

PART 1:  
GLOBAL  
CONNECTEDNESS

# Chapter 2

## The Web of Trade Agreements and Alliances and Impacts on Regulatory Autonomy

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### 2.1 Introduction

Since the advent of the World Trade Organization (WTO), the number of free trade agreements (FTAs) has steadily increased.<sup>1</sup> All trade agreements limit national regulatory autonomy to some degree; however, since the formation of the WTO in 1995, FTAs have become broader in scope and increasingly address more and different types of “behind the border” regulation, including, for example, consumer safety regulation and public health measures. This new role of FTAs has led to concern about whether it is in a country’s interest to allow such incursions into regulatory policy. The counterbalance to that concern is that greater global connectedness will improve world welfare in the long run. Moreover, there are typically direct gains accruing to citizens of countries that seek to take advantage of international standards and institutions.<sup>2</sup>

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<sup>1</sup> As at 15 January 2012, 319 regional trade agreements were in force “Regional Trade Agreements” (2012) World Trade Organization <[www.wto.org](http://www.wto.org)>.

<sup>2</sup> See [2.3.1] below. On trade effects, see Ricardo A Lopez “Trade and growth: Reconciling the macroeconomic and microeconomic evidence” (2005) 19 *Journal of Economic Surveys* 623; Francisco Alcalá and Antonio Ciccone “Trade and productivity” (2004) 119(2) *Quarterly Journal of Economics* 613; more recently Rosario Crino and Paolo Epifani “Export intensity and productivity” (2012) 122 *Economic Journal* 1206. On institutional effects, see discussion in S Girma, M Henry, R Kneller and C Milner *Threshold and interaction effects: in the openness-productivity growth relationship: The role of institutions and natural barriers* (GEP

Trade agreements operate on political, economic and institutional levels. Crucially, a trade agreement – to be durable – must be viable on all these levels. In other words, it has to be acceptable politically; institutions have to be able to interpret and apply trade rules consistently; and it has to be economically coherent over the long run. As trade agreements encompass new areas, the issues become more complicated. This chapter examines, from legal and economic perspectives, how some of the issues and challenges brought about by an increasingly complex web of trade agreements and alliances, impact on regulatory autonomy. The primary example we use to illustrate this phenomenon is the pursuit of the extension of the term of patents.

### ***2.1.1 The politics is of pre-eminent importance, but information can be distorted***

A trade deal is always dependent on politics because the agreement has to be authorised at the government level. But, as Tip O'Neill<sup>3</sup> once said, “all politics is local”. In other words, the electoral system is vote-driven and voters perform their own decision calculus on what affects them. International agreements, however, are not easy policies to assess from a voter standpoint; they are often complicated and the changes they cause are difficult to work out and value. Information is frequently hard to come by, depends on interpretation, and may be garbled in transmission.

To illustrate the confusion and complexity of issues at stake, the current debate on plain packaging for cigarettes is instructive. At a local political level any suggestion that regulatory autonomy has been curbed, particularly in relation to health and consumer matters, has been denied. In 2012, for example, Prime Minister John Key stated that New Zealand has not signed any free trade agreement that will stop plans to sell cigarettes in plain packaging.<sup>4</sup> One media article quoted the Prime Minister as claiming that “Australia’s circumstances are different to New Zealand’s, because it has a free trade agreement with the United States and New Zealand doesn’t”. In the same article Labour’s foreign affairs spokesman was quoted as saying:<sup>5</sup>

Every nation has the right to regulate in the public interest and there’s no trade agreement we have entered into, or should ever enter into, that takes away that sovereign right.

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Research Paper series, 2003). A differing view on causality is expressed in, for instance, F Rodrigues and D Rodrik “Trade policy and economic growth: A skeptic’s guide to Cross National Evidence” in B Bernanke and K Orgoff (eds) *NBER Macroeconomics Annual 2000* (NBER and MIT Cambridge (Mass), 2000) at 261.

<sup>3</sup> Former United States Democratic congressman and Speaker of the House of Representatives.

<sup>4</sup> Kate Chapman “Key: Free trade won’t snuff plain smokes” (2012) [www.stuff.co.nz/national/politics/6789833/Key-Free-trade-won-t-snuff-plain-smokes](http://www.stuff.co.nz/national/politics/6789833/Key-Free-trade-won-t-snuff-plain-smokes).

<sup>5</sup> “Labour backs plain tobacco packaging” (27 April 2012) 3 News [www.3news.co.nz/Labour-backs-plain-tobacco-packaging/tabid/1607/articleID/252014/Default.aspx](http://www.3news.co.nz/Labour-backs-plain-tobacco-packaging/tabid/1607/articleID/252014/Default.aspx).

The same article continued:<sup>6</sup>

British American Tobacco says it will “take every action necessary” to protect its intellectual property rights.

Philip Morris says enforcing plain packaging will “trigger a variety of adverse consequences and violate numerous international laws and treaties”.

These quotes addressing New Zealand’s regulatory autonomy over the plain packaging of cigarettes raise numerous issues, and some of the points made are questionable. First, it is not yet clear that all plain packaging measures are consistent with the whole of the WTO agreements, to which New Zealand belongs. In particular, compliance with the TRIPS Agreement<sup>7</sup> and the TBT Agreement<sup>8</sup> have been much discussed, but not definitively determined. Compliance with WTO agreements is currently the focus of three complaints brought against Australia for its plain packaging legislation.<sup>9</sup> Also, depending on the nature of any plain packaging laws, the New Zealand FTA with China and the expropriation of investment provisions may be relevant.<sup>10</sup>

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<sup>6</sup> “Labour backs plain tobacco packaging” (27 April 2012) 3 News <[www.3news.co.nz/Labour-backs-plain-tobacco-packaging/tabid/1607/articleID/252014/Default.aspx](http://www.3news.co.nz/Labour-backs-plain-tobacco-packaging/tabid/1607/articleID/252014/Default.aspx)>.

<sup>7</sup> The arguments relating to the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) are complex. The key provision that plain packaging might infringe is article 20, which provides that: “The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements ...”. The TRIPS Agreement also provides, in article 8.1 Principles, that: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” This article is relevant to the interpretation of article 20. The interpretation of the word “unjustifiably” will be central to determining the outcome of the TRIPS Agreement dispute. For further discussion see Susy Frankel and Daniel Gervais “Plain Packaging and Interpretation of the TRIPS Agreement” (2013, forthcoming in *Vand J Transnat’l L*).

<sup>8</sup> The Agreement on Technical Barriers to Trade (TBT), art 2.2 provides: “Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: ... protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information related processing technology or intended end-uses of products.”

<sup>9</sup> The Ukraine, Honduras and the Dominican Republic have requested consultations under the auspices of the World Trade Organization. See *Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS434/R (panel established but not yet composed, 28 September 2012); *Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/R (in consultations, 4 April 2012); *Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS441/R (in consultations, 18 July 2012).

<sup>10</sup> New Zealand-China Free Trade Agreement (1 October 2008), available at

It seems likely that the WTO question will be answered in the disputes brought against Australia, and the regulatory management tactic New Zealand will employ might be described as waiting to see the outcome before implementing its own plain packaging law.

As noted above, Mr Key seeks to draw a distinction between the New Zealand and Australian positions. First, the actions brought against Australia relating to its plain packaging laws have not been brought directly by the United States, but by tobacco companies under bilateral investment treaties,<sup>11</sup> before the High Court of Australia under the Australian constitution<sup>12</sup> and by Ukraine, Honduras and the Dominican Republic at the WTO. There is interestingly, however, under the Australia-United States Free Trade Agreement (AUSFTA), the possibility of a different cause of action of a non-violation complaint about the intellectual property provisions.<sup>13</sup> Second, New Zealand is currently seeking the very same

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<[www.chinafta.govt.nz/1-The-agreement/2-Text-of-the-agreement/index.php](http://www.chinafta.govt.nz/1-The-agreement/2-Text-of-the-agreement/index.php)>. Article 145.1 provides:

Neither Party shall expropriate, nationalize or take other equivalent measures (“expropriation”) against investments of investors of the other Party in its territory, unless the expropriation is:

- a. for a public purpose;
- b. in accordance with applicable domestic law;
- c. carried out in a non-discriminatory manner;
- d. not contrary to any undertaking which the Party may have given; ...

Annex 13 defines expropriation. It provides:

4. A deprivation of property shall be particularly likely to constitute indirect expropriation where it is either:
  - a. discriminatory in its effect, either as against the particular investor or against a class of which the investor forms part; or
  - b. in breach of the state’s prior binding written commitment to the investor, whether by contract, licence, or other legal document.
5. Except in rare circumstances to which paragraph 4 applies, such measures taken in the exercise of a state’s regulatory powers as may be reasonably justified in the protection of the public welfare, including public health, safety and the environment, shall not constitute an indirect expropriation.

The New Zealand position presumably would be that plain packaging is reasonably justified in the protection of public health. Provided any law is non-discriminatory and is primarily targeted at protecting public health, these clauses suggest it is not an indirect expropriation. However, because it could diminish the economic value of trade marks it could be seen as an equivalent measure. It is unclear if the indirect expropriation described in Annex 13 applies to equivalent measures.

<sup>11</sup> Claim by Philip Morris Asia Ltd to the Commonwealth of Australia pursuant to Agreement between the Government of Hong Kong and the Government of Australia for the Promotion and Protection of Investments (27 June 2011).

<sup>12</sup> *JT International SA v Commonwealth of Australia; British American Tobacco Australasia Ltd v The Commonwealth* [2012] HCA 43, (2012) 291 ALR 669, (2012) 97 IPR 321.

<sup>13</sup> For a discussion of the relevance of the Australia–United States FTA see Tania Voon and Andrew Mitchell “Time to Quit? Assessing International Investment Claims against Plain Tobacco Packaging in Australia” (2011) 14(3) J Int Economic Law 515. The authors do not mention, however, that in the dispute settlement chapter of that FTA there is provision for violation and non-violation disputes. At the WTO non-violation complaints cannot be brought in relation to the TRIPS Agreement. They can, however, be brought under AUSFTA. This is particularly pertinent for the plain packaging argument because, even if it were

trade agreement with the United States as Australia in the form of the Trans-Pacific Partnership (TPP).<sup>14</sup> The leaked negotiating positions, in the form of proposed texts suggest that even more extensive intellectual property protections will be included in any agreement.<sup>15</sup>

The plain packaging of cigarettes and the related unfolding legal disputes are a clear example of the difficulties that can be incurred as international agreements become more pervasive in their domestic reach. Their effects shift from being driven only by the trade outcomes to involving a more subtle and far-reaching task of balancing domestic and international objectives. Whatever the outcome of the plain packaging disputes, this balance of objectives is a key issue in many areas of regulation. The uncertainty at the political level is likely to continue and this will have an unpredictable impact on the type of agreements negotiated.

### **2.1.2 *Top-down and bottom-up approaches to trade agreements***

The institutional and economic imperatives follow from the politics. While they are less crucial to finalising an agreement, the decisions politicians make are influenced by domestic institutional capability and economic coherence. This means that the way a particular trade agreement impacts on the domestic regulatory environment depends on its coverage and structure.

In the first part of the New Zealand Law Foundation Regulatory Reform Project, two of us discussed the ways in which New Zealand's ability to regulate as it sees fit, is affected by trade agreements to which New Zealand is a party, and even agreements to which it is not a party.<sup>16</sup> We discussed how, in the bilateral context, New Zealand has certain unique harmonisation commitments with Australia and in a broader context New Zealand is a member of many FTAs. Also, Australia's commitments to the United States, in AUSFTA, may indirectly impact on New Zealand's regulatory options. Further, Australia and New Zealand are both members of an FTA with ASEAN and as noted above, are negotiating the TPP together with nine other countries.<sup>17</sup> New Zealand and Australia are thus intertwined in numerous different ways.

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accepted that AUSFTA is not violated because there is a justification (a point that is complex and not yet clear), there may be a non-violation. That is, the letter of the agreement is not violated but an expected benefit is not being realised. This very issue has arisen in the non-violation discussions under TRIPS, see Susy Frankel "Challenging Trips-Plus Agreements: The Potential Utility of Non-Violation Disputes" (2009) 12(4) J Int Economic Law 1023 at 1060–1061.

<sup>14</sup> New Zealand is also attempting to attract other Asian nations into the TPP as time goes on while at the same time forging other FTAs in the region.

<sup>15</sup> Leaked text of the United States proposals is available at <[keionline.org/node/1091](http://keionline.org/node/1091)>.

<sup>16</sup> See Susy Frankel and Meredith Kolsky Lewis "Trade Agreements and Regulatory Autonomy: The Effect on National Interests" in Susy Frankel (ed) *Learning from the Past, Adapting for the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011).

<sup>17</sup> The current parties to the negotiations are Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. Canada and Mexico joined the process in October 2012 and began participating in negotiations as of December

In the first stage of this project we contrasted the top-down style of trade agreements (best illustrated by various bilateral FTAs) with agreements New Zealand has with Australia that feature more of a bottom-up integration element. A top-down agreement is characterised by a negative integration approach, which is used in most WTO agreements. These agreements broadly indicate what types of regulations are not permitted. Trade agreements are not wholly framed on the negative integration model, as some aspects of such agreements require the enactment of detailed positive laws, or in other words “behind the border” regulation. The TRIPS Agreement is an example. FTAs also prescribe laws. In the leaked drafts of the TPP, for example, both the intellectual property chapter and the regulatory coherence chapter prescribe behind the border regulation. Although FTAs involve more than traditional negative integration elements, they still mostly differ from bottom-up agreements. Bottom-up agreements are usually developed through regulatory cooperation. Regulatory cooperation can be informal, but where such cooperation leads to a trade agreement, such an agreement will most likely prescribe considerable detail. This may leave the parties with less flexibility. However, that is not necessarily problematic for New Zealand if it has had an active role in formulating that detail.<sup>18</sup> The bottom-up approach was exemplified by the New Zealand and Australia food standards regulatory regime. We contrasted this with New Zealand’s pharmaceuticals regulatory framework, which is compliant with international multilateral obligations, but is seen as being incompatible with the arrangements we have with our trading partners and is under threat from FTAs directly through the TPP, and indirectly through AUSFTA. We concluded:<sup>19</sup>

There is no one-size-fits-all trade agreement. The relationship between trade agreements and regulatory autonomy, however, and how that relationship affects particular sectors, is an important framework to fully assess before any regulatory commitments are made in the FTA context. While the multilateral top-down style of trade agreement is likely to result in benefits for New Zealand without unacceptable constraints on regulatory autonomy, there are some instances where agreements that lead to bottom-up regulation will also be beneficial. In particular, under certain circumstances New Zealand may be able to achieve its policy goals but at a significant cost savings as a result of harmonisation. In other contexts, however, bottom-up prescriptions may not be in New Zealand’s interests.

In this chapter we cannot say which type of agreement is “better” for New Zealand as a conclusive rule applicable in all circumstances. That can only be determined with a detailed analysis of the costs and benefits associated with each issue within a trade agreement. Also, New Zealand is involved in a variety of both types of

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<sup>18</sup> See Susy Frankel and Meredith Kolsky Lewis “Trade Agreements and Regulatory Autonomy: The Effect on National Interests”; Chris Nixon and John Yeabsley “The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road” in Susy Frankel (ed) *Learning from the Past, Adapting for the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011).

<sup>19</sup> See Susy Frankel and Meredith Kolsky Lewis “Trade Agreements and Regulatory Autonomy: The Effect on National Interests” in Susy Frankel (ed) *Learning from the Past, Adapting for the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011) at [15.5].

agreements and many trade agreements have elements of both top-down and bottom-up characteristics, for example, Closer Economic Relations (CER) occurred because the Australians had had enough of the transaction costs and lack of progress associated with New Zealand Australia Free Trade Agreement (NAFTA) – the prescribed top-down element. Consequently the final agreement and subsequent agreements under the umbrella of CER have been collaborative arrangements with many characteristics of bottom-up processes.<sup>20</sup>

To explore these costs and benefits further we have undertaken a detailed analysis, as an illustrative example, of the regulation of patents that have had or might have their term extended from the standard term. This example is used to illustrate the pitfalls of the top-down FTA approach in circumstances where New Zealand arguably has a distinct national interest (different from its trading partners).<sup>21</sup> We emphasise that patent term extension is an illustrative example. We have chosen patent term extension, and where appropriate also discuss other aspects of patent protection, to provide an example of the competing effects of top-down FTAs compared to the bottom-up regulatory cooperation process.

As is discussed below, the patent term example is particularly pertinent because of the differences between Australian and New Zealand law. Australia allows for term extension and New Zealand does not. New Zealand did have patent term extension, but currently has a policy not to have patent term extension in its law. We also use this as an example with currency in the TPP negotiations and the importance of patent term extension and increasing patent protection more generally that the United States negotiators, and consequently other negotiators, are attaching to trade in pharmaceuticals.<sup>22</sup> We also discuss the regulatory coherence proposal in the TPP, as some have suggested (although we contest that proposition), that regulatory coherence may be a worthwhile “exchange” for increased intellectual property. Patents also has currency given moves made in Asia to form a broader ASEAN arrangement, potentially as broad as ASEAN + 6<sup>23</sup> and how more moderate patent policy is likely to be a key interest in that arrangement. Using the research in this chapter we analyse whether increased regulatory autonomy, for New Zealand, is more probable or possible in one trade agreement

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<sup>20</sup> For further information on CER see Chris Nixon and John Yeabsley “New Zealand’s Trade Policy Odyssey: Ottawa, via Marrekech and on” (2003) NZIER Research Monograph No. 68.

<sup>21</sup> In our previous paper, in this project, we indicated that our research path included: Compiling data on all term extensions that were granted in New Zealand before the law was changed and why they were granted (this will include pharmaceutical and other patents).

Examining the question of the impact of patent term extension on the price of pharmaceuticals for human treatment in the New Zealand context.

<sup>22</sup> Including possible attempts to make PHARMAC market transactions more transparent.

<sup>23</sup> ASEAN + 6 includes the 10 ASEAN economies plus Japan, China, South Korea, Australia, New Zealand and India. All ASEAN members are currently WTO members. As some ASEAN countries are developing or least developed countries (LDCs) they have a different timeline for complying with TRIPS requirements. LDCs do not need to comply with some of the TRIPS Agreement patent requirements until at least 2016. The TRIPS Agreement, art 66 allowed for a 10-year compliance time line and this was extended until 2013 and 2016 in relation to pharmaceuticals, see “Least developed countries priority needs in intellectual property” <[www.wto.org/english/tratop\\_e/trips\\_e/ldc\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm)>.



framework rather than the other. The first framework is the top-down framework of which the TPP is our key example. The second framework is the bottom-up integration approach. We look at the trans-Tasman relationship and the ASEAN relationship in the bottom-up context.

In some circumstances the top-down approach sets the parameters for any bottom-up integration and the top-down is so prescriptive that it dominates. That said, we also suggest that in some situations the combination of top-down and bottom-up processes may be more useful than either a solely top-down or bottom-up approach, since having clear rules and applying those rules efficiently, but in a different way in each jurisdiction, may result in better economic outcomes for all participating jurisdictions. To illustrate the strengths and weaknesses of each approach we have set out the advantages and disadvantages of each below.

Table 2.1: Advantages and disadvantages of top-down and bottom-up approaches

Top-down approaches to trade agreements		Bottom-up approaches to trade agreements	
<i>Advantages</i>	<i>Disadvantages</i>	<i>Advantages</i>	<i>Disadvantages</i>
Prescribes the aspiration, direction, and tone for the trade agreement, increasing certainty	May not suit all participants since each economy is at a different stage of economic development	Describes the way trade, businesses and government work in individual economies	Has no overall strategy. Potential for parts of the integration process to work against each other
Defines the boundaries of a trade agreement. Typically the wider the agreement the bigger the benefits	The cost of moving to a standardised approach may impose high transaction (negotiation) costs	Can introduce deeper and on-going integration for participating economies	Can be piecemeal and take much longer to achieve
Sets the objective and provides clarity around those objectives facilitating further trade	Disregards differences in the regulation of domestic transactions	Provides chances for different approaches (mutual recognition)	Potentially reactive, involves guesswork, or be subject to fads
Defines the approach to dispute settlement and compliance	Agreements may be limited in scope, allowing for new barriers to economic growth	Provides for more than one way to settle disputes in a least-cost fashion	It is expensive

Top-down approaches to trade agreements		Bottom-up approaches to trade agreements	
<i>Advantages</i>	<i>Disadvantages</i>	<i>Advantages</i>	<i>Disadvantages</i>
Standardisation of approach (harmonisation) eliminating bad practice. Does not favour any group within society			
Can fill a vacuum by providing rules in a field where they were previously non-existent			

## 2.2 Application to patent extension

### 2.2.1 Patents

The role of patents is contentious because of the supposed link to innovation, but since we have no general theory of innovation the link is questionable.<sup>24</sup> As David puts it:<sup>25</sup>

... there is no settled body of economic theory on the subject that can be stated briefly without doing serious injustice to the sophisticated insights that have emerged over many decades of debate. Instead, the relevant economic literature is extensive, convoluted, and characterized by subtle points of inconclusive controversy ...

What we have is a compromise, where the granting of this exclusive right in the form of a patent is premised on the broad theory that it encourages innovation. The patent holder is likely to reap greater profits if protected from competition from an imitator. These profits are intended to serve as incentives for creating innovative products that benefit the public.<sup>26</sup>

<sup>24</sup> See Paul A David “Intellectual Property Institutions and the Panda’s Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History” in MB Wallerston, ME Mooge and RA Schoen (eds) *Global Dimensions of Intellectual Property Rights in Science and Technology* (National Academy Press, Washington (DC), 1993) 19. There is a large and long-standing literature on this topic. For a discussion on the role of innovation and exclusive rights see Richard Gilbert “Looking for Mr. Schumpeter: Where Are We in the Competition-Innovation Debate?” in AB Jaffe, J Lerner and S Stern (eds) *Innovation Policy and the Economy* (NBER and MIT, Cambridge (Mass), 2006).

<sup>25</sup> Paul A David “Intellectual Property Institutions and the Panda’s Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History” in MB Wallerston, ME Mooge and RA Schoen (eds) *Global Dimensions of Intellectual Property Rights in Science and Technology* (National Academy Press, Washington (DC), 1993) 19 at 23.

<sup>26</sup> For a summary of the role and justification of patents from a legal perspective see Susy

When most people think about R&D and intellectual property rights, they think of patents. Results from a large number of different studies, however, demonstrate that patent protection is prominent in just a handful of industries. The most important of these are pharmaceuticals, fine chemicals and agricultural chemicals.<sup>27</sup>

Patents are known to be imperfect solutions to the market failure associated with the creation of knowledge, since they create market “rents” in the form of the ability for the holder to charge higher prices and, in the case of pharmaceuticals, sometimes monopoly prices for goods whose marginal production cost is close to zero.

In theory, the optimal amount of patent protection is relatively straight forward. It is a trade-off between incentivising dynamic efficiency that leads to a “new” product versus the inefficiency of adversely impacting on the efficient use of knowledge.<sup>28</sup> Therefore, the optimal length of a patent is where the marginal revenue from extra innovation equals the marginal costs associated with the inability to disperse any particular innovation.

Nordhaus has shown that if stimulating investment in inventive activity were the prime concern, patents should be of infinite length. However, if spill-overs are the primary concern, patents should not exist at all.<sup>29</sup> The current system, where patents exist but are time-limited, is a compromise which reflects the inherent trade-offs between encouraging innovation and disseminating innovation through the community. The time limit is a global minimum standard of 20 years.<sup>30</sup> That is a compromise between those negotiating who wanted an even longer term and those who wanted a shorter term.<sup>31</sup> Whether 20 years is optimal, as David suggests, is unclear. Further, the trade-offs between these factors depend upon the individual circumstances of each economy and the nature of the products. Where the innovators are not locally based, but their products are imported, the trade-offs may also be differently weighted.

## 2.2.2 Patent term extension

There are a variety of policy reasons that are given for patent term extension. Broadly, however, the logic runs that the patentee receives an extended term because the effective period of the patent has been shorter than the statutory

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Frankel *Intellectual Property in New Zealand* (2nd ed, LexisNexis, Wellington, 2011) at 389–393.

<sup>27</sup> Richard C Levin, Alvin K Klevorick, Richard R Nelson and Sidney G Winter “Appropriating the Returns from Industrial Research and Development” (1987) 3 BPEA 783; Wesley M Cohen, Richard R Nelson and John P Walsh “Protecting their Intellectual Assets: Appropriability Conditions and why US Manufacturing Firms Patent (or not)” NBER Working Paper No. 7552 (2000).

<sup>28</sup> William D Nordhaus “Invention, Growth and Welfare: a Theoretical Treatment of Technological Change” (MIT Press, Cambridge (Mass), 1969).

<sup>29</sup> William D Nordhaus “Invention, Growth and Welfare: a Theoretical Treatment of Technological Change” (MIT Press, Cambridge (Mass), 1969).

<sup>30</sup> TRIPS Agreement, art 33.

<sup>31</sup> See the discussion in Daniel Gervais *The TRIPS Agreement: Drafting History and Analysis* (4th ed, Sweet & Maxwell, London, 2012) at [2.434].

term, due to some cause. The two main reasons patent term can be “effectively” shorter than 20 years are because of delays in registering the patent or because of delays in the patented product coming to market because of regulatory requirements. For pharmaceuticals, regulatory requirements are particularly relevant.<sup>32</sup>

Prior to entering the TRIPS Agreement New Zealand allowed patent term extension (see below). However, the TRIPS Agreement requires all WTO members (including New Zealand) to provide a minimum patent term of 20 years, which meant that New Zealand extended the term of patents from 14 to 20 years. The 20-year term was in part justified, in the TRIPS negotiations, as necessary because it took into account regulatory delays.<sup>33</sup> Therefore, when New Zealand extended the term from 14 years to 20 years, the government did not consider that any further term extension over and above the 20 years was necessary and it repealed its previous patent term provisions. In some countries, however, including Australia, Singapore and the United States (all TPP negotiating parties), there is term extension over and above the 20-year term. The stated policy reason for the extension in the United States is to support its pharmaceutical industry. Australia agreed to term extension prior to entering the free trade agreement with the United States.<sup>34</sup> Since the coming into force of the TRIPS Agreement, New Zealand has looked at extending pharmaceutical patent term, but has chosen not to do so largely because of the obvious cost to healthcare.<sup>35</sup>

In a WTO dispute the European Communities attempted to argue, in the context of a dispute about patent exceptions, that a regulatory review exception<sup>36</sup> must go hand-in-hand with patent term extension.<sup>37</sup> In other words, a country should have both. This was rejected by the WTO dispute settlement panel.<sup>38</sup>

In the New Zealand context, an exception for regulatory review makes sense as it allows generic manufacturers of competing products to enter the market sooner rather than later. As a relatively minor producer of many pharmaceuticals the

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<sup>32</sup> Medicines cannot be sold in New Zealand until they are approved in accordance with the Medicines Act 1981.

<sup>33</sup> Daniel Gervais *The TRIPS Agreement: Drafting History and Analysis* (4th ed, Sweet & Maxwell, London, 2012) at 510–511.

<sup>34</sup> Patent extension is required by AUSFTA, art 17.9(8)(b).

<sup>35</sup> Ministry of Economic Development “Review of the Patents Act 1953; The Pharmaceutical Patent Term in New Zealand Discussion Paper” (June 2003). For further discussion see [2.5.1] below.

<sup>36</sup> WTO Panel Report *Canada – Patent Protection of Pharmaceutical Products* WT/DS114/R, adopted 17 March 2000. As stated in the WTO Panel summary: “Under the regulatory review exception, potential competitors of a patent owner are permitted to use the patented invention, without the authorization of the patent owner during the term of the patent, for the purposes of obtaining government marketing approval, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires.” See <[www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds114\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm)>.

<sup>37</sup> WTO Panel Report *Canada – Patent Protection of Pharmaceutical Products* (WT/DS114/R, adopted 17 March 2000).

<sup>38</sup> WTO Panel Report *Canada – Patent Protection of Pharmaceutical Products* (WT/DS114/R, adopted 17 March 2000) at [7.82].

presence of competition, or at least potential competition, in the New Zealand market is desirable. It equally makes sense not to have patent term extension for pharmaceuticals in particular, as most, if not all, such applications are made to non-New Zealand-based patent holders.

Patent term extension can take different forms. In this chapter we suggest that the optimal economic position for New Zealand is no patent term extension.<sup>39</sup> If, however, in the name of a trade deal New Zealand agrees to provide for patent term extension, then details as to what patents are possible to extend and why become very important. One pharmaceutical product usually involves several patents. Different issues arise if the patent (or any extension) is for the product, for the method of making the product, or for second or subsequent uses of the product, and so on.

### **2.2.3 *Patent term extension in New Zealand's past***

Before the TRIPS Agreement New Zealand provided for patent term extension where there had been inadequate remuneration,<sup>40</sup> or on grounds of loss resulting from war.<sup>41</sup>

All applications made between 1976–1996 relating to pharmaceutical applications for term extension on the basis of inadequate remuneration were granted (some on appeal), unless they were abandoned prior to a decision being made. In total, 30 applications were made, 22 were granted, one declined and seven withdrawn. At first blush, this number may not seem large but they were for significantly expensive and sometimes blockbuster pharmaceutical products. The average extension was for 7.91 years. Our research has also shown that the extensions of term in New Zealand were often the same as, but sometimes longer than, the extensions for the equivalent patents granted in Australia. Also, both Australia and New Zealand gave extensions when other countries, including the United Kingdom and the United States, did not. Although each country had different laws relating to term the overall effect appears to be that New Zealand has given greater protection to some pharmaceuticals than the countries from which they were sourced.

The government's decision, post-TRIPS, to no longer have the possibility of patent term extension was, as discussed above, because the 20-year term took account of extension. After the TRIPS Agreement proposals to extend patent term were rejected because extension was, and would continue to be, a net cost to New Zealand. In such circumstances, the economically sound approach is not to grant

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<sup>39</sup> See discussion at [2.2.3] below.

<sup>40</sup> Patents Act 1953, s 31(1) (repealed) provided "if upon application made by a patentee in accordance with this section the Court or Commissioner is satisfied that the patentee has not been adequately remunerated by the patent, the Court or Commissioner may by order extend the term of the patent, subject to such restrictions, conditions, and provisions, if any, as may be specified in the order, for such period (not exceeding 5 years or, in an exceptional case, 10 years) as may be so specified; and any such order may be made notwithstanding that the term of the patent has previously expired."

<sup>41</sup> Patents Act 1953, s 32 (repealed).

patent term extension.<sup>42</sup> However, as discussed below, the considerations that bear on such a decision are mostly those outside of the patent regime. That is, a trade-off occurs for a benefit somewhere else.

## 2.3 Trade issues

### 2.3.1 *Evidence-based policy and regulatory coherence*

Patent term extension is a trade issue for New Zealand because we are a significant net importer of patented products. In particular, most patented pharmaceuticals are imported. The real question, therefore, is what, if any, benefit does patent term extension have for New Zealand?

For some time there has been recognition that reform of regulation should proceed on evidence-based policy. In the area of intellectual property, the call for evidence-based policy has been heralded in the United Kingdom, which in a recent report stated that intellectual property law would not be amended in the future without such a policy.<sup>43</sup> Of course, it is always possible to find competing evidence, but in the face of an international drive towards evidence-based policy as a basis for regulation, New Zealand is looking at regulating for patent term extension when there is evidence that it would not be beneficial overall.<sup>44</sup> This is illustrative of, among other things, a lack of regulatory autonomy.

Any evidence-based inquiry about patent law reform should ask what New Zealand's interest is in patents, of which there are many. They include maintaining a good relationship with our trading partners who register patents in New Zealand, but fundamentally patents matter because they should be a tool for supporting New Zealand-based innovation. In a global regime there will always be support of overseas innovation through domestic patent laws, but that is only sensible if local innovation is also supported. The justification for the patent system is the social contract whereby property rights are given to a patentee for a limited period of time in exchange for disclosure of the invention. This social contract rests, in part, on a theory of reward and incentive. Unless patent law also supports New Zealand innovation, then the reward is too remote and is always characterised by local consumers paying higher prices for imported innovation. Worse than that, New Zealand businesses, in some sectors, might be inhibited from developing their competitive edge if patents work against their ability to do so.<sup>45</sup> Allowing the space

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<sup>42</sup> The cost of patent term extension is discussed at [2.5.1] below.

<sup>43</sup> Ian Hargreaves *Digital Opportunity: A Review of Intellectual Property and Growth* (May 2011), available at <[www.ipa.gov.uk/ipreview-finalreport.pdf](http://www.ipa.gov.uk/ipreview-finalreport.pdf)>.

<sup>44</sup> MED *Review of the 1953 Patents Act: The Pharmaceutical Patent Term in NZ* (Discussion Paper, June 2003), available at <[www.med.govt.nz/business/intellectual-property/pdf-docs-library/patents/review-of-patents-act/patents-act-1953-pharmaceutical-patent-terms-pdf](http://www.med.govt.nz/business/intellectual-property/pdf-docs-library/patents/review-of-patents-act/patents-act-1953-pharmaceutical-patent-terms-pdf)>.

<sup>45</sup> Patents can work against innovation because either the patentee refuses to licence their use or the licence is unaffordable. For a general discussion of refusals to licence see Ian Eagles and Louise Longdin *Refusals to License Intellectual Property: Testing the Limits of Law and Economics* (Hart Publishing, Oxford, 2011).

for innovation is about creating new opportunities. It is not about sourcing the cheapest goods. While it can make sense to say we will not make cars, we will only import them because we have no comparative advantage in making cars and so imports will be cheaper, the same logic cannot apply to innovation, which is consequently necessarily both local and imported.

Local innovation can be supported through home-grown innovation or investment in innovation that takes place locally. The latter is, however, about investment in innovation rather than investment in offshoots of innovation. So, for example, the Singapore experience may be instructive here. Singapore has attracted investment in its pharmaceutical industry, but that investment is not in research and development or local innovation, rather the investment has been in using Singapore as a manufacturing and distribution point for the South East Asian market. Although, as the passage below says, most of the trade is from re-exported pharmaceuticals:<sup>46</sup>

The volume of trade in pharmaceuticals flowing in and out of Singapore is disproportionately large compared with the size of the country, due to its status as a distribution centre. The country exports a large amount of pharmaceuticals, although the majority of this total is from re-exported goods. The balance of pharmaceutical trade remains positive.

The stronger patent law is, the harder it can be to promote local innovation. Competition in the generic pharmaceuticals market, for example, is certainly inhibited by patent term extension. New Zealand has some local interest in producing generic pharmaceuticals as well as an interest in purchasing such pharmaceuticals because they are cheaper, even if they are not made here. There may be other aspects of patent law over which retaining autonomy may also be important.<sup>47</sup>

Therefore, those who argue for stronger patent laws (including the introduction of patent term extension) because it will attract additional research monies and increase innovation are only speculating. New Zealand has had relatively strong patent laws for some time and there has been no evidence of any substantial investment from pharmaceutical companies in New Zealand. Arguably, stronger patent laws might attract further investment from pharmaceutical companies; however, there is no evidence it will generate further innovation.<sup>48</sup> The Singapore example may well be evidence that investment from the pharmaceutical companies

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<sup>46</sup> Epsicom Business Reports "The Pharmaceutical Market: in South East Asia to Reach US\$80 Billion by 2017 at Retail Prices", available at <<http://www.prweb.com>>. An important question for Singapore is whether it would have been a centre for pharmaceuticals distribution without government investment to attract pharmaceutical companies. A strong case can be mounted to show that Singapore is a major entry point for many different products and services and thus pharmaceutical companies may have located in Singapore with or without government support.

<sup>47</sup> These include patentability criteria, for example, novelty and inventive step. See discussion in Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in Susy Frankel (ed) *Learning from the Past, Adapting for the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011).

<sup>48</sup> PHARMAC "Submission to the Commerce Committee on Patents Bill 2008".

themselves will not necessarily generate innovation. Further, the windfall gains reaped by pharmaceutical companies through patent extension are likely to be greater than the additional research monies that a country like New Zealand could attract.

Historically, New Zealand could be said to have “swallowed overseas patent law”. This was not an unusual way of augmenting our laws in the past. Indeed, this approach may have been a benefit as it saved resources of redrafting laws and, in this case, may have encouraged locals to seek foreign patenting. Overall, however, the direct evidence with respect to patents<sup>49</sup> is that the law needs more flexibility to benefit New Zealand interests, not increased levels of protection for overseas interests.<sup>50</sup>

### 2.3.2

#### ***Negotiations with Australia and the other TPP partners***

New Zealand and Australia are, in the single economic market (SEM) context, at the time of writing, involved in a bottom-up negotiation over patent examination. Patent term extension does not appear to be part of that discussion. However, both countries are a part of the TPP negotiations, which we see as a top-down negotiation, at least in part. Even though New Zealand has been the smaller player in the bottom-up SEM negotiations, at least in the past, it has had what might be described as an “escape route” for New Zealand interests.

In the food standards regime,<sup>51</sup> there were opt-out mechanisms New Zealand could employ where its interests were different from the trans-Tasman interest. The same is arguably true in the current SEM negotiations, but in the TPP there is unlikely to be an opt-out mechanism. Thus, as far as patent term extension is concerned, New Zealand is “trapped” in a position where, because of top-down arrangements, it will possibly “swallow” another law that will increase costs to the New Zealand consumer and taxpayers. Australia is also involved in both models; however, the limits of the bottom-up model are arguably dictated by Australia’s relationship with its other trading partners and this imports an element of top-down into the bottom-up regime. As time progresses, therefore, in some aspects of the SEM relationship there seems to be less room for a New Zealand position that might differ from that of Australia’s other trading partners.

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<sup>49</sup> See [2.5.1] below.

<sup>50</sup> An example of flexibility would be an experimental use exception. See Patents Bill 2008, cl 136, which proposes the introductions of a statutory experimental use exception. See also Susy Frankel “An Experimental Use Exception from Patent Infringement for New Zealand” (2009) 12(5) JWIP 446.

<sup>51</sup> See Susy Frankel and Meredith Kolsky Lewis “Trade Agreements and Regulatory Autonomy: The Effect on National Interests”; Chris Nixon and John Yeabsley “The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road” in Susy Frankel (ed) *Learning from the Past, Adapting for the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011).



### 2.3.3 Additional TPP considerations

In the TPP there is also a regulatory coherence chapter.<sup>52</sup> That chapter seeks to embed the regulatory impact assessment (RIA) process within all TPP members. The relevant draft provisions are:<sup>53</sup>

1. Through its national coordinating body, process or mechanism, each Party, in carrying out responsibilities for reviewing covered regulatory measures, should generally encourage relevant regulatory authorities, consistent with domestic law, to conduct regulatory impact assessments (RIAs) when developing covered regulatory measures that exceed a threshold of economic impact established by a Party, to assist in designing a measure to best achieve the Party's objective.
  - a. An RIA should identify, among other things:
    - (1) the problem and the policy objective that the regulatory authority intends to address, including an assessment of the significance of the problem and a description of the need for regulatory action;
    - (2) potentially effective and reasonably feasible alternatives to achieve the policy objective; and
    - (3) where appropriate, the grounds for concluding that the selected alternative achieves the policy objectives in a way that maximizes net benefits, including qualitative benefits, while also considering distributional impact.
  - b. An RIA should include the following elements:
    - (1) a consideration of whether, for all aspects of the planned regulatory measure, there is a need to regulate to achieve the policy objective or whether an objective can be met by non-regulatory and/or voluntary means, consistent with domestic law;
    - (2) an assessment, to the extent feasible and consistent with domestic law, of the costs and benefits of each available alternative, including not to regulate, recognizing that some costs and benefits are difficult to quantify and monetize;
    - (3) an explanation why the alternative selected is superior to the other available alternatives identified, including, if appropriate, through reference to the relative size of net benefits of the available alternatives; and
    - (4) decisions based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities, mandates, and resources of the particular regulatory authority

These standards are not necessarily surprising from a RIA perspective.<sup>54</sup> However, it is interesting to consider what a RIA on patent term extension, or indeed other areas on patent law, might look like. It seems unlikely that it would favour such a law at present. While the leaked draft text does not seem to propose that existing

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<sup>52</sup> The leaked regulatory coherence chapter is available at <[www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificRegulatoryCoherence.pdf](http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificRegulatoryCoherence.pdf)>.

<sup>53</sup> Trans-Pacific Partnership Regulatory Coherence Chapter, art X.3, available at <[www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificRegulatoryCoherence.pdf](http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificRegulatoryCoherence.pdf)>.

<sup>54</sup> However, what is covered by an RIA may vary and presumably the TPP parties will have to reach some agreement on coverage. In New Zealand, RIAs are for all cabinet decisions, including those that relate to primary legislation, such as patent law. In the United States, they do not apply to federal legislation, including patents.

regulations would be subject to such analysis, it is possible that in the context of a review, a RIA could show that an intellectual property law already in place is not the best option. If an intellectual property law would need to be enacted because it was agreed in a top-down trade agreement then that enactment could occur without a RIA.<sup>55</sup> It seems that in New Zealand we would honour our international agreement and pass the law. However, this approach is not always found in our trading partners. In the United States unpopular FTA-based law changes are more likely than in New Zealand, to be defeated in the (independent) legislative process.

Thus, despite the existence of RIA and the growing regulatory management regime, New Zealand is negotiating laws through trade agreements which the analysis of these regimes and evidence-based policy would likely suggest<sup>56</sup> New Zealand should not adopt. In such circumstances, the impact on New Zealand's regulatory autonomy might be severe. The risk of accepting a costly new law in the name of another perceived, but yet to be quantified, benefit needs to be widely discussed<sup>57</sup> to ensure that the trade-off is understood, and the quality of the underlying assessment known and accepted.

### **2.3.4 ASEAN + considerations**

New Zealand and Australia have formed an FTA with ASEAN.<sup>58</sup> ASEAN has additionally reached several other agreements with individual countries, collectively known as the ASEAN + 1 agreements. There has been discussion for some time, however, of creating a larger ASEAN + agreement that would link together some of the + 1 countries into a single FTA with ASEAN. In particular, some have advocated an ASEAN + 6 agreement that would include the 10 ASEAN economies, plus Japan, China, South Korea, Australia, New Zealand and India. This idea may come into fruition, as negotiations have just been launched to create an ASEAN + 6 agreement, also known as the Regional Comprehensive Economic Partnership (RCEP).<sup>59</sup> This section considers New Zealand's negotiating interests and strategic implications in the context of the ASEAN + 6 negotiations.

New Zealand's aims for the ASEAN + 6 countries are both generally, and specifically in relation to patents, different from the leaked draft text of the TPP. The focus of the TPP is bringing patent and other intellectual property protection to the forefront, even though New Zealand might aim to keep protection at a TRIPS Agreement level. The main reason that New Zealand should not want to increase

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<sup>55</sup> Though the whole agreement, as an international treaty would require a National Interest Assessment, which, in concept, is supposed to address similar analytical questions about the benefits as those tackled by a RIA.

<sup>56</sup> See discussion at [2.5.1] below.

<sup>57</sup> For a discussion of public participation in the regulatory process see Mark Bennett and Joel Colón-Ríos "Public Participation and Regulation" in Susy Frankel (ed) *Learning from the Past, Adapting for the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011).

<sup>58</sup> ASEAN means Association of Southeast Asian Nations. See ASEAN, Australia and New Zealand Free Trade Agreement, available at <[www.mfat.govt.nz](http://www.mfat.govt.nz)>.

<sup>59</sup> See, for example, ASEAN Launch RCEP China, South Korea, Japan, India, Australia and New Zealand, available at <[www.taiwannews.com.tw/etn/news\\_content.php?id=2078413](http://www.taiwannews.com.tw/etn/news_content.php?id=2078413)>.

overall patent protection in the ASEAN relationship is that the ASEAN + 6 countries are not a major source of patented products, particularly pharmaceuticals, but are a major source of generic pharmaceuticals, which may be cheaper for New Zealand to buy.

On the importing side, New Zealand is concerned with ensuring that product safety standards of generic pharmaceuticals are met. Not only does the trade relationship assist in assuring product safety, it also helps in the development of a competitive market for generic pharmaceuticals, since sources of supply can be diversified.<sup>60</sup>

On the exporting side, New Zealand wants to ensure patent integrity for its exports to ASEAN + 6 countries. This does not include domestically made generic pharmaceuticals because they are not patented, but theoretically it would include exports of other patented products.

Patent term extension is not part of this overall ASEAN patent approach, but potentially strengthening patent offices in the region may be part of the New Zealand (and perhaps more Australian) interest in an ASEAN + 6 agreement. The strengthening of patent offices could be seen as part of a longer term objective by New Zealand to reinforce the institutional quality within the ASEAN + 6 countries.<sup>61</sup> That objective underpins regulation, since effective implementation is an important element of any free trade agreement and improving economic growth rates in those countries should then lead to more purchases of New Zealand products and services.

### (a) *The link between institutional quality and patent law*

While the concept of institutional quality is not new, there are many different definitions used to describe institutions. There is no single agreed definition of what institutional quality is and the terms “institutions”, “institutional quality” and “governance” are used interchangeably.

We have followed Kaufmann and his fellow authors in describing institutional quality as:<sup>62</sup>

... the traditions and institutions by which authority in a country is exercised. This includes the process by which governments are selected, monitored and replaced; the capacity of the government to effectively formulate and implement sound policies; and the respect of citizens and the state for the institutions that govern

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<sup>60</sup> PHARMAC *Annual Review Year ended 30 June 2009* at 7, available at <[www.pharmac.govt.nz/AnnualReport](http://www.pharmac.govt.nz/AnnualReport)>.

<sup>61</sup> See Susy Frankel, Chris Nixon, Megan Richardson and John Yeabsley “The Challenges of Trans-Tasman Intellectual Property Coordination” (ch 4) in this volume. For a discussion of the institutional quality of patent offices generally see Peter Drahos *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge University Press, Cambridge, 2010).

<sup>62</sup> Daniel Kauffman, Aart Kraay and Massimo Mastruzzi *Governance Matters VII: Aggregate and Individual Governance Indicators 1996–2007* (Policy Research Working Paper 4654 of the World Bank Development Research Group of Macroeconomics and Growth and the World Bank Institute of Governance, Regulation and Finance, 2008) at 7.

economic and social interactions among them.

Some views on the importance of institutional quality include that: institutions matter a great deal in economic performance;<sup>63</sup> institutions are difficult to change despite obvious benefits;<sup>64</sup> institutional change is rare and is usually the result of changes in the economic environment; and institutions are a source of comparative advantage in trade.<sup>65</sup>

The connection between institutional strength and economic policy – domestic and external – is strong. For example, Rodrik argues that the growth benefits of trade liberalisation may not actually come from drops in tariffs or other restrictions, but through domestic institutional reform.<sup>66</sup>

Complicating matters is that there are many possible indicators that can shed light on various elements of institutional strength, and the data is subjective. No one indicator or group of indicators can reveal all elements of institutional strength.

Any indicators developed will provide imperfect signals of what is an unobservable concept of institutional strength. We also have to recognise that any indicators will involve some level of measurement error. Further, although institutional strength is overall a positive it is fact specific. In other words, what we gain from institutional strength may vary according to the particular field. In the patent field institutional strength may be seen by some as the ability to register a patent, but real institutional strength may lie in the ability to legitimately refuse to implement TRIPS-plus patent law (when there is no FTA commitment to do so) and to reject, on a legal basis, specific patent applications that are contrary to a country's economic interests. Beyond the patent office, institutional strength may be demonstrated by the ability to negotiate more favourable conditions. This may mean negotiating conditions that mitigate against unfavourable patent law and specific patent conditions that are contrary to a country's economic interests.

### **2.3.5 The path back to the multilateral process: the long-term view**

As discussed in Stage One of this project, New Zealand is somewhat limited, by virtue of its small size, in what it can accomplish in multilateral, plurilateral, or even

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<sup>63</sup> Rafael La Porta and Florencio Lopez-de-Silanes "Capital Markets and Legal Institutions" in Shahid Javed Burki and Guillermo E Perry (eds) *Beyond the Washington Consensus: Institutions Matter* (World Bank Publications, Washington (DC), 1998); Daron Acemoglu, Simon Johnson and James A Robinson "The Colonial Origins of Comparative Development: An Empirical Investigation" (2001) 91 AER 1369; Dani Rodrik *One Economics, Many Recipes: Globalization, Institutions and Economic Growth* (Princeton University Press, Princeton (NJ), 2007).

<sup>64</sup> Daron Acemoglu, Simon Johnson, Pablo Querubín and James A Robinson "When Does Policy Reform Work? The Case of Central Bank Independence" (2008) 1 BPEA 351.

<sup>65</sup> Nathan Nunn "Relationship-Specificity, Incomplete Contracts and the Pattern of Trade" (2007) 122 Quarterly Journal of Economics 157; Arnaud Costinot "An Elementary Theory of Comparative Advantage" (2009) 77(4) Econometrica 1165.

<sup>66</sup> Dani Rodrik "Institutions for High-Quality Growth: What They Are and How to Acquire Them" NBER Working Paper 7540 (NBER, Cambridge (Mass), 2000).

certain bilateral trade negotiations. However, this does not mean that New Zealand cannot influence the outcomes of such negotiations; but it may be required to make difficult choices in order to do so.

Because New Zealand's ability to achieve the outcomes it desires may hinge upon trading off other important interests, it is important to think strategically about what to give away, when, and in exchange for what. A relevant consideration in this context is whether the concession sought in the bilateral (or in the case of the TPP, plurilateral) context is likely to be one that the other party or parties will seek to multilateralise or not. In other words, will New Zealand's trading partners seek to extend the application of the conceded provision (for example, patent term extension) to all WTO members through the multilateral negotiating process? The answer to this question should weigh on negotiators' minds when considering the cost of making concessions in the bilateral or plurilateral context. Below, this concept is developed further, with particular reference to the TPP and an ASEAN + 6 agreement.

## 2.4 What type of agreement?

Obviously the degree to which New Zealand can control the outcome of any international agreement will affect the extent to which the agreement might have unwanted effects on the structure and detail of local regulation. So what sort of influence can New Zealand have?

For trade agreements to be durable the forces holding them together should outweigh the forces pulling them apart over time. In other words, for each of the participants, the "participation constraint" – that the value of being in the deal is greater than the value of being out – is, and continues to be satisfied. Obviously this is a fairly high hurdle, but the approach adopted in some of the previous work of two of us,<sup>67</sup> has been to carefully consider what might undermine either the motivations for signing any particular agreement (domestic and international) or the tacit understandings that underpin that motivation.

Traditionally, the gains from trade policy have been relatively easy to see for New Zealand. The typical straightforward analysis was: if the higher-income nations reduced agricultural protection then the New Zealand economy was likely to gain.<sup>68</sup> In that situation little analysis on the detailed costs and benefits was thought necessary.

Times have changed. The global liberalisation process is now impacting on a wider number of sectors and issues; New Zealand now needs to answer highly specific questions that affect its interests in ways that are complex and difficult to

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<sup>67</sup> Chris Nixon and John Yeabsley "The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road" in Susy Frankel (ed) *Learning from the Past, Adapting for the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011).

<sup>68</sup> The economic case was even more obvious when the question of reducing New Zealand's high levels of protection was the quid pro quo that was demanded; such reductions were welfare enhancing for the local consumers, even without any contribution by counterparties.

trace through to their final outcomes. The “ideal” type of agreement can only be identified when the options in the political, economic, and institutionally feasible set have been fully identified. This requires a more detailed approach to understanding the costs and benefits of any particular agreement; for example, what are the net benefits of moving away from current patent regulations? Or, how would regulatory coherence principles be acted upon within the TPP? Would member states be able to enforce transparent regulatory processes on other signatories in practice or would they just acknowledge that they are important?

#### **2.4.1 *New Zealand’s ability to influence outcomes in trade negotiations***

The prevailing wisdom is that small countries, such as New Zealand, should prefer multilateral trade negotiations under the auspices of the WTO to negotiations with a small number of parties.<sup>69</sup> This is because WTO agreements are reached through consensus of all members, which imposes some limitations on the ability of any one member – such as the United States or European Union (EU) – to act as a term-setter. Countries that do not like the terms proposed by, for example, the United States, can band together and decline to sign them. Alternatively, they can negotiate other forms of concessions in exchange for agreeing to what the more powerful country is seeking. Thus the consensus requirement, coupled with the large number of WTO members, protects countries such as New Zealand to a degree from having terms simply imposed upon it.

However, as we have discussed in an earlier paper, there are situations in which the bilateral or plurilateral negotiating context may actually benefit New Zealand. These include cost savings in certain contexts; the ability to reach agreements relatively quickly and easily on issues where the negotiating parties share the same objectives; and the opportunity to build in flexible and case-specific exemptions, as in the Australia – New Zealand food safety regime.<sup>70</sup>

The more complicated situation arises when New Zealand is faced with a trade negotiation in which it does not share the objectives of a more powerful participant to the negotiation. In the TPP, for example, New Zealand and the United States have different views on a number of issues; most relevant to this discussion are those relating to expanded intellectual property protections such as increased patent term.

New Zealand is not powerless in these negotiations; however, particularly in light of the existing FTAs between the United States and other TPP negotiating members that already incorporate some of the concessions the United States is seeking in the TPP negotiations, New Zealand’s ability to influence outcomes inevitably comes at a cost. In particular, it is likely that various trade-off scenarios are being considered. Perhaps New Zealand will determine that some of the

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<sup>69</sup> The main economic reason for preferring WTO negotiations is that the more countries involved, the greater the likely total benefit.

<sup>70</sup> See Susy Frankel and Meredith Kolsky Lewis “Trade Agreements and Regulatory Autonomy: The Effect on National Interests” in Susy Frankel (ed) *Learning from the Past, Adapting to the Future: Regulatory Reform in New Zealand* (LexisNexis, Wellington, 2011).

intellectual property provisions are such an anathema to its interests, for instance, that it would be willing to give up on its demands for increased access to the United States market for dairy products. Or perhaps – as we suspect may be more likely – the reverse calculus will occur. But in either case, the reality is that in a contested negotiation, New Zealand will not be able to dictate terms except for a price. It is thus important not only to determine what that price might be, but to consider in detail what indirect costs or benefits might result from agreeing to particular terms.

#### **2.4.2 *Sui generis provisions vs potentially universal provisions***

As with any international trade agreement, terms agreed to in the TPP context could have costs or benefits that may not be immediately apparent. However, if agreeing to terms in the TPP makes it more likely the same terms will be adopted in the WTO – or, to the contrary, makes it less likely such terms will be sought in the WTO – then these are considerations about which negotiators should be mindful.

In some circumstances, a proposed FTA term will be designed to address unique particularities between the parties, and as such could be considered to be *sui generis*. Various aspects of New Zealand’s CER agreement with Australia, as well as the CER “upgrade”, the SEM, fit this description. New Zealand and Australia, by virtue of their geographic proximity, high degree of cross-border trade, desire to achieve regulatory efficiencies, similar levels of economic development and certain shared regulatory objectives have agreed to a host of terms that are unique to their trans-Tasman relationship. Such provisions, including forming joint standards-setting bodies for, inter alia, food safety, are not ones that either country is likely to seek to broaden to include other trading partners. The context of some measures therefore, will be limited to the initial agreement in which they are negotiated.

In contrast, other provisions may deal with issues where certain countries will perceive an advantage to broadening the applicability of such provisions. This may occur in the first instance via other bilateral negotiations. The United States is often referred to as having an “FTA template”; this means that there are certain terms the United States has agreed to with its FTA partners that it then seeks to replicate in all of its subsequent FTAs. If a particular provision becomes sufficiently prevalent in FTAs, it may be the case that WTO members whose FTAs feature such a term will seek to multilateralise that commitment to encompass and bind all WTO members. Of course the rest of the WTO membership can, and indeed may, resist this effort; however, the more widespread the use of a particular practice, the less practical it may be to choose that issue on which to hold out. Therefore, there is a strong possibility that terms agreed to in a large plurilateral agreement such as the TPP could be further expanded into other FTAs, and perhaps ultimately be multilateralised into WTO obligations.

Lest the above seem too abstract, it is worth briefly reviewing the history of some previous plurilateral trade agreements. In the pre-WTO era, the General Agreement on Tariffs and Trade (GATT)<sup>71</sup> conducted eight different, multi-year

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<sup>71</sup> General Agreement on Tariffs and Trade 1947, 15 April 1947, Marrakesh Agreement

negotiating rounds. The eighth of these, the Uruguay Round, resulted in the creation of the WTO and was treated as a “single undertaking” pursuant to which a country had to accede to all the covered agreements comprising the WTO in order to become a WTO member. This was a different approach from that taken in earlier GATT rounds. In both the Kennedy (1964–1967) and Tokyo Rounds (1973–1979), agreements were created even though only a subset of signatories elected to join. During the Tokyo Round many such agreements, known as “codes”, were formed.<sup>72</sup> Examples of such agreements included the GATT Subsidies and Countervailing Measures Code;<sup>73</sup> the Standards Code (relating to technical barriers to trade); the Anti-dumping Code;<sup>74</sup> and codes relating to import licensing procedures and customs valuation.<sup>75</sup>

These codes were ultimately incorporated, with amendments, into the Uruguay Round agreements and became commitments applicable to all Members upon the creation of the WTO.<sup>76</sup>

In the first instance, the signatories to the Tokyo Round codes were primarily developed/industrialised countries. In all likelihood it was not initially possible to obtain agreement of all GATT signatories to their terms. Yet in the following negotiating round – the Uruguay Round – these codes became the starting point for negotiating the Anti-dumping Agreement; the Technical Barriers to Trade Agreement; the Subsidies and Countervailing Measures Agreement; the Agreement on Customs Valuation; and the Agreement on Import Licensing.

Not all plurilateral agreements are destined to be multilateralised. Several of the Tokyo codes have remained as codes<sup>77</sup> and have not been signed onto by the entire WTO membership. Nonetheless, there is a real possibility that commitments made in the plurilateral context will lead to future efforts to multilateralise these provisions.

This seems particularly likely in the case of commitments relating to intellectual property because of the way countries choose to implement bilateral or plurilateral intellectual property agreements that extend protections beyond those provided for in the WTO’s TRIPS Agreement. Below we explain why this is the case.

In traditional goods-related free trade agreement provisions, such as committing to lower tariffs on product “X” to zero over the five or 10-year period following the

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Establishing the World Trade Organization (WTO Agreement), Annex 1A, 1867 UNTS 187; 33 ILM 1153 (GATT).

<sup>72</sup> See “The GATT Years: from Havana to Marrakesh” <[www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact4\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm)>.

<sup>73</sup> Interpreting GATT, arts VI, XVI and XXIII.

<sup>74</sup> Interpreting GATT, art VI.

<sup>75</sup> Interpreting GATT, art VII.

<sup>76</sup> Four codes were incorporated into the WTO as an exception to the “single undertaking” rule, meaning that WTO members did not have to agree to the terms of these codes in order to become WTO members. These codes related to government procurement, civil aircraft, bovine meat and dairy products. In 1997, members agreed to terminate the latter two agreements, leaving two extant codes.

<sup>77</sup> See “The GATT Years: from Havana to Marrakesh” <[www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact4\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm)>.



entry into force of the FTA, the party making such a commitment can rather simply amend its tariff code to note that for “X” coming from its FTA partner, the tariff shall be zero. This change does not tend to lead the committing party to lower its tariff on “X” from other countries to zero, because it is not unduly burdensome for customs officials to charge different tariffs based on country of origin, and because the committing party’s FTA partner sees a value in having duty-free access for “X” and presumably would not be pleased if that preferential position were to be erased by the committing country simply removing all tariffs on “X” regardless of origin.

Intellectual property commitments are different, however. Once there is a bilateral agreement to extend intellectual property protections beyond those that the TRIPS Agreement requires, in practice, what is overwhelmingly likely to happen is that the FTA partners will change their applicable law across the board; that is to say, countries are much less likely to apply different patent eligibility criteria or even patent terms to the inventions of each of their trading partners. This is arguably because their multilateral commitments in the TRIPS Agreement mean that they are not permitted to do so. Where they are permitted to do so (which is in limited circumstances), many countries elect not to apply different laws to different countries.<sup>78</sup> In summary then, in practice, what occurs is that once a WTO member enters into an FTA that results in a TRIPS-plus provision, such as extended patent term for pharmaceutical patents, the member changes its law – applicable to all pharmaceutical patents, regardless of country of origin – to the TRIPS-plus level of protection.

The implication of this practice is that TRIPS-plus intellectual property protections are highly susceptible to becoming multilateralised. Once a country has agreed to an extended patent term – perhaps with the United States which often demands TRIPS-plus terms – that country will in practice extend those added protections to all WTO members. As a result, when that country enters into new FTA negotiations, it may well ask for these additional intellectual property protections from its new FTA partner – to make reciprocal what is already occurring unilaterally. In the TPP context, for example, Australia, Singapore and Chile all have extended patent term in their existing FTAs with the United States. Thus, even for a country that did not want to provide TRIPS-plus protections in the first place, once it has agreed to do so once, it may seek to have its patents given the same treatment.

### **2.4.3 Counterfactual**

The previous sections point to the detailed costs and benefits that need to be

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<sup>78</sup> One area where countries can be treated differently relates to copyright term. A country with a long term can apply a shorter term to works from countries with a shorter term. This is an exception in the Berne Convention incorporated into the TRIPS Agreement, art 3. The EU, Australia and the United States all have TRIPS-plus copyright terms of life of the author plus 70 years, or 70 years from the making of a work. The EU only applies the 70-year term to other countries with that term. Australia and the United States apply the longer term to works originating from all countries.

considered before entering into a trade policy negotiation. Crucial to understanding the value of any agreement is to measure it against what might have happened otherwise (the counterfactual). Any number of counterfactuals could be set up, including a unilateral approach to intellectual property protection where New Zealand disregarded international retaliation by protecting New Zealand intellectual property and not offering protection for imported intellectual property or pushing for a multilateral deal on intellectual property.

None of these options is currently on the table since the multilateral process has stalled and a unilateral process is likely to have spill-over costs that are unpalatable. We have chosen a “do nothing beyond existing protection” approach to patents within trade agreements as the counterfactual. This naïve approach has been taken not because we think it is a likely business as usual scenario, but to illustrate what the value might be of alternative trade agreements.

This scenario becomes the baseline from which we measure changes that occur with alternative trade agreements. The following sections set out this preliminary qualitative analysis.

## 2.5 Alternative scenarios facing New Zealand: horses for courses?

Consideration needs to be given to a variety of different factors that determine the success or otherwise of a trade agreement.<sup>79</sup> On the supply side, New Zealand needs to understand what it wants from the negotiations, and whether those goals are realistic. On the demand side, it needs to understand at a detailed level:

- (1) the base condition for an agreement given the history of contact between the negotiating nations and any issues that could hinder or help the prospective trade agreement to succeed; and
- (2) the likely conduct of the stakeholders, understanding as far as possible the institutional, economic and political issues that will have a bearing on the negotiations. This could include judgments on institutional strength.

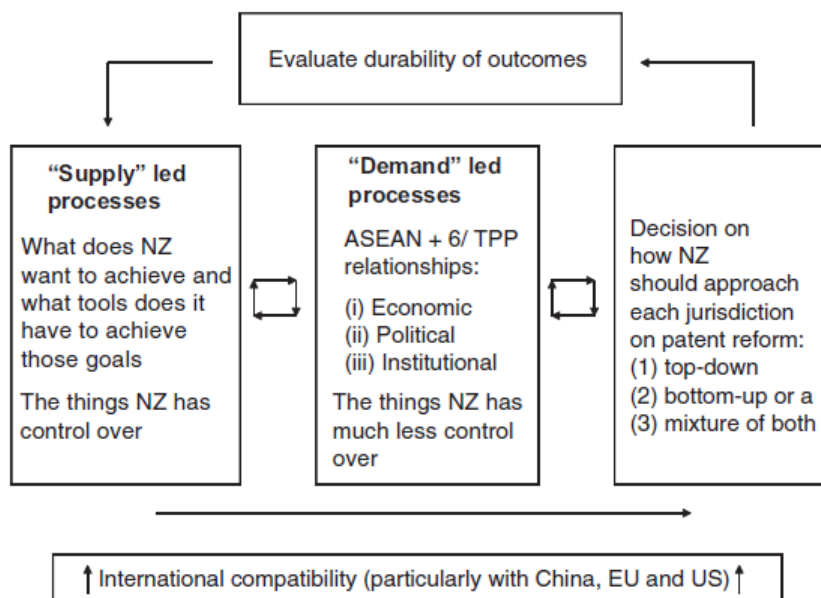
By understanding the supply side (things that New Zealand *can* control) and the demand side (mostly things that New Zealand *cannot* control) we can then shape how New Zealand should approach each negotiation and each country in that negotiation and readjust once an evaluation has been undertaken.

In Figure 2.1 we characterise two alternative trade agreements that can be examined separately or together – they do not have to be mutually exclusive. In both cases they consider the impact of patent term extension under the TPP and ASEAN + agreements.

Figure 2.1: Patent reform in the TPP & ASEAN + 6 nations

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<sup>79</sup> See Figure 2.1 taken from Chris Nixon and John Yeabsley “The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road” in Susy Frankel (ed) *Learning from the Past, Adapting for the Future* (LexisNexis, Wellington, 2011) at 378.



## 2.5.1 Extending patent term under the TPP

As discussed above, New Zealand is likely to be under significant pressure in the top-down TPP negotiations to have increased intellectual property protection, including patent term extension. Overall the costs of doing so appear to outweigh the known benefits.

There is substantial cost involved. Our research examined the question of the impact of patent term extension on the price of pharmaceuticals for human treatment in the New Zealand context. They include a windfall gain to producers of patented medicines already in production and further monopoly rents for pharmaceuticals that clear regulatory hurdles.

Studies have shown the costs at millions of dollars for pharmaceuticals. In a 2003 discussion paper the Ministry of Economic Development (MED) said:<sup>80</sup>

If the patent term for pharmaceuticals is extended, then this would delay the entry of generic pharmaceuticals onto the New Zealand market. Generic pharmaceuticals are generally cheaper than the original patented pharmaceutical. This would have the effect of increasing the total amount that New Zealanders pay for patented pharmaceuticals.

The cost of this would be reflected through higher prices to consumers of the pharmaceuticals. For New Zealand, most of the cost would be incurred by the publicly funded health system. While the actual cost would depend on the design of an extension, the Government's agency for managing pharmaceutical expenditure, PHARMAC, has estimated that the cost of extending patents over the next four years

<sup>80</sup> MED "Review of the Patents Act 1953 The Pharmaceutical Patent Term in New Zealand Discussion Paper" (June 2003) at [46]–[47], available at [www.med.govt.nz/business/intellectual-property/pdf-docs-library/patents/review-of-patents-act/patents-act-1953-pharmaceutical-patent-terms-pdf](http://www.med.govt.nz/business/intellectual-property/pdf-docs-library/patents/review-of-patents-act/patents-act-1953-pharmaceutical-patent-terms-pdf).

could be from \$85 to \$135 million depending on PHARMAC's ability to renegotiate supply agreements. This will either reduce the availability of subsidised pharmaceuticals to New Zealanders or, to maintain the same level of access, require the government to increase health sector funding. There will also be increased costs to consumers for nonsubsidised pharmaceuticals.

Medicines New Zealand has suggested that the absence of patent term extension (and other matters relating to patent law and the setup of PHARMAC) affects the availability of pharmaceuticals in New Zealand.<sup>81</sup> We have not found that to be the case. There are other factors that affect availability, such as the willingness of some sellers to supply a small market.

If New Zealand were to extend patent term, the extra revenue collected by patent holders will go offshore. This is how it is with pharmaceutical patents in any event, but the increase in patent term extension, which is not an international obligation, should arguably be avoided as a further cost. Particularly, as we discuss below, as it is likely that the long-term aim of the United States for including term extension in the TPP is to try and gain momentum for it to be multilateralised. Therefore, one issue for New Zealand is whether it is worth resisting patent term extension in the TPP so that more like-minded interests can join with New Zealand in the multilateral discussion.

The only benefits that could be expected in extending patent term are the long-term trade-offs associated with other parts of the agreement. Some have suggested, for example, that the regulatory coherence chapter may be a worthwhile trade-off, which we discuss further below.<sup>82</sup>

## **2.5.2 Applying the framework to an ASEAN + 6 agreement**

In ASEAN + 6 countries, Nixon and Yeabsley<sup>83</sup> have shown that harmonisation is unlikely to be the dominant model for regulatory interconnection because of the varying per capita GDPs, differing cultures and the varying quality of institutions in an ASEAN + 6 setting. This means that an EU style "one size fits all" approach will not produce an optimal result in most cases (although it could be adopted with the industrialised nations in the region). Potentially, this negotiation could be approached with more of a mixture of top-down and bottom-up processes, with the consequence that the deals are harder to do, more time consuming and potentially more costly.

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<sup>81</sup> See Researched Medicines Industry Memorandum (22 June 2010) <[www.medicinesnz.co.nz/assets/Uploads/Patents-Bill-the-position-in-brief.pdf](http://www.medicinesnz.co.nz/assets/Uploads/Patents-Bill-the-position-in-brief.pdf)>.

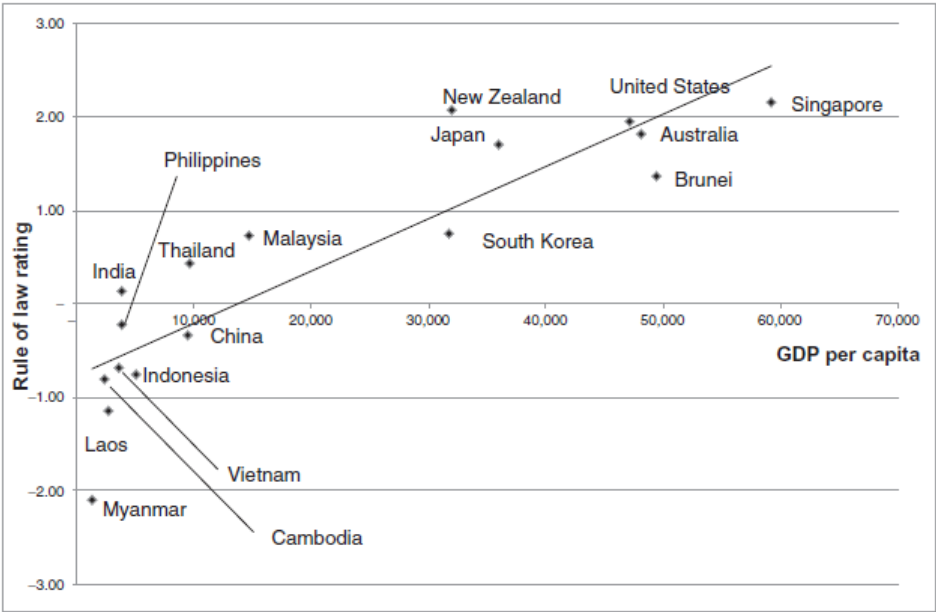
<sup>82</sup> The benefit of regulatory coherence is, among other things "ensuring TPP member countries maintain transparent systems, risk and science based - adhering to international best practice", see "Potential of Regulatory Coherence: A View from New Zealand Food and Agriculture Exporters", TPP Stakeholder Event (September 2011) <[www.mfat.govt.nz/downloads/trade-agreement/transpacific/Regulatory\\_Coherence\\_Presentation\\_\\_TPP\\_\\_Chicago\\_\\_September\\_2011.PDF](http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/Regulatory_Coherence_Presentation__TPP__Chicago__September_2011.PDF)>.

<sup>83</sup> Chris Nixon and John Yeabsley "The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road" in Susy Frankel (ed) *Learning from the Past, Adapting for the Future* (LexisNexis, Wellington, 2011).

In bilateral agreements a different approach is required to achieve the optimal result for New Zealand. To understand what an optimal approach in each case might look like, careful empirical work is needed to assess the trade-offs between assistance (to improve institutions) before and after any agreement is signed, and action to enforce agreements.

Figure 2.2 sets out the approach with the example of patents. On the vertical axis we have made an assessment of the rule of law<sup>84</sup> in each of the 16 countries comprising the ASEAN + 6. The assessment, using World Bank data<sup>85</sup> illustrates the ability of countries to enforce patent law (if it exists).<sup>86</sup> Implicitly this is a judgment on institutional development with the rule of law used as a proxy to illustrate the ability of authorities to deliver patent enforcement.

Figure 2.2: GDP per capita correlated with the rule of law estimates



Source: Conference Board (2012), Levchenko (2010) and NZIER

In the characterisation we have used, this is a bottom-up approach. On the horizontal axis we matched judgments about the rule of law with real GDP per capita – the best index we have for valuing national income. A regression line has been fitted to the variables representing the point where a country should be in its development of

<sup>84</sup> This index is based on Andrei Levchenko “International Trade and Institutional Change”, Table A2 at 38–39, available at <[www.alevchenko.com/Levchenko\\_Trade\\_Institutions\\_December2011.pdf](http://www.alevchenko.com/Levchenko_Trade_Institutions_December2011.pdf)>, adapted from Daniel Kaufmann, Aart Kraay and Massimo Mastruzzi *Governance Matters IV: Governance Indicators for 1996–2004* WPS 3630 (Mimeo, The World Bank, 2005).

<sup>85</sup> Julian di Giovanni and Andrei A Levchenko “Firm Entry, Trade, and Welfare in Zipf’s World” NBER Working Paper 16313 (NBER, Cambridge (Mass), 2010), available at <[www.alevchenko.com/w16313.pdf](http://www.alevchenko.com/w16313.pdf)>.

<sup>86</sup> Myanmar, for example, has no patent law.

(patent) law relative to its per capita GDP. If the jurisdiction is above or around the regression line then its (patent) law development is more fully advanced relative to its GDP than “average”. Being substantially below the line means that work is required to advance patent protection to the level that might be expected.<sup>87</sup>

For those below the line we have classified the jurisdictions into four groups.

- (1) *Assistance only*. There is no point taking any action since they will not be able to enforce a higher quality patent law. What sort of assistance is required depends on the jurisdiction and other political institutional factors. Countries with GDP per capita under USD 5,000 fall into this category.
- (2) *Assistance and action to ensure that a timetable is kept to*. This would be required to ensure progress is made on various aspects of patent law. Here we are assuming an emphasis on assistance but with stricter deadlines for making changes. Countries with per capita GDP of between USD 5,000 and USD 15,000 fall into this category.
- (3) *Action plus some assistance*. In these jurisdictions we expect that the emphasis is on action with only a minimal amount of assistance because of their ability to implement higher quality patent laws. Countries with a per capita GDP of between USD 15,000 and USD 25,000 fall into this category.
- (4) *Sanctions*. Sanctions are mainly for industrialised nations who are able to develop the highest quality patent laws (possibly this means harmonisation). Countries with a per capita GDP over USD 25,000 fall into this category.

### **2.5.3 How might this work over time?**

In reality, categorising each country into specific boxes and standardising an approach to trade agreement compliance based on per capita income and rule of law estimates is unlikely to be practical in all cases. This situation is similar to the long-term contractual arrangements between employee and employer, buyer and supplier, lender and borrower, and regulator and industry firms. As Macaulay observed, in many entities that engage in long-term contracts the contractual terms that govern the relationship are not fully specified.<sup>88</sup> Instead the partners understand that the value of a long-term relationship can help direct behaviour to be mutually beneficial.

A discussion of how this might be worked through is included in Appendix A to this chapter, with the detailed sourcing of the underlying information provided in Appendix B.

### **2.5.4 Regulatory coherence**

A similar approach could be taken to regulatory coherence.<sup>89</sup> Regulatory coherence focuses on creating principles of good governance by prompting a broad range of

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<sup>87</sup> Note that no action is required if the country is on or near the line since its patent laws are about as well developed as they can be given their GDP per capita growth.

<sup>88</sup> Stewart Macaulay “Non-Contractual Relationships in Business: A Preliminary Study” (1963) 28 American Sociological Review 1.

<sup>89</sup> The regulatory coherence chapter is similar to the strengthening markets initiative in the APEC process.

initiatives that create uniform rules around stimulating trade by reducing behind the border impediments; for example, streamlining customs procedures, reducing prescriptive and inconsistent labelling, and reducing certification processes. This is particularly important for New Zealand's agricultural exports which are especially susceptible to time delays caused by inconsistent application of behind the border measures.

A key issue in assessing the likely benefit is the potential compliance to the TPP leaked draft regulatory coherence chapter, since some nations will find it difficult in practice – because of institutional quality – to implement a consistent approach. By classifying each of the countries in accordance with their institutional quality and ability to implement regulatory coherence, a realistic understanding of what can be achieved in the short-, medium- and long-term can be gained.

This mixes top-down and bottom-up methods so that there is a goal to which countries/regions can aspire and also an understanding about what can realistically be achieved with outside assistance.

It is important to be cautious about what can and cannot be achieved since regulatory coherence benefit depends on institutional quality. What we know is that changing institutional quality is a slow process. This potentially disadvantages smaller jurisdictions.<sup>90</sup>

A further issue is the ability to enforce regulatory coherence against larger more powerful nations such as the United States or China. Care is required to ensure that the spirit of the regulatory coherence chapter is able to be adhered to in practice; that is, would New Zealand be able to enforce a change in United States regulatory practices even if there were a clear transgression of the TPP by the United States? While it is difficult to say whether New Zealand could or could not enforce any clear breach of the TPP there is a real risk that New Zealand may not be able to, and this needs to be taken into account in the consideration of any agreement.

## **2.6 Strategic implications for trade policy**

### **2.6.1 Specific implications**

Patent extension will provide a windfall gain for those producing patented products. This is unlikely to benefit New Zealand as a net importer of patented pharmaceuticals. Therefore, what is on the table in each negotiation matters, and the following matters must be considered:

- the size of the markets involved;
- the willingness to do a deal across a broad range of sectors;

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<sup>90</sup> Philip Keefer in "Governance and Economic Growth" in L Alan Winters and Shahid Yusuf (eds) *Dancing with Giants: China, India and the Global Economy* (World Bank Publications, Singapore, 2007) argues that in larger countries, enforcement of international rules may be more lenient. This is because those exporting to larger markets have to weigh up the costs and benefits – including consequences – of making a complaint. On the one hand, making a complaint may jeopardise further market growth; and on the other, putting up with regulatory inconsistencies may allow exporters to maximise market growth.

- the ability to opt in and out of particular parts of the deal; and
- whether the deal can be implemented given the institutional quality.

For an ASEAN + 6 agreement the issue is not patent term extension, but instead our national aims are to safeguard New Zealand consumers so that the imports of patented pharmaceuticals from these jurisdictions are safe and fit for purpose. A second objective is to attempt to protect New Zealand intellectual property products<sup>91</sup> sold into these markets from local competitors ignoring intellectual property protection and to ensure that these products are not immediately copied and sold in markets that are not covered by intellectual property protection.

In the TPP, the strategic problem is different. New Zealand already has in place WTO minimum protection for patents and other intellectual property; while this is a likely outcome all parties to an ASEAN + 6 negotiation would seek, in the TPP context it is likely that the United States will press hard to go further: an extension of patent term and also rules that would have the effect of changing the practices of PHARMAC in the name of transparency<sup>92</sup> or removing PHARMAC from the Commerce Commission exemption<sup>93</sup> in the New Zealand domestic market. This will probably increase the price paid for pharmaceuticals on the New Zealand market, with fiscal consequences. Further, the ability of New Zealand to enter the United States pharmaceuticals market is limited, since only one (highly successful) company has the capability to exploit the market in the short run.

Therefore, New Zealand's objective will be to limit the "WTO-plus" provisions within the agreement so that New Zealand pays as little more as possible for drugs, relative to the situation that exists now.

If regulatory coherence is the objective, how would we value it and which trade agreement is likely to improve coherence and why? The more likely candidate is the TPP since ASEAN + 6 countries have variable quality institutions that may or may not support improved coherence; although we note that the overlap between the two groupings includes Singapore, Malaysia, Vietnam and Australia and New Zealand. However, to illustrate whether or not the TPP will deliver on the promise of improved regulatory coherence will require careful study of the details since the possible gain is unclear.

## 2.6.2 Wider implications

### (a) *Is going it alone a sensible option?*

Table 2.2 sets out a stylised approach and possible impact of different "types" of trade agreements.

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<sup>91</sup> This can include patented, copyright and often trade marked products.

<sup>92</sup> Potentially more "transparency" will restrict PHARMAC's ability to do cross therapeutic class deals with individual pharmaceutical companies. Not only might this increase the pharmaceutical bill but combined with patent extension, prices will be higher for a longer period of time.

<sup>93</sup> This exemption means that PHARMAC's regular business of bulk buying is not a Commerce Act 1986 violation; see New Zealand Public Health and Disability Act 2000, s 53.



A “hard” agreement is an agreement where the costs of signing outweigh the benefits for New Zealand, that is, the TRIPS Agreement in the Uruguay Round or emissions cuts in the Kyoto climate change agreement. A “soft” agreement is one where there is a net gain from signing the trade agreement, that is, CER or the agricultural agreement under the Uruguay Round.

The question we have asked is whether New Zealand going it alone is the best course of action in either a “hard”, top-down, or “soft”, bottom-up, agreement. In both cases, the answer is likely to be the greater number of countries involved in a negotiation, the more likely a small country like New Zealand will benefit. Even in a regional or multilateral negotiation careful analysis to identify the costs and benefits is needed; for example, under the Kyoto negotiation it is clear that Australia secured a favourable deal relative to New Zealand.

Table 2.2: Stylised approach to trade agreements

		Type of trade agreement	
	“Hard” agreement that will cost in the short run	“Soft” agreement where benefits outweigh costs	
Individual country negotiation	New Zealand likely to lose out with a big country	Benefits	
Group negotiation	Potential for “hard” agreements to be watered down. Will depend on situational analysis	The more countries involved the greater the benefit	

Source: NZIER

*(b) Should we choose one or other trade agreement (for example, TPP or ASEAN +6)?*

The short answer is “No”. The lesson from our attachment to Britain between 1880 and 1973 is that it is a major mistake to pick “trade partner winners”, because they will not necessarily remain the winners.

New Zealand should aim to be traders with the world. This means:

- (1) ensuring that exclusive arrangements are not part of any trade agreement;
- (2) ensuring that the structure is “right” before deals are done;
- (3) avoiding either being exclusively in trade blocs or going it alone; and
- (4) ensuring that signing any particular agreement is consistent with other agreements signed.

Negotiators should be mindful as to whether the provisions they are negotiating are ones that could be multilateralised and, if so, how easily. In the case of some TRIPS-plus provisions, multilateralisation may occur rather quickly due to the fact that countries will implement these provisions on a national treatment and MFN basis

because TRIPS requires they do so.<sup>94</sup> Even where there is a TRIPS exception, countries may – out of convenience – nonetheless still implement these provisions on a national treatment and MFN basis.

The TPP and ASEAN + 6 are both multiparty (sometimes called plurilateral) agreements that potentially go in directions not yet reached by the wider WTO membership. It remains to be seen whether the terms of these agreements will become the new norms of the future and ultimately be multilateralised into the WTO. But this possibility cannot be ruled out, and as such negotiators should consider whether they are making a concession (or obtaining a benefit) just as between the parties, or whether there might be flow-on costs or benefits accruing as a result of multilateralising of these plurilateral agreement terms.

Other negotiating commitments may not multilateralise as organically, but nonetheless may become sufficiently widespread as to be accepted as a new norm. Alternatively, there may be measures that are adopted widely by developed countries, but which developing countries will resist. For this latter category, it may be that developing countries will ultimately accede to such provisions, but only in exchange for something of value to them.

New Zealand negotiators should therefore consider not only the costs and benefits of making various concessions in exchange for others' commitments, but also the likelihood that what New Zealand is agreeing to will end up applying not only between New Zealand and the other members of, for example, the TPP, but also between New Zealand and perhaps the entire WTO membership.

To frame the issue slightly differently, we suggest that New Zealand may undervalue its commitments if it sees the benefits of them as only accruing to its fellow TPP members. But the benefit, for example, to the United States, of getting 10 other countries to agree to a particular provision may go far beyond the benefit the United States will recognise from these 10, because once such a large group of countries has agreed to the provision the United States will have an easier time incorporating the provision into more and more agreements. Therefore, negotiators should be cognisant that their acquiescence to certain terms may in practical effect be acquiescing to what will become the new global norm. Surely facilitating such a development should be worth more in concessions from the countries pushing for such provisions than would be expected for commitments that will not have an effect outside the parties' trading relationships.

### *(c) Do we have the evidence to make the right decisions?*

The proliferation of FTAs means that waiting for the right agreement is very important. The right agreement will be the one where given all its constraints of power and small scale, New Zealand can obtain the best set of durable overall benefits.

In the past, as noted, it has been relatively easy to work out what the gains for New Zealand would be under trade agreements.<sup>95</sup> In the post-Uruguay Round

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<sup>94</sup> TRIPS Agreement, arts 3 and 4.

<sup>95</sup> Apart from CER which was the first comprehensive trade agreement New Zealand entered into.

world, the questions that policy makers are now asking have become more issue-specific. Therefore more emphasis needs to be placed on the need for evidence-based outcomes from any particular FTA.

FTAs with intellectual property chapters are least likely to achieve this. This suggests a similar conclusion as that reached by the Australian Productivity Commission, that such chapters should not be included in FTAs, or other top-down deals:<sup>96</sup>

[Australia should] ... avoid the inclusion of IP matter as an ordinary matter of course in future BRTAs. IP provisions should only be included in cases where a rigorous economic analysis shows that the provisions would likely generate overall net benefits for the agreement partners ...

For countries like New Zealand, careful analysis of the costs and benefits of the total effect of an agreement such as the TPP are unlikely to be straightforward, and will often involve costs and benefits that are hard to value. Therefore, to further understand the potential outcomes for New Zealand over time requires developing a robust domestic capacity to analyse them. Such a domestic capacity will enable New Zealand to attempt to answer the “what if” questions posed by the removal or constraining of existing regulatory structures such as PHARMAC.

## 2.7 Conclusions

As the globalisation tide has swept forward since 1945, the trade policy game has constantly shifted and changed. In particular, its interactions with the domestic policy settings that frame a country’s regulatory structure have become tangled and widespread. Consideration of the key decision elements of politics, economics and institutional capacity has become more confused and complex, with reliable information hard to glean, as shown by the political reaction to plain packaging for cigarettes. Further integration within the Asia-Pacific region will require New Zealand to step outside its trade negotiating comfort zone and work up deals in non-traditional products and services. The prospective partners and our goals mean that the economic framework and analytical bases are also different. The strategy to deploy for tariff reductions and removal of regulatory barriers is different from the strategy that needs to be applied to issues that are targeted at affecting regulation behind the border, including intellectual property, investment and regulatory coherence.

Ideally, New Zealand would trade with the world and enjoy the privileges of being an “insider” on world markets, particularly in fast growing markets and in the industrialised world. The degree to which this is achievable will depend on the strategies and tactics devised and used.

For strategies and tactics to be effective an understanding is required of the potential durability of trade agreements and the motivations of the various

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<sup>96</sup> Australian Productivity Commission *Bilateral and Regional Trade Agreements: Productivity Commission Research Report* (November 2010) Recommendation 4 (chapter 14), available at <[www.pc.gov.au/\\_\\_data/assets/pdf\\_file/0010/104203/trade-agreements-report.pdf](http://www.pc.gov.au/__data/assets/pdf_file/0010/104203/trade-agreements-report.pdf)>.

players. Durability requires strong institutions so that implementation is possible and to ensure that the agreement is flexible enough and does not close off options. This suggests that the right type of agreement is very important, because the wrong type will not add to economic growth.

Since the details of each trade agreement inform the strategy, we have chosen patents as a way of exploring the demands of the new trade issues within an ASEAN + 6 agreement and the TPP. The ASEAN + 6 agreement has more features of a bottom-up integration model, and the TPP more of the top-down model.

Both the top-down and bottom-up approaches to trade agreements have advantages and disadvantages (see Table 2.1). We have argued that a durable trade agreement with meaningful reforms that potentially add to a country's economic growth is likely to have a combination of top-down and bottom-up processes. By taking the best of both approaches countries can have a clearly identified vision and direction, but also allow individual countries to implement rules in an efficient way over time.

Our approach to patent law and institutional integration sets out the issues that need to be considered within the Asian region.<sup>97</sup> In Asia our objectives are to safeguard New Zealand's imports of patent pharmaceuticals and protect our limited exporting interests. To test the ability of each country to adhere to these objectives we have matched levels of economic growth with institutional strength by correlating GDP per capita to rule of law estimates. The results suggest that most countries line up as expected. As a "first cut" discussion starter on how we might approach the challenge of ensuring each country was positioned to meet our objectives, we have classified them into four groups ranging from needing assistance, through assistance and action, action and assistance, to action. The method suggested in general is to develop a process and allow it to work through to a sensible (and positive) outcome.

For the TPP the objectives are quite different. The focus of the United States-drafted leaked intellectual property chapter in the TPP is increasing patent (and intellectual property) protection overall. Therefore, the New Zealand TPP approach seems to be: what can we seek to get in exchange for signing up to increased patent protection, including patent term extension. Extending patent protection creates a (fiscal) cost. In short, imported patented goods will cost more and more imported goods may be subject to stronger patents for more aspects of the goods and they will stay patented for longer. Anything that is more strongly patented and patented for longer cannot be as easily used in New Zealand to innovate or to develop improvements. Stronger and extended pharmaceutical patents increase the cost of pharmaceuticals and reduce New Zealand's ability to obtain generic, and or lower cost pharmaceuticals, sooner. These are high costs from a pharmaceutical availability perspective. From a patent perspective increased patent standards are not likely to increase investment in New Zealand innovation, but rather are likely to increase the costs of New Zealand innovation since building on existing

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<sup>97</sup> Our counterfactual is based on a naïve "do nothing" approach to trade agreements associated with patents. We have done this to compare and contrast the potential pros and cons of trade agreements.

technologies will likely either not be possible or will require prohibitive licensing fees for patents, if those licences are available. Therefore, the demand for patent extension will have a negative economic impact on New Zealand, which has to be offset by benefits elsewhere to make the agreement worthwhile. This logic – costs in one part counter-balanced by benefits in another part – complicates the politics. To show that the TPP agreement should be signed requires the strength of evidence associated with the benefit assessment (of parts of the agreement other than the patent extension) to be of a high standard to give New Zealanders confidence that the overall agreement will deliver overall positive benefits.

## **Appendix A: Achieving results in a complex setting — the process**

In the body of this chapter we raised the question of how to work towards a suitable agreement in a complex setting. This Appendix sets out some of the real world factors that might make up such a process.

The key issue is what types of strategies and tactics would be useful in directing a mutually beneficial outcome in each case? Since this will be different in each case only general points can be made about the type of strategies and tactics that could be employed (see Figure 2.3 below).

From a strategic view questions that may inform the choice of compliance model include:

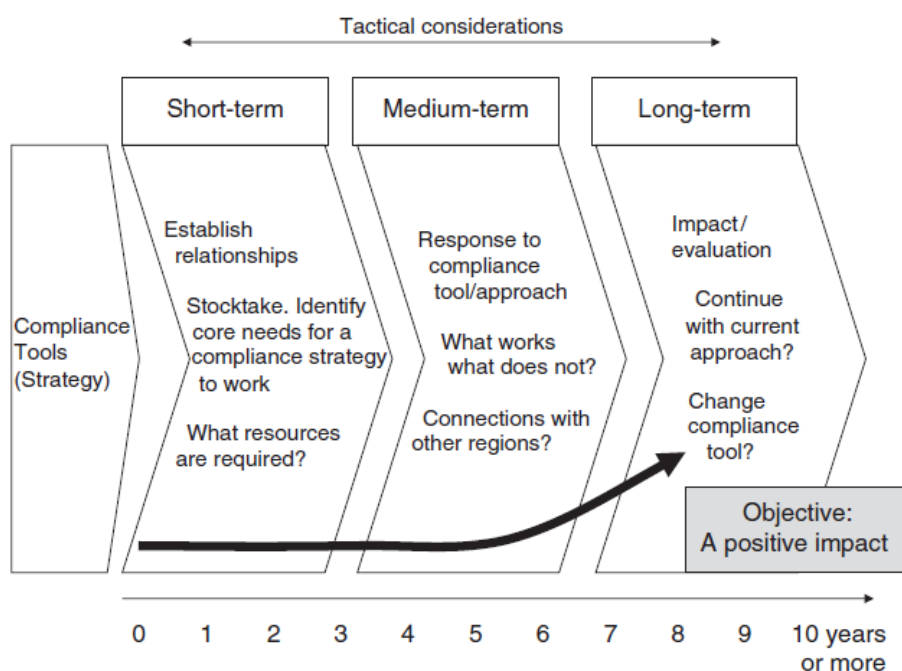
- (1) Weighing up the advantages and disadvantages of voluntary versus compulsory compliance options. Voluntary options are likely to be cheaper, but will they change behaviour in a way that is mutually beneficial in the long run?
- (2) How much assistance is required and do we have the ability to deliver effective assistance over a sustained period of time? How would you measure success in the short-, medium- and long-term?
- (3) What sorts of actions are appropriate? For example, finding ways to embarrass Australian, Canadian and United States governments is likely to have little effect on compliance; however, avoiding embarrassment and saving face are important to Asian nations.
- (4) What sanctions are appropriate? What happens if they fail? The failure of sanctions is likely to be a serious matter that could jeopardise other parts of the relationship and should only be used as a last resort.

The shape of the strategy will also be informed by tactical awareness as the relationship unfolds over time, that is:

- (1) In the short-term the process of trade agreement compliance will be informed by:
  - the relationships developed at all levels and the ability to work together to achieve mutually agreed goals;
  - judgments about the gap between the trade agreement and enforcement and what needs to be done to narrow the gap; and
  - what resources are required to improve the situation over the long term.

- (2) In the medium-term, analysis is required of the behavioural response to compliance efforts. This includes —
  - What has changed as a result of compliance efforts?
  - Do we know what works and what does not work in terms of compliance efforts?
  - Are there connections between what other countries are doing that are influencing behaviour in a positive or negative way?
- (3) In the long-term some sort of judgment on the performance of compliance methods needs to be undertaken. Have the efforts been positive? Are the institutions at a stage that is compatible with their GDP per capita growth? Should other methods be employed to more effectively improve compliance?

Figure 2.3: A process solution to trade policy compliance



## Appendix B: The classification of countries

To group the countries in the body of the chapter we have looked at each and the extent to which they showed respect for law and their GDP per head. This Appendix sets out the details of this work.

In Table 2.3 we have classified each of the ASEAN + 6 nations detailing GDP per capita growth, rule of law scores, approach to enforcement, whether the action is feasible, and relevant comments.

From Figure 2.2 we can quickly deduce that most countries are close to where we would expect them to be. In fact, most jurisdictions are close to or above the

line which suggests that their institutions are where we would expect them to be or better.<sup>98</sup>

In particular, patent law seems to be well developed in the region.<sup>99</sup> One possible reason for this is that many of the countries have no pharmaceutical industry that requires patent protection or government subsidies for pharmaceutical consumption. Therefore, they are likely to have signed bilateral agreements with nations such as the United States that support WTO provisions or include WTO-plus provisions, that is, granting an extended patent term.

This may only be the first round of analysis, since the details of each case are important. As we have found in some jurisdictions (such as Indonesia with meat and Australia with apples) the bilateral or regional agreement might only be the start of a long involved process that requires:

- capitalising on “the shifting sands of political moments” to cement in agreements;
- making strategic withdrawals to fight battles another day (that is, New Zealand’s decision to voluntarily limit chilled meat sales to France even though we could have dramatically increased chilled meat quota sales under the Uruguay Round agreement); and
- taking into account other factors (such as the extraordinary political goodwill that exists between China and New Zealand).

Of course this is merely an illustration of how we might examine each jurisdiction and the assessment can only improve with more information and better understanding of the political, economic and institutional drivers in each case.

Table 2.3: Classification of Countries

Country	Description (GDP per capita US \$; rule of law score)	Classification	Action?	Comment
Australia	47,149; 1.95	Action	Yes	Action in the first instance but tactics modified depending on detail
Brunei	49,400; 1.37	Action	?	Further understanding of the specific situation required
Cambodia	2,363; -0.80	Assistance	?	Needs assessment required
China	9,498; -0.34	Assistance & action	?	Need to weigh costs and benefits

<sup>98</sup> The one exception is Myanmar which is appreciably below the line in Figure 2.2.

<sup>99</sup> See the WIPO description of patent law, available at <[www.wipo.int](http://www.wipo.int)>.

<b>Country</b>	<b>Description (GDP per capita US \$; rule of law score)</b>	<b>Classificatio n</b>	<b>Action?</b>	<b>Comment</b>
<b>India</b>	3,870; 0.14	Assistance	?	Need to weigh costs and benefits
<b>Indonesia</b>	5,089; -0.75	Assistance & action	Yes	Needs assessment required
<b>Japan</b>	35,999; 1.71	Action	Yes	Action in the first instance but tactics modified depending on detail
<b>Korea, Rep of</b>	31,745; 0.76	Action	Yes	Action in the first instance but tactics modified depending on detail
<b>Laos</b>	2,700; -1.15	Assistance	?	Needs assessment required
<b>Malaysia</b>	14,689; 0.73	Assistance & action	Yes	Needs assessment required
<b>Myanmar</b>	1,300; -2.10	Assistance	No	Further connection with the region required
<b>New Zealand</b>	31,978; 2.08	N/A	N/A	N/A
<b>Philippines</b>	3,847; -0.22	Assistance & action	Yes	Needs assessment required
<b>Singapore</b>	59,196; 2.15	Action	Yes	
<b>Thailand</b>	9,615; 0.43	Assistance & action	Yes	Action in the first instance but tactics modified depending on detail
<b>Vietnam</b>	3,597; -0.68	Assistance	?	Needs assessment required
<b>United States</b>	48,087; 1.82	Action	?	Action in the first instance but tactics modified depending on detail

*Source: Conference Board (2012), Levchenko (2010), NZIER*