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The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS

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The Incredible Shrinking Victory: *Eli Lilly v. Canada*, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS

Professor Brook K. Baker and Katrina Geddes***

This Article examines the Eli Lilly v. Canada arbitration award and its potential impact on intellectual property-based investor-state dispute settlements affecting pharmaceuticals. It begins by providing contextual background on ISDS and the underlying Eli Lilly patent invalidations. It then critiques the award and discusses the dangers of its overly cautious grounds of decision and its explicit validation of IP-based ISDS. The Article further illustrates these dangers through a discussion of the stunning judicial reversal of the promise/utility doctrine by the Canadian Supreme Court, the withdrawal of a compulsory licensing proposal in Colombia, and the deregistration of a competing generic Hepatitis C medicine in Ukraine. Ultimately, it recommends that ISDS provisions be removed or rewritten to prevent the possibility of bringing IP-related claims.

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INTRODUCTION

On March 16, 2017, a three-member arbitration tribunal, instituted pursuant to the North American Free Trade Agreement (“NAFTA”) Investment Chapter, delivered its investor-state dispute settlement (“ISDS”) decision in *Eli Lilly v. Canada*,¹ dismissing the pharmaceutical giant’s claims and awarding CDN \$5 million in costs and legal fees to the Canadian government. After a five-year battle, with over CDN \$15 million in attorney and expert-witness fees, Canada’s victory was hardly “resounding,”² given the deterrent effect of this and other intellectual property-based investor-state arbitrations. But the eagerly awaited decision, discussed at length in Section II, did effectively torpedo Eli Lilly’s specific compensation claims. The Tribunal rejected Eli Lilly’s arguments that Canada’s judicial revocations of two new-use pharmaceutical patents had been confiscatory, unfair and inequitable, or discriminatory. However, the Tribunal also failed to close the door to the possibility that invalidation of intellectual property rights (“IPRs”) under domestic law could constitute a violation of international investment law in the future.³ Nor did it question the possibility that domestic patent laws

1. *Eli Lilly and Co. v. Gov’t of Can.*, ICSID Case No. UNCT/14/2, Final Award, (Mar. 16, 2017) [hereinafter Final Award].

2. Nathaniel Lipkus, *Canada’s NAFTA victory a win for judicial sovereignty*, POLICY OPTIONS (Apr. 7, 2017), <http://policyoptions.irpp.org/magazines/april-2017/canadas-nafta-victory-a-win-for-judicial-sovereignty/>; accord Michael Geist, *Panel Rejects Eli Lilly Claim Over Canadian Patent Law, Orders Company to Pay Millions in Costs*, MICHAEL GEIST BLOG (Mar. 21, 2017), <http://www.michaelgeist.ca/2017/03/panel-rejects-eli-lilly-claim-canadian-patent-law-orders-company-pay-millions-costs/> (calling the tribunal decision “an enormous win”); Richard Gold, *NAFTA patent ruling a big victory for Canadian innovation*, THE GLOBE & MAIL (Apr. 6, 2017), <https://www.theglobeandmail.com/report-on-business/rob-commentary/nafta-patent-ruling-a-big-victory-for-canadian-innovation/article34617647/> (arguing that Canada was now free to design a patent system that suits Canada’s needs and industry).

3. Brook K. Baker, *Eli Lilly’s ISDS Claim against Canada Defeated*, MADHYAM (Apr. 6, 2017), <http://www.madhyam.org.in/eli-lillys-isds-patent-claim-against-canada-defeated/> (arguing as well that ISDS claims should not be permitted for IP related claims); Cynthia M. Ho, *Inside Views: TRIPS Flexibilities Under Threat From Investment Disputes: A Closer Look At Canada’s “Win” Against Eli Lilly*, INTELLECTUAL PROPERTY WATCH (Apr. 27, 2017), <https://www.ip-watch.org/2017/04/27/trips-flexibilities-threat-investment-disputes-closer-look-canadas-win-eli-lilly/> [hereinafter Ho, *Inside Views*] (explaining the potential negative effects of the *Eli Lilly* case outcome); Rob Howse, *Eli Lilly v. Canada: A Pyrrhic Victory against Big Pharma*, INT’L ECON. & POLICY BLOG (Mar. 26, 2017), <http://worldtradelaw.typepad.com/ielpblog/2017/03/eli-lilly-v-canada-a-pyrrhic-victory-against-big-pharma-.html> (criticizing the decision to leave the door open to IP-based expropriation claims whenever social, economic, environmental, or other public policy interests lead high courts to announce a fundamental reorientation of a country’s jurisprudence); Howard Knopf, *Canada Won the Eli Lilly NAFTA ISDS Battle Bigly but Who Will Win the War?*, EXCESS COPYRIGHT BLOG (May 1, 2017), <http://excesscopyright.blogspot.com/2017/05/canada-won-eli-lilly-nafta-isds-battle.html> (arguing that Canada made a fundamental mistake by not raising the absence of a fundamental denial of justice as a jurisdictional challenge to Eli Lilly’s case and instead merely arguing that domestic courts must be afforded “substantial deference,” leaving

that are consistent with NAFTA or the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS")⁴ could nevertheless be impugned for disappointing corporate expectations of profit under bilateral investment agreements.⁵ Accordingly, the claim, heralded by some, that the decision finally buries lingering concerns that "trade tribunals will become supranational courts of appeal over domestic property law disputes"⁶ is profoundly misguided—it was at best a temporary, partial, or even pyrrhic⁷ victory.

Despite winning the ISDS battle, Canada has conceded the war. As discussed in Section III, three months after Canada's arbitral victory, the Canadian Supreme Court dramatically loosened its long-standing promise/utility doctrine in *AstraZeneca Canada, Inc. v. Apotex, Inc.*⁸ There, after a protracted pressure campaign from the United States and the pharmaceutical industry, the Supreme Court of Canada eviscerated the promise/utility doctrine, which required confirmatory evidence in the patent application itself where the patent claim made a sound prediction of utility, and adopted a much more forgiving test of utility that requires only "a mere scintilla" of evidence.⁹ Section IV discusses the lingering effect of the patentability-intellectual property claim in *Eli Lilly* on Canada's policy reversal that finds kinship in other intellectual property-based ISDS cases involving a compulsory license in Colombia and data exclusivity in Ukraine. Together, these three examples illustrate the chilling effect of a toxic brew of private ISDS claims, relentless pressure from trading partners, and a pharmaceutical industry bent on preserving monopoly profits and intellectual property ("IP") exclusivities.

Eli Lilly's pending ISDS case received significant scholarly attention¹⁰

the door open to future ISDS challenges to IP rulings).

4. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

5. Ho, *Inside Views*, *supra* note 3 (explaining the potential negative effects of the *Eli Lilly* case outcome).

6. Lipkus, *supra* note 2 (highlighting the positive aspects of the decision for Canada).

7. This description appears to have been first used by Howse, *supra* note 3, though it was Knopf, *supra* note 3, who raised concerns about the risk of backtracking by the Canadian Supreme Court.

8. *AstraZeneca Canada Inc. v. Apotex, Inc.*, 2017 SCC 36.

9. *Id.* at ¶¶ 29, 55.

10. See, e.g., Brook K. Baker & Katrina Geddes, *ISDS, Intellectual Property Rights and Public Health*, in RETHINKING BILATERAL INVESTMENT TREATIES: CRITICAL ISSUES AND POLICY CHOICES, 189–99 (Kavaljit Singh & Burghard Ilge eds., 2016) (explaining the effect of ISDS provisions on legal rights); Jerome H. Reichman, *Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection*, in PROCEEDINGS OF THE ANNUAL MEETING (AMERICAN SOCIETY OF INTERNATIONAL LAW) 108, 313 (Cambridge Univ. Press 2014) (examining the *Eli Lilly* case); Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines – Eli Lilly v. Canada and the Trans-*

and academic debate focused on the chaotic interface between IP and trade-enforcement regimes and the ISDS regime, including their effect on national sovereignty over public health and the public interest more broadly.¹¹ This Article's focus, by contrast, is relatively narrow. It is not

Pacific Partnership Agreement 23 J. INTELL. PROP. L. 1, 9 (2015) [hereinafter Baker & Geddes, *Corporate Power Unbound*] (discussing the dangers countries face when entering into trade negotiations with higher-income countries); James Gathii & Cynthia M. Ho, *Regime Shifting of IP Lawmaking and Enforcement from the WTO to the International Investment Regime*, 18 MINN. J.L. SCI. & TECH. 427 (2017) (discussing how pharmaceutical industry disputes impact the WTO and TRIPS regimes); Cynthia M. Ho, *A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings*, 22 IRVINE L. REV. 395 (2016) [hereinafter Ho, *Collision Course*] (explaining how companies like Eli Lilly are creating a new path for companies to sue companies for interfering with their intellectual property rights); Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH. L.J. 213 (2014) [hereinafter Ho, *Sovereignty Under Siege*] (examining the international impact of Eli Lilly's claim); Ruth L. Okediji, *Is Intellectual Property "Investment"?* *Eli Lilly v. Canada and the International Intellectual Property System*, 35 U. PA. J. INT'L L. 1121 (2014) (discussing the substantial impact the Eli Lilly claim has on international intellectual property obligations); Freedom-Kai Phillips, *Promise Utility Doctrine and Compatibility Doctrine Under NAFTA: Expropriation and Chapter 11 Considerations*, 40 CAN.-U.S. L.J. 84 (2016) (exploring the problems surrounding domestic patent standards, innovation, and investment standards unearthed by the Eli Lilly claim); Valentina S. Vadi, *Towards a New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investments*, 5 N.Y.U. J. INTELL. PROP. & ENT. L. 113 (2015) (discussing the intersection of intellectual property rights and international investment law and arbitration); Henning Grosse Ruse-Khan, *Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation* (U. Cambridge Faculty of Law Legal Studies, Working Paper No. 52/2014, 2014), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711.

11. See, e.g., Susy Frankel, *Interpreting the Overlap of International Investment and Intellectual Property Law*, 19 J. INT'L ECON. L. 145 (2016) <https://academic.oup.com/jiel/article/19/1/121/2357965/Interpreting-the-Overlap-of-International> (discussing how the objects and purposes of IP as an investment asset should be interpreted within the framework of investment disputes on the basis of Vienna Convention rules); Gathii & Ho, *supra* note 10 (arguing that regime shifting from the WTO to ISDS is deeply destabilizing to explicit and implicit understandings of the balance of interests between producers and consumers of IP and to the continuing adoption and use of TRIPS flexibilities); Ho, *Sovereignty Under Siege*, *supra* note 10 (arguing that IP-based ISDS claims, like *Eli Lilly v. Canada*, could disrupt internationally agreed upon norms, allowing countries flexibility in their IP regimes once baseline TRIPS standards have been met, and proposing specific language to incorporate in pending agreements to forestall such harms); Ho, *Collision Course*, *supra* note 10 (arguing that IP-based ISDS claims may have a chilling effect on countries that would otherwise use TRIPS flexibilities and recommending changes to ISDS that would promote TRIPS flexibilities and sovereignty); Kathleen Liddell & Michael Waibel, *Fair and Equitable Treatment and Judicial Patent Decisions*, 19 J. INT'L ECON. L. 145 (2016) (focusing on the growing tension between the fair and equitable treatment standard in investment chapters and the interpretation of national patent laws by domestic courts); Tsai-yu Lin, *Inter-Mingling TRIPS Obligations with an FET Standard in Investor-State Arbitration: An Emerging Challenge for WTO Law?*, 50 J. WORLD TRADE 71 (2016) (noting the risk of fragmented TRIPS interpretations in multiple arbitral awards adversely affecting the security and predictability of the WTO dispute resolution system); Bryan Mercurio, *Safeguarding Public Welfare?—Intellectual Property Rights, Health and the Evolution of Treaty Drafting in International Investment Agreements*, 6 J. INT'L DISP. SETTLEMENT 252 (2015) (evaluating recent investor treaty language for its sensitivity to public health and welfare concerns, finding some protective changes,

indifferent to the cogent critiques of ISDS's disruptive impact on WTO TRIPS dispute settlement or settlement regimes established by other trade agreements. Instead, it is primarily concerned with the second line of critique that focuses on the negative impacts of IP-related ISDS claims on the policy space that governments have to adopt, modify, and use TRIPS flexibilities in order to prioritize public health and the right of access to medicines for all.¹² It focuses on the need to tame the excesses of Big Pharma's unbridled monopoly power and the industry's intent to expand its deterrent use of ISDS claims to intimidate governments into acceding to its relentless pursuit of profits, irrespective of the cost to

but identifying problematic textual language as well); Henning Grosse Ruse-Khan, *Challenging Compliance with International Intellectual Property Norms in Investor-State Dispute Settlement*, 19 J. INT'L ECON. L. 241 (2016) (arguing that investment protection standards should not be construed to allow invoking alleged breaches of international IP norms in ISDS and suggests alternative mechanisms for aligning international IP and investment protections); Pratyush Nath Upreti, *Enforcing IPRs Through Investor-State Dispute Settlement: A Paradigm Shift in Global IP Practice*, 19 J. INT'L ECON. L. 53 (2016) (noting the shift in IP enforcement to ISDS and expressing concerns); Vadi, *supra* note 10 (arguing that ISDS arbitrators should not place excessive emphasis on pharmaceutical patentees' private interests but should instead pay adequate attention to the public interests also embodied in IPRs); Sean Flynn, *How the Leaked TPP ISDS Chapter Threatens Intellectual Property Limitations and Exceptions*, INFOJUSTICE.ORG BLOG (Mar. 26, 2015), <http://infojustice.org/archives/34189> (arguing that adjudication of intellectual property violations should be left to state-state arbitration).

There were earlier investigations of this area of law as well. *See, e.g.*, Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT'L L. 163 (1998) (examining the ramifications of stronger intellectual property rights on foreign direct investment); Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT'L L. 331 (2004) (investigating international investment agreements); Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT'L L. REV. 357 (2010) (discussing the impact of compulsory licenses on foreign direct investment); Christopher S. Gibson, *Latent Grounds in Investor-State Arbitration: Do International Investment Agreements Provide New Means to Enforce Intellectual Property Rights?*, in YEARBOOK ON INTERNATIONAL INVESTMENT LAW & POLICY 2009-10 397 (Karl P. Sauvant ed., 2010); Bryan Mercurio, *Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements*, 15 J. INT'L ECON. L. 871 (2012) (discussing intellectual property rights in international investment agreements); Valentina Vadi, *Mapping Uncharted Waters: Intellectual Property Disputes with Public Health Elements in Investor State Arbitration*, 2 TRANSNAT'L DISP. MGMT. 1 (2009).

12. The 2001 Doha Declaration affirmed the rights of all WTO members to utilize the flexibilities within TRIPS to promote public health objectives. Specifically, the Declaration stated:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/W/2, 41 I.L.M. 755 (2001) [hereinafter TRIPS Declaration].

consumer health.

The Article was originally intended to also counter the non-ISDS offensive that has been waged against Canada's legitimate adoption and use of a TRIPS- and NAFTA-compliant promise/utility doctrine, one that has been useful in weeding out unproven patents claiming new uses of known medicines.¹³ In this regard, it is important to note that neither industry nor the United States government have relinquished their strident criticism of Canada's patentability criterion, the promise/utility doctrine. Eli Lilly,¹⁴ the Pharmaceutical Researchers and Manufactures

13. Canada's promise/utility doctrine was designed to prevent speculative over-patenting which would dissuade innovation by pre-emptively fencing off areas of research in the absence of a realized invention. See *Eli Lilly & Co. v. Gov't of Can.*, ICSID Case No. UNCT/14/2, Statement of Defence, ¶¶ 3–4 (June 30, 2014) [hereinafter Statement of Defence].

14. A report of the outcome stated:

Eli Lilly said that it is “surprised and extremely disappointed” that the tribunal didn't recognize the “significant harm” caused by the promise utility doctrine, adding that the decision sends a message that Canada has a “wide latitude to create an unfair playing field for U.S. investments. We disagree with the tribunal's conclusions and remain concerned about Canada's intellectual property regime, which increases investment risk and adds unpredictability to the Canadian business environment for Lilly and the innovative pharmaceutical industry,” the company continued in its statement.

Caroline Simson, *Lilly, Biz Groups Rip Tribunal's Decision on 'Promise Doctrine'*, LAW360 (Mar. 22, 2017, 8:55 PM), <https://www.law360.com/articles/904857?scroll=1>.

of America (“PhRMA”),¹⁵ and the U.S. Chamber of Commerce¹⁶ have condemned the *Eli Lilly* award, and the United States Trade Representative (“USTR”) has, for the fifth year in a row, criticized Canada in its Special 301 Reports due to its promise/utility doctrine.¹⁷ In

15. The Pharmaceutical Research and Manufacturers of America reacted:

We are disappointed that the tribunal’s decision was made on narrow investment dispute grounds and did not even address whether Canada’s “promise” doctrine is consistent with NAFTA intellectual property rules. The patent utility or “promise” doctrine that enabled Canada to expropriate Lilly’s patents continues to undermine Canada’s stated goal of shifting to an innovation economy. Canada remains the only country in the world that interprets patent utility in this manner, breaking the letter and spirit of its international commitments on intellectual property rights.

Canada has used this discriminatory policy in 28 court decisions that invalidated 25 patents on 21 medicines over the last decade, targeting only pharmaceutical companies. Canada’s actions have undermined patent protection and removed a critical incentive that drives and sustains biopharmaceutical innovation. This policy also hurts Canadian patients and the medical community. Since the institution of the promise doctrine the number of clinical trials conducted in Canada has declined 21 percent.

If Canada truly plans to recognize the importance of innovation, and evolve from a natural-resource based economy to one founded on science, innovation, and research, either the Courts or Parliament must fix this backwards policy.

We know that Canada wants to, and can be, an innovation leader. Fixing this provision will highlight Canada’s commitment to protecting intellectual property, demonstrating that Prime Minister Trudeau’s Government is doing all it can to grow Canada’s economy.

Press Release, Pharmaceutical Research and Manufacturers of America (PhRMA), PhRMA Statement on NAFTA Tribunal Decision in the Eli Lilly Case (Mar. 21, 2017), <http://www.phrma.org/press-release/phrma-statement-on-nafta-tribunal-decision-in-the-eli-lilly-case>.

16. The U.S. Chamber of Commerce reacted:

This was a narrow decision that declined to rule on the legal merits of Canada’s “promise” doctrine; it was not an endorsement of the doctrine’s policy. There can be no dispute that the doctrine dramatically undermines legal certainty for medical innovators in Canada: Since 2005, there has been a sharp increase in medical patent invalidation, with 25 patents revoked that were previously approved by Health Canada and that were being used to treat millions of patients around the world. These actions are outside international norms and have undermined the stability that drugmakers rely on to continue providing the kinds of cures the world needs. For these reasons, we urge the Canadian government to address the stifling challenges the “promise” doctrine presents for medical innovators in Canada.

Press Release, U.S. Chamber of Commerce, Statement on *Eli Lilly v. Canada* Patent Ruling, (Mar. 21, 2017, 4:30 PM), <https://www.uschamber.com/press-release/us-chamber-statement-eli-lilly-v-canada-patent-ruling>.

17. The USTR has listed Canada as a Priority Watch List Country for the last five years with escalating and then repeated concerns expressed about Canada’s promise/utility doctrine. UNITED STATES TRADE REPRESENTATIVE, 2013 SPECIAL 301 REPORT 46 (2013) (“With respect to pharmaceuticals, the United States continues to have serious concerns about . . . the impact of the heightened utility requirements for patents that Canadian courts have been adopting recently.”). As

addition, the newly appointed USTR, Robert Lighthizer, indicated in a hearing before the House Committee on Ways and Means on June 22, 2017, that Canada's promise/utility doctrine was a serious problem and would be addressed as part of the U.S.'s renegotiation of NAFTA.¹⁸ PhRMA has been strenuously lobbying the U.S. government with respect to the pending renegotiation of NAFTA, focusing on the promise/utility doctrine as well.¹⁹ Similarly, PhRMA's 2017 Special 301 Submission Report identified Canada's "restrictive patentability criteria" as its first issue of concern regarding Canadian IP standards.²⁰ Parroting many of the same arguments used by Eli Lilly, PhRMA claimed that Canada's

also cited in the USTR's 2014 Report:

The United States also has serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently. Under this amorphous and evolving standard, courts can invalidate a patent on utility grounds by construing the "promise of a patent" years after the patent has been granted, leading to uncertainty for patent holders and applicants and undermining incentives for investment in the pharmaceutical sector. In applying this standard, courts have invalidated a number of patents held by U.S. pharmaceutical companies, finding now that those products lack utility (i.e., not capable of industrial application), even though such products have been in the market and benefiting patients for years.

United States Trade Representative, 2014 SPECIAL 301 REPORT 49 (2014). As continued in 2015:

The United States also continues to have serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently. In these cases, courts have invalidated several valuable patents held by U.S. pharmaceutical companies on utility grounds, by interpreting the "promise" of the patent and finding that insufficient information was provided in the application to substantiate that promise. These recent decisions, which have affected products that have been in the market and benefiting patients for years, have led to uncertainty for patent holders and applicants, including with respect to how to effectively meet this standard. This unpredictability also undermines incentives for investments in the pharmaceutical sector.

United States Trade Representative, 2015 SPECIAL 301 REPORT 66 (2015). *See also* United States Trade Representative, 2016 SPECIAL 301 REPORT 57 (2016) (reporting the same as noted in the subsequent 2013, 2014, and 2015 reports); United States Trade Representative, 2017 SPECIAL 301 REPORT 62 (2017) (same).

18. *U.S. Trade Policy*, 02:32:02 (C-SPAN television broadcast June 22, 2017) <https://www.c-span.org/video/?430344-1/us-trade-representative-robert-lighthizer-testifies-trump-administration-agenda&live&start=9081> (featuring U.S. Trade Representative Robert Lighthizer testifying before the House Ways & Means Committee on the Trump administration's trade policy).

19. PhRMA said in recent comments to the USTR that contrary to NAFTA "and longstanding international obligations and norms, the Canadian judiciary has created a new and heightened standard for determining patent 'utility,'" called the promise doctrine, which has led to twenty-eight court decisions invalidating twenty-five biopharmaceutical patents for lack of utility since 2005. PhRMA urged the USTR to address this flaw in its renegotiation of NAFTA. *See* Letter from Jay T. Taylor, PhRMA, to Edward Gresser, Chair of the Trade Policy Staff Committee, USTR (June 12, 2017), <http://phrma-docs.phrma.org/files/dmfile/PhRMA-Comments-on-Negotiating-Objectives-for-Modernization-of-NAFTA-June-2017.pdf>.

20. Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission 2017 at 77 (2017), <http://phrma-docs.phrma.org/files/dmfile/PhRMA-2017-Special-301-Submission.pdf>.

“new and heightened requirement for patentable utility . . . has done great damage to the patent rights of innovative pharmaceutical companies”²¹ and discriminated against pharmaceutical products.²² PhRMA members urged the U.S. government to “press the Government of Canada to resolve this issue through, for example, clarifying amendments to the [Canadian] Patent Act” because this higher utility standard “is fundamentally incompatible with the realities of pharmaceutical development.”²³

Regrettably, the Canadian Supreme Court has snatched defeat from the jaws of Canada’s hollow arbitral victory. In a stunning reversal of policy, the Supreme Court of Canada overturned its decades-old promise/utility doctrine, making it easier for the biopharmaceutical industry to patent medicines with only a “scintilla” of evidence that a medicine might eventually prove to be useful²⁴—“essentially a wink-wink rule that will allow drug companies wide discretion to game the patent system to build a thicket of patents around a base compound both to deter follow-on innovation by competitors and to extend the effective term of patent exclusivity well beyond the initial twenty-year term.”²⁵ Rather than granting patents based on proof of all claims of utility as of the time of filing, patentees will be able to make minimally educated guesses on possible future uses, even if those uses do not materialize.²⁶ So long as these guesses are not wholly “fanciful, speculative, or non-operable,”²⁷ the reinterpreted utility test can be satisfied.

Equally problematic, since the initial filing of the Eli Lilly arbitration claims, two other Big Pharma companies, Novartis and Gilead, have filed or threatened to file ISDS claims against Colombia and Ukraine respectively based on putative IP-investment rights. Unfortunately, those cases did not result in favorable arbitral rulings—in both cases, the countries were forced to reverse decisions that would have allowed

21. *Id.* at 78.

22. *Id.* at 79.

23. *Id.* at 80.

24. The Supreme Court of Canada held:

The Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized—a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date.

AstraZeneca Canada Inc. v. Apotex Inc., 2017 SCC 36, ¶ 55.

25. Brook Baker, *Canada Blinks in Face of US/Pharma Pressure – Supreme Court Adopts Wink-Wink Patent Utility Rule*, HEALTH GAP BLOG (July 1, 2017), http://www.healthgap.org/canada_blinks_in_face_of_us_pharma_pressure_supreme_court_adopt_s_wink_wink_patent_utility_rule.

26. *AstraZeneca Canada Inc.*, 2017 SCC 36, ¶ 55.

27. *Id.* at ¶ 57.

generic competition and instead perpetuated the companies' market monopolies.²⁸ Combined, the Canadian, Colombian, and Ukrainian examples clearly demonstrate the escalating threat of IP-based pharmaceutical ISDS claims to national sovereignty over patentability criteria and the use of TRIPS-compliant public health flexibilities to promote access to medicines for all.

After providing a brief contextual background on the Eli Lilly patent invalidations and on ISDS in Section I, Section II of the Article details the *Eli Lilly* arbitral award. Section III critiques the award, particularly its overly cautious grounds of decision and its explicit validation of IP-based ISDS. Those dangers are further discussed in Section IV based on the stunning judicial reversal of the promise/utility doctrine by the Canadian Supreme Court, on the withdrawal of a compulsory licensing proposal in Colombia, and on the deregistration of a competing generic hepatitis C medicine in Ukraine. The chilling effect of investor-state arbitration is swiftly becoming more apparent.²⁹

I. BACKGROUND TO *ELI LILLY V. CANADA* ISDS

In 1991 and 1996, Eli Lilly sought patents for new uses of two already known compounds, olanzapine and atomoxetine, respectively.³⁰ The grant of both patents by Canada's Patents Office was only presumptively valid, and was later challenged in the Federal Court by Eli Lilly's competitor, Novopharm Limited. Both patents were found invalid for want of utility at the time of filing.³¹

Eli Lilly's 1991 application for a further patent on olanzapine (eleven years after its original patent was granted) claimed that the drug provided superior treatment for schizophrenia compared with other members of the same genus of compounds.³² This claim was made on the basis of studies that failed to establish any particular treatment advantage over the already-patented class to which olanzapine belonged.³³ Accordingly, the patent was invalidated by the Federal Court of Appeals³⁴ and subsequent appeals failed to overturn this ruling. Similarly, Eli Lilly's 1996 application for a further patent on atomoxetine asserted a new use, treatment of attention-deficit/hyperactivity disorder ("ADHD"), based on an inconclusive preliminary study that was not disclosed in the patent

28. See discussion *infra* Section IV.

29. See Gathii & Ho, *supra* note 10.

30. Baker & Geddes, *Corporate Power Unbound*, *supra* note 10, at 38–39.

31. *Id.*

32. Statement of Defence, *supra* note 13, at ¶ 3.

33. *Id.*

34. *Eli Lilly Co. v. Teva Canada Ltd.*, 2011 FCA 220.

application.³⁵ This patent was also invalidated by the Federal Court, a ruling that survived subsequent appeals.³⁶

Each patent application filed by Eli Lilly was only one of multiple applications made for each drug that claimed a variety of “new” uses for each compound with little or no supporting evidence, ranging from sexual dysfunction for olanzapine³⁷ to hot flashes for atomoxetine.³⁸ Most of these applications were filed just prior to the expiration of Eli Lilly’s original patents on the base compounds.³⁹ The creation of so-called patent thickets and fences—dense webs of overlapping patent rights that competitors must hack through in order to commercialize new technology—is a common strategy used by pharmaceutical firms to insulate their products from generic competition and to extend the effective period of exclusive rights.⁴⁰ In this case, Eli Lilly’s attempts to extend its patent monopolies by claiming “new” uses of existing compounds were obstructed by nine different Canadian judges who found that Eli Lilly’s secondary, new-use patents were invalid for want of utility.⁴¹

Free trade agreements (“FTAs”) and bilateral investment treaties (“BITs”) typically contain investment clauses designed to attract foreign investment by offering protection against grossly unfair, confiscatory, or discriminatory treatment.⁴² These clauses reassure foreign investors that if their investments are unlawfully devalued by government action, they can seek a remedy through state-state or investor-state dispute settlement channels. Accordingly, investment clauses within FTAs and BITs generally offer protection against: (1) violations of minimum standards of treatment, that is, fair and equitable treatment and full protection and security; (2) direct or indirect expropriation; and (3) violations of national treatment and most-favored-nation principles, which require host

35. Statement of Defence, *supra* note 13, at ¶ 4.

36. *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2012 FCA 232, *aff’d* 2011 FC 1288.

37. Statement of Defence *supra* note 13, at ¶ 67.

38. *Id.* at ¶ 55.

39. *Id.* at ¶¶ 53, 55, 67.

40. See generally BRONWYN HALL ET AL., NAT’L INST. OF ECON. AND SOCIAL RESEARCH, A STUDY OF PATENT THICKETS: FINAL REPORT PREPARED FOR THE UK INTELLECTUAL PROPERTY OFFICE (2012); Michael Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti-Commons Effect*, 280 SCIENCE 698 (1998); C. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 J. INNOVATION POL. & ECON. 119 (2000); Christian Sternitzke, *Knowledge sources, patent protection, and commercialization of pharmaceutical innovations*, 39 RES. POL. 810 (2010); Christian Sternitzke, *An exploratory analysis of patent fencing in pharmaceuticals: The case of PCE5 inhibitors*, 42 RES. POL. 542 (2013); Stu Woolman et al., *Evidence of Patent Thickets in Complex Biopharmaceutical Technologies*, 53 IDEA 1 (2013).

41. Statement of Defence, *supra* note 13, at ¶ 52.

42. Baker & Geddes, *supra* note 10, at 12.

governments to afford foreign investors treatment that is no less favorable than that afforded to domestic entities in similar circumstances or no less favorable than that afforded to investors from another state that has an investment agreement with the host government.⁴³ Initially used to remedy banana-republic confiscations of foreign assets, investor-state arbitration has increasingly been used by deep-pocketed foreign corporations to challenge a broad array of government laws and policies which adversely affect expected profits, including environmental and land-use laws, government procurement decisions, and consumer protection, public health, and public-safety laws.⁴⁴ Broadly defined “investments” protected by FTA investment chapters and BITs can implicate IPRs, as IPRs typically require a commitment of capital or other resources with the expectation of gain or profit. IPRs, such as patents, which create an expectation of monopoly rents, therefore fall within the standard definition of protected investments even when not expressly included,⁴⁵ as in NAFTA.⁴⁶

On November 7, 2012, Eli Lilly filed a Notice of Intent to Submit a Claim to Arbitration seeking compensation for damages arising out of Canada’s alleged violations of its investment obligations under NAFTA Article 1110 (Expropriation and Compensation), Article 1105 (Minimum Standard of Treatment) and Article 1102 (National Treatment).⁴⁷ Eli Lilly claimed damages not less than CDN \$100 million. Seven months later, Eli Lilly filed a new arbitration notice claiming no less than CDN \$500 million plus any payments Eli Lilly would be required to make arising from the “improvident loss” of its Zyprexa and Strattera patents or its inability to enforce those patents.⁴⁸ Four years later, the Tribunal found that the invalidation of Eli Lilly’s patents through application of Canada’s well-established but evolving patent law could not form the basis of an indirect expropriation claim under NAFTA Article 1110, nor a claim for a violation of the minimum standard of treatment under Article 1105, nor an arbitrary or discriminatory measure claim in

43. Baker & Geddes, *supra* note 10, at 12–13.

44. *Id.* at 17.

45. *Id.* at 31 (“Accordingly, unless IP rights are expressly excluded from the investment chapter and from the definition of ‘investment,’ [IPRs] would be implicitly covered.”).

46. North American Free Trade Agreement, Can.-Mex.-U.S., ch. 11, art. 1139, Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA].

47. Eli Lilly & Co. v. Gov’t of Can., ICSID Case No. UNCT/14/2, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven, ¶ 87 (Nov. 7, 2012) [hereinafter Notice of Intent to Submit a Claim].

48. Eli Lilly & Co. v. Gov’t of Can., ICSID Case No. UNCT/14/2, Notice of Arbitration, ¶ 85 (Sept. 12, 2013).

violation of Articles 1110 or 1105.⁴⁹

II. SUMMARY OF TRIBUNAL DECISION

The foundation for Eli Lilly's claims was the invalidation of its Canadian patents on two drugs, Strattera and Zyprexa, by Canadian courts in 2010 and 2011 respectively, on the basis of inutility. According to Eli Lilly, the basis for the judicial decisions was the adoption in the mid-2000s of the "promise utility doctrine," which it considered to be "radically new, arbitrary and discriminatory against foreign pharmaceutical companies and pharmaceutical products."⁵⁰ Eli Lilly claimed that the promise/utility doctrine violated NAFTA Chapter Seventeen, and that the retroactive application of the doctrine to its patents resulted in the unlawful "expropriation" of its investments under NAFTA Article 1110 and a breach of the minimum standards of treatment under Article 1105.⁵¹ In addressing these claims, the Tribunal focused on the following substantive questions:⁵²

- (a) Is denial of justice the only basis of liability for judicial measures under NAFTA Chapter Eleven?
- (b) Has there been a dramatic change in the utility requirement in Canadian patent law?
- (c) Is the utility requirement in Canadian patent law, as applied to the Zyprexa and Strattera patents, arbitrary and/or discriminatory?
- (d) If (b) and/or (c) is answered in the affirmative, did the invalidations of the Zyprexa and Strattera patents breach Canada's obligations under NAFTA Article 1110 and/or Article 1105?⁵³

A. Denial of Justice

According to the Final Award's analysis, Eli Lilly claimed that the "retroactive" application of the promise/utility doctrine to its patents resulted in (i) the unlawful "expropriation" of its investments under NAFTA Article 1110, and (ii) a breach of Canada's obligation to provide the minimum standard of treatment under Article 1105.⁵⁴ Eli Lilly rejected the position that under international law the only possible theory

49. Final Award, *supra* note 1, at ¶ 469.

50. *Id.* at ¶ 5.

51. *Id.*

52. As a threshold matter, the Tribunal considered and rejected Canada's objection that the complaint related to judicial developments that occurred before NAFTA's three-year statute of limitations period, noting that the limitations period ran from when the investor first acquired knowledge of the alleged breach—in this case, when the two patents were invalidated. *Id.* at ¶¶ 160–73.

53. *Id.* at ¶ 110.

54. *Id.* at ¶ 5.

of liability for judicial measures is a denial of justice.⁵⁵ It argued that judicial measures can constitute an indirect expropriation under Article 1110, even in the absence of a denial of justice, where they violate an international obligation and result in a substantial deprivation.⁵⁶ Similarly, with respect to Article 1105, Eli Lilly claimed that “multiple arbitral awards have confirmed that denial of justice is not the only protection against judicial action offered by the minimum standard of treatment.”⁵⁷

With respect to Article 1110, Canada responded by asserting that a denial of justice is the only basis on which a domestic court judgment on the validity of a property right could constitute an expropriation.⁵⁸ To assert otherwise, Canada argued, would be to transform NAFTA Chapter Eleven tribunals into “supranational courts of appeal in domestic property law issues.”⁵⁹ It argued further that international law on expropriation requires first establishing the existence of a property right under domestic law, and that Canadian courts had already found that Eli Lilly no longer held property rights over Zyprexa and Strattera under Canadian law.⁶⁰ Canada argued that Eli Lilly could not point to any examples of a judicial expropriation in the absence of a denial of justice.⁶¹ With respect to Article 1105, Canada argued that the only source of obligations therein is the customary international law minimum standard of treatment of aliens, and denial of justice is the only rule of customary international law applicable to State organs exercising an adjudicative function.⁶² Accordingly, Eli Lilly had failed to state a claim under Article 1105 in the absence of a denial of justice. The Tribunal noted that the United States, in its submission, agreed that, unless there is a denial of justice,

55. *Id.* at ¶ 174. For a comprehensive discussion of the evolving and contested meanings of denial of justice, see generally JAN PAULSSON, DENIAL OF JUSTICE IN INTERNATIONAL LAW (Cambridge Univ. Press 2005) (discussing the evolution of “one of the oldest bases of liability” in international law as applied in several modern landmark cases). See also Patrick Dumberry, *Denial of Justice under NAFTA Article 1105: A Review of 20 Years of Case Law*, 32 ASA BULLETIN 2, 246–64 (June 2014) (discussing how NAFTA tribunals have interpreted and applied the “exhaustion of local remedies” rule as well as the various tests put forward by them to determine whether such a “denial of justice” has been committed).

56. Final Award, *supra* note 1, at ¶ 181.

57. *Id.* at ¶ 183.

58. *Id.* at ¶ 188. This position was supported both by Mexico and the United States. *Eli Lilly & Co. v. Gov’t of Canada*, ICSID Case No. UNCT/14/2, Submission of Mexico Pursuant to NAFTA Article 1128, ¶¶ 12–14, 19–21 (Mar. 18, 2016) [hereinafter Mexico Submission]; *Eli Lilly & Co. v. Gov’t of Canada*, ICSID Case No. UNCT/14/2, Submission of United States of America Pursuant to NAFTA Article 1128, ¶¶ 20–37 (Mar. 18, 2016) [hereinafter U.S. Submission].

59. Final Award, *supra* note 1, at ¶ 190.

60. *Id.* at ¶ 191.

61. *Id.* at ¶ 195.

62. *Id.* at ¶ 196.

international tribunals should defer to domestic courts interpreting matters of domestic law.⁶³ The United States submitted that decisions of domestic courts do not give rise to a claim for expropriation under Article 1110.⁶⁴ Similarly, the United States submitted that judicial measures could form the basis of a claim under Article 1105 only if a denial of justice was proven. Otherwise, “Chapter Eleven tribunals would become supranational appellate courts on the application of substantive domestic law.”⁶⁵

The Tribunal disagreed with Canada, expressing its unwillingness to “shut the door to the possibility that judicial conduct characterized other than as a denial of justice may engage a respondent’s obligations under NAFTA Article 1105.”⁶⁶ The Tribunal reasoned that conduct not amounting to a denial of justice may nevertheless be “sufficiently egregious and shocking” as to violate the minimum standard of treatment required by Article 1105.⁶⁷ The Tribunal also cited the definition of minimum standard of treatment applied in *Glamis Gold v. United States*, which includes “manifest arbitrariness” and “blatant unfairness” alongside “gross denial of justice.”⁶⁸ Similarly, the Tribunal refused to narrow the scope of inquiry of judicial decisions under Article 1110 to circumstances of a denial of justice. It argued that “it is possible to contemplate circumstances in which a judicial act (or omission) may engage questions of expropriation under NAFTA Article 1110, such as, perhaps, in circumstances in which a judicial decision crystallizes a taking alleged to be contrary to NAFTA Article 1110.”⁶⁹

However, the Tribunal reiterated earlier comments that “a NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of national judiciaries”⁷⁰ and emphasized the importance of according “considerable deference” to the conduct and decisions of domestic courts. It explained that it would “only be in very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct, that it will be appropriate for a NAFTA Chapter Eleven tribunal to assess such

63. *Id.* at ¶ 204.

64. *Id.* at ¶ 206.

65. *Id.* at ¶ 208 (summarizing the United States’ position regarding NAFTA Article 1105).

66. *Id.* at ¶ 223.

67. *Id.*

68. *Id.* at ¶ 222 (accepting a minimum standard of treatment with respect to denial of justice involving “an act that is sufficiently egregious and 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 and constitute a breach of Article 1105”).

69. *Id.* at ¶ 221.

70. *Id.*

conduct against the obligations of the respondent State under NAFTA Article 1105(1).”⁷¹ Despite making this arbitral dictum, the Tribunal ruled that it did not need to reach any final decision on the denial of justice limits of liability of a respondent state because the Tribunal saw no breach of NAFTA at all on the facts of the case.⁷² In this particular case, the Tribunal argued, the factual predicate of egregious or shocking conduct that would be necessary to sustain Eli Lilly’s claim of a breach of Article 1105(1) and/or Article 1110 had not been established. In other words, Eli Lilly’s case did not meet “the threshold requirement to proceed under this head.”⁷³

It is also important to note that NAFTA Article 1110(7) explicitly states that Article 1110 “does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).” Canada argued that the judicial invalidation of Eli Lilly’s patents was wholly consistent with Chapter Seventeen: “[w]here a court of competent jurisdiction, applying full due process and reaching a decision pursuant to its mandate, determines that a presumed property right is legally invalid . . . this does not amount to a “taking,” but rather, constitutes juridical determination of the existence and scope of rights at law.”⁷⁴ NAFTA Article 1110(7), Canada argued, was “intended to provide, in the intellectual property context, a further “defence” for the NAFTA Parties against claims of expropriation. This reflected the prominent role of sovereign parties in the regulation and enforcement of intellectual property rights, and consequent risk that such State action might give rise to claims under the expropriation article. Accordingly, the NAFTA Parties provided that Article 1110 would not even apply to determinations in this context, so long as the measure at issue was “consistent with Chapter Seventeen.”⁷⁵ The Tribunal did not read this provision to unduly restrict its inquiry. Moreover, it ignored a more fundamental argument that the Tribunal lacked competence to assess whether Chapter Seventeen IP violations had occurred or whether such violations would be per se violations of the investment chapter, positions advanced by Canada and supported by both

71. *Id.* at ¶ 224 (specifying the Chapter Eleven tribunal’s reviewal role).

72. *Id.* at ¶ 220.

73. *Id.* at ¶ 226.

74. Statement of Defence, *supra* note 13, at ¶ 108 (discussing Canada’s promise/utility doctrine and its potential to chill innovation in the form of speculative over-patenting).

75. *Id.* at ¶ 114.

the United States and Mexico.⁷⁶

B. The Promise/Utility Doctrine

With respect to the second question, Eli Lilly claimed that the promise/utility doctrine represents a “radical departure” both from Canada’s traditional utility standard and the utility standards applied by Canada’s NAFTA partners, the United States and Mexico.⁷⁷ It claimed that the “elevated requirement for utility” imposed by the promise/utility doctrine reflects a “stark divergence” between patentability requirements in Canada and in other NAFTA parties, making Canada an “outlier.”⁷⁸ Based on existing Canadian law, Eli Lilly argued that it held, and reasonably relied on, “legitimate expectations” that its patents would not be invalidated on the basis of a “radically new utility requirement.”⁷⁹ Eli Lilly claimed that the initial grant of the Zyprexa and Strattera patents represented a “commitment” by Canada that Eli Lilly “would have exclusive rights to make, use, and sell its invention until the expiry of the patents”⁸⁰ notwithstanding the common knowledge that patents are temporary rights vulnerable to judicial invalidation at any time. Unusually, Eli Lilly seemed to hinge its claim on the *scope* of perceived change in Canadian law, careful to distinguish between what it described as an “acceptable margin of change” (measured change in the law or clarification of previously unsettled law) and “the adoption of a completely new doctrine in a well-settled area.”⁸¹ The ability of a foreign company to dictate the “permissible” scope of change in domestic law of a sovereign nation illustrates the disquieting precedent set by investor-state arbitration of domestic judicial decisions.

Canada’s response was two-fold: first, it defended the promise/utility doctrine as a long-standing component of Canadian patent law, arguing that it existed “long before Claimant filed its patents or NAFTA entered into force.”⁸² Second, it argued that even if the promise/utility doctrine

76. *Id.* at ¶¶ 82–94; Mexico Submission, *supra* note 58, at ¶¶ 22–31 (noting that a domestic court judgment on the validity of a property right is only an expropriation if justice is denied); U.S. Submission, *supra* note 58, ¶¶ 32–37 (agreeing with the assertion of the Mexico Submission).

77. Final Award, *supra* note 1, at ¶ 227 (holding that Eli Lilly lost to Canada in an ISDS challenge).

78. *Id.* at ¶¶ 236, 258, 259.

79. *Id.* at ¶¶ 261, 263.

80. *Id.* at ¶ 264.

81. *Id.* at ¶ 269.

82. *Id.* at ¶ 274. For an extended discussion of the promise doctrine and its equivalency with patent standards in other Commonwealth countries, see generally E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CAN. INTELL. PROP. REV. 35 (2014). For Gold’s newly contrary view that the “promise doctrine” was made up by Eli Lilly as a straw man for its ISDS case, see E. Richard Gold, *Eli Lilly’s Odyssey to Use a Fake Rule and*

could be construed as a legal shift, it defended its right to jurisprudential development: “[I]t is trite to say that the common law evolves over time. Any sophisticated investor expects developments in the law, particularly in the area of patent law. It simply cannot be that every time a court overrules a precedent, it violates customary international law.”⁸³ With respect to Eli Lilly’s “legitimate expectations” that its patents would not be invalidated, Canada argued that the initial grant of a patent cannot constitute the basis for legitimate expectations because “patents issued by the Patent Office are only presumptively valid, subject to challenge and to final determination by the judiciary.”⁸⁴ In other words, when Eli Lilly filed the Strattera and Zyprexa patents, “it knew, or should have known, that its patents could be invalidated if they did not satisfy the applicable patentability requirements, and that the legal meaning of patentability requirements is constantly being clarified and elaborated through court decisions.”⁸⁵ Finally, with respect to allegations that the promise/utility doctrine also represents a radical departure from the patentability standards of other NAFTA parties, Canada argued that “any differences in patent law regimes across jurisdictions [is] irrelevant, as . . . international patent law is not harmonized by NAFTA or otherwise.”⁸⁶

Rather than firmly defend Canada’s right to jurisprudential development, the Tribunal concluded that Eli Lilly had not adduced sufficient evidence to prove that Canadian patent utility law had undergone a dramatic transformation.⁸⁷ The Tribunal did, however, highlight the unreasonableness of Eli Lilly’s assumption that common law decisions should occur “in a reasonably foreseeable and predictable channel, without significant or material changes.”⁸⁸ Rather, the Tribunal explained that, in common law jurisdictions, “evolution of the law

Fake News to Protect Bad Patents, STAT NEWS (Aug. 16, 2017), <https://www.statnews.com/2017/08/16/eli-lilly-canada-patents-zyprexa-strattera/> (alleging that Eli Lilly invented the promise doctrine by weaving together poorly contextualized statements and baseless allegations of past violations).

83. Final Award, *supra* note 1, at ¶ 306 (quoting Canada’s Response Post-Hearing Memorial).

84. *Id.* at ¶ 302.

85. *Id.* at ¶ 303.

86. *Id.* at ¶ 297. NAFTA Chapter Seventeen (Intellectual Property) contains built-in flexibility with respect to the domestic implementation of its provisions. Statement of Defence, *supra* note 13, at ¶ 115. Specifically, Article 1702 states: “A Party may implement in its domestic law more extensive protection of intellectual property rights than is required under this Agreement, provided that such protection is not inconsistent with this Agreement.” NAFTA, *supra* note 46, at ch. 17, art. 1702. At no point does the text of NAFTA require all signatory parties to implement carbon-copy intellectual property provisions. Statement of Defence, *supra* note 13, at ¶ 115.

87. Final Award, *supra* note 1, at ¶ 308 (finding that Eli Lilly had not met its burden in establishing the utility requirement under Canadian patent law).

88. *Id.* at ¶ 310.

through court decisions is natural, and departures from precedent are to be expected.”⁸⁹ Since Eli Lilly had failed to demonstrate a dramatic change in Canadian law, the Tribunal dismissed its allegation of a violation of its legitimate expectations.⁹⁰

In reaching this decision, the Tribunal assessed the three principal elements of the promise/utility doctrine: (1) the identification of a promise of utility in the patent application; (2) the prohibition against use of post-filing evidence to prove utility as of the time of filing; and (3) a requirement to include evidence demonstrating sound prediction of utility in the application itself.⁹¹ Reviewing the first element, the Tribunal found that the requirement of identifying a promise of utility in the patent application had long existed in Canadian patent law, even if it had not previously played a significant role.⁹² Although the Tribunal found that the second element concerning post-filing evidence was “unexpected,” the reversal of lower court opinions was a natural feature of a “tiered judicial system” that included the reasonable reconciliation of various cases in a manner “not entirely inconsistent.”⁹³ As to the third element, requiring a sound prediction of utility, Eli Lilly had had a patent application rejected on this ground in 2003 and its own lawyers had issued a client update on the issue after another court decision in 2009, reporting that the court had therein “reiterated” the test from earlier cases.⁹⁴

Eli Lilly’s assumption that its patents would not be invalidated did not, according to the Tribunal, constitute a legitimate expectation because at the time it made its investments “it was aware that Canadian patent law required patented inventions to be useful” and “each of the three elements of the alleged promise utility doctrine had a foundation in Canadian law when [its] patents were filed.”⁹⁵ Accordingly, at that time, although Eli Lilly “may not have been able to predict the precise trajectory of the law on utility, it should have, and could have, anticipated that the law would change over time as a function of judicial decision-making.”⁹⁶ The Tribunal concluded that, between the time that the Zyprexa and Strattera patents were granted and subsequently invalidated, Canada’s utility requirement underwent “incremental and evolutionary changes” rather

89. *Id.*

90. *Id.* at ¶ 380.

91. *Id.* at ¶ 313.

92. *Id.* at ¶¶ 316–25.

93. *Id.* at ¶¶ 326–37 (analyzing the second element of the promise/utility doctrine).

94. *Id.* at ¶¶ 338–50 (discussing whether the basis of sound prediction must be disclosed in the patent, based on the 2008 Raloxifene Decision).

95. *Id.* at ¶ 384.

96. *Id.* at ¶¶ 383–84.

than a “fundamental or dramatic change.” Accordingly, Eli Lilly failed to prove that its “legitimate” expectations were violated by the application of Canadian patent law to its patents for Zyprexa and Strattera even if legitimate expectations were considered to be part of NAFTA’s minimum standards of treatment.⁹⁷

The Tribunal refused, however, to determine the “contentious legal question of whether a violation of an investor’s legitimate expectations can constitute a breach of NAFTA Article 1105,” thereby leaving the door open to this possibility.⁹⁸

C. *An Arbitrary and Discriminatory Measure*

Next, the Tribunal addressed the question of whether the promise/utility doctrine was an arbitrary or discriminatory measure, as alleged by Eli Lilly, within the meaning of NAFTA Articles 1105 and/or 1110. Eli Lilly claimed that the promise/utility doctrine was “arbitrary” because it was “unpredictable,” “incoherent,” and “serves no legitimate public purpose.”⁹⁹ Additionally, Eli Lilly claimed that the promise/utility doctrine “discriminates against pharmaceutical patents as a field of technology” in violation of NAFTA Article 1709(7).¹⁰⁰ Eli Lilly also claimed that the promise/utility doctrine discriminates against foreign pharmaceutical companies to the benefit of Canada’s generic drug industry: “[O]nly patents held by foreign firms have been invalidated pursuant to this doctrine.”¹⁰¹

Canada rejected the arbitrariness claim, arguing that patent interpretation is not “arbitrary,” but based on long-standing principles of construction;¹⁰² the ban on post-filing evidence is not “arbitrary,” but designed to prevent speculative patenting;¹⁰³ and requiring patentees to disclose the basis of their sound predictions is also not “arbitrary,” but instead represents the basic quid pro quo that applicants offer in exchange for patent exclusivities.¹⁰⁴ In addition, Canada argued that Eli Lilly had

97. *Id.* at ¶¶ 386–87. Changes between the 1990 and 2009 Manual of Patent Office Practice were not authoritative evidence of the prior state of Canada’s patent law. *Id.* at ¶¶ 352–66. Similarly, Eli Lilly’s statistical arguments addressing the number of patents invalidated after 2005 were unconvincing. *Id.* at ¶¶ 367–76 (charting statistical evidence relevant to the claim).

98. *Id.* at ¶ 381.

99. *Id.* at ¶ 390.

100. *Id.* at ¶ 397. Eli Lilly claimed that more than two dozen pharmaceutical patents had been invalidated pursuant to the promise/utility doctrine since 2005. *Id.* at ¶ 398.b.

101. *Id.* at ¶ 401.

102. *Id.* at ¶ 403 (explaining that this includes the principal that the patent should be construed as a whole (i.e., both disclosure and claims)).

103. *Id.* at ¶ 406 (summarizing Canada’s response to Eli Lilly’s “criticism of the ban on post-filing evidence”).

104. *Id.* at ¶ 407.

failed to provide any statistically significant evidence of either de jure or de facto discrimination against pharmaceutical patents.¹⁰⁵ Its data analysis revealed several flaws, including a fundamental misunderstanding of correlation and causation, and ignorance of the multiplicity of factors that affect litigation outcomes.¹⁰⁶ Finally, contrary to Eli Lilly's claim that foreign pharmaceutical firms face discrimination, Canada pointed out that domestic firms are subject to the same promise/utility doctrine as Eli Lilly.¹⁰⁷

Before addressing the allegations made against the promise/utility doctrine, the Tribunal clarified that it did not regard the judicial invalidations of the Zyprexa and Strattera patents to be arbitrary or discriminatory:

The patent grants to [Eli Lilly] were made in a legal system that historically has, and necessarily, evolves, and this evolution resulted in later decisions, rationally and not unforeseeably, that concluded the initial patent grants were invalid, just as the Canadian statutory patent regime envisions. As such, the challenged decisions of the Canadian courts cannot constitute either a breach of NAFTA Articles 1105 or 1110.¹⁰⁸

With respect to the separate claim that the promise doctrine itself is arbitrary and discriminatory, the Tribunal concluded that Canada's patentability requirements were "the consequence of a rational policy approach in Canada, not an indication of arbitrariness in the law,"¹⁰⁹ and that Eli Lilly's expectations of predictability and certainty revealed a profound misunderstanding of the reality of common law.¹¹⁰ Importantly, the Tribunal emphasized, more than once, that "it is not the role of a NAFTA Chapter Eleven tribunal to question the policy choices of a NAFTA Party."¹¹¹ The Tribunal reasoned that some degree of unpredictability was to be expected in the application of any law,¹¹² and that the promise/utility doctrine had a sufficient and rational connection to a legitimate public policy "that 'the public receives its end of the patent bargain' (particularly but not solely in connection with 'new use' and 'selection' patents), and that 'it encourages accuracy while discouraging

105. *Id.* at ¶ 410.

106. *Id.* at ¶¶ 413–14 (noting that out of the 25,760 pharmaceutical patents granted between 1980 and 2013, only 134 validity challenges were decided).

107. *Id.* at ¶ 415.

108. *Id.* at ¶ 418.

109. *Id.* at ¶ 426 (discussing the Tribunal's understanding of "the difficulty for companies in innovative industries described by [Eli Lilly]").

110. *Id.* at ¶¶ 421, 429.

111. *Id.* at ¶¶ 426, 430.

112. *Id.* at ¶ 421 (further noting that inconsistency in judicial interpretation at this limited scale is to be expected).

overstatement in patent disclosures.”¹¹³ With respect to the second element barring use of post-filing evidence, it was a bright-line rule connected to the valid public policy of preventing speculative patents.¹¹⁴ Although the application of the third element was less precise, this too was not problematic because imprecision “abound[s] in nearly all legal regimes.”¹¹⁵

Concerning allegations of *de facto* discrimination against pharmaceutical patents as a field of technology, the Tribunal found that Eli Lilly had not adduced sufficient evidence to establish a causal link between the promise/utility doctrine and higher invalidity rates in the pharmaceutical sector.¹¹⁶ The Tribunal could not “rule out the possibility that alternative factors [other than the promise/utility doctrine] may give rise or contribute to the difference in rates of inutility finding.”¹¹⁷ Accordingly, the Tribunal found that Eli Lilly failed to prove its allegation that the promise/utility doctrine discriminates against pharmaceutical patents.¹¹⁸

Finally, addressing allegations of discrimination based on nationality, the Tribunal noted:

[Eli Lilly] has not made much effort to fully develop this theory of *de facto* nationality-based discrimination. The only facts [Eli Lilly] has come close to establishing are: (i) since 1 January 2005, the pharmaceutical patents invalidated on the ground of inutility (whether through the application of the promise utility doctrine or not) have been held by foreign pharmaceutical companies, and (ii) the largest pharmaceutical companies in the world are not Canadian. The Tribunal will not infer discrimination from such a bare record. [Eli Lilly] has wholly failed to demonstrate that the promise utility doctrine discriminates against foreign patent holders.¹¹⁹

The Tribunal concluded that Eli Lilly had failed to establish the factual premise on which its allegations of arbitrariness and discrimination were based, and that, in the circumstances of this case, “the evolution of the

113. *Id.* at ¶ 423 (explaining that the Tribunal need not determine whether the promise doctrine is the only or best means of achieving the relevant public policy objectives, but solely whether the promise doctrine is rationally connected to these objectives).

114. *Id.* at ¶¶ 424–25 (arguing that all patent regimes must determine the line between speculation and invention, and there is no perfect way to draw this line, but it does not seem arbitrary to select the patent application’s filing date).

115. *Id.* at ¶ 429 (determining that if Eli Lilly’s argument applied, “the concept of arbitrariness would lose all meaning”).

116. *Id.* at ¶ 433.

117. *Id.* at ¶ 435 (noting as an example that the patenting practices of pharmaceutical companies may result in patents more susceptible to utility challenges).

118. *Id.* at ¶ 439.

119. *Id.* at ¶ 441.

Canadian legal framework relating to [Eli Lilly's] patents cannot sustain a claim of arbitrariness or discrimination going to a violation of NAFTA Articles 1105(1) or 1110(1)."¹²⁰

Based on the “loser pays” principle enshrined in Article 40(1) of the UNCITRAL Rules, the Tribunal determined that Eli Lilly would bear the costs of the arbitration, including 75 percent of Canada’s arbitration and legal fees amounting to CDN \$6.5 million; the Tribunal Members’ fees and expenses and ICSID’s fees amounting to USD \$749,697; and Eli Lilly’s own legal fees exceeding USD \$7.8 million.¹²¹

III. PUBLIC INTEREST CRITIQUES OF THE FINAL AWARD

Despite Canada’s ultimately successful defense, the Tribunal’s judgment was disappointing in several respects. First, the Tribunal stated that a judicial decision *could* form the basis of an investment claim without any denial of justice in exceptional circumstances of egregious and shocking conduct—in essence, judicial decisions are entitled to no more than considerable deference.¹²² Specifically, although it found that the invalidation of the Zyprexa and Strattera patents through application of the promise/utility doctrine “cannot form the basis of an expropriation claim under NAFTA Article 1110 or a claim for a violation of the minimum standard of treatment under NAFTA Article 1105,”¹²³ the Tribunal did not rule out the possibility of other judicial decisions forming the basis for such claims in the future. The Tribunal specifically confined its judgment to the circumstances of the *Eli Lilly* case and expressly refused to close the door on non-denial of justice claims. In doing so, the Tribunal “rejected important protection for state sovereignty” and had “no qualms about saying that an investor can attack decisions of a country’s judiciary about the meaning of its own law even in the absence of a denial of justice—thus allowing the investor to do an end run around the requirement of finality. . . .”¹²⁴

Mere deference, instead of absolute judicial sovereignty over interpretation of national law, is made even more problematic by the

120. *Id.* at ¶ 442.

121. *Id.* at ¶ 459 (summarizing the Tribunal’s findings on legal fees and reimbursement).

122. See Ho, *Inside Views*, *supra* note 3 (detailing concerns about Canada’s “win” and analyzing the effect of such decisions on investor-state tribunals such as NAFTA); Knopf, *supra* note 3 (arguing that Canada made a fundamental mistake by not raising the absence of a fundamental denial of justice as a jurisdictional challenge to Eli Lilly’s case and instead merely arguing that domestic courts must be afforded “substantial deference,” leaving the door open to future ISDS challenges to IP rulings); Howse, *supra* note 3 (calling deference a dangerous and “much too polite” standard).

123. Final Award, *supra* note 1, at ¶ 469 (dismissing Eli Lilly’s claims without further inquiry).

124. Howse, *supra* note 3 (calling deference a dangerous and “much too polite” standard).

Tribunal's assertion that judicial interpretation should progress in an incremental and predictable manner.¹²⁵ Dramatic, fundamental, or radical changes—whether accomplished by judicial interpretation or legislative or regulatory action—are highly suspect, however well-grounded in rationality, changed circumstances, or evolving public interests they may be. In this way, IP investors' frustrated expectations of regulatory stasis could lead to claims designed either to protect existing pro-IP rules or to impugn rules that better address consumer interests, including access to more affordable medicines.

Secondly, the Tribunal considered Eli Lilly's criticism of the "uniqueness" of Canada's law (relative to other jurisdictions) as a valid argument, notwithstanding the domestic flexibilities provided by NAFTA.¹²⁶ The Tribunal cited the statement, found in the 2014 and 2015 editions of the Special 301 Report of the U.S. Trade Representative, that the United States had "serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently."¹²⁷ Rather than dismiss these claims for irrelevance, the Tribunal dismissed them for insufficiency, arguing that the silence of other countries "speaks louder than the single, brief criticism contained in the USTR's Special 301 Report."¹²⁸ The implication herein, that similar criticisms received from additional parties would have swayed the Tribunal's judgment as to the "appropriateness" of allowing Canada to determine its own patentability laws, dishonors long-standing national sovereignty over domestic public health policy. The Tribunal seemed to forget the discretion afforded to sovereign nations by TRIPS to "determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice."¹²⁹

It is now well understood that neither NAFTA nor TRIPS established highly specified criteria for patentability.¹³⁰ Indeed, the references to novelty, inventive step, and industrial applicability are largely unembellished except to recognize the U.S.'s less stringent requirements

125. *See id.* (arguing that the Tribunal's decision may encourage future regulatory takings claims "by implication that the concept of 'expropriation' under NAFTA" may require the state to compensate an investor for dramatic, radical, or fundamental "jurisprudential shifts in the approach of a country's highest courts to that country's law").

126. *See Ho, Inside Views, supra* note 3 (noting that the Tribunal considered it relevant, "despite the fact that among the three NAFTA countries, only the U.S. suggested *in a single report* that Canada's law was a problem") (emphasis added).

127. Final Award, *supra* note 1, at ¶ 378.

128. *Id.*

129. TRIPS Agreement, *supra* note 4, at art. 1.1.

130. For a comprehensive overview of flexibility in international patent law, see generally Sarah R. Wasserman Rajec, *Evaluating Flexibility in International Patent Law*, 65 HASTINGS L.J. 153 (2014).

of non-obviousness and usefulness.¹³¹ There is indeed an enormous degree of heterogeneity and plasticity in statutory patentability criteria and jurisprudence internationally. TRIPS may well establish a very loosely defined harmonized minimum, but it also allows countries to have very stringent standards, as in India, or very lax standards, as in the United States, where hundreds of “evergreening,” secondary patents that extend effective periods of patent exclusivity are granted every year based on minor changes in the chemical entity, formulations, dosages, and uses.¹³²

Canada’s domestic implementation of the “industrial applicability” requirement through the promise/utility doctrine falls well within the bounds of both NAFTA and TRIPS. Yet the Tribunal failed to acknowledge sovereign discretion over domestic implementation of international IP law, instead entertaining Eli Lilly’s criticism of Canadian singularity. In addition to ignoring the flexibility in patentability criteria provided by TRIPS, the Tribunal also failed to mention that “NAFTA does not impose a uniform standard of patentability criteria, and that [Canada] has acted well within its rights under NAFTA to set its own utility requirement.”¹³³

The Tribunal’s failure to champion national sovereignty has the potential to trigger a significant chilling effect on other nations that are considering implementing the very TRIPS flexibilities that this Final Award fails to protect. Developing countries that may be considering introducing heightened standards of patentability (for example, to prevent “evergreening” and speculative patenting) may look to this case as an example of the expensive consequences that may follow. Although Canada could afford to bear over CDN \$6 million in legal fees over five years, resource-poor countries may be far less likely to implement TRIPS flexibilities for fear of incurring crippling legal costs. Disputes challenging domestic IP decisions are still in their infancy, but these initial “wins” should not lull countries into complacency.¹³⁴ Although no state has yet had to pay for TRIPS-consistent action, the decisions to date have left the door open to this possibility, and may have a serious chilling effect on the implementation of TRIPS flexibilities.¹³⁵

131. TRIPS Agreement, *supra* note 4, art. 27.1.

132. See C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, patent challenges, and effective market life in pharmaceuticals*, 31 J. HEALTH ECON. 327, 336–37 (2012) (finding that patent challenges limit the effectiveness of “evergreening” by branded firms).

133. Final Award, *supra* note 1, at ¶ 46.

134. Ho, *Inside Views*, *supra* note 3.

135. *Id.* For example, the introduction of plain packaging legislation for tobacco products in New Zealand was delayed by three years, pending the result of Philip Morris’ investor-state dispute with Australia over similar legislation. Mei Heron, *Govt confident it can send tobacco companies*

Thirdly, the Tribunal did not acknowledge the frivolity of Eli Lilly's claims, stating instead, in its allocation of costs, that Eli Lilly's claims "were not in any sense frivolous, and [Eli Lilly] pursued them in good faith."¹³⁶ The Tribunal's unwillingness to strike down allegations of "expropriation" based on rational and carefully reasoned judicial decisions invalidating state-granted patents under TRIPS-compliant laws is a disturbing reflection of the corporate bias of international investment tribunals.¹³⁷

Finally, as Sean Flynn has argued, investor-state dispute settlement of IP claims represents "a rupture in the fabric of international intellectual property law" which, for the last 130 years, has relied upon state-to-state dispute settlement due to respect for national sovereignty and the less litigious nature of inter-governmental relations.¹³⁸ Canada and Mexico and the United States as interveners argued that NAFTA does not allow an ISDS arbitral panel to consider violations of Chapter Seventeen, the IP chapter, as such disputes are left solely to state-state dispute settlement.¹³⁹ Regrettably, the Tribunal never addressed this issue,¹⁴⁰ even though Canada, the United States, and Mexico as interveners raised it.¹⁴¹ By leaving this issue unaddressed, the Tribunal indirectly contributed to the regime shifting about which scholars James Gathii and Cynthia Ho are most concerned.¹⁴² Rather than leaving the interpretation of national IP laws principally to a nation's appellate courts, and the policing of violations of TRIPS or trade agreement IP chapters to properly constituted state-state dispute resolution mechanisms, ISDS of IP-investor claims leaves interpretation of the basic architectures of

packing, RADIO NEW ZEALAND (Sept. 9, 2016, 6:45 AM), <http://www.radionz.co.nz/news/political/312892/govt-confident-it-can-send-tobacco-companies-packing>.

136. Final Award, *supra* note 1, at ¶ 455.

137. For a detailed study of corporate bias in an ISDS case, see generally Robin Broad, *Corporate Bias in the World Bank Group's International Centre for Settlement of Investment Disputes: A Case Study of a Global Mining Corporation Suing El Salvador*, 36 U. PA. J. INT'L L. 851 (2014-2015). For a more detailed critique of corporate bias in ISDS, see generally PIA EBERHARDT & CECILIA OLIVET, TYLER AMOS & NICK BUXTON, PROFITING FROM INJUSTICE: HOW ARBITRATORS, LAW FIRMS AND FINANCIERS ARE FUELING AN INVESTMENT ARBITRATION BOOM (Helen Burley ed., Corp. Europe Observatory and the Transnat'l Inst. 2014).

138. Flynn, *supra* note 11.

139. Final Award, *supra* note 1, at ¶ 226.

140. The closest the Panel came to addressing this issue was in its initial discussion of its jurisdiction where it said both that "[a] NAFTA Chapter Eleven tribunal is not a tribunal of general jurisdiction with competence to adjudicate claims of breach of other provisions of NAFTA, [and that] [w]ithout prejudice to this appreciation, the Tribunal notes . . . Section A of NAFTA Chapter Eleven does not require the Tribunal to ignore other provisions of NAFTA . . . for the purposes of assessing the claims before it." *Id.* at ¶ 101-02.

141. Final Award, *supra* note 1, at ¶ 226.

142. Gathii & Ho, *supra* note 10.

international, regional, and national IP regimes to the whims of three-member private arbitral panels with scant expertise and little fealty to prior arbitral awards or even to the determinant interpretations of IP trade rules by authoritative bodies. A built-in bias toward investor prerogatives and a probable disregard of IP's balance of interests and of a state's public health and human rights obligations will predictably lead both to significant investor awards and to a chaotic and inconsistent set of IP-investor rulings that will result in even more regulatory chill.

IV. FUTURE IMPLICATIONS: CHILLING EFFECTS REALIZED IN CANADA, COLOMBIA, AND UKRAINE

The risks of regulatory chill are of course exacerbated by general IP-maximalist pressures from the United States, the European Union, Japan, Switzerland, and other pro-pharma countries, and by extra-arbitral pressures relating to specific ISDS claims, such as those described previously concerning the *Eli Lilly v. Canada* arbitration.¹⁴³ In this regard, three instances of policy reversal based on the actuality or reality of arbitral claims are readily apparent: (1) the post-*Eli Lilly* narrowing, indeed, evisceration of Canada's promise/utility doctrine in the *AstraZeneca* case;¹⁴⁴ (2) the retreat from issuing a compulsory license in Colombia on Novartis' cancer medicine, including subsequent challenges to price controls and to the governmental architecture for considering compulsory licenses; and (3) the deregistration of a competing generic medicine in Ukraine in response to Gilead's threat to file an ISDS case challenging Ukraine's alleged failure to enforce a data exclusivity rule.

AstraZeneca's patent, which involves treatment for gastric reflux disorders,¹⁴⁵ was invalidated in lower courts¹⁴⁶ pursuant to the promise/utility doctrine upheld in the *Eli Lilly* arbitration award. However, in ruling that *AstraZeneca*'s patent was not invalid for lack of utility, Canada's Supreme Court found that the promise/utility doctrine misinterprets Canada's Patent Act by looking beyond the claims and by requiring the patent applicant to demonstrate or soundly predict all promises of usefulness made at the time of filing.¹⁴⁷

The Supreme Court reviewed the existing promise/utility doctrine, developed by the Federal Courts' jurisprudence, as requiring "the identification of promises based on a review of the entire specification,

143. See *supra* text accompanying notes 11–20 (discussing generally the impact of the *Eli Lilly* decision on past precedent regarding the promise/utility doctrine as laid out in *AstraZeneca*).

144. *AstraZeneca Canada Inc. v. Apotex, Inc.*, 2017 SCC 36.

145. *Id.* at ¶ 3.

146. *Id.* at ¶¶ 10, 12–17.

147. *Id.* at ¶¶ 44, 51.

i.e. both the claims and disclosure,” even in the absence of claim ambiguity, and that the promises identified must be supported by demonstration or sound prediction.¹⁴⁸ The Court ruled that this doctrine was “excessively onerous in two ways: (1) it determines the standard of utility that is required of a patent by reference to the promises expressed in the patent; and (2) where there are multiple expressed promises of utility, it requires that all be fulfilled for a patent to be valid.”¹⁴⁹

Noting that the utility requirement is “at the core of this appeal,” the Supreme Court reasoned that analysis regarding patentability criteria typically focuses on the claims alone and looks to the patent disclosure only when there is an ambiguity in the claims.¹⁵⁰ “The promise doctrine, by contrast, directs courts to read both the claims and the disclosure to identify potential promises, rather than the claims alone, even in an absence of ambiguity in the claims,”¹⁵¹ the Court said, and this is an incorrect interpretation of the Patent Act. The Court also justified its claim-disclosure/utility ruling by distinguishing between disclosure requirements and the utility criterion.¹⁵² While admitting that “overpromising is a mischief,”¹⁵³ the Court reasoned that such mischief should be addressed through disclosure rule consequences under Sections 27(3) and 58 of the Patent Act, rather than Section 2’s utility requirement.¹⁵⁴

Moreover, with respect to multiple claims concerning utility, the Court opined that the patent application need not provide evidence in support of all the promised utility claims at the time of filing—even a scintilla of evidence in support of one promise of utility would be enough, even if that potential use is never realized.¹⁵⁵ “The Promise Doctrine risks, as was the case here, for an otherwise useful invention to be deprived of patent protection because not every promised use was sufficiently demonstrated or soundly predicted by the filing date,” the Court said.¹⁵⁶ “Furthermore, such a consequence is antagonistic to the bargain on which patent law is based, wherein we ask inventors to give fulsome disclosure in exchange for a limited monopoly.”¹⁵⁷

In sum, the revised promise doctrine might best be called the “one

148. *Id.* at ¶ 31.

149. *Id.* at ¶ 37.

150. *Id.* at ¶ 31.

151. *Id.*

152. *Id.* at ¶¶ 38–46.

153. *Id.* at ¶ 45.

154. *Id.* at ¶ 46.

155. *Id.* at ¶ 55.

156. *Id.* at ¶ 50.

157. *Id.* at ¶ 51.

scintilla, maybe” utility doctrine. Patent examiners and Canadian courts, absent ambiguity, will assess utility only by reference to claims, even if alternative promises are made in the disclosures. Although “not *any* use will do,” any use related to the nature of the subject matter will suffice.¹⁵⁸ With respect to any one claimed use, there need be only a scintilla of utility established either by demonstration or sound prediction as of the filing date.¹⁵⁹ The Court gave assurance that patents will not be granted where uses are speculative.¹⁶⁰ Despite stating that “a scintilla of utility will do,”¹⁶¹ the Court concluded its articulation of the revised utility doctrine with this oddly contradictory statement: “Even though utility of the subject-matter is a requirement of patent validity, a patentee is not required to disclose the utility of the invention to fulfill the requirements of s. 2,” concluding instead that the inventor is not obligated in his or her disclosure of claims to describe in what way the invention is useful.¹⁶²

The Canadian Supreme Court’s decision drew swift and stunned reviews.¹⁶³ One reviewer described the Court as having succumbed to United States and Big Pharma pressures, both in the *Eli Lilly v. Canada* ISDS case and in USTR Special 301 Reports and NAFTA renegotiation objectives.¹⁶⁴ Although it is hard to discern the traces of these pressures in the text of the decision, two interveners raised objections to the lower courts’ rulings by arguing that the promise/utility doctrine was discordant

158. *Id.* at ¶ 53.

159. *Id.* at ¶ 55.

160. *Id.* at ¶¶ 56–57.

161. *Id.* at ¶ 55.

162. *Id.* at ¶ 58.

163. Baker, *supra* note 25; see Natalie Olivo, *Canadian Justices Balk At ‘Promise Doctrine’ In Drug IP Row*, LAW360 (June 30, 2017, 6:15 PM), <https://www.law360.com/articles/940288/canadian-justices-balk-at-promise-doctrine-in-drug-ip-row> (discussing how the Canadian Supreme Court’s ruling in *AstraZeneca* weakened the “promise doctrine”); see also Ed Silverman, *Pharma scores a big win with a Canadian ruling on patent law*, PHARMALOT STAT+ (June 30, 2017) https://www.statnews.com/pharmalot/2017/06/30/canada-patents-astrazeneca-nafta/?s_campaign=stat.rss (reviewing the Canadian Supreme Court’s ruling on patent law). The U.S. Chamber of Commerce responded promptly with praise:

We welcome today’s ruling that upholds AstraZeneca’s patent rights and rebuffs Canada’s so-called promise doctrine. . . . The doctrine’s extremely restrictive approach has created harmful instability and uncertainty for medical innovators by making it difficult to obtain or defend a life science patent in Canada. Today, the Supreme Court has begun to restore much-needed clarity and confidence that biopharmaceutical innovators will be afforded equal protections under the law. This ruling sends an important signal that Canada is open for the business of innovation.

Press Release, U.S. Dep’t of Commerce, U.S. Chamber of Commerce Applauds Supreme Court’s Ruling on Canada’s “Promise Doctrine” (June 30, 2017, 11:30 AM), <https://www.uschamber.com/press-release/us-chamber-applauds-supreme-court-ruling-canadas-promise-doctrine>.

164. Baker, *supra* note 25.

with Canada's international obligations under NAFTA and TRIPS, and footnote 1 to the opinion referenced the pending *Eli Lilly v. Canada* ISDS case.¹⁶⁵ The interveners' argument was not addressed by the Court, but it is obvious that the Supreme Court was aware of the *Eli Lilly* case and that it had been decided at the time of its decision.

Two other IP-related investor disputes demonstrate that the vulnerability of developing countries to investor-state arbitration over pharmaceutical IPR decisions or policies is far from hypothetical.¹⁶⁶ Chronic myeloid leukemia medication, imatinib, marketed as Glivec by Swiss patent holder Novartis, retails for USD \$15,161 per year in Colombia, nearly double its gross national income per capita.¹⁶⁷ Although Novartis holds a monopoly over the drug in Colombia until 2018, the issuance of a compulsory license by the Colombian government could introduce generic competition and extend the lives of thousands of patients who cannot afford the treatment at its current price. In November 2014, civil society groups in Colombia¹⁶⁸ petitioned the Colombian Minister of Health, Alejandro Gaviria Uribe, to issue a compulsory license on Glivec. The Minister's deliberations, however, were met with strong international hostility. The Colombian Ministry of Health received communications from Novartis, the Swiss Confederation,¹⁶⁹ and from U.S. embassy officials (after meeting with the USTR and the Senate Finance Committee) that alleged violations of international law, threatened dispute settlement claims, and warned that a compulsory license on Glivec would jeopardize Colombian interests in the United

165. *AstraZeneca Canada Inc. v. Apotex, Inc.*, 2017 SCC 36 ¶ 21, n.1.

166. Ho, *Inside Views*, *supra* note 3.

167. See *Background FAQ on Glivec (imatinib) compulsory license in Colombia*, KNOWLEDGE ECOLOGY INTERNATIONAL (2016), <http://keionline.org/colombia-imatinib-FAQ>.

168. These groups include: IFARMA, Misión Salud, and CIMUN. *Id.*

169. On May 18, 2015, on the margins of the 68th World Health Assembly in Geneva, the Swiss State Secretary and Director of the Federal Office of Public Health, Pascal Strupler, confronted Colombia's Minister of Health, Alejandro Gaviria, in a bilateral meeting and presented Switzerland's concerns regarding Colombia's efforts to reduce the price of Glivec. Following this meeting, Ambassador Livia Leu, the Swiss Head of Bilateral Economic Relations and Delegate of the Federal Council for Trade Agreements, wrote to Colombia's Ministry of Health and Social Protection explicitly referring to the Novartis patent, and asserted that compulsory licenses were tantamount to an "expropriation" of the patent owner and would deter future research and development of innovative medicines that might benefit Colombia. Andrew Goldman & Thiru Balasubramania, *Switzerland pressures Colombia to deny compulsory license on imatinib*, KNOWLEDGE ECOLOGY INTERNATIONAL (Aug. 17, 2015), <https://www.keionline.org/node/2312>.

States, including funding for the Colombian peace process.¹⁷⁰ In April 2016, Novartis filed a notice of dispute under the Colombia-Switzerland bilateral investment treaty (“BIT”), indicating that it would launch an investor-state dispute against Colombia.¹⁷¹

In a reversal of policy, arguably as a result of the noticed ISDS claim, in June 2016 Mr. Gaviria issued a Declaration of Public Interest, compelling the National Price Pharmaceutical Commission (“NPPC”) to impose price controls on Glivec instead of issuing a compulsory license.¹⁷² In October 2016, the NPPC declared that Glivec would be subject to a price control of 206 pesos per milligram, a 40 percent reduction from its current price.¹⁷³ The Pharmaceutical Research and Manufacturers of America (“PhRMA”) criticized the decision as a “harmful global precedent,”¹⁷⁴ while the U.S. Chamber of Commerce urged Colombia to abandon this “destructive” course of action.¹⁷⁵ Meanwhile, the effectiveness of the price control remains unclear. The Technical Committee for the Colombian Ministry of Health has emphasized that price controls cannot match the price reductions achieved by generic competition.¹⁷⁶ Moreover, the price control *relies on*

170. See Letter from Andrés Flórez, Embassy of Colombia in Washington, D.C., to María Ángela Holguín, Minister of External Affairs (Apr. 27, 2016) (describing pressure from the U.S. Senate Finance and the USTR over Colombian efforts to grant a compulsory license on the Novartis cancer drug Glivec), translated in April 27, 2016 Letter from Colombian Embassy regarding Senate Finance, USTR pressure on Novartis compulsory license, KNOWLEDGE ECOLOGY INT’L (Apr. 27, 2016), <https://www.keionline.org/node/2504>. See also Letter from the Embassy of Colombia in Washington, D.C., to Alejandro Gaviria, Colombian Minister of Health (Apr. 28, 2016) (reporting on a meeting between embassy officials and Everett Eissenstat, the Chief International Trade Counsel for the U.S. Senate Committee on Finance), translated in April 28, 2016 letter regarding US Senate Finance threats over compulsory license on Novartis cancer drug patents, KNOWLEDGE ECOLOGY INT’L (Apr. 28, 2016), <https://www.keionline.org/node/2505>.

171. See Caroline Simson, *Novartis Knocks Colombia Over Leukemia Drug Price Control*, LAW360 (Dec. 1, 2016 7:22 PM), <http://www.law360.com/articles/868104> (explaining that Novartis filed a notice of suit against Colombia).

172. Lisa L. Mueller et al., *Intellectual Property: Review of Compulsory Licenses in Colombia*, NAT’L L. REV. (Oct. 20, 2016), <https://www.natlawreview.com/article/intellectual-property-review-compulsory-licenses-colombia>.

173. Redaccion Salud, *Imatinib, medicamento para tratar el cáncer, costará \$206 por miligramo [Imatinib, a drug to treat cancer, will cost \$206 per milligram]*, EL ESPECTADOR (Oct. 21, 2016 10:44 AM), <http://www.elespectador.com/noticias/salud/imatinib-medicamento-tratar-el-cancer-costara-206-milig-articulo-661514>.

174. Press Release, Pharmaceutical Research and Manufacturers of America (PhRMA), PhRMA Response to Colombia’s Decision to Enforce a Declaration of Public Interest (Sept. 14, 2016), <http://www.phrma.org/press-release/phrma-response-to-colombias-decision-to-enforce-a-declaration-of-public-interest>.

175. Press Release, U.S. Dep’t of Commerce, U.S. Chamber Condemns Colombian Health Minister’s Move Toward Stripping Privately-Held Patents (June 9, 2016 7:15 PM), <https://www.uschamber.com/press-release/us-chamber-condemns-colombian-health-minister-s-move-toward-stripping-privately-held>.

176. According to The Report of the Ministry of Health’s Technical Committee for the Public

Novartis' willingness to continue to supply Glivec at the new price, and there are already indications that it will not.

Throughout this entire process in Colombia, Novartis has played a leading role in efforts to thwart Colombia's lawful use of a TRIPS-compliant compulsory license or a price-control measure. In addition to noticing its intent to institute an ISDS case, Novartis challenged Colombia's public health/CL declaration, filed two Colombia Supreme Court challenges to its price-control measures, and recommended altering Colombia's Declaration of Public Interest procedures to increase the role of the Ministry of Trade in such declarations.¹⁷⁷ In response to U.S. and industry pressure, the government of Colombia has apparently decided that an order to proceed with a Declaration of Public Interest must now be based on consultations with the Ministry of Trade and the National Planning Department; in addition, the new policy has eliminated any option, like price controls, other than a compulsory license to prevent public interest harm.¹⁷⁸

Meanwhile, in Ukraine, the threat of an USD \$800 million ISDS claim by U.S. pharmaceutical firm Gilead Sciences, Inc., was effective in compelling the Ukrainian government to deregister a generic drug in competition with Gilead's prohibitively expensive hepatitis C medication sofosbuvir.¹⁷⁹ Unlike in the Canadian and Colombian cases, this ISDS

Interest Declaration:

[P]rices of Glivec, despite being subject to controls, are still very high compared with generics, which have been progressively leaving the market with the grant of the patent. Direct price controls . . . will never match the results achieved by competition in the market. Without a doubt, the best way to reduce prices is competition.

Ministerio de Salud y Proteccion Social Comité Técnico Declaratoria De Interés Público [The Report of the Ministry of Health's Technical Committee for the Public Interest Declaration] (Feb. 24, 2016) (on file with author). The price reductions facilitated by the introduction of generic competition would represent savings of around USD \$15 million per year for the Colombian Ministry of Health). *Id.*

177. See *Compulsory licensing in Colombia: Leaked documents show aggressive lobbying by Novartis*, PUBLIC EYE (Apr. 12, 2017), https://www.publiceye.ch/en/media/press-release/compulsory_licensing_in_colombia_leaked_documents_show_aggressive_lobbying_by_novartis/ (discussing pharma giants that are threatening Colombia with legal suit); see also Haytham Hashem, *Pharmaceutical Giant Threatens to Drag Government Before Corporate Tribunal for Trying to Make Essential Cancer Drug Accessible*, PUBLIC CITIZEN EYE ON TRADE BLOG (Mar. 24, 2017), <http://citizen.typepad.com/eyesontrade/2017/03/> (explaining the legal threats Colombia is facing for creating an inaccessible market for essential cancer drugs).

178. En Misión Salud, *Ministerio de comercio firma decreto que modifica procedimiento de declaración de interés público [Ministry of Commerce signs decree amending procedure declaration of public interest]* (Apr. 27, 2017), <http://www.mision-salud.org/actualidad/ministerio-de-comercio-firma-decreto-que-modifica-procedimiento-de-declaracion-de-interes-publico/>.

179. Luke E. Peterson & Zoe Williams, *Gilead Pharma corp withdraws investment arbitration after Ukraine agrees to settlement of dispute over monopoly rights to market anti-viral drug*, ISDS PLATFORM (Mar. 16, 2017), <http://isds.bilaterals.org/?gilead-pharma-corp-withdraws>.

case did not involve patent related issues—instead it rested on a TRIPS-plus data exclusivity claim.¹⁸⁰ Gilead had not filed a primary patent application on sofosbuvir, though it had filed a weak secondary patent that had been challenged repeatedly by civil society organizations in Ukraine.¹⁸¹ Gilead’s sofosbuvir was registered in Ukraine in mid-2015 and was entitled to data exclusivity protections under Ukrainian law.¹⁸² Nonetheless, a rival generic equivalent from an Egyptian manufacturer, Europharma International, was registered in November 2015.¹⁸³ Gilead filed a lawsuit against the government demanding deregistration of the competing generic, which Gilead lost at the trial court level and thereafter appealed.¹⁸⁴

During the pendency of that lawsuit, Gilead notified Ukraine of the existence of an investment dispute, believed to have been filed secretly under the U.S.-Ukraine Bilateral Investment Treaty.¹⁸⁵ Following the ISDS threat, the Ukrainian government approved a settlement agreement with Gilead on January 25, 2017, which promised a discounted price for sofosbuvir in exchange for the deregistration of the local generic drug, Grateziano, which was registered by the Ministry of Health in November 2015.¹⁸⁶ As a result, Ukraine’s Health Ministry issued an order on February 22, 2017, to cancel the registration of generic sofosbuvir and exclude it from the State Register of Medicinal Products of Ukraine in exchange for a significant price reduction of sofosbuvir to approximately

180. See Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J. L. & MED. 303, 315–16 (2008) (explaining that Ukraine adopted data exclusivity in 2011 via Law No. 3998-VI, introducing new rules to the Law of Ukraine on Pharmaceutical Products No. 123/96-BP, “3+2+1” DE scheme: three years data exclusivity, two years market exclusivity, opportunity of prolongation up to one year, in case a new indication is discovered).

181. See generally Mykyta Trofymenko, *Civil society struggle for affordable sofosbuvir in Ukraine*, DON’T TRADE OUR LIVES AWAY BLOG (Aug. 2016), <https://dontradeourlivesaway.files.wordpress.com/2016/08/civil-society-struggle-for-affordable-sofosbuvir-in-ukraine.pdf> (discussing Gilead’s patent applications).

182. Peterson & Williams, *supra* note 179.

183. *Id.*

184. *Id.*

185. *Id.*; Treaty Concerning the Encouragement and Reciprocal Protection of Investment, Ukr.-U.S., Mar. 4, 1994, S. TREATY DOC. NO. 103-37 <http://investmentpolicyhub.unctad.org/Download/TreatyFile/2366> (Art. VI of the U.S.-Ukraine BIT allows ISDS).

186. Peterson & Williams, *supra* note 179. Текст документа: “Про підписання Міжнародної угоди між Україною та компанією “Гілеад Сайєнсиз, Інк.” № 45-р — редакція від [On the signing of the Global Agreement between Ukraine and the company “Gilead Sciences, Inc.”], Order No. 45-p, Jan. 25, 2017, <http://www.kmu.gov.ua/control/uk/cardnpd?docid=249699210> (the decision regarding this settlement is published on the Ukrainian government website in the Ukrainian language only).

USD \$750 per course of treatment.¹⁸⁷

All three of these cases involve multiple forms of pressure to reverse lawful use of TRIPS flexibilities. In each instance, pressure exerted through domestic litigation, backdoor lobbying, and government pressure from trade partners was supplemented by IP-related pharmaceutical ISDS claims. In each instance, it is impossible to assert with certainty that ISDS alone was the catalyst for the government's reversal of policy. Yet it is possible to infer that the ISDS cases, pending and even decided, have been factors leading to policy deterrence. Moreover, in each instance, the IP-related claims were not made by governments via state-state dispute settlement, but were instead conceived and initiated by private foreign companies. In the case of *Eli Lilly*, one can also trace the evolution of U.S. Special 301 pressure directly to the earlier filing of an ISDS case. The United States had not complained about Canada's promise/utility doctrine until the case was filed.¹⁸⁸

Rather, the *Eli Lilly-Canada*, *Novartis-Colombia*, and *Gilead-Ukraine* ISDS claims demonstrate that national governments are increasingly confronting a shrinking domestic policy space, hemmed in by the chilling effect of investor-state arbitration on domestic health measures.¹⁸⁹ Foreign investors can bring IP-based claims against *any* government measure that adversely affects corporate profits, prompting arbitrations challenging a wide range of TRIPS-compliant measures, including robust patentability standards, plain packaging legislation,¹⁹⁰ and drug price negotiations. *Eli Lilly*, *Novartis*, and *Gilead's* decisions to file or threaten

187. See *Ukraine Signs Amicable Agreement with U.S. Gilead Biopharmaceutical Producer on Hepatitis C Drug*, INTERFAX-UKRAINE (Feb. 23, 2017), <http://open4business.com.ua/ukraine-signs-amicable-agreement-u-s-gilead-biopharmaceutical-producer-hepatitis-c-drug/>.

188. Ambassador Ronald Kirk, OFFICE OF THE U.S. TRADE REPRESENTATIVE 2011 SPECIAL REPORT 301 (Apr. 2011) (The USTR's 2011 Special 301 Report, although published prior to *Eli Lilly's* launch of the investor-state dispute in November 2012, placed Canada on the Priority Watch List but contained no reference to the promise/utility doctrine.).

189. Lawrence R. Helfer, *Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines*, in TRANSNATIONAL LEGAL ORDER 311 (Terrence Halliday & Gregory Shaffer eds., Cambridge Univ. Press, New York City 2015), http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=6119&context=faculty_scholarship.

190. See *Phillip Morris Asia Ltd. v. Commonwealth of Australia*, PCA Case No. 2012-12, Award on Jurisdiction and Admissibility (Dec. 17, 2015); Tom Miles & Martinne Geller, *Australia wins landmark WTO tobacco packaging case*, REUTERS (May 5, 2017) (discussing WTO upholding an Australian law on restrictive tobacco packing), <http://www.reuters.com/article/us-wto-tobacco-australia-idUSKBN1801S9>. Although Australia was ultimately successful in defending its plain packaging laws in both investor-state arbitrations, these cases have had a significant chilling effect on plain packaging policies in other countries, particularly those which are unable to afford the costs of ISDS. See Lukasz Gruszczynski, *Australian Plain Packaging Law, International Litigations and Regulatory Chilling Effect*, 5 EUR. J. RISK REG. 242, 243-44 (2014) (explaining the precedential impact of the Australian tobacco packaging rule).

to file ISDS claims against the Canadian, Colombian, and Ukrainian governments reflect the extraordinary power given to corporations to challenge national sovereignty over both domestic IP policy and health, and to promote the private arbitration of public interests.

CONCLUSION

The struggle against acquisition, preservation, and extension of pharmaceutical monopolies is threatened in many fora, though the common extraneous forces are the combined might of pharmaceutical multinationals and powerful, affluent governments at their beck and call. ISDS is a formidable arrow in industry's quiver, but it is by no means the sole mechanism by which companies seek to forestall competition that might make medicines more affordable for all. In Canada's case, a narrow and somewhat hollow victory was eviscerated by parallel court challenges and intense pressure from Canada's major trading partner, the United States.

There is something particularly perverse about bypassing domestic courts and using private arbitration to challenge efforts to limit monopolies granted by sovereign states. In truly egregious cases of foul play against foreign investments, one might expect investment treaty parties to bring claims where success is highly likely. But the extra profits arising from exclusive rights—in many instances counted in billions of dollars—give perverse incentives to right-holders to advance spurious and marginal claims, hoping that at least one pellet in the shotgun blast will capture the attention of elite lawyers who make a very comfortable living promoting the expansion of ISDS claims. The growing number of ISDS cases based on IP claims is troubling indeed, as is their *in terrorem* effect.

Proponents of affordable access to life-enhancing and life-saving medicines must become wiler and better resourced. Although significant academic and activist attention was paid to the *Eli Lilly v. Canada* ISDS case, much less was paid to *AstraZeneca Canada Inc. v. Apotex Inc.* as it wound its way through the Canadian courts. Likewise, less attention was paid to overt and covert pressures that were mounted from abroad against the promise/utility doctrine and Canada's temerity to adopt a patentability criterion less forgiving than the U.S.'s. Even worse, the ISDS IP blockbuster is playing in multiple venues, making it that much harder for opponents to fight on various fronts simultaneously. It is for these reasons that the authors once again recommend that ISDS provisions be removed or rewritten to prevent the possibility of bringing IP-related claims.¹⁹¹

191. Baker & Geddes, *Corporate Power Unbound*, *supra* note 10, at 58–59.