing Countries, and International Trade: Research Findings and Prospects’ (2006) 11 *International Negotiation* 499-514, 501

⁷¹⁷ Dupont (n 628) 56-57

II. Results from turning points analysis of empirical data and data triangulation

In total, I interviewed 15 Chilean individuals, including TPP negotiators and former negotiators, government advisers to negotiators, academics, and civil society actors who were actively involved with the TPP and had participated in Chile's *cuarto adjunto* ('side room') mechanism for stakeholder engagement. All except 3 were interviewed in person at various office locations in Santiago, and others were conducted by Skype and audio-recorded.

There were less interviews with Malaysian individuals – a number of government employees, including negotiators, approached for the interviews expressed reluctance to participate. When superiors in these governmental departments were approached for approval to interview their subordinates who were directly involved in negotiations, they stated that they were unable to elaborate on the negotiating strategy of the Malaysian government in FTAs.⁷¹⁸ In total, I interviewed 6 individuals, including a TPP negotiator, one former government official who oversaw the TPP negotiations, a former intellectual property negotiator, a former Minister of Foreign Affairs, and a civil society actor who attended TPP rounds as a registered stakeholder and engaged with Malaysian negotiators.

Due to the paucity in empirical data from Malaysia, data was triangulated with testimonies of negotiators in the media and secondary documents such as official TPP side letters and a commissioned cost-benefit study. External to Chile and Malaysia, interviews with 2 international civil society actors who had attended TPP rounds and engaged with negotiators were also included in data triangulation.

The difference in openness between the two countries may be explained by literature on culture of the civil service and academic institutions in Malaysia. These reveal that while the Malaysian civil service is 'performance-oriented'⁷¹⁹, there is a 'pervasive respect for authority'⁷²⁰ and strong bureaucratic culture, and a lack of transparency⁷²¹. Siddiquee comments that there has been 'very little or no attempt to delegate power at lower levels'⁷²² and that the civil service has a high vulnerability to political influence.⁷²³ External to culture,

⁷¹⁸ Email from Alissa Rode, Ministry of International Trade and Industry to author (3 August 2018)

⁷¹⁹ Willy McCourt and Lee Meng Foon, 'Malaysia as Model: Policy Transferability in an Asian Country' (2007) 9(2) Public Management Review 211-229, 223

⁷²⁰ Ibid

⁷²¹ Chang Da Wan, David W Chapman, Ahmad Nurulazam Zain, Sigrid Hutcheson, Molly Lee, and Ann E Austin, 'Academic Culture in Malaysia: Sources of Satisfaction and Frustration' (2015) 16 Asia Pacific Education Review 517-526, 523

⁷²² Noore Alam Siddiquee (ed), *Public Management and Governance in Malaysia* (Routledge 2013) 16

⁷²³ Ibid 44

the impressions of international civil society may be relevant; Peter Maybarduk from Public Citizen described the Malaysian and Chilean negotiation teams as follows: 'I did have a sense that the Malaysian delegation was a bit more quiet and the Chilean delegation was both organised and vocal and came in with a sense of 'here's what we're about' whereas the Malaysian delegation I think came in – I'm not sure what the right word is to describe it, but, able to hear various ideas, and work on what they thought was appropriate.'⁷²⁴

This results section begins with a review of media articles, Hansard, press statements by negotiators and government officials, and a number of secondary documents to build a narrative of government motivations for joining the TPP, and what were the key expectations of the United States. This will help illustrate what each party saw as a win-set. Section b) then sets out to explain key turning points during the negotiations on biologics exclusivity and how negotiators responded to U.S. demands during the TPP negotiations. Their responses to the United States not only indicate their positions, but also how strongly they held those positions. Section c) describes the key tactics utilised by both the Chilean and Malaysian teams in achieving what they saw as a win, and Section d) elaborates whether there were tangible or less tangible political economy tradeoffs for the result on biologics exclusivity.

a) Political economy portraits on the TPP: Chile, Malaysia, and the United States

Interviewee accounts may help explain political economy outcomes and tradeoffs in these negotiations. In the words of Bennett and Edelman, 'in addition to suggesting an interpretation for a social happening, a well-crafted narrative can motivate the belief and action of outsiders toward the actors and events caught up in its plot.'⁷²⁵ Depending on how they are crafted, a political narrative may or may not represent political reality.⁷²⁶ In the following Subsections I attempted to draw out a dominant theme through triangulation of data gained from interviews with media articles, congressional statements and Hansards, and a number of other secondary documents such as studies commissioned by government agencies negotiating the agreement. In the words of Catherine MacKinnon, 'Dominant narratives are not stories.

⁷²⁴ Interview with Peter Maybarduk, Director, Global Access to Medicines Program, Public Citizen (Marrakech, 16 January 2018)

⁷²⁵ W Lance Bennett and Murray Edelman, 'Homo Narrans/Toward a New Political Narrative' (1985) 35(4) *Journal of Communication* 156-171; 156

⁷²⁶ Shaul R Shenhav, 'Political Narratives and Political Reality' (2006) 27(3) *International Political Science* 245-262, 246

They are called reality.⁷²⁷ In the following paragraphs I try to tease out these stories and present dominant themes from interviewee accounts.

i) Chile

In an interview for this PhD, Dorotea López Giral, Professor of International Economics and Trade Policy at the University of Chile, described Chile's motivations for joining the TPP as more ideological rather than one related to tangible market gains. According to López, 'Chile has some things that they will win with this agreement (such as) in agriculture with Japan, but I believe this point is (closer) to which kind of economic model Chile wants the world to have... It's more of a political issue because we already have free trade agreements with all the countries that are in the TPP and the commitments are not much more than what we have in the free trade agreement with the United States. We see now that the WTO is not going (to have) many success stories, and because we believe in free trade, (we'll join).'⁷²⁸

Felipe Lopeandia, the Chilean Chief Negotiator for the TPP, made similar comments as regards established market access deals with all the other TPP countries. He stated, "Considering that Chile already has trade agreements with the other eleven TPP member countries, the negotiating strategy in this area aimed to advance specific areas and goods in certain markets that are important for us." He emphasised that the objectives on tariff preferences for market access were focused on Japan, Malaysia, Vietnam, and Canada, and focused predominantly on the agri-food sector.⁷²⁹

Asian integration was a dominant narrative that emerged out of DIRECON, the governments trade negotiating authority, as well as the neoliberal think tank Libertad y Desarrollo, who stated that not joining the TPP would not just weaken Chile's positioning in Asia, but also Latin America if Mexico and Peru joined but Chile didn't.⁷³⁰ In a talk at Libertad y Desarrollo in 2015, the Director-General of DIRECON echoed these views, emphasising economic integration in Asia and that the TPP would improve ties with the region.⁷³¹

⁷²⁷ Catharine A MacKinnon, 'Law's Stories as Reality and Politics' in Peter Brooks and Paul Gewirtz (eds), *Law's Stories: Narrative and Rhetoric in the Law* (Yale University Press 1996)

⁷²⁸ Interview with Dorotea López Giral, Professor of International Economics and Trade Policy, University of Chile (Santiago, 17 November 2017)

⁷²⁹ DIRECON, 'Destacan Ventajas del Acuerdo TPP para las Exportaciones de Bienes en Nueva Reunión del Cuarto Adjunto' *Dirección General de Relaciones Económicas Internacionales* (15 October 2015) <<https://www.direcon.gob.cl/2015/10/destacan-ventajas-del-acuerdo-tpp-para-las-exportaciones-de-bienes-en-nueva-reunion-del-cuarto-adjunto/>> accessed 22 March 2019

⁷³⁰ Francisco Garcés, 'Chile y La Importancia del Transpacífico Partnership' *Libertad y Desarrollo* (28 November 2013) <<https://lyd.org/centro-de-prensa/noticias/2013/11/chile-y-la-importancia-del-transpacifico-partnership-tpp/>> accessed 23 February 2019

⁷³¹ Andrés Rebolledo, 'Director de la Direcon expuso sobre la política comercial de Chile en el Asia-Pacífico' *DIRECON* (15 June 2015) <<https://www.direcon.gob.cl/2015/06/director-de-la-direcon-analiza-sobre-actuales-escenarios-y-el-desarrollo->

Meanwhile, civil society began to express concerns about the TPP chapters pertaining to pharmaceutical medicines. Rodrigo López Muñoz, Director at Políticas Farmacéuticas, a Santiago-based NGO focused on pharmaceutical pricing and access to medicines, expressed a number of concerns, including patents for new indications or uses of a medicine, transparency provisions that might negatively affect that ability of the state to negotiate price reductions in the future, and investment provisions that might enable the pharmaceutical industry to sue the Chilean government for perceived breaches.⁷³²

There were more varied views and concerns coming out of the *Cámara de Diputados* (Chamber of Deputies), the lower house of Chile's bicameral Congress. Pressure from civil society had by then caught the attention of members of Congress. In 2013, the fourth year of TPP negotiations, Congressman Marcelo Díaz, the deputy chairman of the Foreign Relations Committee of the *Cámara de Diputados*, said that the Committee would place special attention on TPP Chapters focused on intellectual property, pharmaceutical systems, and regulatory sovereignty.⁷³³ Díaz also acknowledged concerns from domestic civil society, stating:

What we have done in this Committee is to open a space for dialogue and also for the channelling of information from different sectors regarding the TPP and not only from the aspect of world economy, but also from civil society actors concerned about what is happening. We are very happy with what we have done so far, creating a transmission belt of those concerns to open paths between the Executive and the different sectors affected and we will continue to monitor the progress of the negotiations.⁷³⁴

Congresswoman Mónica Zalaquett spoke in the same session, making a request that the Director-General of DIRECON clarify doubts raised in Congress.⁷³⁵ Civil society continued to be very vocal throughout the negotiations. Later than year in November 2013, Francisco Vera Hott from the digital rights organisation *Derechos Digitales* wrote about the implications of the Trans-Pacific Partnership in terms of copyright judgments and civil indemnities, emphasising

[director-de-la-direcon-analisis-sobre-actuales-escenarios-y-el-desarrollo-de-la-politica-comercial-de-chile-en-el-asia-pacifico/](#) accessed 23 February 2019

⁷³² Rodrigo López Muñoz, 'TPP y Los Riesgos en el Acceso a Medicamentos. Más Allá de las Patentes Farmacéuticas' Políticas Farmacéuticas (3 June 2013) <<http://www.politicafarmacauticas.cl/2013/06/03/tpp-y-los-riesgos-en-el-acceso-a-medicamentos-mas-alla-de-las-patentes-farmacauticas/>> accessed 3 April 2019

⁷³³ Parlamentarios y El Asia Pacífico, 'Diputado Marcelo Díaz: "Las Negociaciones del TPP Se Extenderán por Varios Meses Más' *Biblioteca del Congreso Nacional de Chile* (4 September 2013) <

<https://www.bcn.cl/observatorio/asiapacifico/noticias/diputado-marcelo-diaz-negociaciones-tpp>> accessed 22 March 2019

⁷³⁴ Ibid

⁷³⁵ Ibid

that these issues 'should be discussed in an open and participatory manner, with the intervention of experts, civil society and in suitable bodies for this, such as our Congress.'⁷³⁶

The association for generic pharmaceutical industry also expressed opposition to provisions in the TPP, with José Luis Cárdenas, legal advisor to the Industrial Association of Chilean Pharmaceutical Laboratories (*Asociación Industrial de Laboratorios Farmacéuticos de Chile* – ASILFA) stating that the TPP would result in patent extensions and would impede access to medicines, and in response to claims that domestic manufacturers would increasingly innovate originator drugs and benefit from more patents, "It is not realistic to think that developing countries will invest in research and development to produce new molecules."⁷³⁷ ASILFA attended numerous negotiation rounds as registered stakeholders. At the Auckland round, for example, Cardenas had presented to negotiators on data exclusivity in Chile, and attended the Chief Negotiator briefing, primarily to learn about and present ASILFA's position on the rumoured 'irrational' new pharmaceuticals proposal that would contain the biologics provision.⁷³⁸ In an op-ed dated 24 December 2012, he described the impenetrability of the Chief Negotiator briefing to stakeholders (including himself), and how only vague and evasive answers were given on the new proposal.⁷³⁹

Through the negotiations, concerns about access to medicines remained ever present, and magnified once the U.S. proposal on biologics became public knowledge. In November 2015, Congressman Jorge Tarud requested the government clarify what was happening on biologics, stating that all he knew was that exclusivity was maintained at 5 years instead of twelve years as the United States wanted.⁷⁴⁰ Tarud went on to express that he wanted more information about Chile's prospective gains from the TPP, which at this point he still thought was quite vague.⁷⁴¹ From 2015 to present day, the voice of Fundación Equidad, a member of the vocal civil society coalition *Chile Mejor Sin TPP* (Chile Better without TPP) became louder on this issue – pressuring the government and Congress on the negative impact of the TPP on access to medicines with public rallies and briefing documents detailing their concerns.⁷⁴²

⁷³⁶ Francisco Vera Hott, 'El TPP es una renegociación del Tratado de Libre Comercio con Estados Unidos' *Derechos Digitales* (13 November 2013) <<https://www.derechosdigitales.org/6391/el-tpp-es-una-renegociacion-del-tratado-de-libre-comercio-con-estados-unidos/>> accessed 22 March 2019

⁷³⁷ Emilio Godoy, 'Campo Minado para la Salud en Acuerdo Transpacífico' *Inter Press Service* (México, 7 October 2013) <<http://www.ipsnoticias.net/2013/10/campo-minado-para-la-salud-en-acuerdo-transpacifico/>> accessed 3 April 2019

⁷³⁸ José Luis Cárdenas, 'Opinión: El Acceso a Medicamentos Será la Moneda de Cambio del TPP' *El Mostrador* (24 December 2012) <[https://m.elmostrador.cl/mercados/destacados-mercado/2012/12/24/opinion-el-acceso-a-medicamentos-sera-la-moneda-de-cambio-del-tpp/](https://m.elmostrador.cl/mercados/destacados/destacados-mercado/2012/12/24/opinion-el-acceso-a-medicamentos-sera-la-moneda-de-cambio-del-tpp/)> accessed 3 April 2019

⁷³⁹ *Ibid*

⁷⁴⁰ Parlamentarios y El Asia Pacífico, 'Diputado Jorge Tarud: "Queremos Saber Cuáles son las Ventajas de Estar en el TPP"' *Biblioteca del Congreso Nacional de Chile* (2 November 2015) <<https://www.bcn.cl/observatorio/asiapacifico/noticias/diputado-jorge-tarud-tpp>> accessed 22 March 2019

⁷⁴¹ *Ibid*

⁷⁴² Partido Pirata, 'Fundación Equidad Publica Exhaustiva Minuta Sobre El Impacto del TPP en Medicamentos' (6 October 2016) <<https://www.partidopirata.cl/fundacion-equidad-publica-exhaustiva-minuta-sobre-el-impacto-del-tpp-en-medicamentos/>> accessed 3 April 2019

The Chair of Fundación Equidad, Tomás Lagomarsino, detailed how his organisation went to Congress with the information gained from Wikileaks and got a lot of support for their demands. “Most of them (members of Congress) were not sure (about the provisions), and said that they were not good. So the Congress put a lot of pressure on the government during the negotiations. In fact, there was a special session in Congress where the Foreign Minister, Hernando Muñoz, had to go to Congress to say what they were doing with the TPP... They created the *cuarto adjunto* to make the negotiations look more participative.”⁷⁴³ The *cuarto adjunto* (side rooms) were meetings between negotiators and stakeholders and took place after each negotiation round. While Lagomarsino expressed that he thought these meetings were simply a tick-the-box exercise, they illustrated the strength and organisation of domestic civil society.

Not all Congressional interventions were ones of concern, or requests for clarification on TPP provisions. Far-right Congressman José Manuel Edwards lauded the TPP, stating: “[I]t is important to belong to the TPP because... not only the benefit that tariffs are lowered for several markets, but it is to belong and have a kind of insurance that the rules are going to be maintained. For small countries like Chile, in relation to large countries such as Japan, it is a very important opportunity”.⁷⁴⁴ It should be noted here that Edwards is a known *pinochetista* (or supporter of neoliberal ideals a la Pinochet) from a prominent wealthy and conservative family,⁷⁴⁵ and thus his support of the agreement was unsurprising.

The dominant themes, or certainly the ones relevant to biologics and what tradeoffs could be made, were centred around Chile’s economic integration in Asia, certain market access gains with non-U.S. nations focused on agricultural produce, the impenetrable nature of the negotiations, whether to members of Congress or the general public, and the idea that access to medicines was a serious issue that was a red line for vocal civil society and domestic generic laboratories.

⁷⁴³ Interview with Tomás Lagomarsino, President, Fundación Equidad (Valparaíso, 18 November 2017)

⁷⁴⁴ Parlamentarios y El Asia Pacífico, ‘Diputado José Manuel Edwards: “El TPP es una Especie de Seguro que Mantendrá las Reglas”’ *Biblioteca del Congreso Nacional de Chile* (16 November 2015)

<<https://www.bcn.cl/observatorio/asiapacifico/noticias/diputado-jose-manuel-edwards-tpp>> accessed 21 March 2019

⁷⁴⁵ Pascale Bonnefoy, ‘Agustín Edwards, Conservative Media Tycoon in Chile, Is Dead at 89’ *The New York Times* (26 April 2017) <<https://www.nytimes.com/2017/04/26/world/americas/agustin-edwards-dead-chile-publisher.html>> accessed 30

October 2019; Emily Langer, ‘Agustín Edwards Eastman, Chilean Publisher Who Backed Pinochet, Dies at 89’ *The Washington Post*

<https://www.washingtonpost.com/world/the_americas/agustin-edwards-eastman-chilean-publisher-who-backed-pinochet-dies-at-89/2017/04/27/0a99021e-2a88-11e7-b605-33413c691853_story.html> accessed 30 October 2019

ii) Malaysia

The narrative in Malaysia was a little different than Chile in that there was more of a focus on market access to the United States given Malaysia not having previous FTAs with the United States. Similar to Chile, however, were views that the TPP would threaten sovereignty in terms of domestic rulemaking, and that intellectual property provisions would limit access to more affordable generic medicines. Opening up government procurement to foreign companies was a highly sensitive topic – previous trade negotiations had seen Malaysia establish strong red lines on this issue. Due to cronyism and preferential treatment of *Bumiputera* companies,⁷⁴⁶ Malaysia had long been reluctant to opening this sector of the economy to foreign companies and to establish transparent bidding processes. This time, however, despite pressures from *Bumiputera* companies, there was an ideological shift among government officials on this issue – notably that the TPP was an opportunity to increase transparency. In the words of a former government official who oversaw the TPP negotiations:

Yes, Malaysia is in dire need of structural reform. And we've been trying to get that kind of structural reform from the inside. (It) couldn't move. And when I want to purchase something for the Ministry I have to get it from this five companies. Why can't we just have an open bidding system? The regulations won't allow me (to). Those are the things that constrain us. And because of the lack of transparency in government procurement, you've got a lot of nonsense that's taking place.⁷⁴⁷

In 2010, the year in which negotiations began, the then-Deputy Minister of International Trade and Industry Mukhriz Mahathir assured Parliament that government procurement was still in the process of negotiation in the TPP and 'had not become such a big problem'.⁷⁴⁸ It is apparent that there was now a need to balance domestic interests on government procurement – on one hand the interests of *Bumiputera* companies and on the other an increasing desire by government officials and academics to see government procurement become more 'predictable, accessible, and transparent'.⁷⁴⁹ This desire was in line with the

⁷⁴⁶ Andy Mukherjee, 'Goodbye Malaysian Cronyism, Hello Anwarnomics' *Bloomberg* (10 May 2018) <<https://www.bloomberg.com/opinion/articles/2018-05-10/goodbye-malaysian-cronyism-hello-anwarnomics>> accessed 14 April 2019; David S. Jones, 'Curbing Corruption in Government Procurement in Southeast Asia: Challenges and Constraints' (2009) 17(2) *Asian Journal of Political Science* 145-172, 148

⁷⁴⁷ Interview with B (anonymised as per request), former government official who oversaw TPP negotiations, Malaysia (Facetime, 7 February 2018)

⁷⁴⁸ Malaysian Parliament, 'Penyata Rasmi Parlimen Dewan Rakyat (Parliament/House of Representatives Official Hansard)' (2 November 2010) <<https://www.parlimen.gov.my/carian.html?page=3&ipp=30&doctype%5B%5D=DR-hs&dokumen%5B%5D=perbahasan&searchref=hansard-dewan-rakyat&searchrefcode=dr&str=Trans-Pacific+Partnership&str2=&DATATYPE=0&DATERANGE%5B%5D=&DATERANGE%5B%5D=&submit=CARI>> accessed 8 February 2019, 97

⁷⁴⁹ Haniff Ahamat and Nasarudin Abdul Rahman, 'The TPP and Government Procurement in Malaysia' in Julien Chaisse, Henry Gao, and Chang Fa Lo (eds), *Paradigm Shift in International Economic Law Rule-Making* (Springer Singapore 2017)

interests of the USTR, who in their annual trade summaries of nations had often raised concerns about Malaysian government procurement.⁷⁵⁰

In March 2011, Mukhriz⁷⁵¹ faced Parliament again, this time responding to concerns that the TPP would threaten the ability of governments to use TRIPS flexibilities for accessing generic medicines, stating:

The government will ensure that the FTA will not threaten the rights of the government to execute flexibilities that have been allocated under multilateral agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to guarantee Malaysian citizens' access to affordable medicines and health services... The Ministry of Health have an existing system of protection to ensure that any negative effects from the application of data exclusivity can be minimised.⁷⁵²

Civil society continued pressure on pharmaceutical IP, and continued to remind negotiators both foreign and domestic of the importance of the issue on the agenda. At the Auckland round of negotiations in December 2012, I (described as 'a stakeholder from the Malaysian AIDS Council'),⁷⁵³ posed a question to the U.S. Chief Negotiator Barbara Weisel whether the U.S. would be tabling the new pharmaceuticals text containing biologics. Weisel responded 'we know people are patiently waiting for new pharmaceutical text,' noting that it was 'complex, controversial and sensitive', and that USTR would take the time necessary to develop a proposal that would have administration and congressional support.⁷⁵⁴

In July 2013, opposition MPs raised concerns about rulemaking sovereignty, with Member of Parliament Wong Chen referring to an internal UNDP report on the TPP and stating in Parliament: 'the American government today is under the undue influence of giant corporations, multinationals and internet companies. These giant multinational companies lobby and write policies.'⁷⁵⁵ These arguments were backed by civil society and domestic politics bloggers, who claimed the TPP would result in an increase of the 'substantive rights

⁷⁵⁰ USTR, 'Malaysia: Trade Summary' *USTR* (2013)

<<https://ustr.gov/sites/default/files/2013%20NTE%20Malaysia%20Final.pdf>> accessed 14 April 2019

⁷⁵¹ Malaysian names are patronymic and individuals should be referred to by their first names.

⁷⁵² Malaysian Parliament, 'Penyata Rasmi Parlimen Dewan Rakyat (Parliament/House of Representatives Official Hansard)' (22 March 2011) <<https://www.parlimen.gov.my/carian.html?page=3&ipp=30&doctype%5B%5D=DR-hs&dokumen%5B%5D=perbahasan&searchref=hansard-dewan-rakyat&searchrefcode=dr&str=Trans-Pacific+Partnership&str2=&DATETYPE=0&DATERANGE%5B%5D=&DATERANGE%5B%5D=&submit=CARI>> accessed 8 February 2019

⁷⁵³ Krista Cox, 'KEI notes on the 15th round of Trans-Pacific Partnership Agreement (TPPA) negotiations in Auckland, New Zealand' *Knowledge Ecology International* (11 December 2012) <<https://www.keionline.org/22084>> accessed 14 April 2019

⁷⁵⁴ *Ibid*

⁷⁵⁵ Malaysian Parliament, 'Penyata Rasmi Parlimen Dewan Rakyat (Parliament/House of Representatives Official Hansard)' (2 July 2013) <<https://www.parlimen.gov.my/carian.html?page=3&ipp=30&doctype%5B%5D=DR-hs&dokumen%5B%5D=perbahasan&searchref=hansard-dewan-rakyat&searchrefcode=dr&str=Trans-Pacific+Partnership&str2=&DATETYPE=0&DATERANGE%5B%5D=&DATERANGE%5B%5D=&submit=CARI>> accessed 10 February 2019, 125

of the foreign investor' and that the TPP would 'strengthen the power of profit-laden pharmaceutical companies to challenge a country's health policies'.⁷⁵⁶

From 2015 onwards, more positive messaging around the TPP began to emerge – rising from the need to address civil society concerns on the agreement. The CEO of IDEAS, the Malaysian neoliberal think tank, stated that with the TPP, entrepreneurs would have 'immediate access to new markets, and will be able to generate revenues and create jobs.'⁷⁵⁷ In May of that year, Obama's US Trade Representative Michael Froman flew to Malaysia to promote the TPP, dissuade fears, and set a narrative of Malaysia as a regional trade rulemaker, stating:

For a country like Malaysia, there is much to be gained... particularly in helping Malaysia achieve what it has set out to do on its own for its objectives to become an advanced country by 2020, to grow its per capita income to a significantly higher income, and that's why it's been so important to have Malaysia as a founding member of the TPP. To be sitting at the table helping to shape the rules of the road for this region.⁷⁵⁸

In December 2015, a study commissioned by the Ministry of International Trade and Industry found that the TPP would result in a higher GDP in the range of USD\$107-211 billion, additional investments valued between USD\$136-239 billion, that Bumiputera flexibilities were largely preserved, and that 'existing pharmaceutical manufacturers' would be 'minimally impacted by stronger intellectual property for drugs.'⁷⁵⁹

The Malaysian negotiation team was led by J Jayasiri, a negotiator of 35 years' experience in government and with a background in Southeast Asian studies, and who was a negotiator for Malaysia in the Uruguay Round as well as numerous multilateral and bilateral trade negotiations. In 2016, Jayasiri emphasised market access in his description of the benefits of the TPP, stating, 'In one single negotiation, we are getting (access to) four new preferential markets... and these are important ones like the US, Canada, Mexico and Peru.'⁷⁶⁰ He also emphasised the importance of joining the TPP now rather than later, i.e. that 'Those who join the club later will always have to pay a higher price.'⁷⁶¹ He also provided an interesting insight

⁷⁵⁶ Ronald S McCoy, 'TPPA: Malaysia is Not For Sale' *Din Merican Blog* (23 July 2013) <<https://dinmerican.wordpress.com/2013/07/23/tppa-malaysia-in-not-for-sale/>> accessed 14 April 2019

⁷⁵⁷ Wan Saiful Wan Jan, 'OBG talks to Wan Saiful Wan Jan, CEO, Institute for Democracy and Economic Affairs' *Oxford Business Group* <<https://oxfordbusinessgroup.com/interview/obg-talks-wan-saiful-wan-jan-ceo-institute-democracy-and-economic-affairs>> accessed 14 April 2019

⁷⁵⁸ KiniTV, 'US: TPP to Greatly Benefit Malaysia' (7 May 2015) comments by Michael Froman, United States Trade Representative <<https://www.youtube.com/watch?v=YfqmhfK--Us>> accessed 14 April 2019

⁷⁵⁹ PWC, 'Study on Potential Economic Impact of TPPA on the Malaysian Economy and Selected Key Economic Sectors: Final Report' PWC (December 2015) <[https://fta.miti.gov.my/miti-fta/resources/TPPAPwCCBA-FinalReport021215FINAL\(corrected\).pdf](https://fta.miti.gov.my/miti-fta/resources/TPPAPwCCBA-FinalReport021215FINAL(corrected).pdf)> accessed 14 April 2019, 9

⁷⁶⁰ Bursa Marketplace (n 701)

⁷⁶¹ Ibid

into how Malaysian negotiators approached the negotiations, alluding that Malaysia looked to preserving flexibilities on predetermined red (or pink) lines rather than making clear concessions on them for market access:

[W]e were going there with a very tight mandate. Even before we went into the negotiations, we knew that these are important issues (government procurement, labour, affirmative action policies) but the Cabinet made a decision to go into the negotiations with the knowledge that we can negotiate flexibilities so that we will have sufficient policy space to continue with some of these very sensitive policy issues.⁷⁶²

The dominant themes were concentrated around what were red lines for the government – government procurement and *Bumiputera* privileges were key sensitive issues, as well as access to affordable medicines. Gains for Malaysia were predominantly focused on access to markets, and U.S. markets in particular.

iii) United States

As mentioned in previous chapters, the dominant themes in the United States was that the TPP was a way to curb China's influence in the Asia Pacific region and help achieve 'necessary security objectives'.⁷⁶³ In the words of Mitt Romney, the TPP would be a 'dramatic geopolitical and economic bulwark against China'⁷⁶⁴. Ron Kirk, the U.S. Trade Representative at the inception of the agreement, called the TPP the 'largest, most dynamic trade collaboration of our time' and that he expected the TPP 'to serve as a model for the future of American trade'.⁷⁶⁵ Read with discussions of the 'deep integration' character of the TPP in Chapter 1 of this thesis, the United States saw the TPP as achieving three major objectives: 1) the control of China; 2) economic integration via eroding differences in national economic policies ('deep integration'),⁷⁶⁶ and 3) to establish a new standard for trade agreements globally.

On pharmaceutical intellectual property, the United States was guided by the interests of American industry, and backed by a formidable group of bipartisan Senators, who in May 2011

⁷⁶² Ibid

⁷⁶³ Nadia Gire, 'The Trans-Pacific Partnership Agreement: A Revival in United States Trade Policy Reform' (2011-2012) 20 *Currents: International Trade Law Journal* 60-74, 63

⁷⁶⁴ Jane Kelsey, quoting Mitt Romney, 'US-China relations and the geopolitics of the Trans Pacific Partnership Agreement (TPPA)' *Global Research* (11 November 2013) <<http://www.globalresearch.ca/us-china-relations-and-the-geopolitics-of-the-trans-pacific-partnership-agreement-tppa/5357504>> accessed 2 May 2017

⁷⁶⁵ USTR, quoting Ron Kirk, 'USTR Ron Kirk Remarks on Trans-Pacific Partnership Negotiations' *Office of the United States Trade Representative* (15 December 2009) <<https://ustr.gov/about-us/policy-offices/press-office/press-releases/2009/december/ustr-ron-kirk-remarks-trans-pacific-partnership-n>> accessed 15 April 2019

⁷⁶⁶ Kim (n 110) 360-361

wrote to the U.S. President Barack Obama stating that strong IP protections, including those specific to the biopharmaceutical industry, were necessary for the United States to continue being competitive in the global economy and that these were necessary to protect over 19 million American jobs.⁷⁶⁷

In July 2013, the CEO of the Washington, D.C.-based Biotechnology Industry Organization (BIO) wrote to the USTR describing his ideals for the TPP, including 'effective legal protections for innovative biological pharmaceutical products', further stating that these would serve as a 'robust incentive' for the research and development of new biologic products.⁷⁶⁸ Later that year, in November 2013 (see timeline in Section II(b) below), at the Salt Lake City round, the United States would table the biologics provision asking for 12 years of biologics market exclusivity.

In 2015, Barbara Weisel, the U.S. Chief Negotiator, echoed these views before stakeholders at the Kota Kinabalu round of negotiations, although couched in the language of 'balance':

We are looking for the *golden balance* on IP. We are thinking about a system that promotes generics. Balanced against that is the next generation of drugs. We all share an interest in making sure we find that balance. So, we'll take that time. We have to all come to an agreement that satisfies all parties. And it is not an issue of patients versus companies, it is not.⁷⁶⁹
[Emphasis added].

As negotiations progressed and it became increasingly clear that the United States would not achieve the 12-year exclusivity period demanded by domestic stakeholders, Senator Orrin Hatch in particular doubled down and demanded that the other TPP countries accept the 12-year biologics provision.⁷⁷⁰

Public Citizen was one of the strongest domestic civil society voices against the TPP. In 2015, for example, it pointed out how the TPP was abandoning philosophies from the previous administration to reduce negative effects of U.S. trade policy on global access to medicines,

⁷⁶⁷ Letter from Orrin Hatch and Maria Cantwell (representing 28 U.S. Senators), to Barack Obama, President of the United States of America (11 May 2011) <<https://www.finance.senate.gov/ranking-members-news/hatch-cantwell-lead-bipartisan-group-of-senators-in-calling-on-president-to-maintain-strong-ip-rights-in-trans-pacific-partnership-trade-agreement>> accessed 16 April 2019

⁷⁶⁸ Letter from James C Greenwood, President and CEO of Biotechnology Industry Organization (BIO), to Ambassador Michael Froman, U.S. Trade Representative (15 July 2013) <<https://www.bio.org/sites/default/files/letterhead.pdf>> accessed 15 April 2019

⁷⁶⁹ Fifa Rahman and Fran Quigley, 'The Illusion of a 'Golden Balance': Access to Medicines and the TPP' Malay Mail (29 September 2015) < <https://www.malaymail.com/news/what-you-think/2015/09/29/the-illusion-of-a-golden-balance-access-to-medicines-and-the-tpp-fifa-rahma/978703>> accessed 14 April 2019

⁷⁷⁰ Adam Behsudi, 'Hatch wants TPP and his 12 Years, Too' *Politico* (28 September 2016) <<https://www.politico.com/tipsheets/morning-trade/2016/09/hatch-wants-tpp-and-his-12-years-too-216566>> accessed 14 April 2019

a deal dubbed the ‘May 10 deal’ that had been brokered between House Democrats and the George W Bush administration in 2007.⁷⁷¹ Non-IP themes coming out from civil society were focused on American jobs – namely that the TPP would encourage American job offshoring and forgive artificial currency manipulations by East Asian nations.⁷⁷²

b) Key turning points and departures during the negotiation process

Nineteen formal negotiation rounds were held from 2010-2013, with the final formal round occurring in Bandar Sri Begawan, Brunei.⁷⁷³ Subsequent to the conclusion of formal rounds, given that there were a number of outstanding issues, including biologics, 23 additional meetings consisting of meetings of Chief Negotiators and/or Trade Ministers occurred subsequent to the close of the final formal round. Of these additional meetings, the Chief Negotiator’s meeting in Atlanta, Georgia in September 2015 finally saw the negotiations come to a close.

Based on interviews conducted with Chilean and Malaysian negotiators, officials, and stakeholders, there were four rounds that were of most significance on biologics exclusivity: Chicago formal round (September 2011), Salt Lake City Ministerial/Chief Negotiators’ Meeting (November 2013), Guam Chief Negotiators’ meeting (May 2015), and Atlanta Chief Negotiators’ Meeting (September 2015). Other events, including my own experience at the Singapore formal round (March 2013) and footnotes from leaked IP chapters, are also included in this section to provide chronological context.

Figure 4: Timeline on Biologics Exclusivity - TPP and Beyond

1st Round: Melbourne, Australia	15-19 March 2010	The intellectual property negotiating group concluded their first round of discussions on 16 March 2010. (USTR 2010) Biologics was not discussed at this time.
8th Round: Chicago, Illinois	6-15 September 2011	The Chilean intellectual property negotiating team was first informed of US intentions on 12 years of biologics exclusivity. This was done via a presentation – no formal text was tabled.

⁷⁷¹ Public Citizen, ‘TPP vs. May 10 Agreement: Access to Medicines’ *Public Citizen* (9 October 2015) <<https://www.citizen.org/sites/default/files/may10vtp.pdf>> accessed 15 April 2019

⁷⁷² Lori M Wallach, ‘The Trans-Pacific Pact Would Kill Jobs and Consumer Protection’ *The New York Times* (6 October 2015) <<https://www.nytimes.com/roomfordebate/2015/10/06/the-future-of-trans-pacific-trade/the-trans-pacific-pact-would-kill-jobs-and-consumer-protection>> accessed 15 April 2019

⁷⁷³ USTR, ‘Ministerial Guidance Energizes Negotiators’ Work During 19th Round of TPP Negotiations’ (*United States Trade Representative*, 30 August 2013) <<https://ustr.gov/19th-TPP-Round-Summary>> accessed 14 September 2018

15th Round: Auckland, New Zealand	3-12 December 2012	The author attended as a registered stakeholder and in the Chief Negotiator briefing directed a question to the U.S. Chief Negotiator, Barbara Weisel, about when the new pharmaceuticals proposal on biologics would be tabled. Weisel responds that the U.S. is still consulting internally on the proposal.
18th Round: Bandar Sri Begawan, Brunei	23-30 August 2013	First Wikileaks leak of IP negotiating text contains the following 'placeholder for biologics': Article QQ.E.20: [Placeholder for specific provision applying to biologics].
Experts & Chief Negotiators Meeting: Salt Lake City, Utah	12-24 November 2013	Official language on biologics was tabled.
IP Group Meeting: Ho Chi Minh City	May 2014	At this time, the placeholder on biologics in the previous leaked document had been replaced with Article QQ.E.20 stating that there would be [0] / [5] / [8] / [12] years of biologics exclusivity starting from the date of marketing approval. Bracketed text indicates that there was still a lack of agreement on period of biologics exclusivity. (Wikileaks)
Chief Negotiators Meeting: Guam, United States	14-28 May 2015	Chilean team of negotiators and government officials tried to figure out how to get annexes that would protect their access to medicines in the text. The result was a window period – that industry would have to market the biologic within 12 months of market approval in originator country
Chief Negotiators' Meeting: Atlanta, Georgia (Final TPP Talks)	26-30 September 2015	Biologics deadlock in final TPP talks. Australia leads alliance on biologics versus the U.S. into the early hours of the morning.
Date of final IP chapter leaked by wikileaks (Consolidated text, clean)	5 October 2015	Final text states that the biologics exclusivity term was 8 years or 5 years with other measures that deliver a 'comparable market outcome'.
U.S. withdrawal from TPP	24 January 2017	U.S. President Donald Trump pulls out of the TPP, allowing the remaining 11 countries to suspend key provisions, including biologics exclusivity.
Signing of CPTPP	8 March 2018	Repackaged TPP dubbed the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) signed without biologics exclusivity

Repackaged NAFTA includes biologics exclusivity	30 November 2018	U.S., Canada, and Mexico sign the repackaged NAFTA (dubbed USMCA), including a 10-year biologics exclusivity term.
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From this, key departures are extracted and condensed as shown in Crump and Druckman⁷⁷⁴:

Figure 5: Departures on Biologics Exclusivity - the TPP and Beyond

D#1	TPP negotiations begin in Melbourne, Australia	March 2010
D#2	U.S. negotiators present that they intend to table 12 years of biologics exclusivity (Chicago round)	September 2011
D#3	Deadlock and extended delay – U.S. consults with domestic stakeholders	September 2011 – November 2013
D#4	U.S. tables official text on biologics, maintaining 12 years of exclusivity (Salt Lake City round), resulting in further deadlock and extended delay	November 2013
D#5	Text amended with proposals for [0] / [5] / [8] / [12] years of biologics exclusivity (Ho Chi Minh round)	May 2014
D#6	Chile negotiates an annex to incorporate safeguards, in anticipation of final text containing 5 or 8 years of biologics exclusivity (Guam round)	May 2015
D#7	Atlanta deadlock – brief stalemate	September 2015
D#8	U.S. exits TPP	January 2017
D#9	Biologics provision suspended from repackaged TPP (CPTPP)	November 2017
D#10	10 years biologics exclusivity included in repackaged NAFTA (USMCA)	September 2018

According to a Chilean former negotiator, it was in the Chicago formal round of negotiations in September 2011 that the United States first informed intellectual property negotiators from all of the eleven TPP countries of their intentions to table “the gift”⁷⁷⁵ - a pharmaceutical proposal that included 12 years of exclusivity for biologic drugs. This occurred in the format of a presentation of content, and a first draft of language was circulated as hard copies. Open discussion on the text did not occur at this time.

Chile responded to this with outrage. They had made clear that they would not go beyond their current FTA with the United States, and felt blindsided. In the words of a former TPP negotiator, “(It was a) big shock for everybody. When we received this document, we were very disappointed. We had a very big argument with the U.S. Privately, we said (to them) ‘this

⁷⁷⁴ Crump and Druckman (n 331) 18

⁷⁷⁵ Interview with S (anonymised as per request), Chilean former negotiator, Vitacura, Chile (16 November 2017)

was not what we thought was going to come. We always told you we could not accept (this).’ We never thought it would be over (and above) any other FTAs (we had).”

This was a key turning point that changed the logic of the negotiations on biologics. The language in this quote – ‘shock’, ‘disappointed’, ‘big argument’ among others – show that what occurred was an ‘emotional punctuation transition’, i.e. was an abrupt transition characterised by strong emotion, and requires adjustments to the logic guiding the negotiations.⁷⁷⁶ In other words, it was in Chicago that negotiators were confronted by information that required a paradigm shift and deeper strategy to improve their BATNA (Best Alternative to a Negotiated Agreement).

Malaysia responded differently to the 12-year biologics announcement. According to their negotiator:

I wasn’t surprised... [Y]ou must understand, Congress gave them the mandate to negotiate. And if you look at the Congressional reports, the mandate to the USTR is to negotiate an IP standard that reflects the standards contained in US IP laws.⁷⁷⁷

This difference in reaction to the announcement on biologics is interesting for a number of reasons, especially given that at the end of the negotiations Chile and Malaysia were both similarly adamant that they would not go beyond the 5-year period contained in domestic law, suggesting the manner in which they reacted initially was immaterial to their red lines. One could argue that there was a knowledge differential here, that Malaysia knew how the United States seeks to replicate domestic IP standards in international agreements, and that Chile did not, but that argument is flimsy. Chile has an existing FTA with the United States and adopted American IP standards within their domestic law from it. They were unlikely to have not known how U.S. IP standards work. The difference in reaction may more likely be attributable to expectations from a pre-existing relationship or discussions held in the pre-negotiation stage. The pre-negotiation stage is often used to reach a ‘joint definition’ of foreseeable problems,⁷⁷⁸ and Chile may simply have felt that the United States misread or ignored their joint definition. It may have been due to perceived closeness and assurances from previous discussions, or alternatively Chile may simply have been worn out from previous hegemonic behaviour from the United States in the U.S.-Chile FTA.

⁷⁷⁶ Kathleen L McGinn, Elizabeth Long Lingo, and Karin Ciano, ‘Transitions through Out-of-Keeping Acts’ (2004) 20(2) *Negotiation Journal* 171-184, 175-176

⁷⁷⁷ Interview with C (anonymised as per request), Malaysian negotiator, telephone call (4 March 2019)

⁷⁷⁸ Harris and Reilly (n 334) 67

Alternatively, the difference in reaction could've simply been cultural. In a study among negotiators of different nationalities, the Latin Americans and the Spanish ranked themselves as high in emotionalism during negotiations, whereas the Chinese ranked themselves as having moderate levels of emotionalism, and the Japanese ranked themselves as having low levels of emotionalism at the negotiating table.⁷⁷⁹ Chile and Malaysia may both have understood that the United States would table 12 years of biologics exclusivity, and that they were not willing to agree to this, but due to cultural reasons, Chilean negotiators reacted with more emotionalism.

It was also at the Chicago round that the USTR established a strategic initiative called the TEAM (or Trade Enhancing Access to Medicines), which interestingly did not mention biologics exclusivity, but instead included proposals for 'access windows' to bring innovator products to markets quicker, to eliminate tariff barriers for medicines, and to reaffirm commitment to TRIPS.⁷⁸⁰

In March 2013, in Singapore, as was customary, a Chief Negotiators' briefing was held with registered stakeholders, including me in my capacity as then-Head of Policy for the Malaysian AIDS Council. I asked the U.S. Chief Negotiator, Barbara Weisel, about the status of the pharmaceuticals proposal (containing biologics), and whether they would be tabling it soon. She responded that the proposal was 'still under discussion'.⁷⁸¹ This question was followed by a question from a colleague from the Breast Cancer Welfare Association, a Malaysian NGO, who expressed concern about the 12 years of exclusivity for biologics and similarly asked when it would be tabled. Weisel once again said that a decision had not been made on the tabling, but crucially, said that had received feedback from other negotiating countries and that the U.S. was considering that feedback.⁷⁸² A leak of the IP chapter dated August 2013 showed that at that time, there was still no text on biologics, but rather merely a 'placeholder on biologics'.⁷⁸³

In that same month, Burhan Irwan Cheong, the lead IP negotiator for the Malaysian TPP negotiating team, told participants in a consultation meeting that the intellectual property chapter "is one of the largest and more complex chapters and we have a lot of catching up to do to reach a state of consensus in the negotiations, compared with other sections in the

⁷⁷⁹ Jeswald W Salacuse, 'Ten Ways that Culture Affects Negotiating Style: Some Survey Results' (1998) 14(3) *Negotiation Journal* 221-240, 232

⁷⁸⁰ USTR, 'Trade Enhancing Access to Medicines' *Office of the United States Trade Representative* (12 September 2011) <<https://ustr.gov/about-us/policy-offices/press-office/press-releases/2011/september/trade-enhancing-access-medicines-0>> accessed 16 April 2019

⁷⁸¹ Public Citizen, 'News from the Singapore Round' *Public Citizen* (2013) <<https://www.citizen.org/article/news-singapore-round>> accessed 14 September 2018

⁷⁸² *Ibid*

⁷⁸³ Wikileaks, 'Secret TPP Treaty: Intellectual Property Chapter Working Document for All 12 nations with Negotiating Positions' *Wikileaks* (2014) <<https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>> accessed 17 September 2018

agreement.⁷⁸⁴ There was little dispute as to the validity of the leaked text, as some noted that the Malaysian Copyright (Amendment) Act 2012 had been amended in line with proposals in the TPP text.⁷⁸⁵

Later that year in Salt Lake City (November 2013), the official language on biologics exclusivity was tabled, maintaining a demand for 12 years. Public Citizen, the U.S.-based consumer rights NGO, were present at this round, and informed negotiators and government officials that the Obama administration themselves did not want 12 years exclusivity domestically.⁷⁸⁶

In October 2014, there was a second leak of the IP chapter, dated 16 May 2014 (Ho Chi Minh round). The placeholder on biologics in the previous leaked document had been replaced with Article QQ.E.20 stating that there would be [0] / [5] / [8] / [12] years of biologics exclusivity starting from the date of marketing approval. (Wikileaks 2014) The bracketed text indicates that in Ho Chi Minh, negotiators were still undecided on the number of years to be included. However, the U.S. had already at that time made clear that they would not have accepted 0 or 5 years.⁷⁸⁷ The U.S., Canada, and Japan also proposed specific definitions for 'biologics', whereas other countries preferred that biologics be defined according to national law. (Wikileaks 2014: 64 footnote 231)

On 27 October 2014, the Malaysian Ministry of Health submitted its official position to the Malaysian IP negotiators.⁷⁸⁸ This internal document stated that 'with respect to US's proposal to provide (data exclusivity) for biologics for 12 years' that the MOH would provide a maximum protection period of 5 years similar to other pharmaceutical products, but with 5 conditions or safeguard measures, including that the application for exclusivity should be made within 18 months from the date of protection granted from the country of origin, that the duration of exclusivity would run from the date of protection granted in the country of origin, that no exclusivity would be granted for changes in dosage or strength of the product, but could be granted for a second indication, and that the right to compulsory licences would not be affected.⁷⁸⁹

In Guam (May 2015), deliberations were held on biologics, and the Chilean team of negotiators and government officials tried to figure out how to get annexes that would protect their access to medicines in the text. The result of this was Annex 18-B, which among other things, states

⁷⁸⁴ Mike Palmedo, 'Malaysian Parliamentarian Seeks Legislative Oversight of the TPP Negotiations; MITI Holds Public Consultations' (*InfoJustice*, 4 August 2013) <<http://infojustice.org/archives/30371>> accessed 16 February 2019

⁷⁸⁵ Ibid

⁷⁸⁶ Interview with Dr Burcu Kilic, Legal Counsel, Global Access to Medicines Program, Public Citizen, Skype (1 February 2018)

⁷⁸⁷ Interview with S (anonymised as per request), Chilean former negotiator, Vitacura, Chile (16 November 2017)

⁷⁸⁸ Internal Document from Ministry of Health to Ministry of Domestic Trade and Industry, shared with author (27 October 2014)

⁷⁸⁹ Ibid

that data exclusivity shall not apply where the application for registration or health authorisation is filed in Chile 12 months or more after the first registration of health authorisation has been obtained abroad. (Law No. 19.039 on Industrial Property 2007) What this means is that no exclusivity for biologics would be provided if the registration of the biologic product in question in Chile was later than 12 months. This 'window period' provision was supported by several other negotiating countries, and negotiations on it continued at the Atlanta Chief Negotiators' meeting in September 2015.

Biologics discussions were fraught with disagreements, continuing through to 4am.⁷⁹⁰ There were two reasons for this: that the coalition of countries did not want to go beyond 5 years of biologics exclusivity and the U.S. was steadfast on 8 years,⁷⁹¹ and that the coalition wanted the window period incorporated into the main text, as opposed to having it as an annex:

Our goal was to have that kind of rule in the main text of the agreement. Not as a footnote or in an annex. But since the U.S. was opposed to that, strongly. In the end we had to agree with having the rule in the annex. The Chief Negotiator fought hard. This was decided by the last round. We tried to include this in the main text for a long period of meetings, a number of meetings. It was a struggle. At the end, this was the result, we worked until very late at night to finish the negotiations. The agreement was only reached in Atlanta. (interview, government official)

At the end of the negotiations, Malaysia was the only other country that obtained an annex containing a 'window period'. Coalitions can often result in a positive force for countries to think about their best alternatives to a negotiated agreement (BATNA), and allows each member to take coalition-members perspectives.⁷⁹² In this case, it may be argued that the United States had already indicated via the TEAM initiative⁷⁹³ that they were open to incorporating window periods. Was accepting a U.S.-proposed provision on window periods a tradeoff of accepting biologics-specific language? This is discussed further in Section II(d) below.

⁷⁹⁰ Interview with C (anonymised as per request), Chilean negotiator (Santiago, Chile, 17 November 2017)

⁷⁹¹ Ana Isabel Martinez and Krista Hughes, 'Pacific Trade Negotiators Working on Medicines Deadlock: Sources' *Reuters* (3 October 2015) <<https://www.reuters.com/article/us-trade-tpp-medicines/pacific-trade-negotiators-working-on-medicines-deadlock-sources-idUSKCN0RW1XK20151003>> accessed 2 February 2019

⁷⁹² Margaret Ann Neale, Harris Sondak, and Elizabeth A. Mannix, 'Managing Uncertainty in Multiparty Negotiations' in Mara Olekalns and Wendi L. Adair (eds), *Handbook of Research on Negotiation* (Edward Elgar 2013) 294

⁷⁹³ USTR (n 761)

c) Upper middle-income country bargaining power and reliance on a ‘common precedent’

The TPP involved one main rule-setter, the United States, and twelve rule-takers of differing development status, from middle powers such as Australia and Canada, to emerging economies like Vietnam.⁷⁹⁴ The United States held ‘formal power’ as the rule-setter and main source of draft text, and has significant technical and economic resources.⁷⁹⁵ Other countries have less of these resources, resulting in *resource asymmetry*.⁷⁹⁶ The introduction of the novel issue of biologics may have increased this resource and power asymmetry further due to several facts. Novelty means that many countries, including those in the TPP, have yet to develop biosimilar regulatory pathways. While these countries procure and use biologic drugs, even within Health Ministries there is a lack of economic modelling on how reliance on biologics will impact future health budgets vis-à-vis increasing health burdens. Only in 2018, some years after the conclusion of TPP negotiations, did the World Health Organization release a report examining prices of cancer drugs (all biologic).⁷⁹⁷ That is to say, outside the pharmaceutical industry, medical associations and some international medical charities in the developed world, there was a deficit of knowledge on novel market changes and impacts vis-à-vis biologics.

In considering resource asymmetry and power dynamics, the perceptions of external stakeholders of negotiating teams and individuals may be relevant. Mentioned elsewhere in this Chapter is the impressions of Peter Maybarduk, that the Chileans were ‘organised and vocal’ and had clear priorities, whereas the Malaysian team were ‘able to hear different ideas’.⁷⁹⁸ Burcu Kilic, also from Public Citizen, corroborated this view in a separate interview for this PhD:

(The Chileans) were very proactive – they seemed to be really interested in the topic and (in) understanding how (the) patent system is connected to innovation and how it applied to developing countries... (The Malaysian negotiators) were very approachable but they were still trying to figure out their priorities and learn the topic.⁷⁹⁹

Relevant also to bargaining power and resource asymmetries versus the United States is the extent to which domestic subject matter experts – whether from other governmental agencies

⁷⁹⁴ Japan is arguably a rule-maker in its own right, but its late entry into the TPP negotiations meant that much of the text had already been finalised.

⁷⁹⁵ Harris and Reilly (n 334) 76

⁷⁹⁶ Ibid 77

⁷⁹⁷ WHO, *Pricing of Cancer Medicines and Its Impacts* (World Health Organization, 2018)

⁷⁹⁸ Interview with Peter Maybarduk, Director, Global Access to Medicines Program, Public Citizen (Marrakech, 16 January 2018)

⁷⁹⁹ Interview with Dr Burcu Kilic, Legal Counsel, Global Access to Medicines Program, Public Citizen (Skype, 1 February 2018)

or external to government – were on hand to advise negotiators. Chilean Ministry of Health officials reported travelling frequently to negotiation rounds, and receiving financial support from the Ministry of Foreign Affairs to attend:

We have seen other countries. In Chile, we presented always as a team... DIRECON always demanded the presence of Chile, of the Ministry of Health at all the rounds. Even if I could not get financing from (Ministry of) Health, the Ministry of Foreign Affairs took it to the Minister and told them that I was not able to go to the negotiations (without financing). DIRECON always told me that health was above everything, was the (one of the) reddest lines and was taken into account at all the negotiation rounds. I was at the Utah round, the Hawaii round, in Atlanta, New York, at the majority of rounds. We always went as a team, and we always heard the health position.⁸⁰⁰

As aforementioned, the Malaysian Ministry of Health provided a written opinion on biologics intellectual property, detailing a 5-year position, that the duration of exclusivity would run from the date of protection granted in the country of origin, and that the right to compulsory licenses should not be affected, among other details.⁸⁰¹ This document did not reflect material technical asymmetry on the subject matter in question. However, the Malaysian Ministry of Health did not present as frequently as their Chilean counterparts at negotiation rounds, nor were they as engaged with domestic civil society:

They were never at our discussions. So I don't think they were (as involved), unless (meetings) were privately held and we were never told. When we (Breast Cancer Welfare Association) were discussing other things with the Ministry of Health, we did bring it up and we were always told that the Ministry of International Trade was dealing with it, so it looked like there was segregation, watching their own respective territories and not looking at a greater perspective.⁸⁰²

Apparent is a difference between Chile and Malaysia in their approach to trans-governmental relations in the TPP – but whether this resulted in a reduction of bargaining power requires more unpacking. While it is evident that comparatively, Chile had predetermined positions, consultative and institutionalised intra-government relationships, and as discussed above, established market access deals with the United States and trade reliance on China, and therefore inevitably being in a stronger bargaining position than Malaysia, a similar conclusion cannot be easily drawn on resource asymmetry. A weaker consultative relationship with domestic experts in Malaysia may have been counterbalanced with technical cooperation

⁸⁰⁰ Interview with T (anonymised upon request), Chilean government official (Santiago, Chile, 16 November 2017)

⁸⁰¹ Internal Document from Ministry of Health to Ministry of Domestic Trade and Industry, shared with author (27 October 2014), n 80

⁸⁰² Interview with Lim Ching Wei, then-Honorary Secretary, Breast Cancer Welfare Association (Kuala Lumpur, Malaysia, December 2017)

between negotiators, and unit level learning made by the negotiator based on these discussions or on policy research, indicators that were not gleaned from interviews. Responding to a question on biologics concessions, the Malaysian negotiator discussed how countries without existing U.S. bilateral FTAs were in more difficult bargaining positions compared to those who had:

Some countries don't have (U.S.) FTAs, like Malaysia, Brunei, Vietnam, for example. Vietnam, they have the first-generation FTA but that was before TRIPS, so those countries that do not have the recent FTAs have other issues as well. Because other countries that have already signed a modern bilateral FTA like Australia, Singapore, they were comfortable – they were more focused on biologics because they already went through mud – they already went through the sticky points of their domestic issues when they signed the bilateral FTA with the U.S. So New Zealand, Malaysia, Brunei, Vietnam, we had problems, we had other problems, not only on biologics. For example, on *bumiputera* rights, extending copyright terms from 50 to 70 years which is a big concession I guess for everyone, including Japan as well, Japan and Canada. So, countries that do not have bilaterals have other pressure issues (sic), other equally sensitive issues (other than) biologics. So that is why, considering Australia had the common standards that these 4-5 other countries that do not have bilateral FTAs with the U.S., they were comfortable to let Australia drive the discussions on biologics to make sure that the standards in the TPP is five years.

In this quote the Malaysian negotiator demonstrates capacity on the significance of existing U.S. FTAs before entering TPP negotiations, in terms of so-called 'sticky issues' that could have resulted in larger concessions. This realization – that Malaysia was in a more difficult negotiating position compared to those countries who had previously discussed – would have presumably resulted in a greater incentive for unit-level learning and engagement with experts to minimise tradeoffs. Based on Putnam's game theory,⁸⁰³ negotiators often refer to domestic stakeholders in explaining why their hands are tied on concessions during international negotiations, and relying on and consulting with a wide range of experts could potentially have reduced any resource asymmetry, and increased Malaysia's bargaining power. However, given the particular nature of Malaysia's bureaucracy and 'pervasive respect for authority'⁸⁰⁴ discussed in Section II above, it may have been the case that the Malaysian trade negotiators preferred to rely on expertise internal to the Trade Ministries. McKeown's thoughts on hierarchical control may be relevant here – that some governments 'are vulnerable to asymmetries in effective hierarchical control when they are not highly institutionalized and depend heavily on personal relations to manage the government. A lack of resources can

⁸⁰³ Putnam (n 298) 434

⁸⁰⁴ Ibid

exacerbate these problems, but even relatively poor governments can have highly effective hierarchical control.⁸⁰⁵

The quote also alludes to the common standards shared by a number of TPP countries – i.e. data exclusivity periods of 5 years, and how Australia was chosen to drive the negotiations to apply these to negotiations on biologics exclusivity. This phenomenon, i.e. the reliance on a ‘common precedent’ combined with effective coalition building, is what I argue to be a key precipitant of why both Chile and Malaysia did not have to make significant political economy tradeoffs on biologics.

To understand the overall character and outcome of the negotiations, and the precipitants and departures which influenced tradeoffs, if any, the turning points analysis was utilised to analyse interviews and information from secondary documents. This methodology allows us to practically map the crucial moments during the negotiations and consider what factors spur progress beyond a stalemate, including if there were any concessions and what tactics were employed to avoid concessions.⁸⁰⁶ In this particular case study, a proposal was tabled on a novel product (biologics), with an extension of duration compared to what negotiating countries already had in domestic legislation for non-biologic drugs. The United States wanted 12 years exclusivity, and a coalition of 10 countries including Chile and Malaysia, and led by Australia, negotiated this down to the ambiguous provision of 5 or 8 years, but one that would be interpreted either way and satisfied the coalition’s initial red line of 5 years contained in domestic law. Given that the initial preferences of Chile, Malaysia, and other countries in coalition, were reflected in the final text, this is arguably effective negotiation.⁸⁰⁷ But what led to this effectiveness, as mapped out by the turning points analysis, was a result of the effective utilization of several tools to move away from deadlock and towards resolution. These tools included reliance on precedent, effective-coalition building, and unit-level learning from international NGOs. Throughout the negotiations, as shown in Figures 5 and 6 below, these tools and or how they were used were categorised as ‘precipitants’ for departures.

Precipitants are defined as ‘factors inside or outside the negotiation that trigger change or departure’, and they consist of decisions made to change the structure or format of the talks (procedural precipitant), new ideas or concepts introduced by one or more of the parties (substantive precipitant), and events that occur outside the talks, including policy and

⁸⁰⁵ Timothy J McKeown, ‘The Big Influence of Big Allies: Transgovernmental Relations as a Tool of Statecraft’ in Helen V Milner and Andrew Moravcsik (eds), *Power, Interdependence, and Nonstate Actors in World Politics* (Princeton University Press 2009) 210

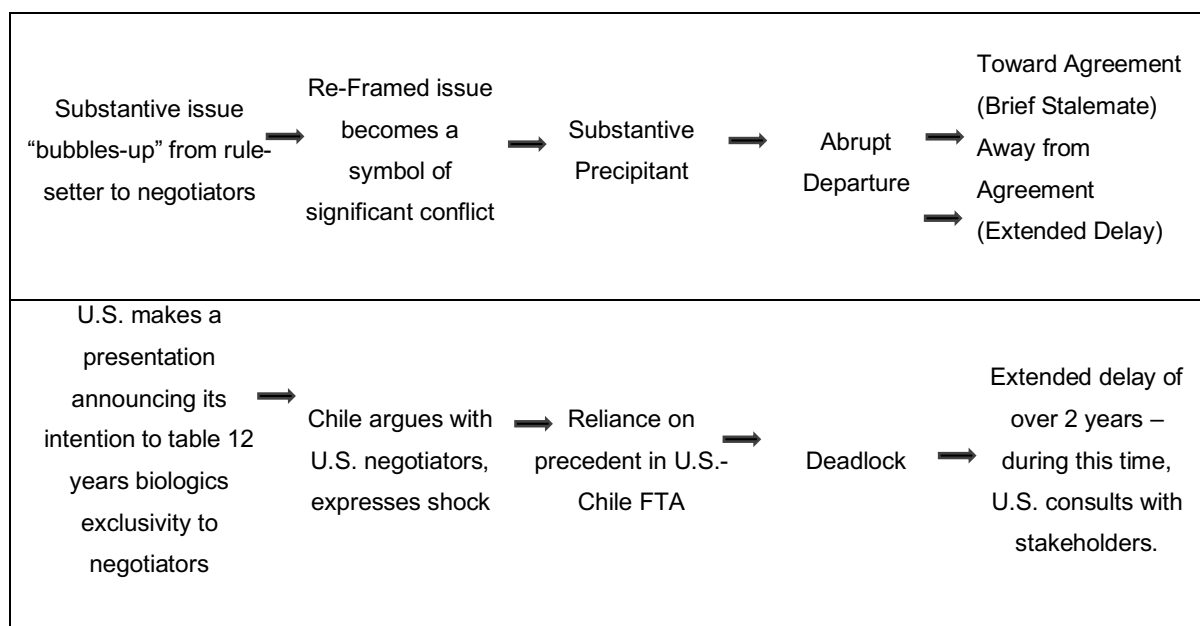
⁸⁰⁶ Crump and Druckman (n 326) 11; Crump and Druckman (n 331) 18

⁸⁰⁷ Diana Panke, ‘Negotiation Effectiveness: Why Some States are Better than Others in Making their Voices Count in EU Negotiations’ (2012) 10 *Comparative European Politics* 111-132, 111

leadership changes and third-party interventions (external precipitant).⁸⁰⁸ The most prominent precipitants of the departures listed in Table 1 above were the reliance on precedent, effective coalition-building, and unit-level learning from international NGOs.

On one hand, the United States sought to establish a precedent, a ‘gold standard’ to be the norm in terms of biologics IP worldwide.⁸⁰⁹ On the other hand, several countries including Chile had data exclusivity provisions in their laws of 5 years duration, albeit not specific on biologics. For a couple of countries, these provisions had arisen as a result of U.S. intervention and/or pressure; Chile via the U.S.-Chile FTA and for Malaysia via being included in the Special 301 Priority Watch List, i.e. the United States ‘naughty list’ for violators of their IP standards. It was in Chicago that U.S. negotiators first informed the other TPP countries of their intentions to possibly incorporate 12 years of biologics exclusivity within the agreement. Crump and Druckman’s process model⁸¹⁰ explaining how deadlocks occur is helpful to clarify what happened at the Chicago round – and illustrates that reliance on precedent i.e. a substantive precipitant – resulted in the deadlock:

Figure 5: Process Model - Chicago Biologics Deadlock



Weinhardt’s socially constructed ideas on mechanisms that can delay cooperation help explain the deadlocks that occurred.⁸¹¹ U.S. negotiators were aware that Chile would not go beyond what was included in their previous FTA and they would rely on their precedent.

⁸⁰⁸ Crump and Druckman (n 326) 16

⁸⁰⁹ Isfeld (n 37)

⁸¹⁰ Crump and Druckman (n 331) 32

⁸¹¹ Clara Weinhardt, ‘Playing Different Games: Uncertain Rules in EU-West Africa Trade Negotiations’ (2017) 61(2) International Studies Quarterly 284-296, 284

However, according to Weinhardt's choice-range disjuncture mechanism, actors mistakenly assume there is a common understanding of the normatively acceptable 'moves' in a game, and in this case, the United States perceived tabling 12 years of biologics exclusivity to be a legitimate move, most likely based on the views of their domestic stakeholders, i.e. the pharmaceutical industry. On the other hand, as shown by Chile's strong reaction to the tabling, suggests that consistent with Weinhardt's theory, Chile interpreted this as illegitimate. According to Weinhardt, this 'produces resistance based on negative feelings of unfair treatment', which in turn yields understanding on why Chile demanded to know the rationale for a specific period of 12-years, their coalitional diplomacy, their reliance on NGO data, and efforts to include safeguards in the text.⁸¹² Malaysia on the other hand, based their reaction on knowledge of previous FTAs, and not only saw the tabling of 12 years of legitimate, but also predictable.

In a bilateral negotiation between parties of asymmetrical power relations, the United States could have arguably been able to use more leverage to establish the precedent they wanted given the restricted power of individual negotiating countries and poor BATNA relative to the United States.⁸¹³ In a plurilateral negotiation with asymmetrical power relations, while the United States remained the rule-setter, the fact that a number of countries were relying on precedent, enabled Chile and Malaysia to use other tools to increase their leverage. This common precedent gained legitimacy and clout through coalition-building.

Impasses or stalemates can happen because negotiators are relying on established norms within domestic law or previous negotiations – i.e. some form of precedent that they have been instructed to not make concessions on.⁸¹⁴ Referring to historical precedent confers upon the negotiator 'legitimacy and authority', and provides clarity to the opposing side of strategic considerations.⁸¹⁵ Relying on a precedent can be very powerful, particularly where multiple parties in a multilateral agreement have precedent on the same issue. In the case of biologics – Chile, Malaysia, and Australia, among other countries, had a precedent of 5 years of data exclusivity, and thus were able to form a coalition with other countries that did not want to see 12 years biologics exclusivity (e.g. Canada) and countries that did not yet have data exclusivity domestically (e.g. Vietnam). The strong coalition combined with a reliance on a 'common precedent' arguably reduced the possibility of needing to make tangible tradeoffs.

⁸¹² Ibid

⁸¹³ Crump (n 705) 91; Jennifer R Overbeck and Yoo Kyoung Kim, 'Power, Status, and Influence in Negotiation' in Mara Olekalns and Wendi L Adair (eds), *Handbook of Research in Negotiation* (Edward Elgar 2013) 148

⁸¹⁴ Crump (n 705) 87

⁸¹⁵ Ilai Alon and Jeanne M Brett, 'Perceptions of Time and their Impact on Negotiations in the Arabic-Speaking Islamic World' (2007) 23(1) *Negotiation Journal* 55-73, 66

The role of a strong coalition against 12 years on biologics was imperative in obtaining a reduced duration of exclusivity and ‘softer’ or more ambiguous language on biologics. This is consistent with Singh’s observation that effective coalition building was especially important when services was introduced into GATT, and at that time had never been addressed before in a trade context.⁸¹⁶ The case study at hand, Chile, Malaysia, and other countries with a common position versus the United States in the TPP, is a typical example of approaching a deadlock in an asymmetrical negotiating relationship. Coalitions of weaker parties bound by a common interest are particularly useful in an asymmetrical negotiating relationship, and has been seen by example in the Cairns Group in the GATT negotiations, where a middle power (Australia) and developing countries such as Colombia, Indonesia, and Malaysia developed enough of a collective weight to be considered a ‘third force’ in the GATT negotiations.⁸¹⁷ In the TPP, the coalition on biologics saw the United States, as a major power and standard setter in this agreement, being unable to apply its power in a straightforward manner.⁸¹⁸

The role of Australia in the biologics coalition is inextricable from any analysis of Chile’s and Malaysia’s effectiveness in these negotiations – with Australia playing the role of a leader driving the issue negotiations, and Chile, Malaysia, and other TPP countries playing the role of defenders.⁸¹⁹ Decision-making towards Australia playing a leading role in opposing extended exclusivity for biologic drugs was centred around the common precedent and the recognition that countries that did not have established deals with the United States would not be in the best position to go head-to-head with the United States on biologics:

[C]onsidering Australia had the common standards that these 4-5 other countries that do not have bilateral FTAs with the U.S., (countries) were comfortable to let Australia drive the discussions on biologics to make sure that the standards in the TPP is five years.⁸²⁰

A relevant question perhaps for future research is the role of ‘ideological distance’ in the effectiveness of this coalition – Australia’s defence of its Pharmaceutical Benefits Scheme in other trade agreements, Chile establishing the Ricarte Soto Law in response to expensive (biologic) treatments, and Malaysia issuing government use licences to override patents and obtain generics, or a general approach to health as a human/constitutional right – i.e. to what degree did domestic challenges to health funding, affect ease of coalition building? Reduced

⁸¹⁶ Singh (n 710) 501

⁸¹⁷ Higgott and Cooper (n 629) 604

⁸¹⁸ Harris and Reilly (n 334) 76

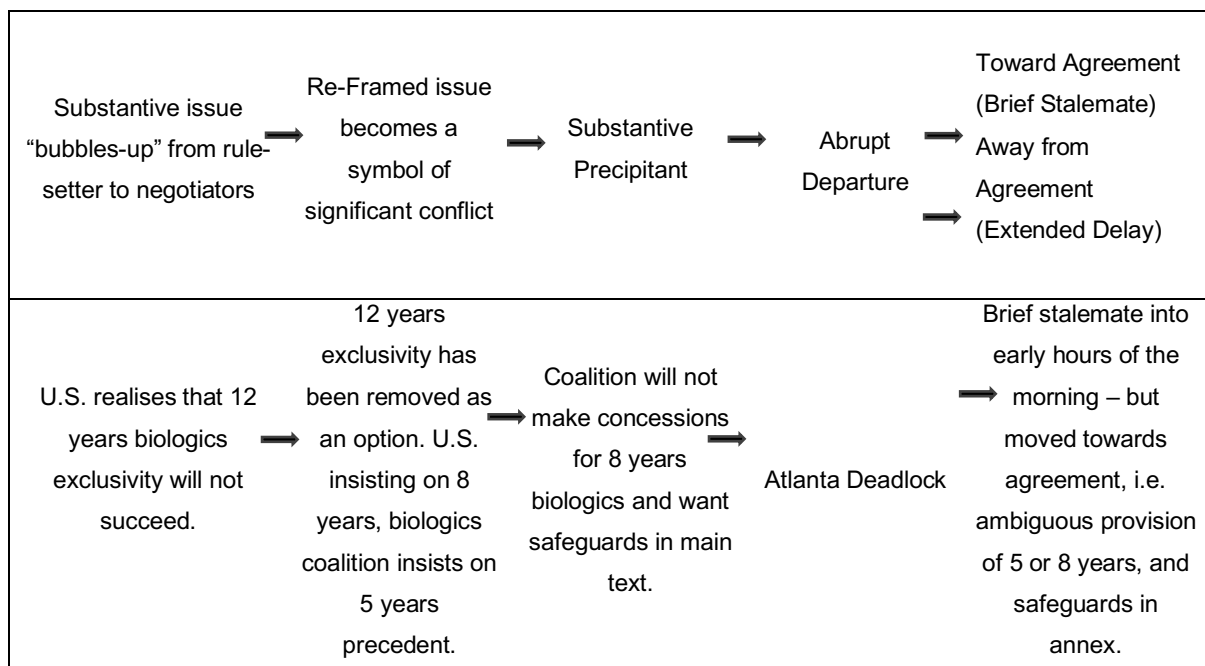
⁸¹⁹ Dupont (n 628) 56-57

⁸²⁰ Interview with C (anonymised as per request), Malaysian negotiator, telephone call (4 March 2019)

ideological distance has been noted by a number of authors to facilitate coalitions, consensus, and dialogue.⁸²¹

Effective coalition-building in combination with common precedent was arguably what precipitated the deadlock at the Atlanta round, and meant that the United States was not able to secure the number of years of exclusivity that they wanted at that point of time (8 years) and concede for the ambiguous 5- or 8-years provision. The following process model illustrates:

Figure 7: Process Model - Atlanta Biologics Deadlock



External precipitants (such as a state policy or interventions of third parties) were also clearly observable in, for example, Public Citizen’s discovery and advocacy with negotiators on the domestic concerns of U.S. government on the duration of biologics exclusivity. In addition to relying on information from foreign NGOs such as Public Citizen, a strong coalition of domestic NGOs i.e. *Chile Mejor Sin TPP* campaigning against 12 years of biologics exclusivity provided negotiators with a reference point when balancing interests at the TPP negotiations. This is an illustration of Putnam’s two-level game theory,⁸²² where domestic groups at one level (Level II) pursue their interests by pressuring the government, and at the international level, governments seek to satisfy these interests ‘while minimizing the adverse consequences of foreign developments’ (Level I). In this case, negotiator positions on the duration of exclusivity

⁸²¹ Dupont (n 628) 55; Mark L Haas, *The Clash of Ideologies: Middle Eastern Politics and American Security* (Oxford University Press 2012) 8

⁸²² Putnam (n 298) 434

overlapped with the interests of the NGOs, which can increase negotiation effectiveness.⁸²³

The mapped turning points, departures, and precipitants not only point to Chile having a preordained preference – i.e. that they would not go beyond IP precedent in their previous FTA, but that as they learnt that the U.S. did not have a rationale for proposing a 12-year exclusivity period, and that there was internal disagreement on exclusivity periods, they made decisions that would allow them to maximise their utility, i.e. to work towards ambiguous wording that would allow them to interpret the provision to their favour and to leverage upon common precedent in the laws of other TPP countries.

Chile's unwavering position, and strength, is also interesting. Far from behaving like a 'blank space' that was waiting to be filled with Western influence,⁸²⁴ they refused to budge on predetermined red lines, and developed a cohesive, coordinated strategy with likeminded countries. A deadlock occurred in Atlanta, and in fact at a number of different rounds where heated discussions occurred on biologics. This suggests a perception of a symmetrical or near symmetrical power status – it matters not whether it was objectively true that the power status was the same,⁸²⁵ but rather than Chile perceived itself to be in near-symmetry with the U.S., due to previously established trade deals, strong internal capacity on IP, and strong economic dependence on China.

Chile's strong position on biologics is reflected in their demands for justifications and rationales for the 12-year proposal from the United States. The fact that the United States was unable to provide a satisfactory answer further buttressed Chile's decision to reject the 12-year proposal. In the words of a former negotiator:

We also asked for data. We wanted to better understand what was the philosophy of 12 years. Did you pick 12 years because that day you thought it was a very interesting number? Or is it really because you did some homework that you could convince me that that's the way it should go? And that never did happen in any one round. So we weren't convinced at all.⁸²⁶

Nor did Malaysia behave like a blank space, although they recognised that due to other countries already having gone through 'the sticky points of their domestic issues'⁸²⁷ that they were in a weaker bargaining position compared to countries who had established FTAs with

⁸²³ Cecilia Albin, 'Can NGOs Enhance the Effectiveness of International Negotiation?' (1999) 4(3) *International Negotiation* 371-387, 377

⁸²⁴ Roxanne Lynn Doty, *Imperial Encounters: The Politics of Representation in North-South Relations*. (University of Minnesota Press 1996) 11

⁸²⁵ I William Zartman and Jeffrey Z Rubin, *Power and Negotiation* (University of Michigan Press 2000) 272

⁸²⁶ Interview with S (anonymised as per request), Chilean former negotiator (Santiago, 16 November 2017)

⁸²⁷ Interview with C (anonymised as per request), Malaysian negotiator, telephone call (4 March 2019)

the United States. While Malaysia appeared more subdued to external actors as discussed above, there is no evidence that this occurred at the negotiating table. While Malaysia did not mention biologics in the closing press conference after the Atlanta Ministerial (unlike Chile),⁸²⁸ Malaysia did maintain strong opposition towards a 12-year period of biologics exclusivity as initially presented by the United States.

One of the key external precipitants of the departures was learning from Public Citizen that there were proposals in the United States to amend their own law to reduce the 12-year exclusivity period to less years. A former negotiator elaborated, “Public Citizen was very hardworking in developing a lot of documents that could help negotiators... there were many that served us while we were making our decisions on the table.” U.S. domestic disagreements about the duration of biologics exclusivity was a key piece of information that influenced the decisions of the Chilean negotiators and government officials: “President Obama wanted to reduce from (sic) the 12 years. As far as I know there is still some bill in the U.S. Chambers about the reduction. It seems that that was the reason why (the biologics proposal) was (came) so late in the negotiations.”⁸²⁹

The economic situation of the state – i.e. its economic reliance on China over the U.S., and established market access deals – combined with public health realities on the ground such as high out-of-pocket expenditure for pharmaceuticals, and stretched pharmaceuticals budget, also may explain Chile’s strong stance against 12 years’ biologics exclusivity. These would be categorized as external precipitants according to the turning points analysis.

The negotiators also benefited from substantive precipitants in the form of internal reports and structured analysis from the Ministry of Health. Notably, the report stated that due to the fact that there is no price containment or price regulation of pharmaceuticals in Chile, that the 12 years exclusivity would be harmful for Chilean health. A government official elaborated: “We did an analysis that shows that for every year of extension, the financial impact was very high. It was a *very red line*.”⁸³⁰

Negotiators also stated that learnings from other negotiators were important. They developed relationships where it was possible to sit down and share experiences – including on

⁸²⁸ USTR, ‘Transcript of the Trans-Pacific Partnership Atlanta Ministerial Closing Press Conference’ USTR (5 October 2015) <<https://ustr.gov/about-us/policy-offices/press-office/speechestranscripts/2015/october/transcript-trans-pacific>> accessed 30 April 2019

⁸²⁹ Interview with E (anonymised as per request), government official who attended negotiation rounds (Santiago, 15 November 2017)

⁸³⁰ Interview with T (anonymised upon request), Chilean government official (Santiago, 16 November 2017)

implementation of different IP provisions in-country. Chief Negotiators from other countries had also called upon Chilean IP negotiators to explain the impact of certain IP provisions.⁸³¹

In Guam, negotiators accepted that they would have to agree to some form of biologics exclusivity, and thus worked on ensuring there were safeguards or limitations enshrined in the main text. Chile was unable to obtain this in the main text, and instead obtained the 'window period' safeguard as an annex. U.S. Congressional approval, or 'certification', was an essential reason cited:

[The United States] didn't want any kind of language that would undermine the general standard. The usual reason that the U.S. would give is that their stakeholders would withdraw support in Congress for the approval of the treaty. And that pharma is a big industry for the USTR and for the U.S. Congress and therefore, the discussion was not on a theoretical level. It was not about whether we need exceptions and limitations or not, because under U.S. law they have a lot of exceptions and limitations in their pharmaceutical sector, but rather about how we can maintain support for the agreement when they needed to fulfil all their Congressional standards for approval.⁸³²

Aforementioned is the fact that the TEAM initiative⁸³³ was open to incorporating window periods as a safeguard, and as a U.S.-proposed provision, this may in itself have been a tradeoff to accepting an explicit provision on biologics, even if the number of years of exclusivity was perceived to be no different to domestic laws, and even if Malaysia and Chile perceived the window period to be a gain for their nations. In considering tradeoffs in the next Section of this Chapter, it is useful to note the comments of the then-U.S. trade representative Michael Froman, that the TPP was 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'.⁸³⁴ The tradeoffs may not have been for tangible goods such as dairy products, but rather the tradeoff may have been hinged on a perceived status quo, when in fact the agreement established a powerful precedent for the United States to move forward on.

d) Political economy tradeoffs: results from the turning points analysis of empirical data

Mentioned in previous chapters, IP is never negotiated in a silo, but rather in the context of other topics, for example market access or perceived technology transfer gains.⁸³⁵ Also

⁸³¹ Ibid

⁸³² Interview with C (anonymised as per request), Chilean negotiator (Santiago, Chile, 17 November 2017)

⁸³³ USTR (n 72)

⁸³⁴ USTR (n 809)

⁸³⁵ Pugatch (n 20) 57

discussed in prior chapters and elsewhere in this chapter is the idea that tradeoffs may not be explicitly clear as a barter-type situation, for example, the widely publicised situation in the TPP with New Zealand's deal for dairy market access provided a deal on biologics exclusivity.⁸³⁶ This less tangible aspect manifests itself as 'perceived tradeoffs', as seen in an unclassified U.S. Department of Commerce document on Dominica's perceived shortcomings in its application of the TRIPS Agreement:

It could either support the interests of a small group of IPR pirates, or support the interests of the free trade zone exporters who could be hurt by trade sanctions if adequate IPR legislation is not passed and implemented.⁸³⁷

In that sense, the U.S. as the demandeur of biologics exclusivity, would present to the opponent either/or scenarios that would 'limit the range of alternatives open to the opponent'.⁸³⁸ In order, this section will discuss i) wins sought by the United States, Malaysia, and Chile; ii) any tangible tradeoffs; and iii) perceived tradeoffs. Firstly, the United States sought to win extended exclusivity for biologics. This began with the initial proposal of 12 years and eventually culminated in a provision the U.S. interpreted as 8 years. They also sought to establish, for the first time in any free trade agreement, explicit reference to biologics exclusivity so they could export the standard into other agreements and establish a new universally accepted intellectual property norm. Whereas Malaysia and Chile wanted to maintain a 5-year period of exclusivity as contained in their domestic laws.

At the Atlanta deadlock there were a number of final attempts by the United States to get countries allied on biologics to concede. While there is little granularity on what exactly these offers were, it was clear that these had created discomfort among intellectual property negotiators, and a resolve to not make any tradeoffs on biologics:

[T]here were a lot of *take it or leave it propositions* on issues of bilateral importance with the U.S. and there were a lot of unhappy people at the end in the IP group... essentially it made everyone more determined to hang tough on biologics. [Emphasis added].⁸³⁹

In the closing press conference of the deadlocked Atlanta round, Chile's Minister for Trade, Andrés Rebolledo, stated:

⁸³⁶ Reuters in Atlanta, 'TPP Trade Deadlock: Pacific Countries Near Deal After Biotech Breakthrough' *The Guardian* (4 October 2015) <<http://www.theguardian.com/business/2015/oct/04/tpp-trans-pacific-partnership-pacific-countries-pharmaceuticals>> accessed 29 December 2015

⁸³⁷ Department of Commerce, 'Dominican Congressional Leaders Claim They Want TRIPS-Compliant IPR Legislation, but Will They Make the Necessary Fixes?' (Unclassified) (18 November 2004)

⁸³⁸ Brian H Tracy and Haus Rissen, 'Bargaining as Trial and Error: The Case of the Spanish Base Negotiations 1963-1970' in I William Zartman (ed), *The Negotiation Process: Theories and Applications* (SAGE Publications 1978) 195

⁸³⁹ Interview with Rex (anonimised as per request), former IP negotiator (interview conducted over Skype, 20 September 2018)

(The) biologics issue is – was one of the most sensitive issues in the negotiations, at least in the case of Chile. It was an exhaustive negotiation during the entire process, but also during this round. In the case of Chile, we are very pleased with the final result. We really think that we have a balanced result. *We are going to maintain our internal regulation in data protection, and also we are going to keep the regulation we already have in the previous free trade agreement.*⁸⁴⁰ [Emphasis added.]

For Chile, therefore, this was a win and there were no particular tradeoffs on biologics, as they had interpreted the finalised biologics provision to mean that there was five years exclusivity instead of the U.S. perception of 8 years. Furthermore, given established market access deals in previous trade agreements with all TPP countries and a strong trade relationship with China, unlike New Zealand, Chile did not have a specific market access concession for biologics exclusivity in particular.

Malaysia was in a weaker position in terms of market access. According to Malaysia's Chief Negotiator, J Jayasiri, access to US markets (for textiles and the automotive sector),⁸⁴¹ good governance, the visibility aspect of attracting foreign investment, were seen as key objectives and gains from joining the TPP.⁸⁴² As seen in Section II(a) above, government officials also saw the TPP as an opportunity to increase transparency on government procurement and address some of the problems of cronyism in government tender systems; problems that were difficult to reform solely as a result of domestic initiatives and pressures. Similar motives have been documented elsewhere, for example in regard to Mexican negotiators being less concerned with market access in the NAFTA, but were rather motivated by the desire to 'tie their own hands' on domestic reforms.⁸⁴³

At the same time, the recognition of Malaysia's *bumiputera* policies, the exemption of halal certification from being considered as technical barriers to trade, and safeguarding access to medicines were considered key red lines.⁸⁴⁴ There are a number of questions to consider, some within the realm of this thesis and some without. What tradeoffs were perceived to be 'worth it', what Malaysia was not willing to tradeoff, and how it ensured its red lines were defended. Basically, in the context of biologics, was the final standard, i.e. 5 or 8 years of

⁸⁴⁰ Andres Rebolledo, in < <https://ustr.gov/about-us/policy-offices/press-office/speechestranscripts/2015/october/transcript-trans-pacific>> accessed 12 February 2019

⁸⁴¹ John O'Callaghan, "Solid Progress" at Pacific Trade Talks but No Quick Japan Entry' Reuters (Singapore, 13 March 2013) < <https://www.reuters.com/article/us-trade-asiapacific/solid-progress-at-pacific-trade-talks-but-no-quick-japan-entry-idUSBRE92C04Q20130313>> accessed 12 February 2019

⁸⁴² Stephanie Jacob, 'TPP "Access Window" a Win for Malaysia: Jayasiri' *KiniBiz* (Kuala Lumpur, 26 November 2015) <<http://www.kinibiz.com/story/corporate/202963/tpp-access-window-a-win-for-malaysia-jayasiri.html>> accessed 12 February 2019

⁸⁴³ Conconi and Perroni (n 169) 615

⁸⁴⁴ Jacob (n 842)

exclusivity for biologics, deemed worth it in the name of U.S. market access and tying one's hands on government procurement?

The concluding sentiments on market access were fragmented. At the conclusion of the TPP, Jayasiri, the Chief Negotiator, stated that Malaysia obtained 'most of what it wanted' out of its trading partners.⁸⁴⁵ Analysis commissioned by MITI found that for textiles, products that met the 'yarn forward'⁸⁴⁶ rule of origin were 'likely to be more competitive' as there would be a 10% import duty reduction across all product types, resulting in approximately \$46.6 millions of savings.⁸⁴⁷ The report also stated that 87% of total textile exports to Canada would see duty elimination under the TPP, but that access to the United States would be compromised by preferential zero tariff and no yarn forward rules for non-TPP countries such as Haiti and Jordan.⁸⁴⁸ For automotive components, Malaysia sought a reduction in tariffs into the United States, Mexico, and Canada. Analysis found that tariff reduction in this sector would benefit component manufacturers, but did not specify whether these tariff reductions were for the aforementioned target markets. The report additionally identified potential barriers to entry due to differences in standards, to which the U.S. and Canada indicated their interest for technical cooperation and capacity building in Malaysia, which could potentially lead to a harmonisation of standards.⁸⁴⁹

This type of capacity building is categorised by Singh as 'moral largesse', or in other words assurances in lieu of concrete tariff reductions as a way to placate the developing country.⁸⁵⁰ It is perhaps due to these considerations that in an interview for this PhD, a Malaysian government official who formerly oversaw the talks stated:

Market access was the last bit to be negotiated and at the end it was a shallow agreement when it came to market access. But the parties accepted it on condition that we would do better in the review process.⁸⁵¹

It should be noted that market access gains were not negotiated in the context of biologics a la New Zealand. The Malaysian negotiator stated:

⁸⁴⁵ *ibid*

⁸⁴⁶ This rule dictates that all yarn used to form the fabric must originate in a TPP country.

⁸⁴⁷ PWC (n 759)

⁸⁴⁸ PWC (n 759) 152

⁸⁴⁹ PWC (n 759) 200, 203

⁸⁵⁰ Singh (n 710) 375

⁸⁵¹ Interview with B (anonimised as per request), former government official who oversaw TPP negotiations, Malaysia (Facetime, 7 February 2018)

Because for us there is no way in terms of public policy for us to justify (sic). Which is why you will never find, any negotiators from Malaysia that would say, we will give up 8 years, 12 years biologics for 100% textile or palm oil exports.⁸⁵²

This means that like Chile, there were no tangible market access tradeoffs for Malaysia. However, tradeoffs seem to have manifested themselves differently – for membership of a prestigious trade partnership, Malaysia had accepted specific language on biologics (even if Malaysia did not consider the provision a material change from existing domestic legislation) and a shallow market access deal. The ‘window period’ for companies to register products within 18 months was not seen as a tradeoff by negotiators, but instead as an incentive for early introduction of products to Malaysia’s market, and in fact was an integral part of Malaysia’s domestic legislation. Negotiators further perceived that the window period would have technology transfer benefits:

It’s about incentivising new products to Malaysia’s market, while it may be expensive for a few years, at least the government will have the data and have the ability to access to data, whether the product is safe to be consumed and whether it was really effective for Malaysian people, and at the same time you are creating a corridor for cheaper products, cheaper generics to follow on, to learn, to reverse engineer it, in a way that can provide competition after the test data protection is over.⁸⁵³

In summary, due to established market access deals in previous trade agreements and an effective coalition, there were less political economy tradeoffs and no market access tradeoffs for biologics for Chile. While Malaysia was in a weaker position than Chile due to no established market access deals with the United States, they did not make market access tradeoffs. However, while not directly traded off for specific language on biologics, Malaysia accepted a substandard market access deal and increased regulations as the price for being part of the TPP.

Additionally on political-economic factors that motivated tradeoffs; in Chapter 1 I detailed how it would be intriguing to see if negotiators took into account biotechnological development in both Chile and Malaysia as a reason to increase monopolies on biologics. This did not come through as a significant factor. As above, the negotiators could not justify an increase in exclusivity periods based on public policy.

⁸⁵² Interview with C (anonymised as per request), Malaysian negotiator, telephone call (4 March 2019)

⁸⁵³ Interview with C (anonymised as per request), Malaysian negotiator, telephone call (4 March 2019)

III. Summary of Findings

We've seen in this Chapter that both Chile and Malaysia perceived that there was no difference between the TPP standards and standards contained in their own laws. From a United States point of view, however, this agreement was to be, before the Trump exit and the modification of the TPP into the CPTPP, the establishing of a new minimum standard on exclusivity on biologics in any trade agreement, and of course that that standard was 8 years and not 5 years as the other countries claimed.

Secondly, albeit having different reactions to the biologics announcement, both Chile and Malaysia ultimately had similar positions – that they would not go beyond existing exclusivity periods in their domestic legislation – i.e. a 'common precedent'. Both were steadfast on their positions throughout and did not make any market access tradeoffs specifically for biologics, unlike some other TPP countries. Over and above the common precedent – Australia, a middle power, was the main driver of discussions around sticking to a 5-year biologics term, and both Chile and Malaysia played a 'defending' role⁸⁵⁴ to Australia.

Thirdly, Malaysia was in a weaker economic position as they wanted access to American markets, whereas Chile had established market access deals through their previous trade agreement with the U.S., and had a stronger trading relationship with China. This may explain Malaysia's more cautious approach to the negotiations – although this may also be due to cultural reasons. In any case, Chile came across more explicitly as having a predetermined agenda, in contrast to the more cautious and measured approach of Malaysia.

Malaysia also saw the agreement as the key machinery through which transparency in government procurement could occur domestically. Chile's keenness on joining was arguably more ideological – they saw the agreement as central to Asia Pacific economic integration with Chile. Ultimately, ideological closeness on access to medicines issues – due to constrained budgets and drug pricing – in combination with the driving force of Australia and reliance on common precedent were cumulatively the main reasons why the keenness to sign and ratify the TPP did not result on tradeoffs on biologics.

While no direct market access tradeoffs (e.g. dairy for biologics) occurred for either Chile or Malaysia, indirect tradeoffs may have occurred solely by virtue of agreeing to have specific biologics language in the text. At least for Malaysia, there were marginal market access gains

⁸⁵⁴ Dupont (n 628) 56-57

to the United States, and promises of cooperation, technology transfer, and harmonisation, which are less tangible trade gains.

IV. Conclusion

This chapter highlights the approaches of two diverse upper middle-income countries to intellectual property demands and potential tradeoffs. Within the conceptual toolbox, it drew upon a turning points analysis and negotiation theory to understand whether tradeoffs were made and what political economy imperatives underlay those decisions. Within plurilateral trade agreements where there is asymmetry, developing nations and emerging markets use a multitude of tools to prevent tradeoffs on specific red lines, but success of these interventions still is very dependent on the prowess of a middle power.

This is not to undermine the power of reliance on a 'common precedent' – this theory underpinned and created legitimacy and leverage for Australia to drive discussions at the biologics deadlock. Common ideations brought a set of diverse countries, all invested in a ratified Trans-Pacific Partnership, together in a coalition against extended exclusivity for biologic drugs. It does, however, raise the question of what would have happened had Australia not been in the negotiations – would there have been direct tradeoffs for biologics? In the following pages, i.e. the final chapter in this thesis, I discuss the role of Australia in the ultimate biologics result, and analyse reasons underpinning the findings above.

Chapter Six

Analysis of findings, implications, lessons for developing countries, and future research

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I. Analysis

Findings in the penultimate chapter sought to answer the question: *How do upper middle-income countries strategise for, respond to, engineer, and justify political economy tradeoffs to maximalist intellectual property provisions that they may not necessarily agree to?* A brief summary of the findings shows that there were no direct tangible market access tradeoffs for the biologics exclusivity provision, and that this was the result of a number of political economy factors, including impossibility of justifying long exclusivities on public health grounds, and existing market access deals reducing the need for concessions on intellectual property. As to how these upper middle-income countries strategised on biologics intellectual property demands – they formed coalitions and relied on common precedent, as well as were strategic in allowing a middle power, i.e. Australia, to lead discussions with the United States in advancing their common position.

The findings are consistent with established literature that coalitions are a key tool for moving past an impasse and moving closer to consensus,⁸⁵⁵ and that binding negotiators' hands with domestic legislation (i.e. common precedent) improves bargaining power and reduces the likelihood of significant political economy tradeoffs.⁸⁵⁶ In that sense relying on Putnam's two-game theory to underline my approach made sense – negotiators relied on the domestic circumstances to bind their hands at the international stage, and that per Schelling's conjecture this created a notion that these countries had very little negotiation slack, thus had more bargaining leverage. However, as results emerged from my analysis, it became clear that reliance on these alone did not illustrate the full picture. This analysis fills the gap in the initial proposed methodology.

a) How Negotiation Tactics Modify Asymmetry in Negotiations

This thesis involved the United States demanding extended intellectual property exclusivities for biologics from negotiating partners with less bargaining leverage. The United States has historical regime-making capacity⁸⁵⁷ and economic, military, and political might. Combined with its might in production and in technological know-how, one would say that the United States has structural power,⁸⁵⁸ and therefore are more likely to be able to secure outcomes that they want. However a number of authors posit that countries can employ various tactics to reduce the power differential. In the words of Pfetsch and Landau:

There is a tendency during the negotiation process by the weaker party to reach *functional equality* in its negotiations with the stronger party... Whereas the stronger wants to play out its strength and exploit the asymmetric relationship, the weaker wants to equalise its position and negotiate on the basis of symmetry.⁸⁵⁹ [Emphasis added].

This is indicative of the fact that there can be a modification of symmetry/asymmetry as the negotiation progresses and upon the adoption of various tools. The strength of ideation on a particular red line is known to reduce asymmetry in an agreement.⁸⁶⁰ For example, in security negotiations between a government and rebel groups, while a government may have economic might and international legitimacy, 'the rebels' intense commitment to their cause

⁸⁵⁵ Singh (n 710); Carlo Carraro, Carmen Marchiori, and Alessandra Sgobbi, 'Advances in Negotiation Theory: Bargaining, Coalitions, and Fairness' World Bank Policy Research Working Paper 3642, June 2005

<<http://documents.worldbank.org/curated/en/847051468160502761/pdf/wps3642.pdf>> accessed 18 December 2019; John S Odell, 'Breaking Deadlock in International Institutional Negotiations: The WTO, Seattle, and Doha' (2009) 53(2) International Studies Quarterly 273-299

⁸⁵⁶ Crump (n 705) 87

⁸⁵⁷ Peter Gowan, 'Contemporary Intra-Core Relations and World Systems Theory' (2004) 2 Journal of World-Systems Research 471-500, 476-477

⁸⁵⁸ Strange (n 7) 565

⁸⁵⁹ Frank R Pfetsch and Alice Landau, 'Symmetry and Asymmetry in International Negotiations' (2000) 5 International Negotiation 21-42, 23

⁸⁶⁰ Dupont (n 628) 55

as the single defining mission of their existence creates an obvious challenge to the others' straightforward application of its power... and can create a destabilising effect',⁸⁶¹ and this situation can 'modify' an asymmetrical relationship.

Throughout this thesis bargaining power or leverage is discussed numerous times and at length. But following this notion of common ideation, trade expert Hosuk Lee-Makiyama comments that 'leverage' isn't everything and that there are other forms of negotiating capacity. In his words, the approach enshrined in the P4 (Brunei, Singapore, Chile, and New Zealand, the initiators of the TPP) is to 'build your leverage on the world stage with your ideas and ambitions, rather than your market size. And the world's biggest economies will come to you.'⁸⁶² Undoubtedly this meant that common ideas about market liberalisation and rule harmonisation in a geopolitically strategic region attracted large powers such as the United States and Japan. But it possibly also enabled the countries who were instigators of the TPP to make demands that they wouldn't have been able to had they not embraced common ideologies with the United States in other areas.

Also raised in the previous chapter that Malaysia was aiming for better access into the U.S. market than it at the time had, and Chile had existing market access deals in place with the United States, and had become more economically reliant on China versus the United States. These relation to the notion of there being asymmetric interdependence, i.e. that Malaysia was dependent on the prospective market access offers from the United States and had more to lose. The notion of asymmetric interdependence centres around the idea that the actor that profits less can be less cooperative.⁸⁶³ Perhaps this was evident in Chile's clear and open rejection of U.S. demands on biologics versus Malaysia's more muted approach, but this could also be rooted in cultural differences – Latin American negotiators are known to react with more emotionalism with Asian negotiations generally situated at the other side of the spectrum.⁸⁶⁴ Ultimately the asymmetry in terms of what Malaysia wanted versus what Chile did not need (American market access) did not materially affect the results on biologics. The modification of the asymmetrical relationship had in this case been materially modified as a result of reliance on a common precedent and the coalition led by Australia.

In other words, while a country may not be economically or militarily on a similar level to the opposing side, it can achieve a kind of symmetry for the purposes of the negotiations at hand, or 'functional equality/symmetry'. In the previous chapter, while the United States had the

⁸⁶¹ Harris and Reilly (n 334) 76

⁸⁶² Jonathan de Leyser, 'Forget Leverage: There's a Better Way to Liberalise Trade' Initiative for Free Trade (12 June 2019) <<http://ifreetrade.org/article/renouncingleverageheresabetterwaytoliberalisetrade>> accessed 12 June 2019

⁸⁶³ Robert O Keohane and Joseph S Nye, *Power and Interdependence: World Politics in Transition* (Little, Brown 1977)

⁸⁶⁴ Salacuse (n 779) 232

economic leverage to suggest ‘take it or leave it propositions’⁸⁶⁵ to the other countries, it was apparent that common ideation, common precedent, a strong coalition, and perhaps hostilities that had arisen during the negotiations, had merely led to Australia, Chile, Malaysia, and most other TPP members to strengthen resolve against any tradeoffs. That is to say, in the case of biologics and the TPP, functional equality was advanced through the formation of a coalition, and having a joint position championed by a middle power or nation closer in economic strength (Australia) to the demandeur (United States).

The modification of asymmetry into a more symmetrical relationship can be contextualised in terms of utility. In the words of Pfetsch and Landau, “‘Good’ negotiations between a strong and a weak negotiator are characterised by bringing about satisfactory wins to both parties, hence symmetric outcomes are measured in terms of utility’.⁸⁶⁶ The United States did not achieve its original goal of 12-years exclusivity for biologics, and this was criticised by some pro-pharmaceutical industry Senators.⁸⁶⁷ An optimistic, or diplomatic, American characterisation of the biologics negotiations then emerged. This was evident in the then-U.S. Trade Representative’s response to a journalist at the closing press conference of the negotiations in Atlanta in November 2015. Carter Dougherty, from International Business Times, asked:

[R]egarding the compromises you’ve reached about biologics – or about patents in general: Would you characterize this as has been an effort to ensure that current diversities in national systems of intellectual property can flourish or have you sought to meld something supranational in this context?⁸⁶⁸

Michael Froman, the USTR, responded:

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 lifesaving 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.⁸⁶⁹ [Emphasis added.]

⁸⁶⁵ Interview with Rex (n 839)

⁸⁶⁶ Pfetsch and Landau (n 859) 24

⁸⁶⁷ Needham (n 265)

⁸⁶⁸ Carter Dougherty, in ‘Transcript of the Trans-Pacific Partnership Atlanta Ministerial Closing Press Conference’ *United States Trade Representative* (5 October 2015) < <https://ustr.gov/about-us/policy-offices/press-office/speechestranscripts/2015/october/transcript-trans-pacific>> accessed 22 August 2019

⁸⁶⁹ Michael Froman, in *ibid*

The minimum standard on biologics, had it remained intact, would've been made a requirement in all future trade agreements and exported as an intellectual property norm. In that sense, the agreement had perceived utility to the United States, albeit greatly diminished utility to their original demands. While utility, like the notion of 'national interest', is greatly ambiguous and subjective,⁸⁷⁰ in the context of U.S. perceived utility in this thesis it is taken to mean the idea of maximalist intellectual property being beneficial to the U.S. economy and the financial interests of its moneyed stakeholders, rather than being in the interest of ordinary Americans necessarily.

Back to the notion of utility gained by TPP parties; it was theorised that Congress would've demanded changes to the 5 or 8-year term at the certification stage of the trade agreement, which would've increased perceived utility gained by the United States, but due to Trump's withdrawal this never materialised. The greater utility was arguably won by Australia, Chile, Malaysia, and the other 7 countries in the biologics coalition – there were interpreting it as 5 years and not 8 years, and for countries like Australia, Chile, and Malaysia, this means that they did not have to enact any modifying legislation. What was modified was the initial situation of asymmetry between the United States and Japan, and everyone else.

b) Changing global philosophy on access to medicines

The outcome that no material tradeoffs were made in negotiations for intellectual property on biologics requires some context. Over decades the international rulemaking scene has seen declining hegemony by certain nation states and the rise of the emerging market economies in shaping international regimes. Pfetsch and Landau describe how the EU, Turkey, South Korea, and other nations of varying developmental levels were strongly opposed to liberalisation in agriculture in the Uruguay round, stating that 'in international economic negotiations, the North-South cleavage is not always manifest'.⁸⁷¹ Nor is the North-South cleavage necessarily manifest in international negotiations outside the strictly economic sphere – relevant to this thesis are negotiations on a drug pricing transparency resolution at the World Health Assembly in 2019, where Italy, Malaysia, the Russian Federation, South Korea, Spain, South Africa, Uganda, Eswatini, and other countries co-sponsored a resolution to increasing transparency on drug research and development.⁸⁷² Another example is the

⁸⁷⁰ Donald E Nuechterlein, 'National Interests and Foreign Policy: A Conceptual Framework for Analysis and Decision-Making' (1976) 2 *British Journal of International Studies* 246-266, 246-247

⁸⁷¹ Pfetsch and Landau (n 859) 26

⁸⁷² World Health Organization, 'Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products' (A72/A/CONF./2 Rev. 1) 28 May 2019 < http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72ACONF2Rev1-en.pdf > accessed 20 August 2019

Cairns Group – which some have described as ‘difficult to classify in terms of the traditional geopolitical criteria of North, South, East, and West’⁸⁷³, and included countries such as Australia, Chile, Malaysia, New Zealand and Uruguay, and represented a united front on numerous issues related to agriculture.

The United States, somewhat unexpectedly, supported the WHO resolution, raising general questions about a shift in philosophy on drug pricing and access to medicines globally, and even manifesting in the diplomatic decisions of nations known to advance policies that are engineered to increase profitability of pharmaceutical medicines. To elaborate, high drug prices are no longer a developing country problem, with patients having to form buyers’ clubs in the United Kingdom to access the cystic fibrosis drug Orkambi,⁸⁷⁴ patients dying due to substitution of originator insulin in the United States,⁸⁷⁵ and CAR-T cancer therapy for cancers being priced at €320,000 per patient in Germany.⁸⁷⁶ The predominant view is that these high prices result from an intellectual property system that enables the lengthening or ‘evergreening’ of patents and other monopolies, and other forms of patent abuse⁸⁷⁷ and the notion that high drug prices are needed to sustain innovation of future drugs,⁸⁷⁸ with minority views that high prices are due to levies, a lack of direct price controls, import licences that discriminate against foreign companies rather than the intellectual property system,⁸⁷⁹ and the industry view that poverty and a lack of health infrastructure is the root cause of a lack of access to medicines, rather than high prices.⁸⁸⁰

⁸⁷³ Higgott and Cooper (n 629) 590

⁸⁷⁴ Sarah Boseley, ‘Families Create Buyers Club for Cut-Price Cystic Fibrosis Drug’ *The Guardian* (4 June 2019) <<https://www.theguardian.com/society/2019/jun/04/families-create-buyers-club-for-cut-price-cystic-fibrosis-drug>> accessed 20 August 2019

⁸⁷⁵ Ritu Prasad, ‘The Human Cost of Insulin in America’ BBC News (14 March 2019) <<https://www.bbc.co.uk/news/world-us-canada-47491964>> accessed 20 August 2019

⁸⁷⁶ James Paton, ‘A Breakthrough Cancer Drug Has Been Approved. Now Comes the Battle Over the Price’ *Bloomberg* (12 September 2018) <<https://www.bloomberg.com/news/articles/2018-09-12/novartis-faces-price-tussle-in-europe-after-cancer-breakthrough>> accessed 20 August 2019

⁸⁷⁷ Tahir Amin, ‘The Problem with High Drug Prices Isn’t ‘Foreign Freeloading’, It’s the Patent System’ CNBC (27 June 2018) <<https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html>> accessed 20 August 2019; I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices* (2018); Ashley Newsome, ‘Side Effects of Evergreening May Include Decreased Competition & Increased Prices in the Pharmaceutical Industry’ (2017) 45(4) *AIPLA Quarterly Journal* 791-822; UN Secretary-General’s High-Level Panel on Access to Medicines, *Report of the UN Secretary-General’s High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* (2016); Ayalew Tefferi et al., ‘In Support of a Patient-Driven Initiative and Petition to Lower the High Price of Cancer Drugs’ (2015) 90(8) *Mayo Clinic Proceedings* 996-1000; Hagop Kantarjian et al., ‘High Cancer Drug Prices in the United States: Reasons and Proposed Solutions’ (2014) 10(4) *Journal of Oncology Practice* e208-e211.

⁸⁷⁸ Ezekiel J Emanuel, ‘Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up’ *The Atlantic* (23 March 2019) <<https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/>> accessed 25 September 2019

⁸⁷⁹ Richard P Rozek and Ruth Berkowitz, ‘The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries’ (1998) 1(2) *Journal of World Intellectual Property* 179-244

⁸⁸⁰ David Rosenberg, GlaxoSmithKline, Submission to the UN Secretary-General’s High Level Panel on Access to Medicines (27 February 2016) <<http://www.unsgaccessmeds.org/inbox/2016/2/27/david-rosenberg-on-behalf-of-glaxosmithkline>> accessed 25 September 2019; Martin Bernhardt, Sanofi, Submission to the UN Secretary-General’s High Level Panel on Access to Medicines (28 February 2016) <<http://www.unsgaccessmeds.org/inbox/2016/2/28/martin-bernhardt>> accessed 25 September 2019

Concerns about intellectual property as a driver of high prices has long been evident in developing country diplomatic discourse.⁸⁸¹ Results from this thesis do not show that negotiators explicitly and predominantly framed their biologics negotiations from the viewpoint of public health imperatives, but rather with the central message that they would not go beyond what was in domestic law, and they wanted the United States to justify why extended exclusivities were necessary. There is plenty to indicate, however, that their messaging was underlined by public health imperatives, or that public health imperatives were somehow implicit. Chilean negotiators, from DIRECON,⁸⁸² for example, made clear to the United States from the beginning that they would not go beyond what was in their existing trade agreement with the U.S. Advisors within the government agencies stated that:

Our immediate reaction was that we didn't want to go for it. That we wanted to stay with our 5 years and not more... we thought that was enough for protecting any kind of pharmaceutical, synthetic or biologic. Because that was what we provided internally. So, we didn't want to go beyond the five years.⁸⁸³

We did an analysis that shows that for every year of (biologics exclusivity) extension, the financial impact was very high. It was a very red line.⁸⁸⁴

Whereas Malaysian negotiators said that there was no way to public policy reason to justify increasing the duration of exclusivity. While negotiators did not refer to the sea change in how global philosophies on drug pricing and access to medicines affected discourse, and more likely relied on knowledge on domestic access to medicines concerns, it would be amiss to say that these developments didn't lubricate the process. Civil society representatives, including the international humanitarian medical organisation *Medécins Sans Frontières*, access to medicines teams from U.S.-based public interest NGO *Public Citizen*, and myself from the Malaysian HIV charity, the Malaysian AIDS Council, were present at many negotiation rounds, presenting consistent messaging and data about access to medicines and effects of extended intellectual property globally. Domestic press, including in Australia, through the negotiations highlighted threats of the TPP to access to medicines, including to the Australian Pharmaceutical Benefits Scheme.⁸⁸⁵ In addition, reviews commissioned by the

⁸⁸¹ Ilona Kickbusch, Gaudenz Silberschmidt, and Paolo Buss, 'Global Health Diplomacy: The Need for New Perspectives, Strategic Approaches and Skills in Global Health' (2007) 85(3) *Bulletin of the Global Health Organisation* 230-232, 231; Reddy T Prashant, 'TRIPS and TRIPS-Plus Development in India' in Daniel Gervais (ed), *Intellectual Property, Trade, and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford University Press 2014)

⁸⁸² Then the *Dirección General de Relaciones Económicas Internacionales* (Directorate General of International Economic Relations), now the SUBREI or *Subsecretaría de Relaciones Económicas Internacionales* (Subsecretariat of International Economic Relations) in the Ministry of Foreign Affairs, Chile.

⁸⁸³ Interview with I (anonymised upon request), Chilean government official (Santiago, 14 November 2017)

⁸⁸⁴ Interview with T (anonymised upon request), Chilean government official (Santiago, 16 November 2017)

⁸⁸⁵ Belinda Townsend, Deborah Gleeson, Hazel Moir, Joel Lexchin, and Ruth Lopert, 'Time for Costly Medicines Monopolies to Go From TPP Trade Talks' *The Conversation* (9 November 2017) <<http://theconversation.com/time-for-costly-medicine-monopolies-to-go-from-tpp-trade-talks-87176>> accessed 22 August 2019

Australian government found that extension of exclusivity periods for biologic drugs were unnecessary, stating that exclusivity ‘appears to have little impact on the levels of pharmaceutical investment’.⁸⁸⁶ These are all indications that the idea of excessive intellectual property negatively impacts access to medicines having been accepted by governments as somewhat of a norm versus claims only posited by developing nations and/or activists.

c) Where is trade-related intellectual property law going?

As far as biologics IP within trade agreements, at least for the foreseeable future, not far. When Trump pulled the United States out of the TPP and the agreement morphed into the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), the remaining 11 countries agreed to suspend a number of provisions, including that on biologics exclusivity.⁸⁸⁷ Because the TPP, and subsequently the CPTPP by default, was intended to be the standard setting agreement on biologics exclusivity, when the suspensions were made, it was necessary for pharmaceutical industry lobbyists to set their sights on another agreement. This opportunity came about when U.S. President Donald Trump announced that he wanted to renegotiate the North American Free Trade Agreement (NAFTA).⁸⁸⁸

Rebranded as the USMCA (U.S.-Mexico-Canada Agreement), at time of writing the deal concluded without incorporation of biologics exclusivity, as aforementioned.⁸⁸⁹ In trying to understand the context of why, I interviewed Lori Wallach, the Director and Founder of Global Trade Watch, a division of the Washington D.C.-based consumer interest group Public Citizen. Significant, she said, was that Nancy Pelosi, who has historically voted for trade agreements containing TRIPS-plus provisions, appointed 8 Representatives to be a part of a working group charged with negotiating changes with the Trump administration.⁸⁹⁰ This working group included Reps. Rosa DeLauro (D-Connecticut) and Jan Schakowsky (D-Illinois), who have been allied with consumer groups on a number of drug pricing issues. According to Wallach:

⁸⁸⁶ Tony Harris, Dianne Nicol, and Nicholas Gruen, 2013 *Pharmaceutical Patents Review Report* (Commonwealth of Australia, 2013) 160

⁸⁸⁷ Australian Government, ‘CPTPP Suspensions Explained’ (Department of Foreign Affairs and Trade, January 2019) <<https://dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions-explained.aspx>> accessed 24 August 2019

⁸⁸⁸ Richard Partington, ‘Nafta: What Is It and Why Is Trump Trying to Renegotiate?’ *The Guardian* (30 August 2018) <<https://www.theguardian.com/us-news/2018/aug/30/nafta-what-is-it-why-is-trump-trying-to-renegotiate>> accessed 24 August 2019

⁸⁸⁹ CBS News (n 286)

⁸⁹⁰ Adam Behsudi, ‘USMCA Working Groups Get To It’ *Politico* (14 June 2019) <<https://www.politico.com/newsletters/morning-trade/2019/06/14/usmca-working-groups-get-to-it-447295>> accessed 24 August 2019

Speaker Pelosi's appointment of strong consumer allies on the committee to negotiate with the administration about changes to the revised deal Trump signed is a big deal, and means that there will either be major fixes or no deal with the administration on USMCA.⁸⁹¹

On whether biologics was a significant factor in the opposition to the USMCA text as is, Wallach explained:

The medicine IP issue and the changes demanded from the Dems are not just (related to) biologics, although that is a big issue... Yes, the entire article providing special protections for biologics will have to be cut. But the Democrats also are insisting on changes relating to patent evergreening and more. The administration has seemed pretty resigned to having to rollback the IP chapter in significant ways.⁸⁹²

In a sense this part of the Chapter relates very much to subsection (b) above – drug pricing issues in the United States and elsewhere have reached the general public, much due to the unrelenting and united focus by congressional Democrats in the past two electoral cycles and the persistent work of civil society such as Public Citizen and local activists. As well, district-by-district political work has changed the House Democrats' voting positions on trade.⁸⁹³ Trade-related IP may be doomed – pharmaceutical lobbyists may have to 'forum shift'⁸⁹⁴ away from trade agreements to advance IP on biologics and therapies of the future like gene therapies. Forum shifting has been the traditional route for IP demandeur countries – for example when it was too difficult for the United States to advance IP through the WTO, it shifted to bilateral and plurilateral trade agreements, or an earlier example where the U.S., finding that it was not gaining sufficient mileage on intellectual property maximalisation in WIPO in 1986, increased efforts into the Uruguay Round of GATT negotiations.⁸⁹⁵

This created a type of fragmentation which 'provides powerful states with the opportunity to abandon - or threaten to abandon - any given venue for a more sympathetic venue if their demands are not met'.⁸⁹⁶ But these threats vis-à-vis pharmaceutical IP in trade at the moment do not have a sympathetic venue, and are unlikely to find one. As Lori Wallach surmises,

I think it will be harder politically for future US administrations to put outrageous meds IP stuff into trade agreements... we did focus groups and polls in late 2018 and learned that *both* Trump

⁸⁹¹ Interview with Lori Wallach, Director, Global Trade Watch, Public Citizen (via email, 12 August 2019)

⁸⁹² *ibid*

⁸⁹³ *ibid*

⁸⁹⁴ Gathii and Ho (n 400) 429

⁸⁹⁵ Sell describes this as a 'forum shift', but technically the U.S. did not completely shift out of WIPO, but retained a presence in one forum and opened up efforts in another. Susan K Sell, 'TRIPS was Never Enough: Vertical Forum Shifting, FTAs, ACTA and TPP' (2011) 18(2) *Journal of Intellectual Property Law* 447-478, 450

⁸⁹⁶ Eyal Benvenisti and George W Downs, 'The Empire's New Clothes: Political Economy and the Fragmentation of International Law' (2007) 60 *Stanford Law Review* 595-632, 597

and Clinton voters were infuriated to know the revised NAFTA was “rigged by pharma” and could lock in high medicine prices. The meds price/pharma giveaways issue was the only one that moved people across all political, gender, geographic demographics.⁸⁹⁷

What this means for political economy tradeoffs for trade-related IP is that developing nations and emerging markets can rely on a host of tactics and arguments to not have to make them. This does not, however, mean that countries negotiating trade agreements shouldn't be vigilant. New forms of therapies, for example CAR-T, where a patient's T-cells are modified using CRISPR technology to attack their own cancer cells, have numerous patent applications being applied for despite legal and scholarly discussion on whether these cells are novel or whether in fact they are drugs, rather than methods of medical treatment.⁸⁹⁸ The categorisation of CAR-T as one or the other would potentially restrict the number of patents applicable and/or change the shape and form of trade-related IP provisions. Despite a persisting lack of clarity on patents and cell/gene therapy, as a presentation from James Packard Love at the WIPO Standing Committee on the Law of Patents indicates, there is a clear upsurge of the number of patent applications with the term CRISPR in them, i.e. from only two applications in 2008 to 1380 applications in 2018.⁸⁹⁹ The CAR-T market alone is predicted to grow to \$8 billion worldwide in 2028.⁹⁰⁰ As described earlier, pharmaceutical or medicines IP evolves with the market. But given recent visibility on drug pricing debates, the path to further IP will not be easily gained through trade. If patents for these new therapies cannot be advanced through trade agreements, and especially so because of the exorbitant prices attached to them,⁹⁰¹ perhaps what developing countries need to be wary of is adoption of IP through ‘harmonisation exercises’, or through technical cooperation agreements.

⁸⁹⁷ Wallach (n 891)

⁸⁹⁸ Luis Gil Abinader and Jorge L Contreras, 'The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around the World' (2019) 34(4) *American University International Law Review* 705-762, 708

⁸⁹⁹ James Love, 'Exceptions for Inventions Involving the Treatment of Humans' *Knowledge Ecology International* (6 December 2018) <<https://docs.google.com/presentation/d/e/2PACX-1vRaOrCX5z9C60yiJR22INgvW563w7ZFxcg0qI0mgDeevkKSD0NUR-K0I9glvqGNqBiuh1QSXZ6IQHh/pub?start=false&loop=false&delayms=10000&slide=id.g49a8144848015>> accessed 28 August 2019

⁹⁰⁰ Jeannie Baumann, 'Breakthrough Cancer Therapy Stalls in Manufacturing Bottleneck' *Bloomberg Law* (12 February 2019) <<https://news.bloomberglaw.com/pharma-and-life-sciences/breakthrough-cancer-therapy-stalls-in-manufacturing-bottleneck>> accessed 28 August 2019

⁹⁰¹ One CAR-T therapy, Kymriah, for paediatric leukemia, is priced at \$475,000 per dose. Samantha DiGrande, 'UK Knocks Down Yescarta as CAR T Therapy Gains European Authorization' *AJMC* (28 August 2018) <<https://www.ajmc.com/newsroom/uk-knocks-down-yescarta-as-car-t-therapy-gains-european-authorization>> accessed 28 August 2019

II. Implications and wider contribution

a) The new political economy of pharmaceutical intellectual property law

Previous scholarship on political economy tradeoffs in intellectual property have referred to how negotiators balance between the need to provide more intellectual property with the intention to stimulate innovation, but having to tradeoff on lower prices of goods and innovation downstream,⁹⁰² and that domestic intellectual property policies are influenced very much by international commitments and external pressures, such as membership of the WTO, dependence on the United States, or threats from the United States in the form of the Special 301,⁹⁰³ the latter two which I've discussed elsewhere in this thesis. Shadlen, Shrank, and Kurtz called this the *new* international political economy of intellectual property,⁹⁰⁴ and analyse propensity of intellectual property protection using a number of metrics, including a measure of R&D scientists per 1,000 inhabitants of the country.⁹⁰⁵

This thesis identified the negotiators' own metrics for accepting or not accepting maximalist intellectual property on biologics – notably a lack of public policy space to justify concessions on IP and Ministry of Health objections to further maximalisation. Underlying this is the political-economic explanation that Shadlen et al. refer to above, i.e. the international commitments and developments that created an environment where the notion of accepting more intellectual property was simply not worth it. These international developments were namely the sea change in visibility of drug pricing and access to medicines issues. These factors constitute the new international political economy of *pharmaceutical* intellectual property.

In other words, the implication of this is that the United States and other notable demandeurs of maximalist trade-related intellectual property such as Japan and the EU can no longer carry on as usual trying to establish global minimum standards simply because there are ongoing debates at home about pricing and accessibility of these medicines and increasing attention on the levels and appropriateness of IP to stimulate innovation. And for developing countries and emerging markets, this means that utilising public policy concerns, including drug pricing, in avoiding needing to make tradeoffs, are likely to be less encumbered.

⁹⁰² Kenneth C Shadlen, Andrew Shrank, and Marcus J Kurtz, 'The Political Economy of Intellectual Property Protection: The Case of Software' (2005) 49 *International Studies Quarterly* 45-71, 50

⁹⁰³ *Ibid* 48, 58

⁹⁰⁴ *Ibid* 48

⁹⁰⁵ *Ibid* 59

b) Theoretical contribution on 'common precedent'

International relations theorists introduced the notion of negotiators relying on precedent to bind their hands at the negotiating table. Defined as 'past behaviours or events that guide or dictate present positions', examples include Chileans pre-emptively incorporating more lenient European standards on financial services, so when up against the United States, they had established precedent to show what they would not go beyond.⁹⁰⁶ There is also the example of U.S. navy ships being literally rammed by Soviet ships and pushed into international waters as the precursor of a bilateral agreement on interpretation of right of free passage, and this being a precedent for how negotiations should be approached with China on similar conflicts in the South China Sea.⁹⁰⁷

Both of these examples of how creating or relying on an established precedent can be used as a defence against modified or increased demands on similar issues – but both of these examples pertained to bilateral agreements. In plurilateral environments, such as the TPP or the TTIP, one party relying on a domestic law or policy will not have the similar gravitas that it would have in a bilateral agreement. As such, negotiating parties in this type of agreement have to undertake research to determine whether there are commonalities with other countries, in the hope that they can establish a coalition and add on to the bargaining leverage that a precedent can create. In this case, at least five countries – Australia, Malaysia, Chile, New Zealand, and Singapore, had 5 years of data exclusivity in domestic laws, policies, or regulations. Especially when trying to modify asymmetry as discussed in Subsection I(a) above, realising and effectively applying this 'common precedent' increases bargaining leverage.

III. Lessons for developing countries

From the above analysis, there are a number of lessons that can be gleaned for developing countries. Lessons for developing countries, however, differ depending on the developmental levels and socio-political realities. There is some discomfort with the use of the term 'developing countries' – as Georgalakis notes there is broad diversity in income levels in this group with countries like Malawi (GNI per capita of \$320) and Mexico (\$8,610) and 'ignores the multidimensional nature of poverty'⁹⁰⁸ and indeed these countries are bound to have very different economic and political needs in trade. Small and Vulnerable Economies (SVEs) such

⁹⁰⁶ Crump (n 705) 87

⁹⁰⁷ Siniša Vuković and Riccardo Alfieri, 'Bumping, Precedents, and De-escalation in South China Sea: Options for the United States and China' (2018) 5 *Asia & The Pacific Policy Studies* 665-671, 668

⁹⁰⁸ James Georgalakis, 'Is There Still Such a Thing as a Developed Country?' (*Institute of Development Studies*, 22 June 2016) <<https://www.ids.ac.uk/opinions/is-there-still-such-a-thing-as-a-developing-country/>> accessed 16 May 2019

as Guatemala and Cuba⁹⁰⁹ are have differing needs, capacity, and approaches to political economy tradeoffs and face 'structural barriers to participating in global trade on the same terms'⁹¹⁰ different to those that middle powers, or even non-BRICS emerging markets such as Chile and Malaysia, face. For the purposes of this thesis, I focus predominantly on middle income countries that may already have forms of intellectual property incorporated in domestic law, and who have some economic leverage.

These lessons, based on the above analysis, are as follows:

a) **Anticipate and prepare for IP for new types of therapies.**

Medicines, therapies, and other health technologies are moving away from small molecule structures and will increasingly be of biologic origin, include gene- and cell-based therapies. This will attract different forms of IP that traditional IP demandeurs will seek to have incorporated in enforceable agreements. As discussed above, these may no longer be trade agreements – but may be negotiated by way of soft diplomacy or in other types of agreements;

b) **Enact pre-emptive legislation.**

Pre-empting trade-related IP negotiations with domestic legislation that will 'bind negotiators hands' can reduce unwanted political economy tradeoffs. This is, however, contingent on interdependence on trade partners and effective utilisation of negotiating tools. This could include patentability exclusions on methods of treatment, so as to create a precedent on gene therapies;

c) **Capitalise on a sea change in philosophy and visibility on drug pricing and access to medicines.**

As discussed in Subsection I(b) above, no longer is drug pricing and access to medicines a developing country or emerging market issue. Developed nations are struggling – and developing countries no longer have such a large ideological gap with many developed nations on the issue of pharmaceutical pricing and access.

⁹⁰⁹ Courtenay Lindsay, 'Norm Rejection: Why Small States Fail to Secure Special Treatment in Global Trade Politics' (2019) 2(1) Small States & Territories 105-124, 106

⁹¹⁰ Ibid 107

d) **Find and utilise a ‘common precedent’.**

Forming coalitions with other countries that have common domestic standards (‘common precedent’) or common ideations, and especially if that country is a developed country or ‘middle power’⁹¹¹, increases bargaining power and reduces political economy tradeoffs – thus in the pre-negotiation stage countries must map potential negotiation partners’ IP laws, drug pricing and access to medicines barriers, and ideologies around health. Less ideological distance creates stronger coalitions;

- e) **Balancing economic interdependence.** The United States, the European Union, and Japan continue to be the main demanders of trade-related IP. Diversifying trade and/or reducing proportion of trade dependence on certain countries can reduce the need for direct tradeoffs in trade agreements with these nations. While the example in this thesis shows an increased trade dependence on China, this in turn can result in tradeoffs elsewhere. For example, Malaysia’s trade and investment agenda with China has resulted in denialism regarding human rights violations in Uighur concentration camps.⁹¹² As such, the emphasis would still be on balancing economic interdependence through diversification of interests;

f) **Involve civil society in meaningful consultation.**

Civil society and other stakeholders can be the source of technical information that may be powerful in negotiation settings, and can create enough noise domestically to ‘bind negotiators’ hands’;

The idea that IP is never negotiated in isolation underlines much of the above recommendations – negotiating trade-related IP is always couched in the language of concessions and tradeoffs and countries must rely on a number of strategies to ensure they maintain an adequate win-set. Developing countries should also be wary of being overly focused on market access – as discussed in Chapter 1 of this thesis, modern trade agreements are less about the exchange of goods and services and more about amending beyond-the-border regulations, i.e. ‘deep integration’.⁹¹³ As evidenced in the TPP – which is predominantly a deep integration agreement with only 4 chapters pertaining to traditional

⁹¹¹ Middle powers are countries with capabilities immediately below those of the great powers, but still far above most secondary states in the international system. Bruce Gilley and Andrew O’Neil, ‘China’s Rise through the Prism of Middle Powers’ in Bruce Gilley and Andrew O’Neil (eds), *Middle Power and the Rise of China* (Georgetown University Press 2014) 2

⁹¹² Agence France-Presse, ‘Malaysian Minister Criticised for Uighur Camp Visit’ *Agence France-Presse* (1 July 2019) <<https://www.france24.com/en/20190701-malaysian-minister-criticised-uighur-camp-visit>> accessed 30 August 2019

⁹¹³ Kim (n 110) 360-361

goods and services – these agreements seek to discourage internal regulations that could be perceived as technical barriers to trade, or seen as unfair to investors, and this could include sanitary and phytosanitary measures, or even legitimate public health measures. Nor are tradeoffs always framed in IP versus market access, despite the examples being inclined in that direction in this thesis. An example of this is how Colombia announcing intentions to issue a compulsory license for the cancer drug Glivec led to the United States threatening to impair the approval of aid finance for the Colombian peace process initiative ‘Paz Colombia’ in 2016.⁹¹⁴ Tradeoffs for IP can therefore occur or have reverberations outside of market access, and so countries would need to embark on building strategic partnerships with others to counter threats on key pressure points.

Developing countries who are seeking to gain economically from trade should also consider economic ramifications of more abstract losses – such as through productivity losses from ill health, or financial losses from litigation through Investor-State Dispute Settlement (ISDS) mechanisms provided for in these mega-regional agreements, which can often rack up bills into the hundreds of millions of dollars.

And while there is little doubt that the TPP was intended to be a geopolitical and security manoeuvre by the United States against China, as with other mega-regional trade agreements and modern bilateral agreements, military security did not feature strongly in the agenda, contrary to many realist theories.⁹¹⁵ According to Keohane and Nye’s ‘complex interdependence’ theory - issues that are important to nations are ‘not arranged in a clear or constant hierarchy’,⁹¹⁶ and so in designing a negotiating strategy, developing countries need to have adequate technical capacity to be able to identify emerging issues, and that this occur not just throughout negotiations, but also in the pre-negotiation stage.⁹¹⁷ It is in pre-negotiations that ascertaining common precedent and ideation in both IP and access to medicines can create in early strategic gains.

To close this subsection is the idea that countries can enact legislation to pre-empt or mitigate potential tradeoffs on IP in the future. As aforementioned, while small molecule medicines will continue to be produced, it very much seems that the proportion of the market that is biologic, gene-based, or cell-based, will increase. CAR-T, for example, involves the use of CRISPR technology to edit the T-cells of a human being with a retroviral, enabling the cell to be returned

⁹¹⁴ Goldman and Struver (n 21)

⁹¹⁵ Robert O Keohane and Joseph S Nye, *Power and Interdependence* (Scott Foresman and Company 1989) 25

⁹¹⁶ Ibid

⁹¹⁷ Harold H Saunders, ‘We Need a Larger Theory of Negotiation: The Importance of Pre-Negotiating Phases’ in J William Breslin and Jeffrey Z Rubin, *Negotiation Theory and Practice* (Program on Negotiation Books 1991, 1993) 60

to its original human source to attack cancer cells.⁹¹⁸ There is scholarship theorising that CAR-T and other gene and cell therapies are not products in themselves but rather therapeutic methods or medical treatments.⁹¹⁹ TRIPS Article 27(3) provides that countries may exclude 'diagnostic, therapeutic, and surgical methods' from patentability, and as discussed by Abinader and Contreras, many, if not all, patents that have already been filed for these treatments may contravene many statutory exclusions in developed nations, given that patentability of medical treatments is prohibited throughout much of the developed world.⁹²⁰ Incorporating these statutory exclusions and increasing technical capacity on pre-grant oppositions may help in preparing for these future forms of IP.

IV. Future research

A gap exists in terms of what happened in the pre-negotiation stage in terms of what was communicated to both Chile and Malaysia on U.S. expectations for the intellectual property chapter, and whether these discussions, if any, were at all material to the end result on biologics. Equally material were discussions on other chapters – and whether conflicts elsewhere could have set the tone for how countries approached discussions on issues for which there were the greatest disagreement. For example, undue heavy-handedness in a topic entirely different from the topic at hand, say on affirmative action policies or on insufficient market access, could result in retaliatory action in discussions on biologics.

Pre-negotiations are important for several reasons, including that it is critical to ensuring parties don't 'use the wrong instruments in trying to move the process forward',⁹²¹ in terms of its causality in setting the actual agenda of the official negotiations, in eliminating non-negotiable issues, 'avoiding non-starters',⁹²² and whether or not they played a 'central role in shaping the style and content of the official negotiations'.⁹²³ Taking a wider viewpoint, more in-depth research on bilateral country relationships and the surrounding political environments, and how those impact on specific negotiating approaches and behaviours is understudied. Garnizova comments: 'Dynamics of negotiation is one thing – but we need to look at the broader framework within which countries interact and the regulatory gap'.⁹²⁴ While this thesis draws upon political economy factors such as trade reliance on China and drug

⁹¹⁸ Abinader and Contreras (n 898) 708

⁹¹⁹ *Ibid*

⁹²⁰ *Ibid* 737

⁹²¹ Saunders (n 917) 60

⁹²² Ilan G Gewurtz, 'Transition from Conflict: The Importance of Pre-Negotiations in the Oslo Peace Process' (2000) 6(3-4) *Israel Affairs* 177-199, 181

⁹²³ *Ibid*

⁹²⁴ Elitsa Garnizova, 'The New Political Economy of Trade: Understanding the Treatment of Non-Tariff Measures in European Union Trade Policy' (Thesis, London School of Economics 2018) 271

pricing concerns across the world, due to a narrow scope it can only do so superficially – and scholarship may benefit from comprehensive analysis on political economy factors that influence negotiating behaviour both within international trade-related intellectual property agreements and international agreements in different fields.

As mentioned above, due to the scope of this PhD, I was unable to provide recommendations for LDCs, small and vulnerable economies (SVEs), and Small Island Developing States (SIDS). Some limited thoughts on least developed nations and small and vulnerable economies (SVEs) is that lessening ideological distance may be the first step towards building strong coalitions. Barriers to this cohesiveness were described by West Indies trade expert Courtenay Lindsay – that least developed nations, SVEs, and SIDS are ‘economically and ideologically dependent on a predominantly neoliberal global economy’, and in addition there is ‘inadequate unity and cohesion’ among them.⁹²⁵ This lack of cohesiveness may find its roots in, among other things, a hesitancy to work with richer countries as it may reduce their chances of receiving preferential treatment.⁹²⁶ It would be interesting to see how SVE and SIDS scholars examine how their countries operate in this space, and whether they are able to capitalise the common ‘politics of resentment’ – i.e. that emerging markets ‘they relate to the global system with a mutually reinforcing sense of historical grievances and claim to represent the interests of all developing countries’⁹²⁷ and whether these are material considerations at all in the economics and trade considerations of these smaller nations.

The thesis also predominantly examines the interactions between the two upper middle-income countries and the United States, but not interactions between each other. An in-depth look at how countries forming coalitions communicate, at what point after disagreements they communicated, whether established close relationships and positive socialisation dynamics⁹²⁸ eased formations of coalitions or increased gains in other areas, and whether there were bilateral promises made between them is unexamined in this thesis, and could generate further useful insights for developing country negotiations.

It would be intriguing also to see documentation expanding on the concept of a common precedent and where it was utilised in agreements outside intellectual property, for example in security or climate negotiations, to avoid unwanted political economy tradeoffs. Finally – as aforementioned, it will be difficult from now on for IP maximalist demandeurs to advance their

⁹²⁵ Courtenay Lindsay, ‘Norm Rejection: Why Small States Fail to Secure Special Treatment in Global Trade Politics’ (2019) 2(1) *Small States & Territories* 105-124, 116-117

⁹²⁶ *Ibid* 117

⁹²⁷ Andrew F Cooper and Daniel Flesmes, ‘Foreign Policy Strategies of Emerging Powers in a Multipolar World: An Introductory Review’ 34(6) *Third World Quarterly* 943-962, 951-952

⁹²⁸ Singh (n 710) 501

aims through international trade agreements. Future research tracking how pharmaceutical industry lobbyists seek to cement their monopolies would be strategically important.

Finally, this thesis discussed the failure of the TPP (and subsequently the USMCA) in establishing a new biologics IP world trade order. Haass talks about how the establishment of a new world order 'needs skilled statecraft, since an order is made, not born. And no matter how ripe the starting conditions or strong the initial desire, maintaining it demands creative diplomacy, functioning institutions, and effective action to adjust it when circumstances change and buttress it when challenges come.'⁹²⁹ There is little doubt that with the U.S. concession on biologics, 'skilled statecraft' and 'creative diplomacy' will be employed in adjusting expectations in the future on IP expansion, especially in the context of changing tides on drug pricing in the developed world. Documentation of this is imperative.

⁹²⁹ Richard Haass, 'How a World Order Ends: And What Comes in Its Wake' *Foreign Affairs* (January/February 2019) <<https://www.foreignaffairs.com/articles/2018-12-11/how-world-order-ends>> accessed 24 December 2019

ANNEX A

Confirmation of Ethics Clearance

The Secretariat
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UNIVERSITY OF LEEDS

Nur Afifah A Rahman
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**ESSL, Environment and LUBS (AREA) Faculty Research Ethics Committee
University of Leeds**

10 October 2017

Dear Fifa

Title of study: Intellectual Property (IP) Politics, Access to Medicines and the Trans-Pacific Partnership (TPP): a Comparative Analysis of Responses to IP Political Economy Tradeoffs in Chile and Malaysia
Ethics reference: AREA 16-194

I am pleased to inform you that the above research application has been reviewed by the ESSL, Environment and LUBS (AREA) Faculty Research Ethics Committee and following receipt of your response to the Committee's initial comments, I can confirm a favourable ethical opinion as of the date of this letter. The following documentation was considered:

Document	Version	Date
AREA 16-194 20171004 Signed GD ethics form.pdf	2	04/10/17
AREA 16-194 Fieldwork Risk Assessment form endorsed.pdf	1	27/07/17
AREA 16-194 20170711 TOPIC GUIDE PhD v1.docx	1	27/07/17
AREA 16-194 20170713 Information Sheet v2.docx	2	04/10/17
AREA 16-194 20170713 Participant Consent Form v2.doc	2	04/10/17

Committee members made the following comments about your application:

- Thank you for responding to the suggestions so clearly and constructively.

Please notify the committee if you intend to make any amendments to the information in your ethics application as submitted at date of this approval as all changes must receive ethical approval prior to implementation. The amendment form is available at <http://ris.leeds.ac.uk/EthicsAmendment>.

Please note: You are expected to keep a record of all your approved documentation and other documents relating to the study, including any risk assessments. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited. There is a checklist listing examples of documents to be kept which is available at <http://ris.leeds.ac.uk/EthicsAudits>.

We welcome feedback on your experience of the ethical review process and suggestions for improvement. Please email any comments to ResearchEthics@leeds.ac.uk.

Yours sincerely

Jennifer Blaikie
Senior Research Ethics Administrator, the Secretariat
On behalf of Dr Kahryn Hughes, Chair, [AREA Faculty Research Ethics Committee](#)
CC: Student's supervisor(s)

ANNEX B

SCHEDULE OF INTERVIEWS

No.	Assigned Pseudonym <i>(If Real Name Consented To, Highlighted in Red)</i>	Pronoun Consented To	Location of Interview	Date of Interview
1.	Montague	Government Official	Santiago, Chile	15 November 2017
2.	Smithers	Government Official	Santiago, Chile	15 November 2017
3.	Daphne	Government Official	Santiago, Chile	15 November 2017
4.	Therese	<i>Funcionario de Gobierno</i> (Government Official)	Santiago, Chile	16 November 2017
5.	Lispeth	Former Negotiator	Vitacura, Chile	16 November 2017
6.	Merle	Negotiator	Santiago, Chile	17 November 2017
7.	Dorotea López Giral	Dorotea Lopez	Santiago, Chile	17 November 2017
8.	Tomás Lagomarsino	President of Equidad Chile	Valparaíso, Chile	18 November 2017
9.	Lim Ching Wei	Civil Society	Kuala Lumpur, Malaysia	December 2017
10.	Peter Maybarduk	Director, Public Citizen	Marrakech, Morocco	16 January 2018
11.	Dr Burcu Kilic	Legal Counsel, Access to Medicines Program, Public Citizen	Skype	1 February 2018
12.	Belinda	Former Malaysian Government Official	Skype	7 February 2018
13.	Pedro Roffe	Senior Fellow, International Centre for Trade and Sustainable Development (ICTSD)	Skype	13 February 2018

14.	Rex	Former Negotiator	Skype	20 September 2018
15.	Syed Hamid Albar	Syed Hamid Albar	Kuala Lumpur, Malaysia	18 December 2018
16.	Ursula	Former Malaysian TRIPS Negotiator	Kuala Lumpur, Malaysia	20 December 2018
17.	Brian	Negotiator	Whatsapp Call	4 March 2019
18.	Lori Wallach	Lori Wallach, Director, Global Trade Watch, Public Citizen	Written answers through email	12 August 2019

ANNEX C

Sample of Topic Guide for Interviews

DATE: DD/MM/YYYY

PARTICIPANT CODE: _____ / _____ / _____ / _____

Pseudonym, town/city of interview,
country code (CL/MY/US), gender (M/F/TG)
and role (NEG = negotiator, CS = civil society, A = academia,
PI = pharmaceutical industry, GA = government agency).

TOPIC GUIDE

Main research question: “How did upper middle income countries in the TPP respond to political economy tradeoffs?”

Subquestions include: “What intrinsic and extrinsic factors influenced negotiator decision making processes?” “Due to established market access deals with all TPP countries, was Chile in a stronger position?” “Did domestic industrial development in biologics and/or biosimilars influence the decisions of the negotiators?” “If not, what did?” “Did the novelty of biologics, both as an IP provision in trade agreements and as a public health commodity, change political economy tradeoffs?” “Were the countries seen as potential points where more maximalist IP could be spread within their own regions?”

Dialogue: Thanks so much for agreeing to speak with me. I’d like to begin by asking about the country’s approach to the negotiations.

No.	Domains	Possible questions [begin with general question – then probe]
1.	Country approach to TPP negotiations (ideological/historical/politico-economic)	<p>Could you tell me a little bit about you and your negotiating team’s preparation and approach prior to, or at the beginning of the trade negotiations? Could you tell me about the history of IP in Chile? How do you see IP contributing to the economy? How is it important to adapt IP to your country? What is IP to you? Is it a necessary evil?</p> <p>Do you remember when you first were told about your role in the TPP? Do you think there was a predetermined approach to the TPP? Was there a historical reason for this? What were your key negotiating aims? What about predetermined red lines? How strict were these red lines? Were there areas where you thought you had leeway on concessions? Do you think previous experience with U.S.-led negotiations/U.S. negotiators have influenced your negotiations this time around?</p> <p>[To non-negotiators: How would you</p>

		<p>characterise the country's approach to the TPP? How have you formed your opinion on this?]</p>
2.	Unit-level learning	<p>What were the biggest learning points during this entire TPP negotiation process? What informed your decision on biologics exclusivity? Why did you react so strongly to biologics?</p> <p>(If had predetermined red lines): Did your red lines/negotiating strategy change throughout the negotiations? What informed this? Do you feel like the negotiation strategy on biologics exclusivity was sufficiently informed or based on informed decisions? To what extent did any economic studies inform your decision? Did you consult any stakeholders in designing your strategy?</p> <p>[To non-negotiators: Could you tell me about engagement with negotiators? Did you feel like you were getting through? How would you characterise your relationship? What materials or information did you give to negotiators? Have you attended any negotiation rounds? Was your attendance specifically requested?]</p>
3.	Turning points	<p>I'm interested in turning points, i.e. any significant events that happened in the context of the negotiations for biologics. Can you tell me if there were any?</p> <p>Do you remember when you first found out that the U.S. were asking for 12 years of market exclusivity for biologics? What were your thoughts? Were you prepared to agree with 12 years of biologics exclusivity? Why not? Were there any heated moments as pertains pharmaceutical IP and/or biologics? Can you tell me anything about those moments?</p> <p>The media reported that for New Zealand, biologics was contingent on a deal on dairy. Was there a similar deal for you? What did the U.S. want from you?</p> <p>Were any alliances formed on pharmaceutical IP?</p> <p>What were the circumstances that led to the Chilean Annex 18B/Malaysian side letter on biologics? The media reported a biologics deadlock at the Atlanta round between U.S.-Australia, was there a similar deadlock with you?</p>

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