INFRINGING ON INVESTMENT: HOW ONE COMPANY IS USING INVESTMENT PROTECTIONS OF NAFTA TO SAVE ITS INTELLECTUAL PROPERTY

Jillian Rabe

I. INTRODUCTION

A. Eli Lilly v. Canada

In 1994, twenty years ago, the United States, Canada, and Mexico signed the North American Free Trade Agreement ("NAFTA") into law.[1] It had a number of goals, including the intent "to eliminate barriers of trade and investment between the United States, Canada and Mexico."[2] NAFTA has a number of provisions to achieve its goals, including decreasing the tariff between the three countries in order to increase trade.[3] The decreasing tariff was intended to lower trade barriers with the hope of making consumer products cheaper.[4] With respect to a number of consumer products, this hope was made into a reality.[5] Importation from Mexican and Canadian factories without trade barriers made a number of goods, including automobiles, electronics, and clothing, cheaper in the United States.[6]

However, there is one area of consumer products that did not achieve the hoped for price decline in the United States: the prescription drug industry. There is a long-held belief in the United States that prescription drugs are made available at cheaper prices in countries such as Canada because of the availability of generic drugs.[7] While this may not always be true in the cases of some prescription drugs,[8] there is a basis for this claim.[9]

---

[1] *The North American Free Trade Agreement (NAFTA)*, BOUNDLESS (last accessed Feb. 12, 2014) https://www.boundless.com/marketing/textbooks/boundless-marketing-textbook/global-marketing-7/important-international-bodies-and-agreements-54/the-north-american-free-trade-agreement-nafta-266-4078/ [hereinafter *NAFTA I*].

[2] *Id.*

[3] *Id.*

[4] Amy Fontinelle, *Pros and Cons of NAFTA*, INVESTOPEDIA (Dec. 21, 2012), http://www.investopedia.com/financial-edge/1212/pros-and-cons-of-nafta.aspx.

[5] *NAFTA I*, *supra* note 1.

[6] Vincent Intondi, *On the 20th Anniversary of NAFTA*, HUFFINGTON POST, Nov. 3, 2013, *available at* http://www.huffingtonpost.com/vincent-intondi/nafta-immigration_b_4209250.html.

[7] David Gross, *Prescription Drug Prices in Canada*, AARP PUBLIC POLICY INSTITUTE, 2009, http://assets.aarp.org/rgcenter/health/ib62_can_rx.pdf.

[8] While there are a number of reasons that Canadian pharmaceuticals may be cheaper than their American counterparts (including, but not limited to price caps and other restrictions, which are

http://dx.doi.org/10.18060/7909.0031

Since 2005, Canadian courts have invalidated the patents of eighteen prescription drugs produced by a number of pharmaceutical companies due to its interpretation of the Canadian Patent Act.[10] As the basis for their claim, Eli Lilly claims that Canada has unfairly invalidated two of its patents prior to their expiration date because the Canadian courts have started using this different interpretation of the Canadian Patent Act.[11]

It is well recognized that patents play an important role in innovation, having been recognized since Ancient times. "In the ancient Greek city of Sybaris in about 500 B.C., ['Jencouragement was held out to all who should discover any new refinement in luxury, the profits arising from which were secured to the inventor by patent for the space of a year.['J]"[12] Patents entered into English common law in 1449 when John of Utynam was granted one for a "twenty-year monopoly" for a new method of staining glass.[13] This twenty-year period of exclusive rights to patented ideas has become the standard of today's world, both in the United States and abroad[14]. However, some countries—such as Canada—have invalidated patents before this twenty-year period expires based on their interpretation of their respective Patent Acts despite the fact that the patents that were granted were supposed to be valid for the standard twenty-year period.[15]

The importance of protecting patents is as vital to innovation today as

---

outside the scope of this paper), one reason is the effect of the Canadian Patent Act. The judicial interpretation has invalidated a number of American pharmaceutical patents before the patent was set to expire. When a company does not have to spend so much money on the research and development of a pharmaceutical, the product can be distributed at a cheaper rate than the original version of the drug. Michael Bihari, *Why Are Medications Cheaper in Canada?*, ABOUT.COM (Jan. 7, 2009) http://drugs.about.com/od/faqsaboutyourdrugs/f/Canada_ cheap.htm.

[9] Gross, *supra* note 7.

[10] *Notice of Arbitration*, *Eli Lilly v. Canada* (NAFTA 2013), ¶11, *available at* http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-03.pdf [hereinafter *Notice of Arbitration*].

[11] *Id.*

[12] *About Cybaris*, CYBARIS INTELLECTUAL PROPERTY LAW REVIEW (last accessed Feb. 12, 2014), http://web.wmitchell.edu/cybaris/, citing CHARLES ANTHON, A CLASSICAL DICTIONARY: CONTAINING AN ACCOUNT OF THE PRINCIPAL PROPER NAMES MENTIONED IN ANCIENT AUTHORS, AND INTENDED TO ELUCIDATE ALL THE IMPORTANT POINTS CONNECTED WITH THE GEOGRAPHY, HISTORY, BIOGRAPHY, MYTHOLOGY, AND FINE ARTS OF THE GREEKS AND ROMANS TOGETHER WITH AN ACCOUNT OF COINS, WEIGHTS, AND MEASURES WITH TABULAR VALUES OF THE SAME 1273 (Harper & Brothers 1841), *available at* http://books.google.com/books?id=3iQQAAA AYAAJ&oe=UTF-8.

[13] *United Kingdom Patent Applications*, LEXISNEXIS (last accessed Feb. 12, 2014), http://w3.nexis.com/sources/scripts/info.pl?278252.

[14] Gerald T. Bodner, *U.S. Patent System Under GATT and NAFTA*, BODNERROURKE.COM (last accessed Feb. 12, 2014), http://www.bodnerorourke.com/pdf/NAFTA.pdf. In the earlier days of the Republic, the United States granted patents for a period of seventeen years. However, the patent granting practice was modernized to twenty year period. *Id.*

[15] Patent Act, R.S.C., 1985, c.P-4, §44 *available at* http://laws-lois.justice.gc.ca/eng/acts/p-4/ [hereinafter Canadian Patent Act].

it was in Sybaris in 500 B.C. This is especially true in the realm of pharmaceuticals, where innovations can have exponential beneficial effects on the quality of life for individuals. In addition to the importance these pharmaceuticals have on the quality of life, they are also incredibly expensive to produce.[16] Pharmaceutical companies argue that they spend hundreds of millions of dollars for research and development on each drug that they are able to market to the public.[17] Patents are necessary for those companies to protect all of the money they invested in producing those drugs. Without them, the pharmaceutical companies may become hesitant to continue on the path of innovation.[18]

Furthermore, companies need to have a way to enforce the patents that they have been granted. Normally, they have an enforcement mechanism in the form of the courts in the violator's country under the protections of that country's patent act. However, the Canadian courts have invalidated two of Eli Lilly's patents that should have been protected by the Canadian Patent Act.[19] In response to the court's invalidation of its two pharmaceutical patents, Eli Lilly filed its most current Notice of Arbitration against the Government of Canada under NAFTA on September 12, 2013, seeking $500 million in damages for lost profits on the two drugs that were invalidated prior to their expiration date.[20]

NAFTA contains an entire chapter on intellectual property that expands protection of patents.[21] Eli Lilly's claim asserting violations of Chapter 17's intellectual property rights are used to support its basis for relief under Chapter 11's investment protection from "unfair treatment."[22] While it has been postured that Chapter 11 protections can be used to

---

[16] Matthew Herper, *The Cost Of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change*, FORBES.COM (Aug. 11, 2013), *available at* http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/.

[17] *Id.*

[18] Josh Bloom, *Should Patents on Pharmaceuticals be Extended to Encourage Innovation?*, WALL STREET JOURNAL (Jan. 23, 2012), *available at* http://online.wsj.com/news/harticles/SB10001424052970204542404577156993191655000.

[19] *See generally Eli Lilly v. Novopharm* (Zyprexa), [2009] F.C. 1018 (Can.), *available at* http://decisions.fct-cf.gc.ca/site/fc-cf/decisions/en/item/57179/index.do [hereinafter *Zyprexa 2009*]; *Eli Lilly v. Novopharm* (Zyprexa), [2010] F.C.A. 197 (Can.), http://decisions.fca-caf.gc.ca/site/fca-caf/decisions/en/item/36863/index.do[hereinafter *Zyprexa 2010*]; *Eli Lilly v. Novopharm* (Zyprexa), [2011] F.C. 1288 (Can.), http://decisions.fct-cf.gc.ca/site/fc-cf/decisions/en/item/60137/index.do [hereinafter *Zyprexa 2011*]; *Eli Lilly v. Novopharm* (Strattera), [2010] F.C. 915 (Can), http://decisions.fct-cf.gc.ca/site/fc-cf/decisions/en/item/58458/index.do [hereinafter *Strattera 2010*].

[20] *Notice of Arbitration*, *supra* note 1, ¶85.

[21] Sharan Leslie Goolsby, *Protection of Intellectual Property Rights under NAFTA*, 4 NAFTA L. & BUS. REV. AM. 5, Fall 1998, 9.

[22] *Notice of Arbitration*, *supra* note 10, ¶13; Eli Lilly concedes in its complaint that a breach of Chapter 17 alone is not enough to support a Chapter 11 claim, but that it is a factor to consider. *Id.* at footnote 2.

protect intellectual property rights,[23] this marks the first time that a patent claim has been challenged through the use of investment protection.[24] The lawsuit alone creates a number of issues for all NAFTA countries, and the result, regardless of which side wins, will create further problems that will have to be addressed moving forward, either through the amending of domestic laws or the amending of the trade agreement. It can also open a floodgate of litigation that can negatively impact the signatories of NAFTA because of the costs associated with defending against any future companies that may decide to make a similar claim.

B. Issues

This Note will start of by discussing background information on NAFTA. It will focus on the requirements to file a claim under both Chapter 17, the intellectual property provision, and Chapter 11, the foreign investment protection provision. The Note will then look at the history of the NAFTA claim that has been brought by Eli Lilly, including an analysis of the two lawsuits in the Canadian courts that led to the rise of Eli Lilly's claim under NAFTA. It will also compare the difference between the interpretation of Canadian patent laws and their international counterparts, as one of the allegations is that Eli Lilly could not have been expected to anticipate such a strong departure from international norms when it the patents were first accepted.[25]

Next, the Note will take an in-depth look at the Notice of Arbitration filed by Eli Lilly where the company claims that it is entitled to damages because Canada allegedly failed to meet its obligations under the foreign

---

[23] *See* John Terry, Lou Ederer, and Jennifer A. Orange, *Cross-Border NAFTA: the first treaty to protect IP rights*, INTELLECTUAL ASSET MANAGEMENT MAGAZINE (Jan. 2005); *available at* https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CCcQFjAA&url=http%3A%2F%2Fwww.torys.com%2FPublications%2FDocuments%2FPublication%2520PDFs%2FAR2005-1NT.pdf&ei=L976UuWOO-qq2wW0s4DoBg&usg=AFQjCNEiytUQKt0EGO4w8I5RjhOlc_ErUw&sig2=IwxsZzQsZN7u7NiOcR6t6g.

(Experts suggest that Canadian internet pharmacies selling drugs produced in the United States and shipped to Canada for sale before being exported back to American buyers violates Chapter 11 because the pharmaceuticals "are not being granted the full protection and security under Canadian law." However, this issue has not been arbitrated under the North American Free Trade Agreement.)

[24] *See generally NAFTA Investor-State Arbitrations*, U.S. DEPARTMENT OF STATE, http://www.state.gov/s/l/c3439.htm [hereinafter *Investor-State Arbitrators*]. As of the last time the Department of State's website was updated, there was no Chapter 11 claim against any NAFTA member for violating patent protections except for Eli Lilly's claim against Canada; *See also North American Free Trade Agreement – Chapter 11 – Investmen*t, FOREIGN AFFAIRS, TRADE, AND DEVELOPMENT CANADA, http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/nafta.aspx.

[25] *Notice of Arbitration*, *supra* note 10, ¶65.

investment provision of the North American Free Trade Agreement. Analyzing Chapter 11, the Note will discuss how an investor can prove unfair treatment and whether Eli Lilly has met its burden of proof with the current claim which focuses on the discrimination of the pharmaceutical industry as a whole with regards to the protection of intellectual property rights under the current judicial interpretation of the Canadian Patent Act. It will also discuss the general repercussions of the filing of the suit along with the additional consequences depending on which party wins the claim.

Finally, this Note will discuss how and why the claim should be decided in favor of the government of Canada and the policy reasons supporting the government of Canada in this case. It will argue that Canada should not be held liable for the $500 million that Eli Lilly is seeking for the two patents that were invalidated prior to their expiration date because Eli Lilly has not made a sufficient claim against the government of Canada for unfair treatment under NAFTA's Chapter 11. It will discuss any ramifications that this decision may have on both the international community and the innovation and production of drugs in the pharmaceutical industry. Additionally, it will recommend how the NAFTA signatories can attempt to protect themselves from further litigation under Chapter 11.

II. HISTORY/BACKGROUND

A. NAFTA

1. Background of NAFTA

On January 1, 1994, NAFTA was launched, and the final policies were implemented on January 1, 2008.[26] The general goal of NAFTA was to increase trade among the signatories by decreasing trade and investment barriers.[27] The NAFTA signatories had the hope of lowering prices for the consumer goods in Canada, Mexico, and the United States.[28] Among a number of other, more specific goals, NAFTA was established to "ensure a predictable commercial framework for business planning and investment" and "foster creativity and innovation, and promote trade in goods and services that are the subject of intellectual property rights."[29] These

---

[26] Andrea Ford, *A Brief History of NAFTA*, TIME, Dec. 30, 2008, *available at* http://content.time.com/time/nation/article/0,8599,1868997,00.html.

[27] *NAFTA I*, *supra* note 1.

[28] *Id.*

[29] *See generally* North American Free Trade Agreement, U.S.-Can.-Mex., preamble, Dec. 17, 1992, 32 I.L.M. 289 (1993), *available at* http://www.worldtradelaw.net/nafta/preamble.pdf [hereinafter NAFTA II].

intellectual property protections fall under Chapter 17 of NAFTA[30], and the passage of the North American Free Trade Agreement expanded the protection of intellectual property rights to an unprecedented level.[31]

NAFTA has a number of other provisions, including the protection of foreign investments under Chapter 11.[32] If it meets all of the requirements for bringing a claim under Chapter 11, an investor – a company in this instance – may bring a NAFTA claim against one of the signing states even if the claim stems from a violation of the provisions designed to protect intellectual property rights.[33] As will be discussed below, the violation of the intellectual property provisions must show unfair treatment in addition to whatever Chapter 17 violation occurred.[34]

The concept of NAFTA was in circulation long before NAFTA went into effect. On an international scale, as opposed to the regional scale of NAFTA, the General Agreement on Trade and Tariffs ("GATT") was in effect from 1948 to 1994.[35] It also had a goal of increasing trade by lowering tariffs.[36] In 1995 the World Trade Organization replaced GATT.[37] On a more regional level, President Ronald Reagan spoke of a North American trade agreement while campaigning in 1979, fifteen years before NAFTA came into existence.[38] In 1989, the Canada-United States Free Trade Agreement, the precursor to the North American Free Trade Agreement, was signed into law as an agreement between the United States and Canada.[39]

In *Eli Lilly v. the Government of Canada*, two chapters of NAFTA come into play. First, Chapter 17 is necessary to mention as the violations of intellectual property protection partially gave rise to the claim because Eli Lilly alleges that the discrimination against the pharmaceutical industry is indicative of a potential Chapter 11 claim.[40] Second, the notice of arbitration was filed under the investment protections under Chapter 11.[41] Eli Lilly alleges that the pharmaceutical industry in general, and the company specifically, was treated unfairly under Chapter 11 because of the discrimination the pharmaceutical industry faces with regards to how the interpretation of the Canadian Patent Act affects the treatment of their

---

[30] *See generally id.* at ch. 17.
[31] Goolsby, *supra* note 21, at 9.
[32] *See generally* NAFTA II, *supra* note 20, at ch. 11.
[33] Terry, *supra* note 23.
[34] *Id.*
[35] Bodner, *supra* note 14.
[36] *Id.*
[37] *Id.*
[38] Ford, *supra* note 26.
[39] Ford, *supra* note 26.
[40] *Notice of Arbitration*, *supra* note 10, ¶66.
[41] *Id.* ¶3.

pharmaceutical patents.[42]

2. Chapter 17

Chapter 17 of NAFTA sets forth intellectual property protection requirements for the signatories. It requires Canada – along with Mexico and the United States – to grant patents for inventions that "are new, result from an inventive step and are capable of industrial application."[43] This is the usefulness requirement that was at issue in the two cases that led to Eli Lilly's NAFTA claim. The chapter further states that a country "may revoke a patent only when: (a) grounds exist that would have justified a refusal to grant the patent."[44] The provisions for granting and invalidating patents under the North American Free Trade Agreement are greatly expanded beyond what some of the individual countries had previously operated under, allowing for more patents to be granted.[45] The protection of those patents was also supposed to be expanded, but that desired effect may not be extended to all of the industries that have been issued patents in Canada.[46]

NAFTA has a number of provisions relating to intellectual property that include Chapter 17, Articles 2003-21, Annex 2004, and Articles 2106-07.[47] NAFTA creates the "highest standards of protection and enforcement so far achieved by U.S. negotiators."[48] Chapter 17 creates the bare minimum of intellectual property protection, but individual countries are allowed to create domestic laws that provide even more protection if they so choose.[49] Any additional protections that a country invokes must be extended to the other two countries under 1703.[50] However, they are not permitted to lower the standards of intellectual property protection.[51] Eli Lilly is claiming that the judicial interpretation of the Canadian Patent Act had, in fact, lowered the standards of intellectual property protection, at least with regard to the drugs patented by the pharmaceutical industry.[52]

The "bare minimum" of protection includes protecting all intellectual property rights, a phrase that is defined broadly under 1703.[53] With regard to patents, NAFTA has imposed the "first to invent" law of the United

---

[42] *Id*. ¶66.
[43] NAFTA II, *supra* note 20, at art. 1709(1).
[44] *Id*. at art. 1709(8).
[45] Goolsby, *supra* note 21, at 13-14.
[46] *Notice of Arbitration*, *supra* note 10, ¶11 (eighteen patents invalidated since 2005).
[47] Goolsby, *supra* note 21, at 10-11.
[48] *Id.* at 9.
[49] *Id.*at 3.
[50] *Id.*
[51] *Id.*
[52] *Notice of Arbitration*, *supra* note 10, ¶¶10-12.
[53] *See* NAFTA II, *supra* note 29, at art. 1721(2).

States[54] onto Canada and Mexico.[55] Canada and Mexico had previously been under a first-to-file system.[56] This means at the time of this lawsuit, the first person to conceptualize an invention in the United States, Canada, or Mexico can receive the patent if that person shows proof that they were working on it, even if that person was the second to file for the patent in the patent office.[57] "Canada and Mexico recognize that evidence of invention must be subject to U.S. discovery proceedings to the same extent as if the acts occurred in the United States."[58] This has the possibility of giving Canadian and Mexican inventors priority that they may not have had before NAFTA went into effect as inventors in countries previously applying first to file.[59] Under the previous laws of Canada and Mexico, evidence of being the first to start working on an invention had no bearing on who received the patent.[60] In those countries, the first to effectively file for a patent received the patent regardless of whether that person was the first to start working on that particular invention.[61]

Violations of Chapter 17's intellectual property provision can occur in a number of ways.[62] Violation of the intellectual property provision includes the discrimination by one of the treaty signatories against a particular industry.[63] One of the bases for Eli Lilly's claim is that the interpretation of the Canadian Patent Act discriminates against the pharmaceutical industry in violation of Chapter 17.[64]

General dispute resolutions are expressly permitted under Annex 2004.[65] The intellectual property provision of NAFTA provides for "a dispute-settlement procedure with trade related sanctions and, in some

---

[54] *First Inventor to File*, USPTO.GOV (last visited Feb. 12, 2014), http://www.uspto.gov/aia_implementation/faqs_first_inventor.jsp [hereinafter *First to File*]. (In 2011, the United States passed legislation that would change the patent system from first to invent to first to file. The change went into effect on March 16, 2013. This change puts the United States more in line with how the rest of the world determines who will be granted a patent as most countries operate under a first to file system. The effect of the changes in patent legislation on NAFTA intellectual property provisions is beyond the scope of this note.) *Id*.

[55] NAFTA II, *supra* note 29, at art. 1709.

[56] Goolsby, *supra* note 21, at 56.

[57] Bodner, *supra* note 14.

[58] Goolsby, *supra* note 21, at 56, citing *Report of the Industry Functional Advisory Committee for Trade in Intellectual Property Rights on the North American Free Trade Agreement*, Sept. 11, 1992.

[59] *Id*.

[60] *First to File*, *supra* note 54 (explaining the difference between first to invent and first to file).

[61] *Id*.

[62] Most violations of NAFTA's Chapter 17 are outside of the scope of this Note.

[63] Mike Palmedo, *Eli Lilly Formally Requests Arbitration Against Canada Under NAFTA in Dispute Over Drug Patents*, INFOJUSTICE.ORG (Sept. 16, 2013), http://infojustice.org/archives/30694 [hereinafter Palmedo].

[64] *Id.*

[65] Goolsby, *supra* note 21, at 11.

cases, damages payable to intellectual property holders, to provide effective recourse against infringements of intellectual property rights."[66] Those damages, however, are presumably less than the damages Eli Lilly is seeking through the use of the foreign investment protection provisions of NAFTA.

NAFTA also allows enforcement beyond what is normally permitted by Chapter 17.[67]

> [G]eneral enforcement provisions in Chapters 11 and 20 apply to the enforcement of intellectual property rights. Chapter 20 provides a procedure for one state party to bring a complaint against another, to be settled by means of a specified dispute resolution process. Chapter 11 allows a private investor to bring a claim directly against a NAFTA state party.[68]

However, just because there is a violation under Chapter 17 does not mean there is automatically a claim for damages under Chapter 11.[69] There are additional requirements to prove a Chapter 11 claim.

3. Chapter 11

NAFTA's Chapter 11, the section of the trade agreement under which Eli Lilly is seeking damages, protects foreign investments from unfair practices. Specifically, "Article 1105 requires that the [signatory's] investments of [United States] investors . . . be granted full protection and security under the [signatory's] law."[70] NAFTA tends to define investments rather broadly, including most property and business interests.[71] The Chapter 11 provisions even specifically include intangible property (i.e., patents) rights in the definition of investment.[72] The main thing that will exclude a NAFTA claim is if an investor is trying to bring a claim against its own government for harm done in that territory.[73]

NAFTA's Chapter 11 has traditionally been used when a statute or policy of one of the signatories unfairly discriminates against a company or individual of one of the other two signatories in favor of its domestic

---

[66] Terry, *supra* note 23.
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *NAFTA Claim Information*, NAFTACLAIMS.COM (last visited Nov. 3, 2014), http://www.naftaclaims.com/claim-info.html [hereinafter *NAFTA Claims*].
[72] Terry, *supra* note 23.
[73] *NAFTA Claims*, *supra* note 71.

alternative.[74] Claims generally arise from the protectionist nature of those policies and how they harm the foreign party.[75] Under that interpretation, it is a different type of discrimination than Chapter 17, which includes a provision about discrimination against a specific industry when choosing to invalidate patents.[76] While intangible property is protected under Chapter 11, a violation of the intellectual property protections of Chapter 17 does not automatically mean that there is a violation under Chapter 11.[77] "For a rights holder to establish that a state party has infringed Chapter 11, it must establish a breach of one of the provisions of Chapter 11, such as discrimination, unfair or inequitable treatment not in accordance with international law, or expropriation without compensation."[78]

When NAFTA claims are brought under Chapter 11, an international tribunal is established with three members chosen by the investor bringing the claim and the NAFTA party being sued.[79] After arguments by the investor and three NAFTA countries (should the other two choose to intervene on behalf of one side[80]), the tribunal will write a decision called the award.[81] If a NAFTA signatory is found in breach, it will be ordered to pay damages.[82] NAFTA tribunals are not allowed to recommend that a signatory change its laws.[83]

Between the time of its creation and 2010, sixty-four Chapter 11 foreign investment claims were filed for arbitration.[84] Of those cases that have concluded, NAFTA parties have won fifteen times and the foreign entities have won nine times.[85] Of those cases in which Canada was a party, the government has won three times while the investors have won in four instances.[86]

B. How this claim arose

In the 1990s, Canada granted patents protecting Eli Lilly's

---

[74] *See generally Investor-State Arbitrators*, *supra* note 24.
[75] *Id.*
[76] Palmedo, *supra* note 63.
[77] *Id.*
[78] Terry, *supra* note 23.
[79] *NAFTA Claims*, *supra* note 71.
[80] *Id.* (All three NAFTA signatories are allowed to make an argument on behalf of one side or the other. However, it is not required that they address the tribunal.)
[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] *Table of NAFTA "Chapter 11" Foreign Investor-State Cases and Claims November 2010*, PUBLIC CITIZEN (Nov. 2010), https://www.citizen.org/documents/NAFTA_Investor_State_Chart_Nov_2010.pdf [hereinafter *Table*].
[85] *Id.*
[86] *Id.*

pharmaceutical products, Strattera and Zyprexa.[87] The patents should have been valid for the standard twenty-year period.[88] However, "[a Canadian] Federal Court decision in 2010 invalidated Eli Lilly's patent for Strattera (atomoxetine), a drug used to treat attention deficit hyperactivity disorder (ADHD), six years before it was due to expire."[89] Canadian federal courts also made "decisions in 2009 and 2011 [that] voided the patent for Zyprexa (olanzapine), an anti-psychotic drug used to treat schizophrenia, which was to expire in April 2011."[90] The patent had been originally granted in 1991 and it, too, had been anticipated to have the standard twenty-year patent protection.[91] The reasoning for invalidating the patents was similar in all of the written judgments.[92] In both cases, there was an attempt to appeal to the Supreme Court of Canada, which was denied.[93]

Both of these lawsuits were brought against a Canadian pharmaceutical company specializing in generic drugs.[94] Both of these drugs had been deemed effective and safe by Health Canada and had been used by "hundreds of thousands of patients in Canada and are commercially successful products."[95] Yet, both of their patents were invalidated, allowing the generic company to manufacture similar pharmaceuticals legally without spending as much money on developing the drugs.[96]

In November 2012, Eli Lilly announced that it would be making a NAFTA claim against the Canadian government under the unfair treatment investment protection of NAFTA's Chapter 11.[97] The original complaint was for "$100 million in compensation for the Straterra decision."[98] In June 2013, Eli Lilly amended the complaint after the Zyprexa case was decided and "upped the compensation demand to $500 million after the Supreme Court refused to hear its final appeal of the Zyprexa decision in May."[99] Eli Lilly is essentially using a NAFTA tribunal to appeal the decisions of the

---

[87] *Notice of Arbitration*, *supra* note 10, ¶2.

[88] Canadian Patent Act, *supra* note 15, §44.

[89] Kazi Stastna, *Eli Lilly Files $500M NAFTA Suit Against Canada Over Drug Patents*, CBC NEWS, (Sept. 13, 2013, 11:57 PM), http://www.cbc.ca/news/business/eli-lilly-files-500m-nafta-suit-against-canada-over-drug-patents-1.1829854.

[90] *Id.*

[91] Canadian Patent Act, *supra* note 14, §44.

[92] *See generally Zyprexa 2009*, *supra* note 19; *Zyprexa 2010*, *supra* note 19; *Zyprexa 2011*, *supra* note 19; and *Strattera 2010*, *supra* note 19.

[93] *Notice of Arbitration*, *supra* note 11, ¶21.

[94] *See generally Zyprexa 2009*, *supra* note 19; *Zyprexa 2010*, *supra* note 19; *Zyprexa 2011*, *supra* note 19; *Strattera 2010*, *supra* note 19.

[95] *Notice of Arbitration*, *supra* note 11, ¶2.

[96] Ranit Mishori, *Why Are Generic Drugs Cheaper Than Brand-Name Ones?*, WASH. POST (Jul. 11, 2011), http://www.washingtonpost.com/national/health-science/why-are-generic-drugs-cheaper-than-brand-name-ones/2011/07/05/gIQAwZdL9H_story.html.

[97] *Notice of Arbitration*, *supra* note 11, ¶19.

[98] Stastna, *supra* note 89.

[99] *Id.*

Canadian federal courts.

1. Cases at issue

The Canadian Court System is, in relevant parts, structurally similar to the court system of the United States. It has local courts that make original decisions that can be appealed to an appellate court and, if granted review, to the national Supreme Court.[100] Much like the judiciary of the United States, the Canadian judiciary is separate from the executive and legislative branches.[101] "Judicial independence is a cornerstone of the Canadian judicial system."[102] This means that Canadian judges are free to interpret the laws passed by the legislature however they choose. As such, they have the ability to introduce new doctrines into common law through statutory interpretation. The doctrine at issue in Eli Lilly's lawsuit against Canada is what Eli Lilly refers to as the "Promise Doctrine," which will be discussed below.

a. Zyprexa

In 2009, the first case at issue was brought in front of a federal court. Eli Lilly had sued the Canadian generic pharmaceutical company Novopharm for patent infringement for the drug Zyprexa.[103] Novopharm had begun to produce a generic version of Zyprexa in violation of the patent protections.[104] Novopharm even conceded that "if the [ ] patent is valid, it is infringing it by marketing a generic version of olanzapine."[105] Therefore, Novopharm challenged the validity of the patent and won.[106] After an appeal and a remand, the patent was ultimately invalidated by the Canadian courts in 2011.[107] The federal judge provided three principles to analyze:

> 1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
> 2. The whole of the selected members (subject to "a few exceptions here and there") [must] possess the advantage in

---

[100] *How the Courts are Organized*, DEP'T OF JUSTICE CANADA, http://www.justice.gc.ca/eng/csj-sjc/ccs-ajc/page3.html (last visited Nov. 17, 2014) [hereinafter *Court Organization*].
[101] *Keeping the System Fair and Efficient*, DEP'T OF JUSTICE CANADA, http://www.justice.gc.ca/eng/csj-sjc/ccs-ajc/page4.html (last visited Nov. 17, 2014).
[102] *Id*.
[103] *Zyprexa 2009*, *supra* note 19, ¶1 (The patent was approved in Canada in 1998.).
[104] *Id.*
[105] *Id.* ¶11.
[106] *Id.* ¶13.
[107] *See generally Zyprexa 2010*, *supra* note 19; *Zyprexa 2011*, *supra* note 19 (remand and appeal cases).

> question.
> 3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be a special character.[108]

These principles are used to determine whether the patent meets the usefulness requirement of the Canadian Patent Act.[109] In assessing the claim that the patent was invalid, the judge took the following steps:

> [First] is to decide whether one or more of the asserted advantages of olanzapine was known to exist, or was soundly predicted, at the time the [olanzapine] patent was filed in 1991. Second, I must decide whether at least one of them could be considered a substantial advantage over the [similar] compounds and somewhat peculiar to olanzapine. And, if so, the third question is whether the disclosure of that substantial and special advantage in the [olanzapine] patent was adequate. If I decide any one of them in the negative, I must find the [olanzapine] patent to be invalid.[110]

After reviewing the evidence brought forth by both Eli Lilly and Novopharm, the judge in that case determined that "some of the assertions in the [olanzapine] were hopeful. They were based on too little evidence to be factual contentions or even sound predictions of olanzapine's alleged advantages."[111] Because the patent did not have the advantage that it had alleged in its patent application, the judge ultimately decided to invalidate the patent.[112] When reviewed by the Canadian appellate court this decision was upheld.[113]

b. Strattera

In 2010, the Canadian courts invalidated the patent for the drug

---

[108] *Zyprexa 2009, supra* note 19, ¶48.
[109] Canadian Patent Act, *supra* note 14, §2 (at 'invention').
[110] *Zyprexa 2009, supra* note 19, ¶55.
[111] *Id.* ¶ 153.
[112] *Id.*
[113] *See generally Zyprexa 2010, supra* note 19.

Strattera, which is used to treat attention deficit hyperactivity disorder.[114] This case was brought by Novopharm. Novopharm asserted "that as an interested party[115] it [was] entitled to bring this proceeding."[116] Novopharm argued for the Strattera patent to be invalidated and void on the grounds of inutility.[117] In this case, the Canadian federal judge had to decide if the drug met the usefulness requirement of the patent act by doing what Eli Lilly promised it would do:[118]

> . . . it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice. . . . If when used in accordance with the directions contained in the specification the promised results are obtained, the invention is useful in the sense in which that term is used in patent law. The question to be asked is whether, if you do what the specification tells you to do, you can make or do the thing which the specification says that you can make or do.[119]

Under this interpretation of utility, a mere hypothesis that the patent will do what is promised is not enough.[120] The patent must at least partially do what the filer "promised" to do in order to meet the utility requirement.[121]

> The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. . . . Secondly, the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. . . . Thirdly, there must be proper disclosure. Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can

---

[114] *Strattera 2010, supra* note 19, ¶2.
[115] *Strattera 2010, supra* note 19, ¶3. Prior to this proceeding, Novopharm filed a new drug with Health Canada (the Canadian department in charge of, among other things, determining if pharmaceuticals are allowed to be marketed in the country), making it an interested party. Interested parties are allowed to bring claims in Canadian courts.
[116] *Id.*
[117] *Id.*
[118] *Id*. ¶91.
[119] *Id.*
[120] *Id*. ¶92.
[121] *Id.*

> be practised . . . It is generally not necessary for an inventor to provide a theory of *why* the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about it.
>
> It bears repetition that the soundness (or otherwise) of the prediction is a question of fact. Evidence must be led about what was known or not known at the priority date, as was done here. Each case will turn on the particularities of the discipline to which it relates. In this case, the findings of fact necessary for the application of "sound prediction" were made and the appellants have not, in my view, demonstrated any overriding or palpable error.[122]

That court looked at the evidence presented by Eli Lilly and determined that, although it had enough utility to get approval for distribution, Eli Lilly did not produce enough evidence to show that Strattera did what the patent promised it would do:[123]

> An invention is only useful if it does what the inventor claims it will do. In this case the requirement of utility would be met if, at the Canadian filing date of the '735 Patent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted. That was, after all, what the '735 Patent offered - an effective treatment for ADHD - and that was the consideration required of Lilly for the monopoly it claimed. Proof of utility in this context does not, however, equate with the evidence required to obtain regulatory approval.[124]

The court thus invalidated the patent because it did not meet the utility

---

[122] *Id.*
[123] *Id.* ¶93.
[124] *Id.*

requirement required by the Canadian Patent Act.[125]

According to the Canadian Patent Act, inventions must be "new and useful . . . composition of matter, or any new and useful improvement in any . . . composition of matter."[126] The Canadian courts have since interpreted that to mean usefulness under what Eli Lilly refers to as the "Promise Doctrine."[127] It is this "Promise Doctrine" for utility that led to the invalidation of the patents for both Zyprexa and Strattera, along with other patents in the pharmaceutical industry.[128] Under this interpretation, patents are treated to a higher standard than what they were in the past.[129] The judiciary created three main steps that a patent must pass through in order to be valid.[130]

First, a judge subjectively construes the "promise of the patent."[131] Second, a heightened evidentiary standard for proof of utility is applied, which requires that the "promised" utility either be "demonstrated" by the patentee or be based on a "sound prediction" of utility as of the date of filing.[132] Third, with regard to "sound prediction," a heightened disclosure requirement mandates that evidence establishing utility must have been disclosed in the original patent application.[133]

2. Canadian interpretation vs. other interpretations

The United States has a much more liberal interpretation of usefulness. According to the United States Manual of Patent Examining Procedure, "[a] small degree of utility is sufficient" for protection.[134] Courts have interpreted usefulness to allow for further research so as to incentivize research and development.[135] In its cases against Novopharm, Eli Lilly argued for a similar standard for determining utility under the Canadian Patent Act.[136] The company suggested that it only needed to show a "mere scintilla of utility."[137] The judge conceded that if he or she used

---

[125] *Id*. ¶122.
[126] Canadian Patent Act, *supra* note 14, §2'invention.'
[127] *Notice of Arbitration*, *supra* note 11, ¶3.
[128] *Id*. ¶4-13
[129] *Id*. ¶9.
[130] *Id*. ¶36
[131] *Id*.
[132] *Id*.
[133] *Id*.
[134] *US Manual of Patent Examining Procedure §2107.01*, USPTO.GOV, http://www.uspto.gov/web/offices/pac/mpep/s2107.html#d0e198682 (last visited Nov. 17, 2014), *citing E.I. du Pont De Nemours and Co.v.Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980).
[135] *Id*.
[136] *Strattera 2010*, *supra* note 19, ¶93.
[137] *Id*.

the American standard argued by Eli Lilly, that patent would have been valid.[138] "If that phrase means only that atomoxetine be shown to be somewhat useful to treat ADHD, I accept Lilly's point."[139] However, the Canadian courts opted to require a higher standard for usefulness in order for the patents to be valid.[140]

Usefulness in patent law, and particularly in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development.[141] "The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans."[142] "Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer."[143]

The United States courts that looked at the Strattera patent affirmed it, saying that the mere fact that there was a clinical trial was enough to prove the usefulness of the patents.[144] According to the NAFTA complaint, Zyprexa has been challenged and upheld throughout the world, including in the United States, United Kingdom, Australia, Germany, Netherlands, Austria, Czech Republic, Russia, Portugal, Hungary, Romania, Slovakia, China, Finland, Norway, Spain, Bulgaria, and Korea.[145]

Eli Lilly asserts that, with regard to both drugs, Canada is the only country to have overturned these patents.[146] This weighs into their allegation that Canada's patent law goes against international norms and is in violation of NAFTA's intellectual property provisions in Chapter 17.[147]

In addition to the allegation that Canada's interpretation is different than most interpretations, Eli Lilly's claim goes further to state that the current interpretation is an unpredictable departure from what it was when NAFTA was signed and when the patents were applied for.[148] This is the premise of part of their claim for expropriating investments and treating them unfairly.[149] In fact, Eli Lilly continues to say that, due to the unique nature of pharmaceuticals and the uncertainty associated with drugs when patents are first applied for, the pharmaceutical industry is discriminated

---

[138] *Id.*
[139] *Id.*
[140] *Id.*
[141] *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).
[142] *Id.*
[143] *Id*.
[144] *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 923 (Fed. Cir. 2011).
[145] *Notice of Arbitration*, *supra* note 11, ¶65.
[146] *Id.*
[147] *Id*.
[148] *Id*. ¶9.
[149] *Id*. ¶4.

against when compared to other types of patent holding industries.[150]

III. ANALYSIS

A. Eli Lilly v. Canada

Eli Lilly has claimed that by implementing a different utility rule than the standard at the time NAFTA was signed and contrary to international norms, "Canada has expropriated Claimant's investments, including in particular its patent rights in both Strattera and Zyprexa, and has failed to provide Lilly with fair and equitable treatment as required under NAFTA Article 1105."[151]

There are some in the field that believe that this dispute will turn on the question of whether or not Eli Lilly can prove discrimination from other companies based on location of the company.[152] However, Eli Lilly's claim is not that it was put into a disadvantageous state when compared to other companies, but rather that the "Promise Doctrine" Canada's judiciary used when interpreting patent law is discriminating against the pharmaceutical industry as a whole when compared to other industries receiving patents.[153] That claim is a valid one. All of the eighteen patents that have been invalidated under the "Promise Doctrine" interpretation of Canada's Patent Act have been pharmaceuticals.[154]

Chapter 17 of NAFTA states that, "patents shall be available and patent rights enjoyable without discrimination as to field of technology,"[155] and Canada may only revoke a patent on grounds that would have justified a refusal to grant the patent in the first instance.[156] The law supports the contention that the way of interpreting patents in Canada falls below the standard required by NAFTA as evidenced by the fact that the only patents to be invalidated have been from the pharmaceutical industry.[157] Thus, the interpretation of the Canadian Patent Act has discriminated against the pharmaceutical industry. Their complaints regarding Chapter 17's intellectual property therefore is enough to be legitimate one.

However, in order to reach the damages prayed for in the notice of arbitration, Eli Lilly's success turns not on the ability of the company to prove a breach in the intellectual property section, but rather the company's

---

[150] *Notice of Arbitration*, *supra note 10*, ¶12.
[151] *Id*. ¶13.
[152] Simon Lester, *Eli Lilly NAFTA Chapter 11 Claim – Part 3*, INTERNATIONAL ECONOMIC LAW AND POLICY BLOG (Dec. 12, 2012) , http://worldtradelaw.typepad.com/ielpblog/2012/12/eli-lilly-nafta-chapter-11-claim-part-3.html
[153] Palmedo, *supra* note 63.
[154] *Notice of Arbitration*, *supra* note 10, ¶13.
[155] NAFTA II, *supra* note 29, at art. 1709(7) & (8).
[156] *Id*.
[157] *Notice of Arbitration*, *supra* note 10, ¶13.

ability to prove that Canada breached its Chapter 11 investment protection obligation.[158] "It must establish a breach of one of the provisions of Chapter 11, such as discrimination, unfair or inequitable treatment not in accordance with international law, or expropriation without compensation."[159]

1. Unfair Treatment

NAFTA standards set the definition for unfair treatment based on "the customary international law minimum standard of treatment for aliens" as the minimum standard to be allowed for the investments of investors of another NAFTA signatory.[160] "[I]t states that the concept of fair and equitable treatment does not require treatment beyond that required by the customary international law minimum standard of treatment."[161] "In *Neer v Mexico 4 R Int'l Arb Awards (Oct 15 1926)*, it was held in order to meet that standard, a plaintiff is required to show that a country's conduct is 'so far short of international standards that every reasonable and impartial man would readily recognize its insufficiency.'"[162]

This "minimum standard" is a relatively high standard to meet because an investor must prove that a NAFTA signatory's laws and policies deviate so grossly from the international norm that every reasonable and impartial man can tell that the law or policy is inherently unfair. Since the NAFTA provisions went into effect twenty years ago, only nine investors have been able to prove such a strong deviation from the international norm and recover damages under Chapter 11.[163]

2. Expropriation of Investments

Eli Lilly has also claimed that the judicial rulings interpreting Canada's Patent Act equate to an expropriation of investments.[164] While nationalization of a sector or seizure of an asset is indicative of expropriation, the idea extends beyond that to include "actions tantamount to expropriation."[165] This includes "incremental acts attributable to the state

---

[158] Terry, *supra* note 23, at 2.
[159] *Id*.
[160] Anna Kirk, et al., *NAFTA Tribunal Considers Fair and Equitable Treatment*, PRACTICAL LAW, Apr. 21, 2012 http://us.practicallaw.com/1-502-0785?q=&qp=&qo=&qe=.
[161] *Id.*
[162] *Id.*
[163] *Table, supra* note 84.
[164] *Notice of Arbitration, supra* note 10, ¶4.
[165] Latham & Watkins, *Guide to International Arbitration,* LW.COM, 28 (last accessed Feb. 12, 2014), http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0CEkQFjAC&url=http%3A%2F%2Fwww.lw.com%2FthoughtLeadership%2Fguide-to-international-arbitration-2014&ei=ecY-

that unreasonably interfere with an investment to such a degree that the investor is essentially deprived of its fundamental rights of ownership."[166] While the claim invalidating the patents may affect property rights, Eli Lilly still maintains an ownership right over the specific drug. The interpretation of Canada's Patent Act is not "tantamount to expropriation."[167] Therefore, that argument should fail.

3. Discrimination

Finally, Eli Lilly claims that the invalidation of its patent was discrimination. When interpreting discrimination, the standard is that the "host state treat investors no less favourably [sic] than it treats its own nationals or the nationals of any third state (also known as 'most-favoured-nation' or 'MFN' treatment)."[168] As previously stated, Eli Lilly points to absolutely no cases in which similarly situated Canadian pharmaceutical companies were treated more favorably than it was.[169] It also fails to note any instances where a foreign company making generic pharmaceuticals were treated less favorably than Novapharm was in the two cases that invalidated Eli Lilly's patents.[170]

4. Whether Eli Lilly properly stated a claim under Ch. 11

This case will most likely turn on whether Eli Lilly has sufficiently proven that they were treated unfairly when compared to the treatment of a similarly situated domestic company.[171] As the claim currently stands, Canada meets the minimum standard of fair and equitable treatment because Eli Lilly has failed to prove that a reasonable and impartial man could tell that the "Promise Doctrine" is inherently unfair to the company as an investor. In its current complaint, Eli Lilly has failed to even show that it was treated less fairly than a domestic investor.[172] If it cannot even show that it was treated less fairly than a domestic investor, Eli Lilly cannot show that Canada's policy fails to meet NAFTA's minimum standard of "the customary international law minimum standard of treatment for aliens."[173]

Eli Lilly fails to note a single case where a foreign company was

---

VIjuK8ywyAT2wIDIBw&usg=AFQjCNFSkbg1_6nFnJF_Rx7K6L0i8ZDVDA&bvm=bv.77412846,d.aWw.

[166] *Id.*

[167] *Id.*

[168] *Id.* at 29.

[169] *Notice of Arbitration*, *supra* note 10, at 24-25.

[170] *Id.*

[171] Lester, *supra* note 152.

[172] *See generally Notice of Arbitration*, *supra* note 10 (Complaint fails to allege a specific instance where a foreign pharmaceutical company was treated less favorably than a domestic one).

[173] *Kirk, supra note 160.*

treated less favorably than a domestic one under the "Promise Doctrine."[174] Canadian courts are using the same standard when looking at all patents, regardless of the country of origin of the patent holder. If there is any basis for a discrimination claim, it comes in the form of discrimination against the industry, not discrimination with regards to country of origin. It fails to fall "so far short of international standards that every reasonable and impartial man would readily recognize its sufficiency."[175]

Eli Lilly is unable to prove discrimination, unfair or inequitable treatment not in accordance with international law. Its strongest case is expropriation without compensation, but it will most likely fail there as well. While Eli Lilly's patent may have been invalidated, it still maintains an ownership interest in the drug through its ability to sell the pharmaceutical in Canada.

Because Canada meets reasonable international standards for its treatment of foreign investors, the Canadian government should not be liable under the foreign investment chapter of NAFTA. Furthermore, in addition to the insufficiency of Eli Lilly's claim, public policy supports finding in favor of Canada and against Eli Lilly.

5. Arbitration

Arbitration is a binding form of dispute resolution.[176] Arbitration tribunals are expected to make decisions based on applicable law as opposed to what one may consider "fair."[177] The tribunal chosen in this case should decide that Canada has met its obligations under Chapter 11. However, in the interest of equity, Eli Lilly may receive the damages it is entitled to due to the violations of the intellectual property provisions. The relief may not be the entirety of what was prayed for in the notice of arbitration because of the lack of Chapter 11 remedies, but it will still receive some relief.

B. Effect of decision if decided against Canada

In the event that Eli Lilly is successful and the case is decided against NAFTA, there are a number of consequences that would challenge both Canada and the other NAFTA member states. It would force a sovereign nation to change its patent laws and possibly lead to more litigation, both against Canada and the other NAFTA member states. While the prayer for relief in the current litigation is $500 million, the possibility of future

---

[174] *See generally Notice of Arbitration*, *supra* note 10.
[175] *Kirk, supra note 160.*
[176] Latham & Watkins, *supra* note 165, at 1.
[177] *Id.*

litigation can cost Canada, Mexico, and the United States even more.[178] Whenever a government is a party to the suit, the cost of litigation is inevitably passed onto its citizens through taxes. This means that the citizens of Canada will have the ultimate burden of paying to defend the litigation in addition to paying for any damages that Eli Lilly would be entitled to if it won.

1. Effectively forces a change in the laws of a sovereign nation

Because the current issue stems from the judiciary's interpretation of utility that has become a part of its common law, the legislature would have to amend the language in its patent legislation to define utility in a way that is more cohesive with the international community's outlook on what utility means. Without any changes to Canada's current Patent Act, Canada's judiciary would be free to continue interpreting utility under the so-called "Promise Doctrine." Any future patents that could be invalided without a change in the legislation could create a large burden on Canadian taxpayers if other pharmaceutical companies seek similar damages for unfair treatment. The best way to insulate itself from future litigation under NAFTA's Chapter 11 would be to change its current laws, regardless of how the tribunal decides this particular case.

When most treaties are signed, it is with the anticipation that the other signatories will continue to legislate in a way that conforms to the provisions of the treaty. However, NAFTA tribunals are expressly forbidden from recommending that the signatories change their laws.[179] Yet, if Eli Lilly were to succeed in its claim, it would effectively require Canada to amend its current Patent Act. As their Patent Act is currently interpreted, it is possible that future patents, particularly pharmaceutical patents, may be invalidated in the future in a manner similar to how the patents in this dispute were invalidated. Should Eli Lilly win and Canada not make any changes to its current law, there is a possibility that other companies will follow in Eli Lilly's footsteps and file substantially similar claims under NAFTA even after it went through the traditional judicial process in the Canadian courts.

2. Burden on taxpayers for the individual lawsuit

Eli Lilly is seeking "not less than CND $500 million" in damages for the early invalidation of their two drugs.[180] It is also seeking "full

---

[178] Palmedo, *supra* note 63. The $500 million figure only includes the prayer for relief. It does not include any of the costs associated with defending the claim. *Id.*

[179] *NAFTA Claims*, *supra* note 71.

[180] *Notice of Arbitration*, *supra* note 10, ¶85.

professional fees"[181] which would add hundreds of thousands of dollars to the case that has already been in process for years.[182] The government will, most likely, also be expending hundreds of thousands of dollars in defending against the claim.[183] While it is possible that Canada has attempted to insure itself from this sort of liability,[184] the cost associated with litigation will be funded by the state. Furthermore, it is possible that any insurance Canada may have does not adequately cover the value of the claim. If this is the case, any excess damages would have to be paid by the Canadian government as well. The burden of paying for government expenditures is placed onto the taxpayers of the state. Every taxpayer, regardless of whether or not they would have ever used one of the two drug patents invalidated, would have to pay their share of the litigation despite the fact that the invalidation of those patents was most likely anticipated to decrease the cost to the consumers of those pharmaceuticals.[185]

This burden of litigation costs rises exponentially if similarly-situated pharmaceutical companies follow Eli Lilly's route and raises Chapter 11 NAFTA claims against Canada. It is possible that the owners of the remaining sixteen[186] patents that were invalidated under Canada's "Promise Doctrine" may choose to pursue Chapter 11 NAFTA claims if it sees that the claim was effective for Eli Lilly.

3. Opens up the Canadian government to more similarly-situated lawsuits from other pharmaceutical companies

Even by filing this notice of arbitration, Eli Lilly may have exposed the government of Canada to further NAFTA lawsuits. Eli Lilly has met its burden of proof under the intellectual property protections of Chapter 17, and may be entitled to remedies based on that chapter alone. Other companies, seeking some relief for the invalidation of their patents, may choose to follow suit if the remedy is enough.

---

[181] *See generally id.* ¶85.

[182] S*ee generally Eli Lilly v. Canada* (NAFTA 2013), *available at* http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng (Showing that the first notice under NAFTA was in 2012 and that further work has been done since that initial filing, including a notice of arbitration and a memorial).

[183] Palmedo, *supra* note 63.

[184] Gerald R. Gibbons, *Liability Insurance and the Tort Immunity of State and Local Governments*, 1959 DUKE L.J. 588, 588 (1959).

[185] This is evidenced by the fact that the party seeking the invalidation of the patents, Novopharm, is a producer of generic pharmaceuticals that can distribute drugs at a much cheaper cost than original producers, effectively lowering the costs to consumers.

[186] A total of eighteen pharmaceutical patents were invalidated under the "Promise Doctrine." *Notice of Arbitration*, *supra* note 10, ¶13. Subtracting the two patents at issue in this NAFTA claim, there are an additional sixteen patents that had invalidated that could be litigated in a similar manner should the patent holders decide to follow in Eli Lilly's footsteps.

If Eli Lilly were to be successful in its NAFTA claim against the government of Canada, it has the possibility of opening up a floodgate of litigation for all three signatories of NAFTA, particularly in Canada where eighteen pharmaceutical patents have been invalidated under the Canadian courts' "Promise Doctrine."[187] Depending on exactly how the case is decided, the filing of the claim alone could lead to an increase in litigation. If it is decided against Eli Lilly based solely on the insufficiency of the claim, it could cause other companies that have had patents invalidated attempt to use this form of litigation to achieve compensation using similar tactics with a materially different facts—for example, suggesting that some law or policy discriminated against the country of origin of the patent holder as opposed to the industry—in order to claim damages under Chapter 11.

Some companies may simply threaten to make a claim against Canada for Chapter 11 NAFTA violations in hopes of getting better protection of their patents.[188] Those companies that threaten Canada with a NAFTA claim may also be doing so in hopes of expediting any damages that they think they are entitled to with the thought that Canada may not want to have to defend against this type of litigation again.[189]

If Eli Lilly were to win the case, however, it would incentivize even more companies to go after Canada with similar claims. Any patent holder that had a patent invalidated would have the ability to claim that it had been treated unfairly under the Canadian laws. The potential liability for the government of Canada—and thus the Canadian taxpayers—would be almost limitless. Should each of the remaining invalidated patents lead to similar lawsuits, the government would be forced to spend hundreds of thousands of dollars in both defending the allegations in addition to the lost profit damages for invalidating the patent early and attorneys' fees. If all of the companies whose patents were invalidated seek compensation from Canada under NAFTA, it would also take hundreds of hours for government attorneys to prepare a defense for all of the potential lawsuits, taking them away from other needs of their jobs.

4. Possibly opens up other NAFTA countries (Mexico and United States) to similar claims

Similar to the increasing liability on the government of Canada, the governments of Mexico and the United States will be subject to a possible increase in litigation stemming from the invalidation of patents by foreign companies in the name of unfair treatment in investment. Though the claim

---

[187] *Notice of Arbitration*, *supra* note 10, ¶13.
[188] Terry, *supra* note 23, at 2.
[189] *Id.*

is based entirely on Canadian courts' interpretations of utility, similar claims could be used against Mexico and the United States any time the patent is invalidated for that reason. Even if patents are legitimately invalidated or denied,[190] a patent holder or applicant may attempt to follow Eli Lilly's route and make a NAFTA claim against the invalidating country by claiming that it was treated unfairly.

Even though Canada is the only NAFTA signatory with a "Promise Doctrine," Mexico and the United States both have utility as a requirement to receive a patent.[191] Without the so-called "Promise Doctrine" that has been interpreted in Canadian laws, it is more difficult for patents to be invalidated.[192] However, it is possible for patents to be invalidated for lack of utility.[193] If there is any hint of disparity between the utility analysis of a foreign inventor's patent being declined and a domestic one being accepted, the logical conclusion is that a similar lawsuit could be raised under similar grounds that Eli Lilly has used.[194] Even if the invalidation of a patent or declination of an application is legitimate, there is still the possibility that the holder or applicant may try to use a Chapter 11 NAFTA to "claim substantial damages for an alleged infringement."[195] Much like in the current case between Canada and Eli Lilly, any future claims—regardless of whether or not the claims are legitimate—against NAFTA signatories could cost the country being sued hundreds of thousands of dollars in legal fees in addition to whatever relief being prayed for by the inventor.

C. If decided against Eli Lilly

In addition to the aforementioned consequences associated with the case being decided in favor of Eli Lilly, there are also a number of consequences associated with deciding this case against Eli Lilly. Policy reasons behind patent protection have been well established around the world. One of the most important policies of patent protection is

---

[190] For the purposes of this Note, the phrase "legitimately invalidated of denied" is used to describe a patent application that is either not granted or invalidated because it does not meet even the most liberal utility standards and would thus be either invalidated or not granted in the vast majority of jurisdictions.

[191] *See generally* Ley de la Propiedad Industrial [Law of Industrial Property], Diario Oficial de la Federacion [DO], 09-04-2012 (Mex), *available at* http://www.diputados.gob.mx/LeyesBiblio/pdf/50.pdf; *see generally* U.S. Patent Act, 35 USC §§ 1 – 376 (2014).

[192] *Id.*

[193] *See generally Zyprexa 2009, supra* note 19; *Zyprexa 2010, supra* note 19; *Zyprexa 2011, supra* note 19; *Strattera 2010, supra* note 19.

[194] However, this would be true regardless of whether or not Eli Lilly wins; the process of filing the NAFTA claim has created the possibility that other holders of invalidated patents will use this approach or declined applications.

[195] Terry, *supra* note 23, at 2.

encouraging innovation.[196] Without patent protection, there is a possibility that companies may begin to discourage innovation.[197]

Furthermore, this could create a burden on the citizens of Canada when it comes to obtaining necessary drugs at reasonable prices. There are instances of pharmaceuticals being unavailable in Canada,[198] and it is possible that the continuing invalidation of pharmaceutical patents may further limit the ability of Canadians to get the pharmaceuticals that are necessary to achieve their desired quality of life.

1. Harming innovation

One of the largest concerns with patent invalidation is the chilling effect it can have on the invention process. Patents have historically played an important part in innovation.[199] Without patent protection, it is possible for non-inventors to steal the ideas of true inventors and profit off of them.[200] When the ability to profit off of inventions becomes impaired, it has the potential to discourage innovation.[201] Without patents, inventors may see innovation as a waste of time, resources, and effort.[202] This may be particularly true in the pharmaceutical industry where the costs of creating a marketable drug can be astronomical.[203] Enforcing patents provides more incentive for inventors to work, thus making them more willing to share their work with society.[204] This incentive is extremely important with regard to pharmaceuticals as improvements in development relate directly to improvements in the health and welfare of society.[205]

"The innovative pharmaceutical sector relies upon patent protection as the cornerstone of bringing innovative medicines to market."[206] The protection of pharmaceutical patents and the "accompanying guarantee of market exclusivity provide a critical economic incentive to invest in drug development."[207] Pharmaceutical companies argue that it costs hundreds of millions—if not billions—of dollars to bring a new pharmaceutical product

---

[196] Aaron B. Thalwitzer, *Patent Protection: Why Are Patents Important?*, TACTICAL IP (Jul. 11, 2011) http://tacticalip.com/2011/07/11/patent-protection-why-are-patents-important/.
[197] Bloom, *supra* note 18.
[198] William McArthur, *Prescription Drug Costs: Has Canada Found the Answer?* NAT'L CENTER FOR POL. ANALYSIS (May 19, 2000), http://www.ncpa.org/pub/ba323.
[199] Thalwitzer, *supra* note 196.
[200] *Id*.
[201] *Id*.
[202] *Id*.
[203] Herper, *supra* note 16.
[204] Thalwitzer, *supra* note 196.
[205] *In re Brana*, 51 F.3d, at 1568 (illustrating the importance of pharmaceutical innovation with regards to curing cancer).
[206] *Notice of Arbitration*, *supra* note 10, ¶1.
[207] *Id*.

to the market.[208] These costs include the cost of development from the trial and error of various chemical combinations until it finds the best chemical combination that might have the desired effect.[209] Once it has spent all of the time, effort, and money on finding a suitable chemical combination, the pharmaceutical company must engage in an array of testing before it is deemed fit for human consumption.[210] This testing may lead to an issue with the drug that needs to be addressed, leading to more trial and error and more testing.[211] Once it has completed testing the new drugs and the new drugs have been deemed safe for human consumption, the pharmaceutical company that produces the drugs must then spend money marketing the drug to potential consumers.[212]

Eli Lilly claims that for each of its pharmaceuticals, including the two drugs involved in this dispute, "bringing an innovative medicine to market today involves an average investment of $1 billion or more."[213] The goal of all for-profit companies, such as Eli Lilly, is to receive the maximum revenue. This means that the patents have to be effective enough to prevent another company from marketing a chemically identical drug at a cheaper price after re-creating the generic drug from the original drug. Generic pharmaceutical companies do not invest as much money into creating a new product,[214] so they can sell the new product at a lower price,[215] effectively pushing the original drug out of the market and lowering the profits available to the original producer of the drug.

2. Current difficulty in obtaining prescription drugs in Canada may increase

When thinking about Canada and prescription drugs together, many Americans would say that prescription drugs are cheaper in Canada than they are in the United States.[216] With respect to a number of prescription drugs this is a logical conclusion.[217] There are a number of anecdotes about how prescription drugs can cost as much as fifty percent less in Canada than they do in the United States.[218] This is because Canada has, among a number of policies relating to health care, placed a cap on the price of some prescription drugs that lowers how much a company can charge consumers

---

[208] Herper, *supra* note 16.
[209] *Id.*
[210] *Id.*
[211] *Id.*
[212] *Id.*
[213] *Notice of Arbitration*, *supra* note 10, ¶1.
[214] Mishori, *supra* note 96.
[215] *Id.*
[216] Bihari, *supra* note 8.
[217] *Id.*
[218] *Id.*

for their pharmaceutical products.[219] However, not all pharmaceutical companies accept that price cap and the companies opt simply to not market certain pharmaceuticals in Canada.[220]

One of the largest concerns that must be discussed is how the NAFTA decision will affect the availability of prescription drugs in Canada. Under current circumstances, "a large numbers of Canadians come to the United States to buy drugs because so many drugs are not available at any cost in Canada."[221] Should the case be decided against Eli Lilly, the pharmaceutical company and others that are similarly situated may decide that some drugs are not worth marketing in Canada because there is no guarantee that it can make a profit after it spent so much money developing the drug. Considering the importance of pharmaceuticals with regards to health and quality of life, this could cause great harm to Canadian citizens as an increased number of drugs become unavailable in the country.

Furthermore, "[w]hile some drugs do cost less in Canada, others don't."[222] There are a large number of drugs that cost more in Canada than they do in the United States. "Canada has been unable to hold down the overall cost of . . . prescription drugs."[223] If it faces the continued threat of patent invalidation, Eli Lilly and other pharmaceutical companies may attempt to raise the price of their prescription drugs to accommodate the increased risk associated with selling in Canada. This will create a further increase in cost of obtaining necessary drugs in Canada and could harm Canadians in the long run.

IV. RECOMMENDATION

The recommendation is split up into two parts. First, the NAFTA tribunal should decide the case against Eli Lilly so that the government of Canada is not liable for the invalidation of the patents. This is because of both the failure to prove unfair treatment under NAFTA's Chapter 11 and also because public policy slightly favors Canada over Eli Lilly. Second, there are ways in which Canada (and the other two NAFTA signatories) can attempt to insulate themselves from further litigation, including taking proactive steps to amend current legislation to best avoid future accusations of unfair treatment under their respective Patent Acts.

---

[219] *Id.*
[220] McArthur, *supra* note 198.
[221] *Id*.
[222] *Id*.
[223] *Id*.

A. Why the claim should be decided for Canada (or, if a decision comes down, why it should have been)

Canada has a number of good defenses against Eli Lilly's claim. First, Eli Lilly's complaint is insufficient to grant relief to the company because it fails to prove unfair treatment that meets the standard set by NAFTA. Second, public policy—being forced to change its laws, the burden on the taxpayers, and the possible floodgate of litigation that would be faced by Cana—favor deciding the case in favor of Canada instead of Eli Lilly.

1. Insufficiency of the claim

There are several issues with Eli Lilly's claim as it currently stands. Eli Lilly has claimed unfair treatment because of the nature of the judiciary's proceedings.[224] However, in the claim itself Eli Lilly has failed to meet its standard of proof—that Canada's treatment of Eli Lilly's investment fell "so far short of international standards that every reasonable and impartial man would readily recognize its insufficiency."[225] There is no showing that Canada is treating Eli Lilly unfairly in comparison to other companies. There is no suggestion that domestic entities are being treated better than the Eli Lilly or any other foreign producer. Eli Lilly failed to suggest that a Canadian patent holder had a patent treated more favorably on this alleged "Promise Doctrine."[226] It also failed to suggest that Canadian owned generic companies were more successful in challenging the validity of patents than foreign-owned companies making similar challenges.[227]

The claim, however, is enough to prove that Canada's law was a violation of the Intellectual Property protections provided by NAFTA. Eli Lilly's claim sufficiently argued that the "Promise Doctrine" discriminated against the pharmaceutical industry as a whole in violation of NAFTA's intellectual property protections in Chapter 17.[228] As mentioned above, showing an intellectual property violation is not indicative of a violation of the foreign investment protections provided by NAFTA.[229] Therefore, while the claim was sufficient for the damages provided by Chapter 17,[230] there is not enough evidence to entitle Eli Lilly to the $500 million (plus costs) that it seeks under Chapter 11.

---

[224] Intondi, *supra* note 6.
[225] *Kirk, supra note 160.*
[226] *See generally Notice of Arbitration, supra* note 10.
[227] *See generally id.*
[228] Palmedo, *supra* note 63.
[229] Terry, *supra* note 23, 2.
[230] Palmedo, *supra* note 63.

2. Public Policy Considerations

There are a number of public policy considerations that weigh in favor of Canada. First and foremost is the importance of allowing a country to continue to make its own laws. The burden on the taxpayer and the threat of future litigation, which goes hand in hand with the laws of the country, are also important matters.

The ability of a country to determine its own laws is a well-established right. Canadian patent laws had to be amended dramatically to reach the heightened standards for protection negotiated with the United States and Mexico.[231] In compliance with 1703,[232] the Canadian legislature has not significantly amended its patent laws in this respect since NAFTA was signed. It was neither an act of the legislature nor an order from an executive that led to the change in interpretation. The judiciary made a decision—independent of the legislative and executive branches—that is expected to be respected.

As discussed above, the Canadian courts have an independent ability to interpret the laws that the legislature has passed.[233] Unfortunately, this has lowered the standard expected under Chapter 17 of NAFTA.[234] A violation of Chapter 17, however, is not enough to succeed in an investment protection claim.[235] While the change may be required to avoid future litigation under Chapter 17,[236] it should not be the result of a Chapter 11 claim as the standard arises under a different chapter than the claim. Furthermore, as NAFTA tribunals are not even allowed to recommend that a signatory change its laws,[237] a decision that effectively requires Canada to change its patent laws[238] would go against the policies of NAFTA.

Effectively requiring that change in legislation would also make Canada more vulnerable to other Chapter 11 claims or threats of claims. The cost of defending each of the possible claims outweighs the potential harm done if Canada wins. While there is the slight chance that it will harm innovation, it unfathomable to think that Eli Lilly or any other pharmaceutical company will stop trying to produce new drugs. Even the

---

[231] Goolsby, *supra* note 21, at 59-60.

[232] NAFTA II, *supra* note 20, at art. 1703.

[233] *Court Organization*, *supra* note 100.

[234] *See generally* NAFTA II, *supra* note 20, at art. 1703.

[235] *Notice of Arbitration*, *supra* note 10, at 16 n.2.

[236] *See generally* Goolsby, *supra* note 21 (citing *Report of the Industry Functional Advisory Committee for Trade in Intellectual Property Rights on the North American Free Trade Agreement*, Sept. 11, 1992.); Any ramifications of an IP violation claim is beyond the scope of this Note.

[237] *NAFTA Claims*, *supra* note 71.

[238] When I say a decision effectively requires a country to change its laws, it is a decision that states that Eli Lilly has a valid claim under Chapter 11 and is entitled to damages under the foreign investment clauses.

possibility of restricting access to pharmaceuticals in Canada to a greater extent than it already is unlikely. Because the risks associated with a decision in favor of Canada are smaller than the social costs associated with an Eli Lilly victory, public policy suggests that Canada should win.

B. How NAFTA signatories may protect themselves from Ch. 11 IP claims.

There are a number of ways for NAFTA signatories to protect themselves from investment claims brought under Chapter 11 for invalidations of patents held in one of the other two countries. First, as the basis for unfair treatment is the protection of a domestic entity at the expense of a foreign entity, countries can do their best to ensure that all patents—regardless of the nationality of the owner—are inspected with the same standards. If there is no deviation and each entity has its patent examined with the same standards of every other entity's patents, there can be no claim for unfair treatment.

As a last resort, one that appears to be relatively unnecessary provided that it follows the aforementioned advice and does not treat a foreign entity differently from a domestic entity, a signatory may choose to change its laws. Amending its laws does not equate to admitting fault, so the change will not make them liable for future claims set up the same way as Eli Lilly's. The important difference to note between this recommendation and a reason for holding against Eli Lilly is that any change that occurs would be because it was the choice of the Canadian legislatures and not because it was forced to change its laws to comply with a treaty.

V. CONCLUSION

NAFTA has a number of goals, and it also encompasses the intent "to eliminate barriers of trade and investment."[239] NAFTA has a number of provisions to achieve its goals, including decreasing the tariff between the three countries to increase trade.[240] Among these provisions are Chapter 17's intellectual property provisions, which expanded the protections of patents beyond what had existed in Canada and Mexico,[241] and Chapter 11's foreign investments provisions, which protect against unfair treatment of a signatory against an investor.[242] It is possible to use intellectual property violations in support of a violation of the foreign investment

---

[239] *NAFTA I*, *supra* note 1.
[240] *Id.*
[241] Goolsby, *supra* note 21 (citing *Report of the Industry Functional Advisory Committee for Trade in Intellectual Property Rights on the North American Free Trade Agreement*, Sept. 11, 1992, at 15).
[242] *See generally* NAFTA II, *supra* note 20, at Ch. 11.

provisions, but certain requirements must be met.[243]

While an innovative way to bring a lawsuit, Eli Lilly will ultimately fail on the sufficiency of the claim. The claim does not support a violation of minimum standard of "the customary international law minimum standard of treatment for aliens."[244] The claim fails to show any sign that Canada's domestic pharmaceutical companies have been favored over foreign pharmaceutical companies. Even if the claim was sufficient, there are significant policy reasons that would support the government of Canada over Eli Lilly in this case, including the cost—both monetarily and temporarily—in getting bogged down in litigation.

It is for those reasons that Canada should not be liable to Eli Lilly for the prayed relief of $500 million dollars. However, this litigation shows a warning that, if it can prove the foreign investment standards, a patent holder may have a legitimate claim against a NAFTA signatory for violations of Chapter 11 when a patent is invalidated. The claim in this case is insufficient, but it is possible that another company might have a stronger claim than Eli Lilly does in this case. If that should happen, the country defending the complaint may be liable for damages under NAFTA's Chapter 11 for failure to protect the foreign investment of a patent. All NAFTA signatories should be wary of this possibility and should keep it in mind when drafting any amendments to their current patent laws or if courts begin to read in more stringent requirements.

---

[243] Terry, *supra* note 23, at 2.

[244] *Kirk, supra note 160*.