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ELI LILLY AND COMPANY V THE GOVERNMENT OF CANADA AND THE PERILS OF INVESTOR-STATE ARBITRATION

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INTRODUCTION

We live in a world today where it is routine for foreign private companies to sue sovereign countries, claiming that domestic laws interfere with foreign investment activities. Take the case of *Eli Lilly v the Government of Canada*. Eli Lilly and Company ("Eli Lilly"), a multinational pharmaceutical corporation, is presently suing the Government of Canada ("Canada"), alleging that the invalidation of two patents amounts to an unlawful expropriation of Eli Lilly's intellectual property. The company claims Canada's patent laws are arbitrary, discriminatory, and in breach of the minimum standard of treatment owed to foreign investors under the *North American Free Trade Agreement* ("*NAFTA*"). The company is seeking damages in excess of half a billion dollars.¹

The two patents—for the drugs Strattera and Zyprexa—were found invalid in separate judgments of the federal courts, and both decisions were upheld on appeal. Despite the findings of Canadian courts, Eli Lilly relies upon its right under *NAFTA* to haul Canada before an *ad hoc* tribunal and have the country defend the laws and processes of its legal system. Canada must answer to Eli Lilly's argument of what Canadian law ought to be.

Eli Lilly's claim against Canada raises the question of whether and under what circumstances a foreign investor can circumvent domestic judicial outcomes through international arbitration. This article takes the position that the role of investor-state arbitration should not be expanded to provide a forum of *de facto* appeal. Eli Lilly's claim challenges Canada's regulatory sovereignty, undermining the country's right to determine its own substantive patentability standards and govern intellectual property within its borders. The allegation that Canada interfered with Eli Lilly's expectation of monopoly profits may have a chilling effect on the willingness of courts and lawmakers to regulate the brand-name pharmaceutical industry, and may ultimately impact the accessibility and affordability of medicines in Canada's healthcare system.

This article is structured in three parts. Part I outlines the nature of investor-state arbitration and briefly introduces Canada's international trade policy and investment

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¹ Eli Lilly and Company v The Government of Canada, Notice of Intent to Submit a Claim to Arbitration under NAFTA (12 September 2013) UNCT-14-2 (NAFTA/UNCITRAL) at para 4 [Notice of Arbitration]; North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States, 17 December 1992, Can TS 1994 No 2, 32 ILM 289 (entered into force 1 January 1994) [NAFTA].

treaty regime. Part II critically discusses Eli Lilly's arbitration claim and the substantive *NAFTA* provisions on which the claim rests. It is argued that the treaty obligations material to Eli Lilly's claim—the minimum standard of treatment and expropriation provisions—should be interpreted to properly balance foreign investment protection with domestic policy autonomy. Part III considers the implications of Eli Lilly's claim for Canada's judicial and regulatory sovereignty, and comments more generally on the risks of allowing foreign investors to circumvent domestic legal processes through investor-state arbitration.

PART I. CANADA'S INTERNATIONAL TRADE POLICY AND INVESTMENT TREATY REGIME

Investor-state arbitration is a dispute settlement process recognized under public international law whereby a foreign investor is granted the right to bring a claim directly against the government hosting its investment. A tribunal presides over the dispute and decides whether the host government has breached its obligations towards the foreign investor and should be liable for damages. Investor-state tribunals derive their jurisdiction from international trade agreements, in which states agree to be bound by certain obligations in regard to foreign investment.

As of 1 June 2013, Canada has signed thirty-three bilateral investment treaties ("BITs"), which are referred to in Canada as Foreign Investment Promotion and Protection Agreements.² With respect to multilateral agreements, Canada is a party to *NAFTA* along with the United States and Mexico. More recently, Canada signed a *Comprehensive Economic and Trade Agreement* ("CETA") with the European Union and became a party to the ongoing *Trans-Pacific Partnership* ("TPP") negotiations.³ Canada also recently ratified the World Bank's *International Centre for Settlement of Investment Disputes* ("ICSID") Convention, a multilateral treaty that institutionalizes foreign investment dispute resolution.⁴

Canada's growing thirst for bilateral and multilateral trade agreements is consistent with the government's new international trade plan, which is said to adopt a "market-first approach to foreign policy." Trade agreements are intended to both enhance the

² Canada has signed and ratified agreements with Argentina, Armenia, Bangladesh, Barbados, Bosnia and Herzegovina, Costa Rica, Croatia, Czech Republic, Ecuador, Egypt, Hungary, Jordan, Latvia, Lebanon, Panama, Peru, Philippines, Poland, Romania, Russian Federation, Singapore, Slovakia, Thailand, Trinidad and Tobago, Ukraine, Uruguay, and Venezuela. Agreements with Benin, China, El Salvador, Kuwait, South Africa, and the United Republic of Tanzania have been signed but are not yet in force: Bilateral Investment Treaties signed by Canada, UNCTAD (2013), online: http://unctad.org/Sections/dite_pcbb/docs/bits_canada.pdf>.

³ Canada-European Union Comprehensive Economic and Trade Agreement (agreed in principle 18 October 2013; ratification expected in 2015). Canada entered TPP negotiations 8 October 2012: Foreign Affairs, Trade and Development Canada, Trans-Pacific Partnership Free Trade Agreement Negotiations (last updated November 2013), online: http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/index.aspx.

⁴ Julius Melnitzer, "Canada ratifies World Bank's ICSID Convention", Financial Post (2 November 2013), online: https://business.financialpost.com/2013/11/02/canada-raitifes-world-banks-icsid-convention; Convention on the Settlement of Investment Disputes between States and Nationals of Other States.

John Ibbitson, "Tories' new foreign-affairs vision shifts focus to 'economic diplomacy'", The Globe and Mail (27 November 2013) online: http://www.theglobeandmail.com/news/politics/tories-new-foreign-affairs-vision-shifts-focus-to-economic-diplomacy/article15624653; see also Department of Foreign Affairs, Trade and Development Canada, Global Markets Action Plan: The Blueprint for Creating Jobs and Opportunities for Canadians Through Trade (27 November 2013), online: http://international.gc.ca/global-markets-marches-mondiaux/assets/pdfs/planeng.pdf.

protection afforded to Canadian investors abroad as well as promote foreign investment within Canada. Central to Canada's approach in negotiating trade agreements is the inclusion of investor-state dispute resolution provisions. For example, Section B of Chapter 11 of *NAFTA* provides that an "investor of a Party may submit to arbitration [...] a claim that another Party has breached an obligation [...] and that the investor has incurred loss or damage by reason of, or arising out of, that breach." This provision allows a foreign investor to bring a claim directly against a host state on the basis that the state breached one or more of its Chapter 11 substantive treaty obligations. These obligations include national treatment (Article 1102), most-favoured-nation treatment (Article 1103), minimum standard of treatment (Article 1105), performance requirements (Article 1106), transfer provisions (Article 1109), and requirements for expropriation and compensation (Article 1110).

Historically, foreign investors from capital-exporting states used investor-state arbitration to protect themselves from the expropriation or nationalization of their assets. Foreign investors viewed the international nature of arbitration as more reliable than the national court systems of developing host states. Today, however, some countries question the purported utility of resolving foreign investment disputes through investor-state arbitration. Australia—an advanced capitalist democracy with a rule of law culture similar to that of Canada—openly renounced the inclusion of arbitration in future BIT negotiations. More recently, some German officials have objected to the inclusion of the investor-state dispute settlement provisions in the Canada-European Union *CETA*, on the basis that the provisions inhibit a host state from passing domestic measures in the public interest. On

Other critics argue that investor-state arbitration lacks transparency and institutional independence, that conflicts of interest are common among arbitrators, and that the structural failings of the system raise a reasonable apprehension of bias in favour of investor rights.¹¹ Proponents of investor-state arbitration, in contrast, argue that the process provides a neutral and convenient forum for resolving disputes, and that investment treaties themselves impose reasonable obligations upon governments.

While evaluating the arguments for or against investor-state arbitration is beyond the scope of this article, the debate is relevant to the extent that it colours the nature of Eli Lilly's arbitration claim—a challenge to the "promise doctrine" of patentability.

⁶ See, for example, Canada's Model Foreign Investment Promotion and Protection Agreement: Agreement Between Canada and -- for the Promotion and Protection of Investments, online: <www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/fipa-apie/index.aspx?lang=eng>.

⁷ NAFTA, supra note 1, art 1116.

⁸ Andreas F Lowenfeld, "The Responsibility of Host States to Foreign Investors: Customary International Law" in *International Economic Law*, 2d ed (London: Oxford University Press, 2008) at 483-85.

⁹ See Leo E Trakman, "Choosing Domestic Courts Over Investor-State Arbitration: Australia's Repudiation of the Status Quo" (2012) 35:3 UNSW Law Journal 979 at 981.

¹⁰ Gordon Isfeld, "Canada, EU leaders sign CETA pact despite German concerns", Financial Post (26 September 2014) online: http://business.financialpost.com/ 2014/09/26/stephen-harper-euleaders-meet-amid-ceta-cloud>.

¹¹ George Kahale III, "Is Investor-State Arbitration Broken?", *Transnational Dispute Management* 7 (October 2012) online: http://www.transnational-dispute-management.com/article. asp?key=1918>; see also Gus Van Harten, "Toward an independent rules-based system of trade and investment", *MacDonald-Laurier Institute Commentary* (28 September 2011) online: http://www.macdonaldlaurier.ca/files/pdf/State-Investor-Arbitration-Commentary-Sept-28-2011.pdf>.

PART II. ELI LILLY'S CHALLENGE TO THE PROMISE DOCTRINE

Eli Lilly's claim rests on the invalidation of two of its patents—one for the drug Strattera (atomoxetine), used to treat attention deficit hyperactivity disorder, and the other for the drug Zyprexa (olanzapine), used to treat schizophrenia and related psychotic disorders. ¹² Canadian federal courts invalidated the patents on the grounds that Eli Lilly failed to demonstrate or soundly predict the promised utility of the inventions at the time the patents were respectively filed. ¹³ The separate trial decisions were upheld at the Federal Court of Appeal, and leave to the Supreme Court of Canada was refused on both occasions. ¹⁴ In the case of Zyprexa, the Supreme Court of Canada made a rare order for an oral hearing of the application for leave to appeal. Notwithstanding the process afforded to Eli Lilly, the company alleges that the "improvident loss" of its patents was a breach of Canada's obligations under *NAFTA*. ¹⁵ Before discussing the *NAFTA* obligations at issue in Eli Lilly's claim, it is important to understand the legal grounds upon which the patents were invalidated.

To patent a drug, a pharmaceutical company must be able to prove that the drug has an intended use. ¹⁶ A "mere scintilla of utility" will normally suffice, unless the inventor discloses a promise of utility in the patent. ¹⁷ Where a pharmaceutical patent *promises* utility—by specifying an advantage of using the drug—that promise must be demonstrated or soundly predicted prior to the filing of the patent application. A patent that does not demonstrate or soundly predict its stated promise can be found to be invalid, and evidence of pharmacological utility after the filing date will not validate an otherwise invalid patent. Unlike the law of the United States, Canadian courts will generally not accept post-patent proof for the purpose of turning "dross into gold." ¹⁸ In a unanimous decision of the Supreme Court of Canada, Justice Binnie justified the doctrine on the grounds that "the public is entitled to obtain a solid teaching in exchange for the patent rights." ¹⁹ The promise doctrine reflects the principle that monopoly rights are extended to a patented invention in exchange for the disclosure of that invention

¹² Notice of Arbitration, supra note 1 at para 2.

¹³ For Strattera, see *Novopharm Limited v Eli Lilly and Company*, 2010 FC 915 (available on CanLII); for Zyprexa, see *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288 (available on CanLII) [*Zyprexa* FC].

¹⁴ For Strattera, see Eli Lilly and Company v Teva Canada Limited, 2011 FCA 220 (available on CanLII), leave to appeal to SCC refused, 34396 (December 8, 2011); for Zyprexa, see Eli Lilly Canada Inc v Novopharm Limited, 2012 FCA 232 (available on CanLII), leave to appeal to SCC refused, 35067 (May 16, 2013).

¹⁵ Notice of Arbitration, supra note 1 at para 85.

¹⁶ See Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77 at para 52 (available on CanLII) [emphasis in original] [Apotex]:

It is important to reiterate that the only contribution made by Glaxo/Wellcome in the case of AZT was to identify a new use. The compound itself was not novel. Its chemical composition had been described 20 years earlier by Dr. Jerome Horwitz. Glaxo/Wellcome claimed a hitherto unrecognized utility but if it had not established such utility by tests or sound prediction at the time it applied for its patent, then it was offering nothing to the public but wishful thinking in exchange for locking up potentially valuable research turf for (then) 17 years.

¹⁷ See, for example, Eli Lilly Canada Inc v Novopharm Ltd, 2010 FCA 197 at para 76 (available on CanLII); Sanofi-Aventis v Apotex Inc, 2013 FCA 186 at para 50 (available on CanLII).

¹⁸ Apotex, supra note 16 at para 46.

¹⁹ *Ibid* at para 69.

to the public.²⁰ In this respect, patents are seen in Canada as providing both a societal benefit and an incentive for innovation. The standards required for patentability—novelty, utility, and inventiveness—exist to balance the private interests of the innovator with the interests of the public, including competitors and consumers.

The promise doctrine is particularly relevant in the context of the pharmaceutical industry, where drug companies often seek patents for "a new use for an old chemical compound." Jim Keon, president of the Canadian Generic Pharmaceutical Association, argues that the doctrine "exists to prevent the grant of speculative patents that overpromise and under-deliver—both of which are harmful to society and stagnating to innovation." Eli Lilly notes that 18 pharmaceutical patents have been invalidated for lack of utility since the promise doctrine emerged as a sword for generic pharmaceutical companies to challenge brand-name patents. Many of those patents were for new uses of existing drugs. From the perspective of generic pharmaceutical companies, the promise doctrine is a judicially crafted response to the problem of "early speculative" and shotgun patenting on behalf of brand-name companies, who are alleged to abuse lax patentability standards in the hopes that at least some of their dross turns to gold in the future. In Ironically, however, it is the gold that is invalidated, as generic pharmaceutical companies only have incentive to seek the invalidation of patents that prove to be medically and commercially successful, as Strattera and Zyprexa exemplify.

According to Eli Lilly, Canada is the only jurisdiction in the world that invalidated the patents on the basis of inutility. ²⁶ John Lechleiter, Eli Lilly's chairman, president, and chief executive officer, has gone so far as to state that the utility standard set by the Canadian courts "makes successful acquisition and maintenance of a patent on an

²⁰ As Canada submits, "[d]isclosure to the public is at the heart of the patent bargain, as it allows others to study and build upon existing inventions, avoid duplicative research, and properly use the invention once the monopoly expires. [...] Patent systems around the world are founded on this same bargain": Eli Lilly and Company v The Government of Canada, Statement of Defence of the Government of Canada (30 June 2014) UNCT-14-2 (NAFTA/UNCITRAL) at para 13 [Statement of Defence]. Eli Lilly agrees with this point, recognizing that in exchange for monopoly rights, "the inventor must disclose its invention to the public by adequately describing it in the patent application": Eli Lilly and Company v The Government of Canada, Claimant's Memorial (29 September 2014) UNCT-14-2 (NAFTA/UNCITRAL) at para 27 [Claimant's Memorial].

²¹ Apotex, supra note 16 at para 46.

²² Jim Keon, "Canada's Patent Laws Promote Genuine Medical Innovation", Canadian Generic Pharmaceutical Association (23 September 2013) online: http://www.canadiangenerics.ca/en/news/sep_23_13.asp.

²³ Notice of Arbitration, *supra* note 1 at paras 11, 66. In its Claimant's Memorial, *supra* note 20 at para 3, Eli Lilly submits that the Canadian federal courts have invalidated a pharmaceutical patent on the grounds of nonutility a total of 23 times over the past nine years.

²⁴ Other patents, like the one for Zyprexa, were for compound(s) selected from a pre-existing patent over a larger group (or genus) of compounds. These are known as selection patents, where "the invention is the discovery of a substantial advantage over the genus compounds": Zyprexa FC, supra note 13 at para 265.

²⁵ Keon, *supra* note 22. Canada notes in its Statement of Defence, *supra* note 20 at para 55 that "[Eli Lilly] filed at least ten alternative patent applications for the use of atomoxetine [Strattera] for the treatment of ten other pathologies" and at para 67 that "[Eli Lilly] filed at least 29 other Canadian patent applications relating to olanzapine [Zyprexa], purporting to have invented at least 16 distinct new and surprising uses for the compound". Eli Lilly, in response, notes that "for every drug that succeeds, thousands of compounds have failed": Claimant's Memorial, *supra* note 20 at para 3.

²⁶ Notice of Arbitration, *supra* note 1 at paras 56, 65. Eli Lilly points out that neither the United States nor the United Kingdom adheres to the promise doctrine, and neither jurisdiction found the Strattera or Zyprexa patents invalid in similar litigation. For Zyprexa, see *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly and Company Ltd*, [2009] EWCA Civ 1362 and *Eli Lilly and Co v Zenith Goldline Pharmaceuticals Inc*, 471 F 3d 1369 (Fed Cir 2006).

innovative new medicine in Canada essentially impossible." Moreover, the promise doctrine has attracted criticism from the United States Trade Representative, which has made known its "serious concerns" about the "heightened utility requirements" adopted by the Canadian courts. The high level of intellectual property protection demanded by the United States government reflects the increasing reliance of the American economy on its innovative industries. Eli Lilly is a prime example. It maintains that patent protection is the "lifeblood" of the company. 29

Eli Lilly characterizes Canada's actions as a form of foreign free riding, whereby Canadians enjoy the low prices of generic competition while Americans foot the bill for pharmaceutical innovation. Canada, by contrast, views Eli Lilly's claim as the last-ditch effort of a disappointed litigant whose claim unduly impinges on Canada's need to navigate its own patent laws and policy landscape. With this context in mind, I now turn to the *NAFTA* claim—that the invalidation of the Strattera and Zyprexa patents on the grounds of inutility breaches two *NAFTA* Chapter 11 obligations: Article 1105, the minimum standard of treatment, and Article 1110, expropriation.

A. Article 1105: Minimum Standard of Treatment

Eli Lilly alleges that the application of the promise doctrine to its patents, and Canada's failure to rectify the doctrine, violates the minimum standard of treatment guaranteed to foreign investors under NAFTA Article 1105. The provision provides that each "Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security".30 The standard of fair and equitable treatment is included in most trade agreements and pleaded in almost every investor-state arbitration claim.³¹ The standard has been held to obligate states to ensure (a) vigilance and protection; (b) due process; (c) lack of arbitrariness and non-discrimination; and (d) transparency and stability, including the protection of legitimate expectations.³² Eli Lilly's claim rests on the latter three principles—that the federal courts' decisions were "improper and discreditable" and thus lacking in due process; that the promise doctrine was applied "discriminatorily and arbitrarily" to pharmaceutical patents including Strattera and Zyprexa; and that Eli Lilly was entitled to reasonably rely upon the "stability, predictability, and consistency of Canada's legal and business framework", as well as the legitimate expectation that Eli Lilly's patent rights would not be revoked.³³

NAFTA tribunals have considered the scope and interpretation of Article 1105 extensively. In *SD Myers Inc v The Government of Canada* ("*SD Myers*"), the tribunal stated that an infringement of the minimum standard of treatment under Article 1105 occurs only when a foreign investor has been treated "in such an unjust or arbitrary manner that the treatment rises to the level that is unacceptable from the international perspective."³⁴ The

²⁷ John Lechleiter, "How Lax Patent Rules In Canada Are Suffocating Life-Saving Innovation", Editorial, Forbes (26 August 2013) online: http://www.forbes.com/sites/johnlechleiter/2013/08/26/how-lax-patent-rules-in-canada-are-suffocating-life-saving-innovation.

²⁸ Demetrios Marantis, Acting United States Trade Representative, Office of the United States Trade Representative, 2013 Special 301 Report (May 2013) at 46.

²⁹ Claimant's Memorial, supra note 20 at para 25.

³⁰ NAFTA, supra note 1, art 1105 [emphasis added].

³¹ Katia Yannaca-Small, "Fair and Equitable Treatment Standard: Recent Developments" in August Reinisch, ed, Standards of Investment Protection (London: Oxford University Press, 2008) 111 at 112.

³² Ihid at 118

³³ Notice of Arbitration, *supra* note 1 at paras 80-84; Claimant's Memorial, *supra* note 20 at paras 261-91.

³⁴ SD Myers Inc v The Government of Canada, Partial Award (13 November 2000, NAFTA/UNCITRAL) at para 263 [SD Myers].

tribunal emphasized that the determination must be made with due regard to the "high measure of deference" that international law extends to the right of sovereign states in regulating "matters within their own borders."³⁵ In *Glamis Gold, Ltd v United States of America*, the presiding tribunal stated that conduct that violates Article 1105 must be "sufficiently egregious or shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons—so as to fall below accepted international standards."³⁶ In *Mondev International Ltd v United States of America*, the tribunal considered the minimum standard of treatment in the context of denial of justice in judicial proceedings:

The test is not whether a particular result is surprising, but whether the shock or surprise occasioned to an impartial tribunal leads, on reflection, to justified concerns as to the judicial propriety of the outcome, bearing in mind on the one hand that international tribunals are not courts of appeal, and on the other hand that Chapter 11 of *NAFTA* (like other treaties for the protection of investments) is intended to provide a real measure of protection. In the end the question is whether, at an international level and having regard to generally accepted standards of the administration of justice, a tribunal can conclude in the light of all the available facts that the impugned decision was clearly improper and discreditable, with the result that the investment has been subjected to unfair and inequitable treatment.³⁷

With respect to the legitimate expectations of foreign investors, *NAFTA* tribunals consider whether a host state created reasonable and justifiable expectations that were relied upon by the investor.³⁸ The justification for the doctrine is that a foreign investor's decision to invest in a particular host state is based on (1) representations made by the host state's government officials and (2) an understanding that the legal structures of the host state will remain stable, transparent, and receptive to their investment activities.³⁹

Thus, taken together, the fair and equitable treatment standard protects foreign investors and investments from government measures that are arbitrary, discriminatory, lacking in due process, or in breach of representations reasonably relied upon. The standard is additionally subject to a binding interpretation of the Free Trade Commission ("FTC"), mandating that Article 1105 prescribes the minimum standard of treatment under customary international law, and that "fair and equitable treatment" as set out in the article does not exceed that which is required by customary international law. Further,

³⁵ Ibid.

³⁶ Glamis Gold, Ltd v United States of America, Award (8 June 2009, UNCITRAL) at para 627, cited in Statement of Defence, supra note 20 at para 99 (Canada arguing that the threshold set for a violation of the minimum standard of treatment is set extremely high under customary international law).

³⁷ Mondev International Ltd v United States of America, Award (11 October 2002) ARB(AF)-99-2 (NAFTA/ICSID) at para 127 [Mondev].

³⁸ See, for example, Metalclad Corporation v The United Mexican States, Award (30 August 2000)
ARB(AF)-97-1 (NAFTA/ICSID) at para 99 [Metalclad]; see also International Thunderbird Gaming
Corporation v The United Mexican States, Award (26 January 2000, NAFTA/UNCITRAL) at para 147,
finding a breach of fair and equitable treatment "where a Contracting Party's conduct creates
reasonable and justifiable expectations on the part of an investor (or investment) to act in
reliance on said conduct, such that a failure by the NAFTA party to honour those expectations
could cause the investor (or investment) to suffer damages."

³⁹ Ibid

⁴⁰ Waste Management, Inc v United Mexican States, Award (30 April 2004) ARB(AF)-00-3 (NAFTA/ ICSID) at para 98 [Waste Management].

⁴¹ NAFTA Free Trade Commission, *Notes of Interpretation of Certain Chapter 11 Provisions* (31 July 2001), online: http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/NAFTA-Interpr.aspx.

the FTC interpretation mandates that a breach of a separate international agreement or another provision of *NAFTA*, such as the intellectual property provisions of Chapter 17, does not establish a breach of the minimum standard of treatment under Article 1105. 42

The question is thus whether the common law promise doctrine and its application to Eli Lilly's patents constitute unfair and inequitable treatment to such an extent that they violate the minimum standard of treatment under customary international law. To support the argument that Canada's measures were arbitrary, discriminatory, lacking in due process, and contrary to Eli Lilly's legitimate expectations, Eli Lilly cites Canada's international obligations, including the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS")⁴³ and the intellectual property protections enshrined in NAFTA Chapter 17. Article 27.1 of TRIPS provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."⁴⁴ NAFTA Article 1709(1), which was based on a draft of the TRIPS agreement, ⁴⁵ similarly states as follows:

[E]ach Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively.⁴⁶

Eli Lilly argues that the meaning of "capable of industrial application" or "useful" should be determined by reference to the patent laws of the United States and Europe, as the laws of these jurisdictions formed the basis for the language used in both *NAFTA* Article 1709(1) and *TRIPS* Article 27(1).⁴⁷

Eli Lilly's argument, if accepted, effectively denies the interpretation of Canadian legislation in accordance with Canadian law, and runs afoul of the principle—as espoused in *SD Myers*—that a high measure of deference ought to be extended to domestic authorities in regulating matters within their own borders. Within Canada's borders, patent laws find their source in legislation, subordinate regulations, and common law jurisprudence. The *Patent Act* defines an invention as any new and useful "art, process, machine, manufacture or composition of matter" or any new and useful improvement thereof. This definition is consistent with *TRIPS* and *NAFTA*. While the patent laws of the United States and Europe may be of some help in determining the normative content of this definition, domestic courts and administrative decision-makers must

⁴² Ibid.

⁴³ Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex IC of the Marrakesh Agreement establishing the World Trade Organization, 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (signed in Marrakesh, Morocco) [TRIPS].

⁴⁴ Ibid. art 27.1.

⁴⁵ See Canada – Patent Protection of Pharmaceutical Products (Complaint by the European Communities and their Member States) (2000) WTO Doc WT/DS114/R at para 4.6 and n 29, cited in Eli Lilly and Company v The Government of Canada, Notice of Intent to Submit an Arbitration Under NAFTA Chapter 11 (7 November 2012) UNCT-14-2 (NAFTA/UNCITRAL) at para 10 [Notice of Intent]; also cited in Notice of Arbitration, supra note 1 at para 42.

⁴⁶ NAFTA, supra note 1, art 1709(1).

⁴⁷ Notice of Intent, supra note 45 at para 10.

⁴⁸ SD Myers, supra note 34 at para 263.

⁴⁹ Patent Act, RSC 1985, c P-4, s 1.

⁵⁰ According to Canada, "[TRIPS] left ample room for national variations and approaches to substantive patent issues": Statement of Defence, supra note 20 at para 91.

interpret and apply patentability standards on a case-by-case basis in accordance with Canadian law. The United Nations Conference on Trade and Development has stated that Article 27.1 of the *TRIPS* Agreement

sets up the criteria of patentability, without however harmonizing the way in which they have to be implemented. Thus, Members have considerable leeway in applying those three criteria (novelty, inventive step and industrial applicability).⁵¹

Notwithstanding this flexibility, Eli Lilly argues that Canada must adopt a harmonized meaning of utility that is more particular than the broad definitions under *TRIPS* and *NAFTA*. Canadian courts are not bound to interpret the broad patentability standards of *TRIPS* and *NAFTA* in accordance with European and American patent law. They are, however, bound to interpret standards of patentability in accordance with Canadian law. For this reason, Eli Lilly's argument that it had a legitimate expectation that Canadian law would abide by the company's preferred interpretation of patentability standards is untenable. On the contrary, a foreign investor reasonably and legitimately expects that its investment will be subject to the legal system of its host state and the domestic laws therein.

While domestic law as applied to foreign investors should not breach minimum standards of customary international law, the minimum standard should not be equated with the preferred laws of other legal systems. Domestic measures will breach the minimum standard if they display "a wilful disregard of due process of law, ... which shocks, or at least surprises, a sense of judicial propriety"52 or "unreasonably depart from the principles of justice recognized by the principal legal systems of the world".⁵³ Like any legal rule, the promise doctrine is not immune from critique. However, it is not enough for an investor-state tribunal to believe that a court decision is wrong under the laws of the relevant domestic legal system.⁵⁴ To establish a breach of the minimum standard of treatment, the decisions must be "grossly unfair or inequitable under the customary international law standard of treatment". 55 To hold otherwise, a tribunal would be encroaching on domestic appellate jurisdiction. As Canada points out, tribunals have "repeatedly emphasized" that they do not serve the function of de facto Courts of Appeal.⁵⁶ In this case, the promise doctrine was developed, clarified, and approved by Canada's highest judicial body. The federal courts applied the doctrine to Eli Lilly's patents following the due process of a full adversarial trial, and these decisions were reviewed by appellate bodies. In this regard, the interpretation and application of the promise doctrine presents no unreasonable departure from principles of justice. While the doctrine may be different from the standard of patent usefulness in other legal systems, it falls within the internationally accepted mandate that domestic authorities apply the criteria of patentability flexibly within their borders.

⁵¹ United Nations Conference on Trade and Development-ICTSD, *Resource Book on TRIPS and Development* (Cambridge: Cambridge University Press, 2005) at 358, cited in "Eli Lilly Investor-State Fact Sheet", *Public Citizen* (last updated March 2013) online: http://www.citizen.org/eli-lilly-investor-state-factsheet.

⁵² Mondev, supra note 37 at para 127.

⁵³ Louis B Sohn & RR Baxter, Harvard Draft Convention on the International Responsibility of States for Injuries to Aliens (1959), art 8(b), cited in Mondey, supra note 37.

⁵⁴ ADF Group Inc v United States of America, Award (9 January 2003) ARB(AF)-00-1 (ICSID) at para 190 [ADF Group Inc], cited in Statement of Defence, supra note 20 at para 98.

⁵⁵ ADF Group Inc, supra note 54 at para 190.

⁵⁶ Ibid, citing, for example, Mondev, supra note 37 at para 136; Robert Azinan and others v United Mexican States, Award (1 November 1999) ARB(AF)-97-2 (ICSID) at para 99; SD Myers, supra note 34 at para 261; see also Statement of Defence, supra note 20 at para 99.

Further, it is reasonable for a foreign investor to expect that domestic law, particularly in a common law jurisdiction, is subject to clarification and development, and that prevailing law will apply to investment activities, foreign or otherwise. Patents themselves are subject to contestation, and some disputes will lead to invalidation whereas other disputes will lead to validation.⁵⁷ By nature, the case-by-case determination of patent validity will lead to different outcomes. Such outcomes are not necessarily arbitrary or discriminatory, but a natural and necessary consequence of the judicial system. Canadian courts must formulate and apply legal rules as is necessary to fairly and justly resolve the particular dispute before them. For all these reasons, the claim that Canada breached the minimum standard of treatment owed to Eli Lilly cannot be reasonably sustained.

B. Article 1110: Expropriation

Eli Lilly also claims that Canada directly or indirectly expropriated the rights conferred by the Strattera and Zyprexa patents. The determination of what constitutes an expropriatory measure is contentious. Some commentators have suggested that the streams of jurisprudence on the doctrine of expropriation are "at best incoherent" in both international and national law.⁵⁸ This incoherence leads to considerable uncertainty in the adjudication of expropriation claims. Whether a claimant will succeed in arguing that a particular government measure constitutes expropriation turns not only on the substantive principles of the law of expropriation, but also on the particular doctrinal position of the individual tribunal members deciding the dispute, as gleaned from their previous writings and awards.⁵⁹

Despite the lack of predictability on the law of expropriation, it is generally accepted that arbitral awards have widened the basis upon which foreign investors may claim expropriatory conduct by a host state. Entry Entry

- 1. No Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment ('expropriation'), except:
 - (a) for a public purpose;
 - (b) on a non-discriminatory basis;
 - (c) in accordance with due process of law and Article 1105(1); and
 - (d) on payment of compensation [...].

⁵⁷ Canada argues that the "reasonable understanding of a rational actor" is "well aware that initial patent grants" are "only presumptively valid" and "subject to court review": Statement of Defence, *supra* note 20 at para 104. It further argues that that "[u]nder Canadian law, an initial patent grant is always made subject to invalidation by the Federal Court, the ultimate arbiter of patent validity and the authoritative interpreter of *Patent Act* requirements": *ibid* at para 43.

⁵⁸ Campbell McLachlan, Laurence Shore & Matthew Weininger, International Investment Arbitration: Substantive Principles (Oxford: Oxford University Press, 2007) at 8.03, citing Rosalyn Higgins, "The Taking Of Property by the State: Recent Developments in International Law" (1982) 176 Recueil des Courts 259 at 268.

⁵⁹ McLachlan, Shore & Weininger, supra note 58 at 8.06.

⁶⁰ Ibid at 8.05.

In Waste Management, Inc v The United Mexican States, the NAFTA tribunal clarified the distinction between expropriation and a measure tantamount to expropriation in Article 1110, finding that the latter requires "no actual, transfer, taking or loss of property by any person or entity." A measure tantamount to expropriation need only render the ownership of the foreign investor's property ineffective or irrelevant. Perhaps the broadest conception of expropriation was found in Metalclad Corporation v The United Mexican States ("Metalclad"), where the tribunal stated that expropriation under Article 1110 included

covert or incidental interference with the use of property which has the effect of depriving the owner, in whole or in significant part, of the use or reasonably-to-be-expected economic benefit of property even if not necessarily to the obvious benefit of the host State.⁶³

On judicial review of the *Metalclad* decision, Justice Tysoe of the Supreme Court of British Columbia found that the definition was "extremely broad" and would encompass, for example, "legitimate rezoning of property by a municipality or other zoning authority." Indeed, this extremely broad definition would also seem to encompass the determination of patent validity by a federal court. It is undisputed that there must be something more to this definition, and Eli Lilly readily concedes that a state may revoke a patent, provided it does not violate a rule of international law in doing so.65

With respect to the limits of the expropriation and compensation provision, Article 1110(7) provides that Article 1110 does not apply "to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with [Chapter 17]." Accordingly, for Eli Lilly's expropriation claim to succeed, the promise doctrine as applied by the federal courts to the Strattera and Zyprexa patents must be *inconsistent* with *NAFTA* Chapter 17, the chapter governing intellectual property. Eli Lilly argues that the invalidation of its patents was unfair and "contrary to recognized principles for the protection of intellectual property", for therefore, Eli Lilly alleges that the failure of Canada to adequately protect the company's intellectual property rights is inconsistent with Chapter 17.

The problem with Eli Lilly's argument is that Chapter 17 in *NAFTA* is of considerable generality, contemplating both the need for robust intellectual property protections as well as the right of state regulatory autonomy. This generality is exemplified in the principle provision at issue in Eli Lilly's claim, Article 1709(1), which leaves "capable of industrial application" undefined as a patent standard, except to say that it is synonymous

⁶¹ Waste Management, supra note 40 at para 143.

⁶² Conversely, see Feldman v United Mexican States, Award (16 December 2002) ARB(AF)-99-1 (NAFTA/ICSID), another NAFTA dispute where the tribunal stated that indirect expropriation and measures tantamount to expropriation are functionally equivalent.

⁶³ Metalclad, supra note 38 at para 103.

⁶⁴ United Mexican States v Metalclad Corp, 2001 BCSC 664 at para 99 (available on CanLII).

⁶⁵ Claimant's Memorial, supra note 20 at para 15.

⁶⁶ NAFTA, supra note 1, art 1110(7). Canada argues that the tribunal has no jurisdiction over any alleged violations in Canada's international intellectual property obligations under TRIPS or NAFTA Chapter 17: Statement of Defence, supra note 20 at para 84.

⁶⁷ Notice of Arbitration, supra note 1 at para 78.

with "usefulness." The substantive standards of patentability, including the concept of utility, were left to domestic legal development and clarification.

Additional provisions in Chapter 17 further support the proposition that the promise doctrine is not inconsistent with the chapter. Article 1709(8) allows a state to revoke a patent when "grounds exist that would have justified a refusal to grant the patent." Arguably, this provision contemplates a state's right to invalidate a patent on the grounds that the patent failed to demonstrate or soundly predict its promised usefulness at the time of filing. At the very least, it affirms that the granting of a patent at first instance is subject to subsequent review and possible revocation. Article 1709(2) provides that states may exclude inventions from patentability in order to "protect human health." While it is not suggested that the Strattera and Zyprexa doctrines were invalidated on exclusionary grounds, the fact that *NAFTA* Chapter 17 provides for public policy exceptions adds further indication to the chapter's contemplation of domestic regulatory autonomy. Other examples include Article 1704, which mediates the balance between the intellectual property rights afforded in Chapter 17 and the need for domestic authorities to regulate their internal markets:

Nothing in this Chapter shall prevent a Party from specifying in its domestic law licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. A Party may adopt or maintain, consistent with the other provisions of this Agreement, appropriate measures to prevent or control such practices or conditions.⁷¹

These examples demonstrate both the breadth and nuance of Chapter 17. They suggest that the promise doctrine is no more inconsistent with Chapter 17 than it is consistent. Chapter 17 establishes a principled framework for a patent regime while leaving a host state with flexibility in the regime's particular domestic implementation. While Eli Lilly argues that Canada has "clearly and substantially redefined utility as contemplated by *NAFTA*",⁷² the fact remains that utility was left undefined as a patent standard. Without second-guessing the appropriate interpretation and application of Canadian patent law with respect to this standard, a tribunal has no basis upon which to conclude that Canada's approach to utility is in violation of a rule of international law.

Nevertheless, Eli Lilly cites the introductory provision of Chapter 17—states should provide "adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade"—as the overarching obligation which Canada has breached.⁷³ While it is true that the protection of intellectual property rights is the core purpose of Chapter 17, it does not necessarily follow that Canada failed to protect intellectual property rights by invalidating Eli Lilly's patents. On the contrary, the patents were invalidated out of a concern for protecting legitimate claims to intellectual property. Lax patentability standards may be just as much a barrier to

⁶⁸ NAFTA, supra note 1, art 1709(1). Notwithstanding, Eli Lilly's argument necessarily implies that utility under NAFTA in fact has an "internationally-accepted" meaning: see, for example, Notice of Arbitration, supra note 1 at paras 17, 196. Canada, in reply, contends that "as in TRIPS, reflecting substantial differences in their respective intellectual property regimes, the NAFTA Parties were unable to agree even on common terminology for core concepts of patentability": Statement of Defence, supra note 20 at para 88.

⁶⁹ NAFTA, supra note 1, art 1709(8).

⁷⁰ Ibid, art 1709(2).

⁷¹ Ibid, art 1704; see also TRIPS, supra note 43, art 40.

⁷² Claimant's Memorial, supra note 20 at para 17.

⁷³ NAFTA, supra note 1, art 1701(1); Notice of Arbitration, supra note 1 at paras 5, 43.

legitimate trade as strict patentability standards. Unmeritorious patent holders exercising their monopoly rights may hinder the efforts of legitimate innovators and efficient competitors. As Justice Binnie noted in *Apotex Inc v Wellcome Foundation Ltd*, "[a] policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove *invalidity*, without the patent owner's ever being put in a position to establish validity."⁷⁴ The promise doctrine, which assesses utility on the merits of the patent, is thus consistent with the recognition and enforcement of intellectual property rights.

Finally, Eli Lilly cites the ICSID arbitration award of Saipem v Bangladesh ("Saipem") for the proposition that "a judicial decision contrary to the host State's treaty obligations is an illegal decision."75 It is argued that because the federal court decisions invalidated Eli Lilly's patents in breach of Chapter 17, the decisions are illegal and thus expropriatory in nature. However, the decisions of the Canadian federal courts are in no way comparable to the impropriety of the Bangladeshi courts in Saipem. In Saipem, the Bangladeshi national courts failed to recognize and enforce an award of the International Chamber of Commerce, and a subsequently constituted ICSID tribunal found that the conduct of the Bangladeshi courts constituted an "abuse of rights" amounting to an illegal expropriation under Article 5 of the Italy-Bangladesh BIT.76 The apparent lack of independence and neutrality in the Bangladeshi courts influenced the ICSID tribunal in applying the internationally accepted principle of prohibition of abuse of rights to rectify an otherwise manifestly improper decision. A court exercising its "supervisory jurisdiction for an end which [is] different from that for which it [is] instituted"77 is clearly distinguishable from a court lawfully exercising its statutory mandate and function at common law. The foregoing analysis suggests that the federal courts have exercised their judicial function in a manner consistent with Canada's treaty obligations and consistent within the policy space that such international treaties readily allow. Judicial interpretation of the provisions of Canada's Patent Act is both allowable and desirable, and a decision contrary to the financial interests of a foreign investor does not, by itself, amount to an expropriation.

PART III. CHILLING EFFECTS

In addition to the taxpayer burden of a half a billion-dollar award, Eli Lilly's arbitration action may narrow Canada's policy space with respect to pharmaceutical patent rights and constrain domestic control over the country's healthcare system. The threat of costly arbitral awards may cause legislators, judges, and policymakers to think twice about measures that might limit, regulate, or affect the rights of pharmaceutical patentholders. Following a *NAFTA* award in favour of Eli Lilly, federal court judges would likely abandon the promise doctrine altogether, for any subsequent foreign investor could bring suit against Canada if their patent was invalidated on the basis of the doctrine. Thus, notwithstanding the findings of the Federal Court, upheld by the Federal Court of Appeal and undisturbed by the Supreme Court of Canada, a single arbitral award could have the effect of changing Canada's patent laws.

While a *NAFTA* tribunal does not have the authority to render the patents valid under Canadian law, a judgment in favour of Eli Lilly is functionally the same as if Strattera and Zyprexa were valid. Eli Lilly would be entitled to its expected monopoly profits from the drugs, and future patent challenges in Canadian courts would not be subject to Canada's

⁷⁴ Apotex, supra note 16 at para 46.

⁷⁵ Notice of Intent, *supra* note 45 at para 92; see *Saipem SPA v The People's Republic of Bangladesh*, Award (30 June 2009) ARB-05-07 (ICSID).

⁷⁶ *Ibid* at para 204.

⁷⁷ Ibid at para 161.

promise doctrine. Accordingly, an award would effectively extend the jurisdiction of Eli Lilly's preferred patent laws within Canada's borders. Indeed, the action might open up additional claims, whereby other Canadian courts that deviate from applying the preferred law of a foreign investor may be subject to international challenge.

To be clear, this article does not suggest that foreign investors are never justified in claiming damages against host states. Nor is it suggested that the promise doctrine is necessarily preferable over other interpretations of patent utility. A critique of the actions of Eli Lilly does not depend upon the substantive merits of the promise doctrine, except to the extent I have argued that the doctrine is an appropriate expression of the Canadian common law and not in breach of NAFTA and customary international law, including NAFTA Chapter 17, the minimum standard of treatment, and the provisions against expropriation. Further, this article does not take a position between how the interests of brand name pharmaceutical companies and the interests of generic companies should be balanced, recognizing that both have a role to play in bringing innovative medicines to a competitively efficient and affordable market. Instead, the scope of my argument is that states are required to mediate this balance, and are entitled to a measure of judicial and regulatory sovereignty in doing so. Judicial and regulatory sovereignty is necessary for a host state to effectively attend to the myriad of interests that must be represented, including but not limited to the interests of foreign investors.

Eli Lilly's arbitration claim rests on a rejection of judicial and regulatory sovereignty that is both extreme and without merit. In profiting from its investment in Canada, Eli Lilly is required to comply with Canadian laws, regulations, and court directives. While government measures can and do treat foreign investors unfairly and inequitably, Eli Lilly's loss of two court challenges in fair hearings does not justify using investor-state arbitration for a de facto appeal. Eli Lilly is challenging Canada's legal process not because the process is contrary to international law, but because circumventing the Canadian courts through investor-state arbitration is in the company's interests, Canadian law notwithstanding. Canada, of course, expressly assented to NAFTA, including the dispute resolution provisions of Chapter 11. Even if Eli Lilly's claim is unfounded, affording foreign investors access to investor-state arbitration is a part of the agreement of NAFTA from which Canada also receives benefits. However, investor-state arbitration should not be a conduit by which a foreign investor can reject Canada's legal system for its own corporate objectives.

In addition to Eli Lilly's claim, Canada's conclusion of CETA and engagement with TPP negotiations raises further concerns with respect to expansive patent protections creating barriers to affordable medicines. During CETA negotiations, for example, it was estimated that the proposed lengthening of the period of exclusivity for innovative pharmaceuticals would lead to an annual increase in drugs costs in the range of CDN \$2.8 billion.⁷⁸ The government of the Province of Ontario has already indicated that it will demand that the federal government "mitigate the impact" of CETA on Ontario's healthcare sector.⁷⁹ This comes at a time when healthcare costs are already steadily rising as a result of an aging population. Standard & Poor has warned that Canada will face

⁷⁸ Paul Grootendorst & Aidan Hollis, *The Canada-European Union Comprehensive Economic & Trade Agreement: An Economic Impact Assessment of Proposed Pharmaceutical Intellectual Property Provisions*, commissioned by the Canadian Generic Pharmaceutical Association (7 February 2011).

⁷⁹ Ontario, Ministry of Economic Development, Trade and Employment, Statement from the Minister of Economic Development, Trade and Employment on a Trade Deal Between Canada and the European Union (17 October 2013), online: http://news.ontario.ca/medt/en/2013/10/statement-from-the-minister-of-economic-development-trade-and-employment-on-a-trade-deal-between-can.html>.

credit downgrades unless policymakers takes proactive measures, including increasing the provision of private sector health services and reducing the extent of coverage.⁸⁰

Eli Lilly's claim risks pulling on yet another thread from the fabric of Canada's public healthcare system, as the cost of monopoly medicine creates perverse incentives for privatization. Questions regarding healthcare privatization, as well as the balance between protecting pharmaceutical innovators and promoting public health interests through generic competition, are becoming increasingly important to Canada's social and economic future. Once again, this article does not take a position on how those questions should be answered—it only seeks to maximize the space in which Canada can answer these questions on its own terms.

CONCLUSION

The arbitration against Canada serves as a cautionary tale to the country. The benefit of expanded trade relationships—obtained by granting foreign investors expansive rights under investment treaties—must be balanced with the need for effective policy autonomy. At a time when the executive branch of government is boldly entering into new trade agreements, it is important to be mindful of how the increased state obligations that attach to foreign investment can affect other levels and branches of government, including provincial legislatures, Parliament, and the judiciary. In the absence of adequate democratic consultation, extending unbounded rights to foreign investors may result in unforeseen and possibly irretrievable losses for Canada. It will be difficult to reclaim these losses once gone, and only then at great cost.

^{80 &}quot;Health-care costs could downgrade Canada's credit", *CBC News* (31 January 2012) online: http://www.cbc.ca/news/business/health-care-costs-could-downgrade-canada-s-credit-1.1183525>.