

Chapter 15

Trade Agreements and Regulatory Autonomy: The Effect on National Interests

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15.1 Introduction

In October 2010, Philip Morris International commenced an arbitration proceeding against the government of Uruguay before the International Centre for Settlement of Investment Disputes (“ICSID”).¹ Philip Morris claims that its trade marks are investment assets that have been expropriated in contravention of the bilateral investment treaty between Switzerland and Uruguay. As a legal matter the claim is based on three regulations. The regulations are all measures that Uruguay has in place to warn consumers of the health risks of smoking. In the public arena of the Internet, Philip Morris has stated that it supports health warnings about cigarettes.² It alleges, however, that the Uruguay measures go too far. The regulations include:

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¹ *Philip Morris Brand SA (Switzerland) v Oriental Republic of Uruguay* ICSID Case No ARB/10/7. The case is currently pending, see “List of Pending Cases” (2011) International Centre for Settlement of Investment Disputes icsid.worldbank.org/ICSID/FrontServlet?requestType=GenCaseDtIsRH&actionVal=ListPending (last accessed 28 August 2011).

² See Philip Morris International “Bilateral Investment Treaty claim, Uruguay” (2010) www.pmi.com/eng/media_center/company_statements/pages/uruguay_bit_claim.aspx (last accessed 28 August 2011).

- 1 a regulation that companies sell only one pack variation per cigarette brand;
- 2 a requirement that health warnings on tobacco products should cover 80 per cent of the packaging; and
- 3 a requirement to print images of the health effects of tobacco on cigarette packs.

Philip Morris alleges the first regulation has “required us to withdraw 7 of the 12 cigarette varieties we sold in Uruguay. We had already taken all descriptors off our cigarette packs such as lights, but the former government decided to force us to eliminate all brand variations as well”.³

With regard to the 80 per cent coverage requirement, Philip Morris claims, “[a]lthough we support regulations requiring prominent health warnings, the requirement of 80 per cent leaves virtually no space on the pack for display of legally protected trademarks”.⁴

Philip Morris alleges that the images on tobacco packaging that are required “include repulsive and shocking pictures, such as a grotesquely disfigured baby. We do not oppose the use of graphic health warnings but believe that images should accurately depict the health effects of smoking”.⁵

Uruguay’s formal response to these allegations is not yet public, but it has stated that it has instituted these regulations to reduce the incidence of smoking-related health issues in Uruguay.⁶

Similarly, Philip Morris Asia Limited (based in Hong Kong) has also recently initiated an arbitration against Australia pursuant to the dispute settlement provisions of a bilateral investment treaty between Australia and Hong Kong. In that arbitration Philip Morris is complaining that the value of its trademarks will be severely diminished if Australia proceeds with its plans to implement plain packaging for cigarettes and to require graphic pictures of smoking-related health ailments.⁷

³ Philip Morris International “Bilateral Investment Treaty claim, Uruguay” (2010) www.pmi.com/eng/media_center/company_statements/pages/uruguay_bit_claim.aspx (last accessed 28 August 2011).

⁴ Philip Morris International “Bilateral Investment Treaty claim, Uruguay” (2010) www.pmi.com/eng/media_center/company_statements/pages/uruguay_bit_claim.aspx (last accessed 28 August 2011).

⁵ Philip Morris International “Bilateral Investment Treaty claim, Uruguay” (2010) www.pmi.com/eng/media_center/company_statements/pages/uruguay_bit_claim.aspx (last accessed 28 August 2011).

⁶ Uruguay has a population of 3.4 million and at the beginning of implementing its anti-smoking campaign it was estimated that one third of the population smoked. There are other anti-smoking regulations which are not at issue in the ICSID dispute. One of those is the banning of smoking in public places.

⁷ See, for example, Kristen Gelineau “Philip Morris fights Australian packaging rules” (2011) Yahoo! Finance www.finance.yahoo.com/news/Philip-Morris-fights-apf-396175943.html?x=0&.v=2 (last accessed 28 August 2011).

The outcome of these disputes will depend on the arbitration panels' interpretation of the relevant bilateral investment treaties on which the proceedings are based. In entering these treaties, Uruguay and Australia may have agreed to limit their national autonomy over domestic measures such as their anti-smoking laws. Notably, both disputes are being brought by a private investor against a government. In agreeing to the investment chapters in their bilateral investment agreements, both Australia and Uruguay have surrendered autonomy over aspects of domestic regulatory measures to private and foreign challenge. Just how far that national autonomy has been constrained will be determined in the arbitration proceedings.⁸

New Zealand is currently negotiating several trade agreements, including the Trans-Pacific Partnership (TPP).⁹ The Prime Minister has said that the New Zealand Government being sued in investor-state arbitration was “far-fetched”.¹⁰ Subsequent news reports, however, suggest that the Prime Minister's statement does not mean that investor-state arbitration will not be part of the TPP.¹¹

Although the details of investment treaties are not the focus of this chapter, these investment disputes highlight the effect that trade agreements (including investment treaties) have on regulatory autonomy.¹² Both arbitrations also demonstrate the importance of understanding the potential

⁸ Some bilateral investment treaties and investment chapters of free trade agreements provide for investor-state dispute settlement via arbitration; others do not, and instead limit the foreign investors to claims in the host state's domestic courts. In more recent agreements Australia has refused to include the type of investor-state dispute settlement it agreed to in, *inter alia*, its BIT with Hong Kong.

⁹ Trans-Pacific Strategic Economic Partnership Agreement (opened for signature 15 June 2005, entered into force 1 January 2006). The Agreement is available online at New Zealand Ministry of Foreign Affairs and Trade “Trans-Pacific Strategic Economic Partnership Agreement” (2011) www.mfat.govt.nz/downloads/trade-agreement/transpacific/main-agreement.pdf (last accessed 28 August 2011).

¹⁰ See the article by Alastair Thompson “‘No Ordinary Deal’ Book Launch & PM Response” (2010) Scoop Independent News www.scoop.co.nz/stories/HL1011/S00125/no-ordinary-deal-book-launch-pm-response.htm (last accessed 28 Aug 2011). Australia has also formally rejected such arbitration: Gillard Government Trade Policy Statement *Trading our way to more jobs and prosperity* (Department of Foreign Affairs and Trade, Australia, April 2011) at 14.

¹¹ Voxy “Key Backtracks, Says Foreign Firms Can Sue NZ Government under TPPA” (2011) www.voxy.co.nz/politics/key-backtracks-says-foreign-firms-can-sue-nz-government-under-tppa/5/80937 (last accessed 28 Aug 2011). See also Simon Lester “Update on New Zealand and Investor-State” (2011) International Economic Law and Policy Blog worldtradelaw.typepad.com/ielpblog/2011/02/update-on-new-zealand-and-investor-state.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+ielpblog+%28International+Economic+Law+and+Policy+Blog%29 (last accessed 29 August 2011).

¹² For a discussion of issues relating to the regulation of foreign direct investment in New Zealand, see Daniel Kalderimis “Regulating Foreign Investment in New Zealand” in this volume (ch 16).

ramifications of agreeing to various terms in one's international economic law agreements.

The central issue this chapter explores is how to balance New Zealand's interests in being a successful participant in international trade against losing too much autonomy over domestic regulatory regimes. There are any number of reasons why New Zealand might agree to relinquish some autonomy over regulatory systems. Regulatory cooperation can be a method of building better trading relationships.¹³ It is, therefore, sometimes in New Zealand's interest to join regulatory forces, particularly across the Tasman.¹⁴ On the other hand, there will be some contexts in which New Zealand's interests are sufficiently distinct or valued that regulatory harmonisation would not be desirable. Paul Conway of the OECD has said:¹⁵

An ongoing push for greater regulatory harmonisation, mutual recognition and integrated institutions, where appropriate, would continue to reduce spatial transaction costs between New Zealand and Australia and mitigate the negative impact of economic geography. As such, the recent Memorandum of Understanding between the New Zealand and Australian governments, which encourages more cooperation between regulators and policymakers and sets out a range of co-ordination initiatives to deepen business integration, is most welcome. The principles underlying these arrangements need to be broadened and extended to other potential trading partners, particularly in Asia, to reduce the additional compliance costs for firms doing business in offshore markets. However, as with all significant regulatory changes, it is important that harmonisation initiatives be consistent with New Zealand's own objectives and circumstances.

If New Zealand wants to enter into an international arrangement that affects areas where it has a distinct interest, it may be preferable to regulate via the top-down, negative integration approach used in most of the World Trade Organization Agreements. In other words, New Zealand may, in some contexts, prefer to reach international agreement on what types of regulations are *not* permitted rather than adopting a bottom-up approach (via regulatory harmonisation) of agreeing on substantive measures that *must* be adopted. The determinants for whether regulatory cooperation is a positive or a negative as compared with regulating via negative integration include

¹³ As discussed below, the Australian Productivity Commission considers regulatory cooperation to be a preferred method of building trading relationships.

¹⁴ For a discussion of when it may or may not be in New Zealand's interests to coordinate regulatory regimes with Australia, see Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" (ch 17) and Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" (ch 18) in this volume.

¹⁵ Paul Conway *How to Move Product Market Regulation in New Zealand Back Towards the Frontier* (OECD Economics Department, Paris, 2011). The paper is also available www.oecd-ilibrary.org (last accessed 25 September 2011).

New Zealand's small size, the relative availability of resources and New Zealand's particular priorities and values. In this project we call these the New Zealand questions.¹⁶ We are therefore assessing in what circumstances a top-down regulatory approach through trade agreements will be effective to achieve New Zealand's goals, and in what circumstances a bottom-up approach through regulatory cooperation will be more suitable for New Zealand's needs. We do not eliminate the possibility that a combination of these may be effective.¹⁷

The TPP negotiations reveal another interesting twist to the relationship between regulatory cooperation and trade agreements. The negotiations include the possibility of including a regulatory coherence chapter within the agreement. Such a chapter may, for example, suggest that the TPP trading partners agree to a common approach to assessing regulatory impacts at the domestic level. One possible approach is that of regulatory impact analysis, pioneered by the OECD¹⁸ and adopted and adapted in many countries, including New Zealand.¹⁹

International economic law agreements – including the World Trade Organization (“WTO”); free trade agreements (“FTAs”); and bilateral investment treaties (“BITs”) – can impact regulatory freedom in a number of important ways. Such agreements may include provisions that either mandate or encourage regulatory reform. Reforms may be called for in order to bring about harmonisation; to facilitate cross-border trade and investment through regulatory cooperation; or merely to comply with newly established international, plurilateral, or bilateral standards. New Zealand's participation in an array of trading arrangements, therefore, has significant implications for the country's regulatory autonomy and ability to make policy decisions. Trade agreements can impact New Zealand's regulatory options both directly – through provisions in agreements to which New Zealand is a party, and indirectly – as a result of agreements between some of New Zealand's trading partners to which New Zealand is not a party. This indirect impact should not be underestimated. It is beyond the scope of this chapter to canvass all of these issues in detail. Instead, the chapter has three objectives: first, to identify the agreements that may impact upon New Zealand's regulatory autonomy both directly and indirectly (at [15.2] and [15.3] of this chapter); second, to use

¹⁶ See the introduction to this volume (ch 1).

¹⁷ For a discussion of the spectrum of integration models see Chris Nixon and John Yeabsley “Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration” in this volume (ch 17).

¹⁸ Organisation for Economic Cooperation and Development “Regulatory Impact Analysis” (2011) www.oecd.org/document/39/0,3746,en_2649_34141_35258801_1_1_1_1,00.html (last accessed 29 August 2011).

¹⁹ The Treasury *Regulatory Impact Analysis Handbook* (2009) available at www.treasury.govt.nz/publications/guidance/regulatory/impactanalysis (last accessed 25 September 2011). See also Derek Gill “Regulatory Management in New Zealand: What, Why and How?” in this volume (ch 7).

the context of two different national interests to provide specific examples of the ways in which trade agreement commitments affect policy-making options (at [15.4]); and third, to discuss empirical and further research that will be conducted in the next project phase with the aim of measuring the effects trade agreements have on New Zealand's regulatory autonomy in the consumer interests area (at [15.5]). Within the broad category of consumer interests and related business interests, this chapter will focus on regulatory regimes that affect food safety, biosecurity, the safety and purchasing of pharmaceuticals, and product safety and performance standards.

15.2 Trade agreements and regulatory autonomy

Before embarking upon any regulatory reform it should be routine to identify international obligations – both those New Zealand has entered into and in some cases agreements of others – that may constrain or enhance the policy options available. One might ask why trade agreements have in some instances been the first step, rather than a comprehensive review of the regulatory field preceding the trade agreement. This is a good question: indeed, precursor study of the potential impacts of an agreement would be wise. In 2010, Australia undertook a review of its trade agreements, and reached this same conclusion. In particular, the Australian Productivity Commission Report recommends that to ensure bilateral and regional trade agreements (“BRTAs”) are in Australia's interests:²⁰

Pre-negotiation modelling should include realistic scenarios and be overseen by an independent body. Alternative liberalisation options should also be considered.

A full and public assessment of a proposed agreement should be made after negotiations have concluded — covering all of the actual negotiated provisions.

The Government should also develop and publish an overarching trade policy strategy, to better coordinate and track the progress of trade policy initiatives, and to ensure that efforts are devoted to areas of greatest likely return.

And also that:²¹

²⁰ Australian Productivity Commission *Bilateral and Regional Trade Agreements: Productivity Commission Research Report* (2010) at xx. The document is also available online at www.pc.gov.au/_data/assets/pdf_file/0010/104203/trade-agreements-report.pdf (last accessed 29 August 2011).

²¹ Australian Productivity Commission *Bilateral and Regional Trade Agreements: Productivity Commission Research Report* (2010) at xxxii.

More generally, the Australian Government should not include matters in BRTAs that increase barriers to trade, raise industry costs or affect established social policies without separate review of the implications and available options for change.

The report is lengthy and cannot be summarised in detail here. One of its key findings, however, is that while some benefits may have come from the bilateral and regional trade agreements into which Australia has entered, other aspects have not benefited Australia.²² In part this is attributed to the trade agreements being the wrong model – the suggestion is made that memorandums of understanding and mutual recognition, for example, may be better models in some circumstances. In many parts of the report the Australian-New Zealand relationship, either through CER (now known as the single economic market “SEM”) or the more recent agreement Australia and New Zealand FTA with ASEAN, are cited as the best practice.²³ In summary, the report concludes that BRTAs are not necessarily either negative or positive – it depends on their content and design.

We note that limitations on policy autonomy through FTAs are not necessarily a negative. In some instances the international legal frameworks to which New Zealand has bound itself impose disciplines that should lead to better regulatory practices and give New Zealand a platform on which to pursue deeper regulatory cooperation that may save New Zealand resources in the long-run. However, not all are as sanguine about regulatory cooperation as the Australian Productivity Commission. For example, Michael Trebilcock and Robert Howse have argued that policy harmonisation can be welfare-reducing under certain circumstances.²⁴ In particular, Trebilcock and Howse argue that there is a risk that harmonisation processes, particularly those involving parties with unequal bargaining power, will not reflect a balanced negotiation to identify the preferred policy but instead imposition by the will of the stronger.²⁵ None the less, whether trade agreement commitments are viewed through a positive or negative lens, it is clear these commitments can limit policy options and the processes by which decisions are made. Consequently, it is important to be aware of these limitations. This section discusses the main agreements that impact upon New Zealand’s regulatory

²² See, for example, Australian Productivity Commission *Bilateral and Regional Trade Agreements: Productivity Commission Research Report* (2010) at xxiv and 144–145.

²³ Australian Productivity Commission *Bilateral and Regional Trade Agreements: Productivity Commission Research Report* (2010) at 54–55 and ch 13 generally.

²⁴ Michael Trebilcock and Robert Howse “Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics” (1998) 6 *Eur J Law Econ* 5.

²⁵ Michael Trebilcock and Robert Howse “Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics” (1998) 6 *Eur J Law Econ* 5 at 9. This point is also noted in the Australian Productivity Commission Report, where Australia’s small size, unilateral reform and consequently weak bargaining position is noted: Australian Productivity Commission *Bilateral and Regional Trade Agreements: Productivity Commission Research Report* (2010) at 191–192.

autonomy in the area of consumer interests, either directly or indirectly. Those agreements are the multilateral Agreements of the WTO, bilateral and regional trade agreements (collectively referred to as free trade agreements or FTAs) and bilateral investment treaties (BITs). Other fora of relevance are the FTAs that New Zealand's trading partners have, to which New Zealand is not a party.

15.2.1 *The World Trade Organization*

Pursuant to the WTO,²⁶ New Zealand has undertaken a variety of commitments that in some ways constrain New Zealand's autonomy to regulate, including in the area of consumer protection and safety and related business interests. Certain of the relevant agreements are discussed at [15.3] below. In addition to the SPS Agreement,²⁷ the TBT Agreement,²⁸ and the TRIPS Agreement²⁹ discussed below, two other agreements are of particular relevance to regulating consumer protection and safety. These are the GATT³⁰ and the GATS.³¹

The majority of the WTO agreements, including the GATT and the SPS and TBT Agreements, are structured on the negative integration model. With respect to all WTO agreements, New Zealand has agreed with the other WTO members that various types of conduct, such as failing to give most-favoured nation ("MFN") or national treatment, is impermissible. So long as these prohibitions are abided by, New Zealand retains a significant amount of policy space to regulate in the areas covered by the negative integration-style agreements.

The WTO agreements do not all take the form of purely negative integration agreements. For example, the GATS agreement takes a positive list approach and the TRIPS Agreement takes a minimum standards approach.

²⁶ The World Trade Organisation is a multilateral treaty comprising 153 members, including New Zealand: Agreement Establishing the World Trade Organisation (opened for signature 15 April 1994, entered into force January 1995) .

²⁷ Agreement on the Application of Sanitary and Phytosanitary Measures (opened for signature 15 April 1994, entered into force 1 January 1995) [SPS].

²⁸ Agreement on Technical Barriers to Trade (opened for signature 15 April 1994, entered into force 1 January 1995) [TBT].

²⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 April 1994, entered into force 1 January 1995). This Agreement is also known as the TRIPS Agreement.

³⁰ General Agreement on Tariffs and Trade (opened for signature 15 April 1994, entered into force 1 January 1995) [GATT]. The GATT Agreement governs trade in goods, and requires, *inter alia*, that New Zealand provide most-favoured-nation and national treatment to other WTO members, and that New Zealand not apply quantitative restrictions (in the form of import bans or quotas) on imports from other WTO members.

³¹ General Agreement on Trade in Services (opened for signature 15 April 1994, entered into force 1 January 1995) [GATS].

Under GATS, although New Zealand was able to tailor and select its commitments, it is bound by the particular commitments it elected to make in its services schedule. Commitments can be made across several different modes of supply.³² New Zealand has made a range of commitments across a variety of services sectors. These commitments may constrain New Zealand's ability to, for example, limit foreign suppliers of certain types of services consumed by individuals.³³ Under the TRIPS Agreement New Zealand must provide certain minimum standards of intellectual property protection.³⁴ The standards must be met in domestic intellectual property law, although there is some policy space about how those standards are implemented, and additional protections are permitted.³⁵

15.2.2 FTAs and BITs

New Zealand is party to a number of FTAs, the terms of which may constrain New Zealand's policy autonomy to various degrees. These include FTAs with Australia, China, Hong Kong, Thailand, Malaysia and Singapore.³⁶ Currently

³² General Agreement on Trade in Services (opened for signature 15 April 1994, entered into force 1 January 1995), art I(2). Mode 1 is cross-border supply, where both the service provider and consumer remain in their own countries (for example, a lawyer providing advice via international telephone call); mode 2 is consumption abroad, where the consumer travels to another country to consume the service (for example, tourism services); mode 3 is commercial presence, where the service provider has a physical office or plant in another country and provides services from that location (for example, an overseas branch office of a law firm); and mode 4 is presence of natural persons, whereby a person travels overseas to provide a service (for example, foreign labourers).

³³ There are limited exceptions to both the GATT and GATS rules. See General Agreement on Trade in Services (opened for signature 15 April 1994, entered into force 1 January 1995), art XIV and *XIVbis* General Agreement on Tariffs and Trade (opened for signature 15 April 1994, entered into force 1 January 1995), art XX.

³⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 April 1994, entered into force 1 January 1995), art 1.1

³⁵ See Susy Frankel "Eroding National Autonomy from the TRIPS Agreement" in Meredith Kolsky Lewis and Susy Frankel (eds) *International Economic Law and National Autonomy* (Cambridge University Press, Cambridge, 2010).

³⁶ New Zealand – Hong Kong, China Closer Economic Partnership (29 March 2010, entered into force 1 January 2011) [NZ-HK CEP]; New Zealand – Malaysia Free Trade Agreement (26 October 2009, entered into force on 1 August 2010) [MNZFTA]; ASEAN – Australia – New Zealand Free Trade Agreement (– 27 February 2009, entered into force 1 January 2010) [AANZFTA]; New Zealand - China Free Trade Agreement (7 April 2008, entered into force 1 October 2008) [NZ - China FTA]; Trans-Pacific Strategic Economic Partnership Agreement (opened for signature 18 July 2005, entered into force 28 May 2006) [P4]; New Zealand - Thailand Closer Economic Partnership (19 April 2005, entered into force 1 July 2005) [NZTCEP]; Agreement between New Zealand and Singapore on a Closer Economic Partnership (14 November 2000, entered into force 1 January 2001) [NZSCEP]. All of these Agreements are available at Ministry of Foreign Affairs and Trade "Trade Relationships and Agreements" (2011) www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/index.php (last accessed 29 August 2011).

there are negotiations with Korea, India, the Gulf Co-operation Council and collectively with Russia, Belarus and Kazakhstan. In addition, New Zealand has entered into plurilateral FTAs. These include the P-4 Agreement (with Singapore, Chile and Brunei);³⁷ the expansion thereof into the TPP (discussed below); and the agreement New Zealand and Australia have with ASEAN, known as the “ASEAN³⁸ – Australia – New Zealand Free Trade Agreement”, or AANZFTA.³⁹ New Zealand has many overlapping commitments to Australia, in the form of both countries having WTO membership; CER/SEM; the AANZFTA; and the TPP (under negotiation).

Investment chapters are increasingly common additions to FTAs, including those to which New Zealand is a party. However, many countries enter into agreements solely concerned with investment called bilateral investment treaties, or BITs. New Zealand has not entered into a large number of bilateral investment treaties, but does have such agreements with Argentina, Chile, China, and Hong Kong Special Administrative Region of China.

FTAs can have both top-down and bottom-up elements to them. Many FTA commitments are in the form of negative integration and thus preserve a relatively high degree of regulatory autonomy. Other commitments are bottom-up, however, and entail New Zealand agreeing to undertake certain specific regulatory measures. These may include joint standards-setting or other forms of regulatory harmonisation. These latter types of commitment should only be undertaken after careful consideration. To the extent New Zealand has the same priorities and values as its FTA partner(s) in a given regulatory area, harmonising may result in resource savings for New Zealand without unduly impinging on regulatory autonomy. On the other hand, to the extent New Zealand would be acceding to standardisation or harmonisation on terms that are contrary to New Zealand’s policy preferences, the pros and cons of such commitments need to be weighed more carefully.⁴⁰ In the Regulatory Management chapter in this volume the use of regulatory impact assessments (known as RIAs) is discussed.⁴¹ It is notable that these do not apply to trade agreements.

A selection of important agreements affecting New Zealand’s regulatory autonomy is discussed below.

³⁷ Trans-Pacific Strategic Economic Partnership Agreement (opened for signature 18 July 2005, entered into force 28 May 2006).

³⁸ See Chris Nixon and John Yeabsley “The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road” in this volume (ch 14).

³⁹ ASEAN – Australia - New Zealand Free Trade Agreement (27 February 2009, entered into force 1 January 2010).

⁴⁰ See Paul Conway *How to Move Product Market Regulation in New Zealand Back Towards the Frontier* (OECD Economics Department, Paris, 2011).

⁴¹ See Derek Gill “Regulatory Management in New Zealand: What, Why and How?” in this volume (ch 7).

(a) Trans-Tasman relationship

Broadly, the economic and trade relationship between Australia and New Zealand is based on a comprehensive set of trade and economic arrangements which “underpin substantial flows of merchandise trade, services, investment, labour and visitors between the two countries”.⁴² The Australia New Zealand Closer Economic Relations Agreement (“ANZCERTA”), commonly called CER, entered into force on 1 January 1983, replacing the earlier New Zealand Australia Free Trade Agreement (“NAFTA”) in force since 1 January 1966.⁴³ The ANZCERTA provided a basis upon which the Governments of Australia and New Zealand have built a wide range of agreements and arrangements.⁴⁴ After achieving the goal of integration through free trade in goods and services in 1990, “both countries moved progressively towards a much deeper integration of policies, laws and regulatory regimes through processes of coordination, mutual recognition and harmonisation”.⁴⁵ There are several Memorandums of Understanding made in the CER context, some of which we discuss in this chapter. These developments have led more recently to the relationship being called the single-economic market (SEM).⁴⁶

This relationship thus began as a fairly traditional top-down agreement, but since 1990 has increasingly included significant bottom-up elements.

(b) AUSFTA

The Australia – United States Free Trade Agreement (AUSFTA) came into effect on 1 January 2005. Although New Zealand is not a party to this

⁴² Ministry of Foreign Affairs and Trade “New Zealand – Australia Closer Economic Relations” (2011) www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Australia/index.php (last accessed 29 August 2011).

⁴³ Australia New Zealand Closer Economic Relations Trade Agreement (28 March 1983, entered into force 1 January 1983) [ANZCERTA]; Ministry of Foreign Affairs and Trade “The Australia – New Zealand Closer Economic Relationship” MFAT *The Australia-New Zealand Closer Economic Relationship Booklet* (2005) at 9, available at www.mfat.govt.nz/downloads/foreign-relations/australia/anzcer-cep.pdf (last accessed 29 August 2011); A “Heads of Agreement” had been entered into by the Australian and New Zealand Governments on 14 December 1982. This meant that the basic provisions of the ANZCERTA came into effect on 1 January 1983, although it wasn’t signed until 28 March 1983 in Canberra: MFAT *The Australia-New Zealand Closer Economic Relationship Booklet* (2005) at 8.

⁴⁴ Ministry of Foreign Affairs and Trade “New Zealand – Australia Closer Economic Relations” (2011) www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Australia/index.php (last accessed 29 August 2011).

⁴⁵ Ministry of Foreign Affairs and Trade “New Zealand – Australia Closer Economic Relations” (2011) www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Australia/index.php (last accessed 29 August 2011)

⁴⁶ See Susy Frankel and Megan Richardson “Trans-Tasman Intellectual Property Coordination” in this volume (ch 18).

agreement, it nonetheless has an indirect impact on New Zealand. Pursuant to CER, New Zealand and Australia have undertaken a number of harmonisation efforts.⁴⁷ Australia has agreed to make fairly significant changes in some of its regulatory structures through AUSFTA. In particular, Australia has agreed to heightened restrictions on pharmaceutical purchasing arrangements and labelling systems, and increased protection for intellectual property (including patented pharmaceuticals).⁴⁸ Because Australia's regulatory regime has changed in certain areas slated for harmonisation with New Zealand (the Trans-Tasman Therapeutic Authority being one of them),⁴⁹ New Zealand can now expect that Australia will want New Zealand to agree to harmonise consistent with AUSFTA. This issue is discussed in further detail at [15.4] below.

(c) TPP

The Trans-Pacific Partnership (TPP) is a trade agreement currently being negotiated by nine countries that has its origins in the P-4 trade agreement.⁵⁰ The TPP comprises the P-4 countries of New Zealand, Chile, Singapore and Brunei, plus the United States, Australia, Peru, Vietnam, and Malaysia. The stated aim is to gradually expand the number of countries that are party to the TPP, with the ultimate goal of serving as the model for a free trade agreement of the Asia-Pacific.

The TPP has the potential to impact New Zealand's regulatory autonomy rather significantly. In addition to traditional negative integration commitments, the TPP is likely to feature a variety of specific positive commitments that will encroach upon policy autonomy to at least some degree. For example, the United States has frequently insisted on certain provisions in its FTAs, including heightened requirements about the regulation of pharmaceuticals, intellectual property protection and investment rules, which New Zealand has not as yet agreed to in any of its trade agreements. A number of the United States' existing FTA partners that are also participating in the TPP negotiations (Peru, Chile, Australia, Singapore) have already agreed to

⁴⁷ See, for instance, Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" (ch 17), and Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" (ch 18) in this volume.

⁴⁸ See, generally, Thomas A Faunce, Kellie Johnston and Hilary Bambrick "The Trans-Tasman Therapeutic Products Authority: Potential AUSFTA Impacts on Safety and Cost-Effectiveness Regulation for Medicines and Medical Devices in New Zealand" (2006) 37 VUWLR 365.

⁴⁹ See Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" in this volume (ch 17).

⁵⁰ For useful background on the TPP, including the evolution from the P4 to the TPP, see Ministry of Foreign Affairs and Trade "Trans-Pacific Strategic Economic Partnership Agreement" (2011) www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Trans-Pacific/index.php (last accessed 29 August 2011).

a number of such heightened measures. It seems likely, therefore, that there will be pressure for those newly linking with the United States (such as New Zealand) to agree to similar terms. New Zealand may well make concessions in areas that are of key interest to the United States, such as intellectual property and investment, in order to secure an overall agreement.⁵¹ Should the TPP adopt increased intellectual property protections and requirements relating to pharmaceuticals, such as those found in the AUSFTA or even more heightened levels of protection,⁵² New Zealand may find that its ability to source low-cost pharmaceuticals will be impacted.⁵³

In addition, it bears noting that the Philip Morris litigations described in the introduction have direct relevance to New Zealand in the context of the TPP negotiations. The United States generally insists on investor-state arbitration provisions in the investment chapters of its FTAs. Notably, Australia refused to accept such terms in the AUSFTA. News reports have suggested that New Zealand might agree to such provisions.⁵⁴

15.3 Types of constraints imposed by trade agreements

Trade agreements can limit regulatory autonomy directly, through their requirements on New Zealand as a member of an agreement. Agreements can also have an indirect effect, whereby New Zealand is impacted even by agreements to which it is not a party. Examples of each of these phenomena are discussed in this section.

⁵¹ Some of these heightened protections are discussed in Susy Frankel and Megan Richardson “Trans-Tasman Intellectual Property Coordination” in this volume (ch 18).

⁵² The United States’ proposed intellectual property text has been leaked on the Internet, see United States Government “Trans-Pacific Partnership Intellectual Property Rights Chapter: Draft – February 10, 2011” (2011) Knowledge Ecology International keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf (last accessed 29 August 2011). It proposes an AUSFTA plus level of protection. New Zealand’s and Chile’s proposed texts have also been leaked: New Zealand Government “Chapter ‘X’ Intellectual Property” (2011) Info Justice infojustice.org/wp-content/uploads/2011/02/NZ-Proposal-022011.pdf (last accessed 29 August 2011); Chilean Government “Chile TPP Submission: Preliminary Considerations for TPP IPP Chapter” (2011) Info Justice infojustice.org/wp-content/uploads/2011/02/Chile-Proposal-022011.pdf (last accessed 29 August 2011).

⁵³ For a more detailed discussion of intellectual property law see Susy Frankel and Megan Richardson “Trans-Tasman Intellectual Property Coordination” in this volume (ch 18).

⁵⁴ See Simon Lester “Update on New Zealand and Investor-State” (2011) International Economic Law and Policy Blog worldtradelaw.typepad.com/ielpblog/2011/02/update-on-new-zealand-and-investor-state.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+ielpblog+%28International+Economic+Law+and+Policy+Blog%29 (last accessed 29 August 2011) for a discussion of John Key’s statements on the issue.

15.3.1 *Direct effects of trade agreements*

Trade agreements directly impact on New Zealand's ability to regulate in a variety of ways. First, the agreement itself may prescribe processes that must be followed before regulations are applied. For example, under the WTO's SPS Agreement (discussed at [14.5] below), New Zealand cannot (consistent with the WTO rules) impose a measure designed to prevent the introduction of a new pest into the country unless it first conducts a risk assessment to determine the likelihood such a pest would be introduced and spread within the country. That assessment must also directly link to the measure imposed; New Zealand must be careful not to impose measures more stringent than are necessary to achieve its desired level of risk. While these types of rules impose some limitations on New Zealand, they are more in the nature of procedural steps that must be taken rather than constraints on substantive policymaking. Secondly, the agreement may call for harmonisation or mutual recognition of standards, which more significantly limits the policy options available to New Zealand.⁵⁵ In the case of food safety standards, various options were considered before the final regime (discussed below) was adopted. This includes some possibilities for opting out.⁵⁶ Thirdly, a trade agreement may prohibit the taking of certain actions, or permit them only under limited circumstances. For example, the WTO Agreements in general prohibit members from imposing quantitative restrictions (bans or quotas).⁵⁷

15.3.2 *Constraints imposed indirectly by agreements to which New Zealand is not a party*

In addition to the direct effects on regulatory autonomy as a result of the trade agreements it has entered into, New Zealand also experiences indirect effects on its ability to regulate as a result of certain trade agreements to which it is *not* a party. While this may sound counterintuitive, an example demonstrates the point.

⁵⁵ For a discussion of the full spectrum of regulatory coordination see Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" in this volume (ch 17).

⁵⁶ Trans Tasman Mutual Recognition Act 1997, ss 75–87.

⁵⁷ See, for example, General Agreement on Tariffs and Trade (opened for signature 15 April 1994, entered into force 1 January 1995), art XI:1: "[n]o prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party." There are limited exceptions to this general rule. If New Zealand wished as a policy matter to limit the amount of imports of a certain product from entering the country, it could not do so under the WTO rules, unless it could identify an applicable exception (which is difficult in the context of attempting to justify a quota).

Under the terms of CER, New Zealand and Australia have agreed to progressively try to harmonise certain aspects of their regulatory schemes.⁵⁸ For example, under the banner of the SEM the countries have agreed to work together to form a joint therapeutic products agency, to be called ANZTPA (Australia New Zealand Therapeutic Products Authority).⁵⁹ The proposed scheme failed to pass the New Zealand Parliament in 2009, but has not been abandoned and has been relaunched in 2011.⁶⁰ Any such scheme will be dictated by constraints in AUSFTA and the regime already in place in Australia.

Another SEM announcement has been the move towards a single patent application and common patent examination.⁶¹ At the same time as this bottom-up regulatory cooperation is being developed the details of substantive intellectual property law are being negotiated in the top-down model through the TPP. As far as intellectual property and regulation of pharmaceuticals are concerned, the TPP is likely to have more extensive requirements than AUSFTA. In this way the simultaneous working of the top down and bottom up approaches is like to significantly reduce New Zealand's regulatory autonomy over intellectual property and consequently over aspects of research and commodification of research.⁶²

While New Zealand is not a party to AUSFTA, and indeed would not have been consulted during the negotiations, the agreement Australia struck with the United States impacts on New Zealand trade and regulation.⁶³ Arguably, due to Australia's inferior bargaining power, in AUSFTA it agreed to changes to, for example, its pharmaceuticals purchasing process that it would not have made absent the FTA. Now, New Zealand will likely be pressured to have compatible approaches to pharmaceuticals purchases through the TPP process. Indeed, the United States in its trade watch list, known as the

⁵⁸ See, for example, Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" (ch 17), and Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18).

⁵⁹ See Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" in this volume (ch 17).

⁶⁰ Australia New Zealand Therapeutic Products Agency (ANZTPA) fact sheet tga.gov.au/about/international-anztpa-factsheet.htm (last accessed 30 August 2011).

⁶¹ See discussion in Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18).

⁶² The details of intellectual property law and the trans-Tasman difference are discussed in Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18). Here the focus is on the way in which that law comes into place.

⁶³ See Meredith Kolsky Lewis "The Politics and Indirect Effects of Asymmetrical Bargaining Power in Free Trade Agreements" in Tomer Broude, Marc L Busch and Amelia Porges (eds) *The Politics of International Economic Law* (Cambridge University Press, New York, 2011) 19.

Special 301 report, has named New Zealand's pharmaceutical bulk purchasing agency, Pharmac, as a concern for United States trade.⁶⁴

15.4 Regulating in the consumer protection arena

This section identifies the effects of trade agreements on regulatory choice in the two illustrative contexts: first, the regulating food safety and biosecurity; and secondly, the establishment of product safety, performance standards and aspects of the regulatory regimes around pharmaceuticals.

These are examples that have elements of top-down and bottom-up regulation. In relation to food safety in particular there is considerable trans-Tasman coordination as well as overlapping multilateral obligations. The regulatory framework is well-coordinated and for the most part achieves its goals. It also has review procedures. By comparison there is not much trans-Tasman coordination in relation to pharmaceuticals. In New Zealand, the regulatory arrangements are fractured between different bodies for different purposes and there is no one coordinator of pharmaceuticals-related regulations. At present, aspects of the regulatory regime relating to pharmaceuticals seem more likely to be determined by a top-down FTA approach and then further details will be harmonised through trans-Tasman coordination. So far, attempts at forming a joint therapeutics authority have not been successful.⁶⁵ In any event, that is only one aspect of pharmaceuticals regulation. Another important regulatory feature is the patent regime and the trans-Tasman relationship in both regimes is examined in this project.

The next sections set out the relevant regulatory regimes and related international obligations for food safety and biosecurity and the requirements to establish product safety and performance standards. The chapter then discusses aspects of the regulatory regimes around pharmaceuticals

15.4.1 Biosecurity and quarantine

In addition to the need to ensure the safety of the food supply for human consumption, there is an additional need to regulate to ensure that imported foods do not pose a biosecurity risk. New Zealand has a strong interest in preventing the establishment or spread of pests and plant (or animal) diseases not presently found (or present but tightly controlled) in New Zealand.

⁶⁴ In May 2011, the United States issued its Special 301 report highlighting New Zealand's pharmaceutical purchasing body: Office of the United States Trade Representative *2011 Special 301 Report* (2011) at 14.

⁶⁵ See Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" in this volume (ch 17).

The Protocol to the ANZCERTA on Harmonisation of Quarantine Administrative Procedures (1988) (“Quarantine Protocol”) seeks to align quarantine procedures between Australia and New Zealand.⁶⁶ In the Quarantine Protocol New Zealand and Australia “reaffirm their commitment to the principle that quarantine requirements should not be deliberately used as a means of creating a technical barrier to trade where this is not justified.”⁶⁷ The Quarantine Protocol provides that “where relevant international codes (such as those of the Office International des Epizooties) and standards exist or their completion is imminent, each Member State shall use those codes and standards, or the relevant parts of them, as a basis for quarantine and related inspection standards and procedures” except in special circumstances, such as to protect human, animal or plant life or health.⁶⁸ Only a few exceptions in the Annex to the Quarantine Protocol now remain.⁶⁹ The Quarantine Protocol also provides for the establishment of a bilateral consultative group to provide overall impetus and direction for quarantine harmonisation, coordinate technical committees and help resolve technical differences relating to quarantine.⁷⁰ The Quarantine Protocol is implemented in New Zealand by legislation administered through the New Zealand Ministry of Agriculture and Fisheries.⁷¹

Notwithstanding this protocol, it was Australia’s quarantine requirements that were at issue in the Apples dispute New Zealand successfully brought against Australia before the WTO.⁷² Thus, even when extensive efforts have been undertaken to take a cooperative approach to food and plant safety, disputes may nonetheless arise.

The Australia New Zealand Arrangement on Food Inspection Measures entered into force on 1 December 1997 and aimed to reduce border

⁶⁶ Department of Foreign Affairs and Trade “Closer Economic Relations: Background Guide to the Australia New Zealand Relationship” (1997). The Guide is also available at www.dfat.gov.au/fta/anzcerta/downloads/cer.pdf (last accessed 29 August 2011). Also see Protocol on Harmonisation of Quarantine Administrative Procedures to the Australia New Zealand Closer Economic Relations – Trade Agreement (18 August 1988, entered into force 18 August 1988).

⁶⁷ Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade, Wellington, 2005) at 25.

⁶⁸ Protocol on Harmonisation of Quarantine Administrative Procedures to the Australia New Zealand Closer Economic Relations – Trade Agreement (18 August 1988, entered into force 18 August 1988), art 2.

⁶⁹ Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade, Wellington, 2005) at 25.

⁷⁰ Protocol on Harmonisation of Quarantine Administrative Procedures to the Australia New Zealand Closer Economic Relations - Trade Agreement (18 August 1988, entered into force 18 August 1988), art 7.

⁷¹ Ministry of Agriculture and Forestry “Legislation: Legal Responsibilities” (2011) www.maf.govt.nz/about-maf/legislation (last accessed 29 August 2011).

⁷² *Australia – Measures Affecting the Importation of Apples from New Zealand* WTO DOC WT/DS367/AB/R, AB-2010-2 (2010) (Report of the Appellate Body).

inspection requirements for food products originating in either Australia or New Zealand.⁷³ Most food items exported to the other country are now treated, for inspection purposes, as domestic products.⁷⁴

There may be food safety and/or biosecurity reasons that will lead New Zealand to consider it necessary to ban or limit the importation of certain foodstuffs. New Zealand does not have an unlimited array of policy approaches to the tasks of maintaining food safety and biosecurity because WTO rules impose some constraints in this area. In particular, the Agreement on Sanitary and Phytosanitary Measures (“SPS” agreement) imposes a framework that must be followed before New Zealand can impose measures:⁷⁵

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

To the extent that New Zealand bases an SPS measure on an existing international standard, the measure will be presumed to be consistent with the SPS agreement. If, however, New Zealand elects to apply a more stringent measure, it must be careful to conduct a risk assessment based on scientific evidence, and to then link its measure to the outcome of that assessment in order to achieve the level of protection sought.⁷⁶ In so doing, New Zealand cannot impose measures that are more trade restrictive than necessary to achieve the desired level of protection. The *Apples* dispute New Zealand brought against Australia before the WTO involved the SPS agreement. Australia’s measures at issue in the *Apples* case were allegedly intended to address plant safety, by preventing the introduction and spread of fire blight and other diseases that can adversely affect apple trees. The Panel and

⁷³ Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (2005) at 26; Australia New Zealand Arrangement on Food Inspection Measures (entered into force 1 December 1997).

⁷⁴ Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade, Wellington, 2005) at 26.

⁷⁵ Agreement on the Application of Sanitary and Phytosanitary Measures (opened for signature 15 April 1994, entered into force 1 January 1995), annex A:1.

⁷⁶ World Trade Organization *Australia – Measures Affecting the Importation of Apples from New Zealand* WTO DOC WT/DS367/AB/R, AB-2010-2 (2010) (Report of the Appellate Body) [*Apples*].

Appellate Body determined that Australia had not conducted a proper assessment of risk, and that therefore its measures were not properly based on a risk assessment.

In addition, the SPS agreement also covers certain types of measures aimed at food safety. These would include, as indicated in (b) above, regulations intended to protect citizens from toxins, contaminants, and disease-causing agents found in imported foodstuffs or beverages. Thus, in the infamous Meat Hormones dispute brought before the WTO by the United States and Canada against the European Union, the EU's measures banning the importation of meat from animals that had been treated with hormones (on the basis that consuming such meat was believed to lead to higher incidences of cancer) were deemed to be SPS measures.⁷⁷

In addition, New Zealand may wish to regulate imported food in ways that would not fall under the purview of the SPS Agreement. For example, New Zealand may wish to impose labelling requirements that relate to nutritional claims, ingredient composition or quality; to establish quality requirements for fresh food; or to dictate packaging regulations for foodstuffs. Such regulations would not be governed by the SPS Agreement, but would instead fall under a separate WTO Agreement, the Technical Barriers to Trade Agreement ("TBT Agreement").⁷⁸ The key features of the TBT Agreement are discussed in the next section.

15.4.2 *Product safety and performance standards*

When New Zealand regulates to ensure product safety and performance standards, many of its regulations will be subject to the WTO's TBT Agreement. The TBT Agreement governs mandatory government regulations as well as voluntary standards established by government, for the purpose of establishing product performance standards; labelling requirements; and other technical criteria. Thus, for example, if New Zealand were to establish regulations requiring all processed food to bear nutrition labels, or maximum allowable levels of lead in toys, such regulations would fall under the TBT Agreement.

The TBT requires that technical regulations not be more trade restrictive than necessary to achieve the desired policy objective. To the extent international standards exist, New Zealand, or any other WTO member, must

⁷⁷ World Trade Organization *European Communities — Measures Concerning Meat and Meat Products (Hormones)* WTO DOC WT/DS26/AB/R and WT/DS48/AB/R, AB-1997-4 (1998) (Report of the Appellate Body) [*Meat Hormones*].

⁷⁸ See World Trade Organization "Introduction to the SPS Agreement: SPS and TBT measures" (2011) www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s4p1_e.htm (last accessed 30 August 2011).

use those standards as a basis for determining its own standards.⁷⁹ This does not require New Zealand to use the international standard. However, if it does not, it must link its standards to the international standards with a reason why the international standard is not suitable for New Zealand's objectives. For example, if the international standard for lead content in a consumer product was not more than 1 part per 10 million, but New Zealand wished to apply 1 part per 100 million, it could not do so arbitrarily. It would instead need to be prepared to justify the lower percentage by demonstrating that the international standard would not satisfy New Zealand's particular health objectives, perhaps by showing that New Zealanders are exposed to higher lead levels than international averages, and therefore a more stringent approach to lead exposure is required. In addition, New Zealand must provide MFN and national treatment with respect to its technical regulations. It therefore cannot, as a general matter, impose more onerous safety standards on imported products than it applies to like domestic products.⁸⁰

Since the ANZCERTA, a number of instruments have been negotiated that support the reduction and removal of technical barriers to trade and the establishment of uniform standards in Australia and New Zealand.⁸¹ In the 1988 Memorandum of Understanding (MOU) on Technical Barriers to Trade both governments expressed their commitment to "work towards harmonising requirements relating to such matters as standards, technical specifications and testing procedures, and domestic labelling".⁸²

15.4.3 Importance of food safety regulation

Regulating to ensure a safe food supply is a critical government function, and one that requires regular review to ensure that appropriate measures are in place to address a wide variety of potential risks to New Zealand's consumers. Imported food poses a range of potential risks to New Zealanders. Among these risks are: the possibility that tainted or improperly handled foodstuffs will enter the country (that is, foods that will make consumers sick immediately or shortly after consumption); and the possibility of food entering the country that contains unapproved additives or unacceptably high levels of additives or contaminants (that is, foods which may lead to particular

⁷⁹ Agreement on Technical Barriers to Trade (opened for signature 15 April 1994, entered into force 1 January 1995), art 2.2.

⁸⁰ Agreement on Technical Barriers to Trade (opened for signature 15 April 1994, entered into force 1 January 1995), art 2.1.

⁸¹ Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade, Wellington, 2005) at 24.

⁸² Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade, Wellington, 2005) at 25; Memorandum of Understanding between the Government of Australia and the Government of New Zealand on Technical Barriers to Trade (16 August 1988).

health problems that will not manifest themselves immediately following consumption).⁸³

15.4.4 *The food safety regulatory regime and biosecurity*

In this section we outline in some detail the regulatory regime that has developed out of the SEM framework. This detail is important background illustrating the way in which the regime developed, how national interests were built in during the process, and what autonomy interests were “surrendered” in the national interest. In the following part of this chapter this will be contrasted to the current process of the SEM relationship, particularly in relation to pharmaceuticals and how the national interest may be already compromised.

(a) *The Food Standards Treaty*

In New Zealand, food is regulated under the Food Act 1981 and regulations enacted pursuant to the Act.⁸⁴ Before 1993, proposals for changes to food standards were examined by a Food Standards Committee.⁸⁵ In 1993, the Food Standards Committee was dissolved and replaced by the Officials’ Committee on Food Administration.⁸⁶ The Officials’ Committee on Food Administration was charged with, inter alia, evaluating options for future food regulation.⁸⁷ This led to the signing of the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System (the Food Standards Treaty) that entered into force on 5 July 1996.⁸⁸ The objectives of the Food Standards Treaty are four-fold:⁸⁹

⁸³ For in-depth analysis of issues relating to import safety including food safety, see Cary Coglianese, Adam M Finkel and David Zaring (eds) *Import Safety: Regulatory Governance in the Global Economy* (University of Pennsylvania Press, Philadelphia, 2009).

⁸⁴ New Zealand Food Safety Authority *The Joint Food Standards Setting System between Australia and New Zealand* (2010) www.foodsafety.govt.nz/industry/general/labelling-requirements/regulation-of-food-in-nz/ (last accessed 30 August 2011); The Food Safety Regulations 2002. The New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002 and the Dietary Supplements Regulations 1985 are made under the Food Act 1981, ss 11C and 42.

⁸⁵ Naomi Rees and David Watson *International Standards for Food Safety* (Aspen Publishers, Gaithersburg (Maryland), 2000) at 59.

⁸⁶ Naomi Rees and David Watson *International Standards for Food Safety* (Aspen Publishers, Gaithersburg (Maryland), 2000) at 59.

⁸⁷ Naomi Rees and David Watson *International Standards for Food Safety* (Aspen Publishers, Gaithersburg (Maryland), 2000) at 59.

⁸⁸ Naomi Rees and David Watson, *International Standards for Food Safety* (Aspen Publishers, Gaithersburg (Maryland), 2000) at 59; Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade,

- (a) to reduce unnecessary barriers to trade;
- (b) to adopt a joint system for the development and promulgation of food standards;
- (c) to provide for the timely development, adoption, and review of food standards appropriate for both Member States; and
- (d) to facilitate the sharing of information between the Member States on matters relating to food.

(b) Food Standards Australia New Zealand

The Food Standards Treaty established the first trans-Tasman bi-national regulatory agency, the Australia New Zealand Food Authority (“ANZFA”), to develop joint food standards for Australia and New Zealand.⁹⁰ In 2002 the Food Standards Treaty was amended and the ANZFA was renamed Food Standards Australia and New Zealand (“FSANZ”).⁹¹ The FSANZ is an independent statutory agency,⁹² whose powers and functions are governed by the Food Standards Australia New Zealand Act 1991 (Australia).⁹³ In New Zealand, the Parliamentary Secretary to the Minister for Health has

Wellington, 2005) at 26; Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards (signed on 5 December 1995, entered into force 5 July 1996).

⁸⁹ Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards (signed on 5 December 1995, entered into force 5 July 1996), art 2.

⁹⁰ Department of Foreign Affairs and Trade “Closer Economic Relations: Background Guide to the Australia New Zealand Relationship” (Canberra, 1997); Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards (signed on 5 December 1995, entered into force 5 July 1996).

⁹¹ Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade, Wellington, 2005) at 26; Exchange of Letters Constituting the Mutual Determination referred to in Paragraph 3 of Annex E of the Agreement between the Government of New Zealand and the Government of Australia Concerning a Joint Food Standards System (signed 19 December 2002, entered into force 20 December 2002). There were also amendments by an earlier Exchange of Letters in 2001: Exchange of Letters, done at Canberra on 27 September–25 October 2001, constituting an Agreement between the Government of Australia and the Government of New Zealand amending the Agreement between the Government of Australia and the Government of New Zealand establishing a system for the development of Joint Food Standards of 1995 (27 September–25 October 2001).

⁹² For a more detailed discussion of the institutional set up see Chris Nixon and John Yeabsley “Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration” in this volume (ch 17).

⁹³ Food Standards Australia New Zealand “About FSANZ” (2011) www.foodstandards.gov.au/scienceandeducation/aboutfsanz/; Debbie Wong “Trans-Tasman Regulatory Agencies: Administrative Law Implications” (LLB (Hons) Research Paper, Victoria University of Wellington, 2007) at 8. FSANZ is part of the Australian Government’s Health and Ageing portfolio.

executive responsibility for FSANZ.⁹⁴ FSANZ has offices in Canberra and Wellington, and all employees are members of the Australian public service, including those employed in New Zealand.⁹⁵ The governing Act provides that the primary objective of the FSANZ, in developing or reviewing food standards and variations of food standards, is to protect public health and safety.⁹⁶ Other objectives include the provision of adequate information relating to food to enable consumers to make informed choices⁹⁷ and the prevention of misleading or deceptive conduct.⁹⁸ Although not stated in the Act, another promoted aim of FSANZ is the reduction of barriers to trade.⁹⁹

(c) *Joint Food Standards Code*

The FSANZ is authorised to make food standards for both Australia and New Zealand called the Australia New Zealand Food Standards Code (joint code).¹⁰⁰

FSANZ developed the joint code based on a review of the Australian Food Standards Code.¹⁰¹ The Health Ministers of New Zealand and Australia agreed to the joint code in November 2000.¹⁰² The joint code deals with issues such as production, composition, contaminants and labelling.¹⁰³ There are still a number of areas that sit outside the scope of the FSANZ and are covered by New Zealand Food Standards. These are:¹⁰⁴

⁹⁴ Food Standards Australia New Zealand “About FSANZ” (2011) www.foodstandards.gov.au/scienceandeducation/aboutfsanz/ (last accessed 30 August 2011).

⁹⁵ Food Standards Australia New Zealand “About FSANZ” (2011) www.foodstandards.gov.au/scienceandeducation/aboutfsanz/ (last accessed 30 August 2011).

⁹⁶ Food Standards Australia New Zealand Act 1991 (Cth), s 18(1)(a).

⁹⁷ Food Standards Australia New Zealand Act 1991 (Cth), s 18(1)(b).

⁹⁸ Food Standards Australia New Zealand Act 1991 (Cth), s 18(1)(c).

⁹⁹ New Zealand Food Safety Authority “The Joint Food Standards Setting System between Australia and New Zealand” (2010) www.foodsafety.govt.nz/industry/general/labelling-requirements/regulation-of-food-in-nz/ (last accessed 30 August 2011).

¹⁰⁰ Food Standards Australia New Zealand Act 1991 (Cth), s 7.

¹⁰¹ New Zealand Food Safety Authority “The Joint Food Standards Setting System between Australia and New Zealand” (2010) www.foodsafety.govt.nz/industry/general/labelling-requirements/regulation-of-food-in-nz/ (last accessed 30 August 2011).

¹⁰² New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002. In 2002 the New Zealand Minister for Food Safety, under section 11C of the Food Act 1981, issued the New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002. The New Zealand Food Standards 2001 and its amendments 1–4 were revoked and replaced by the Food Standards 2002. The New Zealand Food Regulations 1984 were also revoked and replaced by the Food (Safety) Regulations 2002.

¹⁰³ New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002.

¹⁰⁴ New Zealand Food Safety Authority “The Joint Food Standards Setting System between Australia and New Zealand” (2010) www.foodsafety.govt.nz/industry/general/labelling-requirements/regulation-of-food-in-nz/ (last accessed 30 August 2011).

- maximum residue limits of agricultural compounds in food;
- food hygiene and food safety provisions (including high-risk imported foods);
- export requirements relating to third country trade; and
- dietary supplements.¹⁰⁵

The Food Standards Treaty preserves important national policy space and contains provisions which allow New Zealand to opt out¹⁰⁶ of a joint food standard for exceptional reasons relating to health, safety, environmental concerns or cultural issues.¹⁰⁷ When New Zealand does opt out on the basis of any of these, any measures it takes still have to remain compliant with WTO agreements, particularly the SPS and TBT agreements discussed below.

(d) Role of New Zealand Food Safety Authority

The New Zealand Food Safety Authority (NZFSA) is an independent statutory agency that co-exists alongside the FSANZ. The NZFSA has the primary responsibility for developing food safety standards for New Zealand (for example, food additives, artificial sweeteners, contaminants in food, food premises registration, food labelling and food complaints).¹⁰⁸ The primary responsibility of FSANZ is to develop food standards (for example, composition, labelling and contaminants) for Australia and New Zealand.¹⁰⁹ These food standards are developed with advice from NZFSA and input from stakeholders and consistent with food regulatory policies issued by the Australian and New Zealand Food Regulation Ministerial Council.¹¹⁰

¹⁰⁵ Dietary supplements could potentially be covered under any Australian or New Zealand therapeutic products authority.

¹⁰⁶ As to the importance of the opt-out provision see Chris Nixon and John Yeabsley “Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration” in this volume (ch 17).

¹⁰⁷ Food Standards Australia New Zealand “Background” (2011) www.foodstandards.gov.au/scienceandeducation/aboutfsanz/background.cfm (last accessed 30 August 2011).

¹⁰⁸ New Zealand Food Safety Authority “The New Zealand Food Regulatory Environment” (2008) www.foodsafety.govt.nz/elibrary/industry/NZ_Food_Regulatory_Environment_March_2008.pdf (last accessed 30 August 2011).

¹⁰⁹ New Zealand Food Safety Authority “The New Zealand Food Regulatory Environment” (2008) www.foodsafety.govt.nz/elibrary/industry/NZ_Food_Regulatory_Environment_March_2008.pdf (last accessed 30 August 2011).

¹¹⁰ New Zealand Food Safety Authority “The New Zealand Food Regulatory Environment” (2008) www.foodsafety.govt.nz/elibrary/industry/NZ_Food_Regulatory_Environment_March_2008.pdf (last accessed 30 August 2011).

(e) Arrangement on Food Inspection Measures

The Australia New Zealand Arrangement on Food Inspection Measures (AFIM) entered into force on 1 December 1997 and aimed to reduce border inspection requirements for food products originating in either Australia or New Zealand.¹¹¹ Most food items exported to the other country are now treated, for inspection purposes, as domestic product.¹¹² However, as is discussed below issues still arise from time to time.

(f) 2006 review of the Food Standards Treaty

A routine review of the Food Standards Treaty in 2006 noted that the Food Standards Treaty had been successful in meeting its objectives and was working well for stakeholders in Australia and New Zealand.¹¹³ However, the review identified areas where further improvements could be made. As a result of the review and subsequent amendments to the Food Standards Australia New Zealand Act 1991 (Australia) in 2007, New Zealand and Australia agreed that the Food Standards Treaty should be amended.¹¹⁴

The review found there were strong advantages to New Zealand in agreeing to amend the Food Standards Treaty, including “provid[ing] an improved mechanism to have New Zealand specific concerns addressed within a joint standard or through a separate standard located with the [Joint] Food Standards Code”.¹¹⁵ In 2010 the Foreign Affairs, Defence and Trade Select Committee conducted an international treaty examination of the Exchange of

¹¹¹ Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs, Wellington, 2005) at 26; Arrangement on Food Inspection Measures, Australia – New Zealand (signed June 1996, entered into force 1 December 1997).

¹¹² Ministry of Foreign Affairs and Trade *The Australia-New Zealand Closer Economic Relationship Booklet* (Ministry of Foreign Affairs and Trade, Wellington, 2005) at 26.

¹¹³ International treaty examination of the Exchange of Letters Constituting an Amendment to the Agreement between the Government of New Zealand and the Government of Australia Concerning a Joint Food Standards System (select committee report) at 6. The National Interest Analysis is contained within appendix B of the Report.

¹¹⁴ International treaty examination of the Exchange of Letters Constituting an Amendment to the Agreement between the Government of New Zealand and the Government of Australia Concerning a Joint Food Standards System (select committee report) at 7. The four areas of amendments to the Food Standards Treaty include: (a) updating references to the Australian Food Regulation Agreement; (b) amending Annex C to bring into effect amendments previously agreed, and already made, to the FSANZ Act in 2007; (c) rewriting Annex D to clarify its operation and to introduce a three tiered system that provides for modifications, separate standards, and opt-out; and (d) creating a new Annex E for temporary standards to provide greater clarity and improve the operation of the mechanism for temporary standards.

¹¹⁵ International treaty examination of the Exchange of Letters Constituting an Amendment to the Agreement between the Government of New Zealand and the Government of Australia Concerning a Joint Food Standards System (select committee report) at 10–11.

Letters Constituting an Amendment to the Food Treaty (2010).¹¹⁶ The Select Committee raised questions about whether New Zealand and Australia had identical production and shelf life dates and the meaning of “cultural grounds”; however, no substantive changes were recommended.¹¹⁷

New Zealand and Australia’s joint efforts with respect to food safety are an example of bottom-up regulation being well-suited to New Zealand’s circumstances. New Zealand and Australia share common objectives and values with respect to much of the food safety regime, meaning that New Zealand did not have to sacrifice its policy preferences. Furthermore, the opt-out provisions preserve policy space for the aspects of the regime where New Zealand and Australia’s policy preferences diverge. The scheme as a whole allows New Zealand to recognise significant cost savings, and such savings do not come at an unacceptable price.

15.4.5 Aspects of the pharmaceutical regulatory regime: safety, and price

It is beyond the scope of this chapter to discuss all of the regulatory regimes that are relevant to pharmaceuticals. These include safety relating to pharmaceuticals, medicines approval and associated data exclusivity,¹¹⁸ intellectual property laws (particularly patents) and pharmaceutical purchasing arrangements¹¹⁹ and competition law. We do not traverse the details of all of those regimes in this chapter, but discuss the key links between many of them and trade agreements.

The regulatory regime relating to pharmaceuticals is complex and raises many issues, but from a national, and particularly a consumer, interest perspective there are two core concerns. These are that pharmaceuticals are affordable (even if this is not affordability direct from the consumer’s purse) and that pharmaceuticals are safe. On the safety side there has been a

¹¹⁶ New Zealand Parliament “Make a Submission: International treaty examination of the Exchange of Letters Constituting an Amendment to the Agreement between the Government of New Zealand and the Government of Australia Concerning a Joint Food Standards System” (2010) www.parliament.nz/en-NZ/PB/SC/MakeSub/6/e/7/49SCFDT_SCF_00DBSCH_ITR_9783_1-International-treaty-examination-of.htm (last accessed 30 August 2011).

¹¹⁷ International treaty examination of the Exchange of Letters Constituting an Amendment to the Agreement between the Government of New Zealand and the Government of Australia Concerning a Joint Food Standards System (select committee report) at 2.

¹¹⁸ Medicines Act 1981. Applications for approval of medicines must be made under s 20. Applications must include information relating to any evidence regarding safety of the products, as per s 21, and the Minister is required to weigh the likely therapeutic value of the medicine against the risk of it injuriously affecting the health of any person as per s 22(1)(b).

¹¹⁹ New Zealand’s Pharmaceutical Management Agency (also known as Pharmac) and its arrangements for purchasing pharmaceuticals are also governed by the New Zealand Public Health and Disability Act 2000, ss 46–53.

proposed joint therapeutics authority, which at first was not successfully established and now another approach to establishment is under way.¹²⁰ Aspects of that proposal are analysed in another chapter in this project.¹²¹ Of relevance to this chapter is that any Australia and New Zealand combined joint therapeutics authority will be structured in a way that meets Australia's AUSFTA obligations.¹²² AUSFTA had a considerable impact on many aspects of Australian pharmaceutical regulation. AUSFTA's impact on the Australian pharmaceutical purchasing scheme, known as the Pharmaceutical Benefits Scheme (PBS), has been strongly criticised.¹²³ It is notable that the provisions in AUSFTA that have impacted the PBS and pharmaceuticals more generally are not all in one place but are spread throughout the agreement; including the intellectual property chapter, the Annex on Pharmaceuticals, the dispute resolution chapter and a side letter.

Historically, the main controls on pharmaceutical prices in New Zealand were compulsory licensing and parallel importation provisions.¹²⁴ Compulsory licensing can take many forms, but in the past compulsory licences were available to ensure local availability and affordable prices of patented pharmaceuticals, often through local manufacturing.¹²⁵ As global trade has increased, imports have taken priority over local manufacturing.

A parallel import is one that is imported into, for example, country A from country B (or possibly a third country) when it was originally made for country B. In the context of pharmaceuticals a parallel import might be described as a version of the pharmaceutical manufactured for a market elsewhere. Both compulsory licensing and parallel importation attracted the wrath of the United States. In relation to parallel importation the United States alleged that New Zealand was compromising the rights of patent owners. This activity put New Zealand on the United States 301 watch list.¹²⁶ The legislation eventually only allowed the importation of off-patent pharmaceuticals, which is arguably

¹²⁰ Australia New Zealand Therapeutic Products Agency (ANZTPA) fact sheet tga.gov.au/about/international-anztpa-factsheet.htm (last accessed 30 August 2011).

¹²¹ See Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" in this volume (ch 17).

¹²² See Chris Nixon and John Yeabsley "Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration" in this volume (ch 17).

¹²³ Peter Drahos and others "Pharmaceuticals, Intellectual Property and Free Trade: The Case of the US-Australia Free Trade Agreement" (2004) 22(3) *Prometheus* 243.

¹²⁴ See Patents Act 1953, s 51 (repealed by the Patents Amendment Act 1992, s 8(1)); Medicines Act 1981, s 32A of the 1981 (repealed).

¹²⁵ Patents Act 1953, s 51 (repealed).

¹²⁶ "How USA's heavy hand forced drug rethink" *National Business Review* (New Zealand, 19 June 1992) at 26. See also Christopher Scott Harrison "Protection of Pharmaceuticals as Foreign Policy: The Canada-US Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91" (2001) 26 *NCJ Intl L & Com Reg* 457 at 500–505, for a discussion of the US 301 watch list.

not necessary to legislate for, as patent law could not prohibit the importation of non-patented goods in any event.

Parallel importation of pharmaceuticals is not, and has never been, prohibited by any multilateral intellectual property agreement. The TRIPS Agreement recognises there is no international agreement on what in intellectual property terms is called exhaustion of rights. Exhaustion of rights refers to when the intellectual property rights are exhausted. Usually after the first sale a patented product can be on-sold, but not necessarily exported and imported (that is, parallel imported). The TRIPS Agreement provides that matters of exhaustion of intellectual property rights are not a matter subject to dispute settlement under the agreement.¹²⁷

It is widely thought that, although the TRIPS Agreement permits compulsory licensing under certain circumstances, those circumstances are narrower than what was permissible pre-TRIPS.¹²⁸ AUSFTA restricts compulsory licensing even further than the TRIPS Agreement¹²⁹ and also prohibits parallel importation of pharmaceuticals.¹³⁰

The main price control mechanism in New Zealand is now outside of the patent system. Price regulation is achieved through Pharmac¹³¹ and its policies of reference pricing, cost-effectiveness evaluations and competitive tendering within a fixed budget cap. Pharmac is exempt from the restrictive trade practices provisions in the Commerce Act 1986.¹³² The New Zealand Supreme Court has interpreted this exemption as applying to pharmaceutical companies as well as to Pharmac.¹³³ Consequently, the major pharmaceutical companies of the world are, for most of their core business purposes, arguably beyond the reach of New Zealand competition law. Thus, Pharmac is the only control on the price of pharmaceuticals in New Zealand and its structure is

¹²⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 April 1994, entered into force 1 January 1995), art 6.

¹²⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 April 1994, entered into force 1 January 1995), art 31 provides situations where compulsory licences can be issued. Article 5 of the Paris Convention for the Protection of Industrial Property (opened for signature 20 March 1883, entered into force 7 July 1884), which is incorporated into the TRIPS Agreement, has a wider scope on what compulsory licensing is legitimate.

¹²⁹ Australia – United States Free Trade Agreement (opened for signature 18 May 2004, entered into force 1 January 2005) art 17.9.7.

¹³⁰ Australia – United States Free Trade Agreement (opened for signature 18 May 2004, entered into force 1 January 2005) art 17.9.4.

¹³¹ Health and Disabilities Services Act 1993, now the New Zealand Public Health and Disability Act 2000, s 47(b) also provides that Pharmac's objectives include "any other objectives it is given by or under any enactment, or authorised to perform by the Minister by written notice to the board of Pharmac after consultation with it".

¹³² New Zealand Public Health and Disability Act 2000, s 53.

¹³³ *AstraZeneca Ltd v Commerce Commission* [2009] NZSC 92, [2010] 1 NZLR 297.

under threat in the current TPP negotiations.¹³⁴ The AUSFTA changes to the PBS system are probably the United States' bottom line. New Zealand's regulatory autonomy in this field has been squeezed already, and is on the path to being constrained even further.

Regardless of Pharmac's situation, it is, nevertheless, a purchaser of pharmaceuticals. Despite negotiation, Pharmac has, to a certain extent, to deal with the price that the sellers propose. Patent law plays a considerable role in price. A patent holder has the exclusive right to make, use, sell and import patented products¹³⁵ and patent holders, while they have the protection of a patent, can charge whatever price they set. Of course, where there are competing products available the price may well come down. But where a patent supports an economic monopoly – that is, the patented product is the only product available – the exclusive rights of the patent owner means it determines the price. Thus, the stronger and broader that patent law is, the more impact it has on price.

15.4.6 *Patent law and the price of pharmaceuticals*

The ways in which patent law affects the price of pharmaceuticals has been recognised in New Zealand, but there has not been a co-ordinated approach to the relationship between price and patent law. There have been two instances in which the link has been made. The first is in relation to patent term extension where the former Prime Minister, Helen Clark, did not pursue a Ministry of Economic Development proposal about extending the patent term of pharmaceutical patents.¹³⁶ It seems, perhaps because of her experience as Minister of Health, she concluded that the cost of pharmaceuticals would increase through patent term extension. Also, Pharmac has challenged the legality of one aspect of patent law. That is the allowance of patents for second uses of already-patented pharmaceuticals.¹³⁷ Pharmac lost that challenge and has not subsequently challenged patentability policy through the courts.

Leaked text from the TPP negotiations indicates a number of ways that patent law might be made more protective, particularly of pharmaceutical patents.¹³⁸ These include ways of strengthening the subject-matter of patents so that more incremental developments are patentable and also ways of

¹³⁴ Office of the United States Trade Representative *2011 Special 301 Report* (2011) at 14.

¹³⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 April 1994, entered into force 1 January 1995), art 28(1).

¹³⁶ Ministry of Economic Development *Review of the Patents Act 1953: The Pharmaceutical Patent Term in New Zealand* (2003).

¹³⁷ *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2000] 2 NZLR 529 (CA).

¹³⁸ Trans-Pacific Partnership Intellectual Property Rights Chapter Draft – February 10, 2011, available at <http://keionline.org/sites/default/files/tp-10feb2011-us-text-ipr-chapter.pdf> (last accessed 2 October 2011).

increasing the term of patents. Those relating to increased subject matter scope and patentability criteria are discussed in the intellectual property chapter in this volume.¹³⁹ Here we discuss patent term and the likely pressure on New Zealand to extend patent term for pharmaceutical patents as a trade-related matter.

The leaked TPP text indicates a “placeholder” for patent term extension, rather than setting out any detailed text about term extension. However, both United States and Australian laws provide for patent term extension, and AUSFTA and other United States FTAs provide for term extension. It is predictable, therefore, what such an article might look like in the TPP. AUSFTA provides:¹⁴⁰

With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

As the AUSFTA text indicates the supposed rationale for such extensions is linked to the regulatory regime for medicines approval. However, there is no requirement under the TRIPS Agreement or any other multilateral intellectual property agreement that patent term extension must be made available because of regulatory approval processes. In fact, one of the reasons that the TRIPS Agreement set patent term at 20 years,¹⁴¹ when before the agreement 14 years was more common, was to take account of claims that patent term extension was necessary.¹⁴² Prior to the TRIPS Agreement New Zealand law did provide for patent term extension. However, when New Zealand changed its domestic law to the 20 year term it no longer provided for patent term extension.¹⁴³

When this linkage between regulatory approval and patent term extension arose, in the context of a dispute at the WTO, the WTO Panel said that there is considerable debate about the linkage and that regulatory review exceptions were permissible without the requirement of patent term extension.¹⁴⁴ Indeed, the TRIPS Agreement does not require patent term extension, but

¹³⁹ See Susy Frankel and Megan Richardson “Trans-Tasman Intellectual Property Coordination” in this volume (ch 18).

¹⁴⁰ Australia – United States Free Trade Agreement (opened for signature 18 May 2004, entered into force 1 January 2005), art 17.9.8(b).

¹⁴¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 April 1994, entered into force 1 January 1995), art 33.

¹⁴² The drafting history shows that some parties proposed including patent term extension, but it was not included in the final draft. See Daniel Gervais *The TRIPS Agreement: Drafting History and Analysis* (3rd ed, Sweet & Maxwell, London, 2008) at [2.96]–[2.300].

¹⁴³ Patents Act 1953, s 31 (repealed).

¹⁴⁴ *Canada - Patent Protection of Pharmaceutical Products* WTO DOC WT/DS114/R, AB-00-1012 (2000) (Report of the Panel) at [7.82].

allows exceptions to patents under certain criteria¹⁴⁵ which the regulatory review exception, in the dispute under Canadian law, met.

Some jurisdictions see patent term extension as a necessary rule in order to balance a regulatory approval exception to patent law. Such an exception allows third parties to obtain regulatory approval for potentially competing products to a patented product. The third party cannot make for commercial scale or sell the patented product during the patent term, but it can make enough to submit that product to regulatory review.¹⁴⁶ This supposed balance, or possibly more accurately trade-off, between legal rules does not factor in the overall economic benefits for a country that imports rather than makes the pharmaceuticals to which patent term extension might apply.

As patent law is premised on economic justifications, it is highly probable that there is no one legal rule to fit differing economies.¹⁴⁷ New Zealand has a regulatory review exception¹⁴⁸ but does not provide for patent term extension. A country that imports most of its pharmaceuticals, such as New Zealand, may very well economically benefit from having a regulatory review exception and not extending patent term.

The next stage of this project will examine the issues raised by possible patent term extension which New Zealand may have to comply with because of a top-down trade agreement model, and the costs and benefits associated with such an extension. Patent term will be used and developed as an example that addresses the key themes in this chapter, in particular the direct and indirect effects of trade agreements on the regulation of national interests. In addition to the top down trade agreement minimum standards for intellectual property model there is regulatory coordination relevant to patents in the SEM context.¹⁴⁹ That proposed coordination is not directly about patent term extension. Term extension is, however, one difference between New Zealand and Australian patent law that arguably should be preserved in a trans-Tasman

¹⁴⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights (opened for signature 15 April 1994, entered into force 1 January 1995), art 30.

¹⁴⁶ The dispute about Canada's regulatory review exception also included a dispute over a stockpiling exception. That is making the product during the patent term and stockpiling so it is ready for sale as soon as the patent expires. The panel found that this making of patented products was not a sufficiently limited exception for the purpose of art 30 of the TRIPS Agreement: *Canada – Patent Protection of Pharmaceutical Products* WTO DOC WT/DS114/R, AB-00-1012 (2000) (Report of the Panel).

¹⁴⁷ As Cooke J observed "... there must be an economic question of particular importance for a country the size of New Zealand, dependent to the extent that it is upon overseas manufacturers": *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA) at 391. A country like New Zealand which is dependent on overseas manufacturing raises particular policy considerations in relation to patent law: see also Susy Frankel "Lord Cooke and Patents: The Scope of 'Invention'" (2008) 39 VUWLR 73.

¹⁴⁸ Patents Act 1953, s 68B.

¹⁴⁹ This is discussed in Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18).

arrangement. New Zealand, however, will probably not have that regulatory autonomy space as a result of combined top-down and bottom-up pressure.

15.5 Further research and preliminary conclusions

As discussed above, New Zealand's regulatory autonomy is impacted by a variety of different types of trade agreements. 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 the AUSFTA may also indirectly impact on New Zealand's regulatory options. Furthermore, Australia and New Zealand are both members of an FTA with the ASEAN, and are negotiating the Trans-Pacific Partnership together with seven other countries. New Zealand and Australia are thus intertwined in numerous different ways.

The food standards regulatory regime has been negotiated between New Zealand and Australia and appears to be a successful model of combining and overlapping trading arrangements. By comparison the pharmaceuticals regulatory framework is compliant with international multilateral obligations, but is incompatible with arrangements with our trading partners and is under threat from FTAs directly through the TPP and indirectly through AUSFTA.

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. The next stages of this project will explore these issues further.

In stage two we will use a more detailed analysis of patent term 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).

We will:

- Compile 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).
- Examine the question of the impact of patent term extension on the price of pharmaceuticals for human treatment in the New Zealand context. Key assumptions include that Australia has the extension while New Zealand does not, so Australia's set up and data can be used to produce the details for a carefully designed counterfactual.

We will also examine:

- the potential response of major intellectual property owning trading partners, such as the United States, and its likely impact; and
- if the absence of term extension affects the availability of certain pharmaceuticals in New Zealand. That is, if we do not allow the extension do we lose access to some pharmaceuticals and how should that loss be valued?

We will contrast the process that is affecting the regulation of pharmaceuticals with the process that led to the foods standards and safety regime and, using these examples, further analyse whether more regulatory autonomy is more probable or possible in one framework rather than the other.

