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Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions

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SOVEREIGNTY UNDER SIEGE: CORPORATE CHALLENGES TO DOMESTIC INTELLECTUAL PROPERTY DECISIONS

Cynthia M. Ho[†]

ABSTRACT

Countries face a new threat that strikes at their ability to balance protection of intellectual property rights against other priorities, such as public health. They may have to pay substantial compensation to companies that dislike domestic intellectual property laws. This threat is much more significant than the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), a landmark international agreement concluded twenty years ago, that for the first time required all countries to provide “minimum” levels of intellectual property rights; before that time, countries were not obligated to provide any such rights at all. Since the conclusion of TRIPS, policymakers and scholars have strived to preserve local flexibilities to consider domestic policies, such as public health. However, those flexibilities may quickly evaporate if companies can bring claims against countries for compromising private investments under so-called “investor-state arbitration” claims.

This is not a theoretical problem—Eli Lilly is currently seeking \$500 million in compensation from Canada because Canadian courts invalidated two of its patents under prevailing law. In addition, there are unique issues raised by Eli Lilly’s claim that transcend broader concerns raised by scholars and commentators concerning investor-state disputes. In particular, if Eli Lilly’s claim succeeds, it will disrupt internationally accepted norms that permit countries to have different standards of protection. This Article provides a detailed analysis of Eli Lilly’s case of first impression. In so doing, the Article both explains why an arbitration tribunal should reject Eli Lilly’s claims, and predicts the likely impending threats to domestic regulation of public health that intersect with the interests of pharmaceutical companies. This Article ultimately proposes specific language to incorporate in pending agreements to forestall such predicted harms.

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TABLE OF CONTENTS

I.	INTRODUCTION	215
I.	BACKGROUND	225
A.	DOMESTIC PATENT LAW AND POLICY	225
B.	THE INTERNATIONAL LANDSCAPE: IP AND FOREIGN INVESTMENTS	227
1.	<i>Intellectual Property: Territoriality and Treaties</i>	228
2.	<i>International Agreements Governing Foreign Direct Investments and Providing Investor-State Disputes</i>	231
C.	ELI LILLY'S CASE.....	236
II.	REVOCATION OF INTELLECTUAL PROPERTY RIGHTS SHOULD NOT BE A BREACH OF INVESTMENT OBLIGATIONS	242
A.	CANCELED INTELLECTUAL PROPERTY RIGHTS SHOULD NOT BE A COVERED INVESTMENT THAT WOULD ENABLE AN INVESTOR-STATE DISPUTE	243
1.	<i>Intellectual Property is Different from Real Property</i>	243
2.	<i>Canceled Intellectual Property Should Be Excluded from Investment Agreements Based on Policy Grounds</i>	246
a)	International Agreements Permit Nations to Decide on the Scope of Intellectual Property Rights; Investment Arbitrations Should Not Disrupt This Norm	247
b)	Domestic Policy Underlying Intellectual Property Supports Deferring to States	252
c)	Considering Intellectual Property an Investment Does Not Foster Traditional Policy Justifying Investor-State Disputes.....	255
B.	INVALIDATION OF PATENT RIGHTS SHOULD NOT CONSTITUTE EXPROPRIATION	258
1.	<i>Canada's Actions May Be Exempt from an Expropriation Claim</i>	259
2.	<i>Canada Could Be Found to Not Have Expropriated Eli Lilly's Patents</i>	263
a)	Canada Should Not Be Found to Have Directly Expropriated Eli Lilly's Patents	263
b)	Canada Should Not Be Found to Have Indirectly Expropriated Eli Lilly's Patents	264
C.	INVALIDATION OF PATENT RIGHTS SHOULD NOT CONSTITUTE A VIOLATION OF THE FAIR AND EQUITABLE TREATMENT STANDARD.....	272

1.	<i>Eli Lilly Has No Legitimate Expectation that Common Law Interpretations Will Not Change</i>	276
2.	<i>An Issued Patent Is Not a State Representation of Permanent Validity That Can Be Justifiably Relied On and Must Be Balanced against State Interests</i>	278
a)	A Patent Is Not a State Representation of Guaranteed Validity.....	279
b)	There Has Been No Negative Reliance upon a State Representation	281
c)	Eli Lilly Has No Legitimate Expectation That Outweighs Canada's Interests	282
III. BEYOND ELI LILLY'S CASE: PENDING PROBLEMS AND HOW TO ADDRESS THEM		283
A.	PUBLIC HEALTH ISSUES IN DANGER OF DISRUPTION.....	283
1.	<i>Patentability Standards and Compulsory Licenses</i>	283
2.	<i>Compulsory Licenses</i>	285
3.	<i>Domestic Regulation of Clinical Data</i>	289
a)	Countries That Do Not Provide "Data Exclusivity" Will Likely Be Challenged	289
b)	Domestic Data Transparency Requirements Are Vulnerable to Challenge	293
B.	PROPOSALS TO PRESERVE FLEXIBILITY UNDER TRIPS.....	297
1.	<i>Exclude Intellectual Property from Investor-State Disputes</i>	298
2.	<i>Limit the Scope of Investment Claims Based on International Agreements Such as TRIPS</i>	300
a)	Limit Expropriation Claims.....	300
b)	Limit Fair and Equitable Treatment Claims	302
IV. CONCLUSION		303

I. INTRODUCTION

Is a company entitled to compensation from a country that declines to provide that company an intellectual property right? Eli Lilly thinks so. Eli Lilly is seeking \$500 million from Canada pursuant to an international agreement that permits foreign—but not domestic—investors to bring “investor-state arbitration” claims before a panel of private arbitrators against countries that interfere with its “investments.”¹ This is the first time a company has initiated an investor-state arbitration to challenge a domestic patent law that arguably complies with international agreements governing patents. In particular, Eli Lilly claims that two of its patents were

1. Alternatively, these are referred to as investor-state dispute settlements (“ISDS”).

investments, and that Canada unduly interfered with these investments when the country's courts invalidated the patents for failing to meet a Canadian patentability requirement.²

Eli Lilly's demand for substantial financial compensation discourages countries from fine-tuning their patent laws, even when domestic laws would comply with separate international agreements concerning intellectual property. International agreements that require protection of patents permit some domestic flexibility to promote social policies other than innovation, such as access to lower-cost medicine. However, when viewed in the broader historical context, the flexibility is in fact significantly limited and further underscores why investor-state disputes pose a particularly significant threat to sovereign rights to protect traditional domestic goals, such as public health. To understand the chilling effect, a brief background of the most important international agreement governing intellectual property and its significance follows. In 1994, over one hundred and twenty countries agreed for the first time to provide "minimum" standards of patent protection pursuant to the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").³ This was a major change for many countries. Before TRIPS, some countries were reluctant to grant patents on drugs because such patents would inevitably result in higher costs and less access to affordable medicine.⁴ For example, some only permitted inventors to patent methods of

2. Eli Lilly & Co. v. Canada, Notice of Arbitration (NAFTA/UNCITRAL Arb. Trib. Sept. 12, 2013) [hereinafter Eli Lilly Notice of Arbitration].

3. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS]; *The 128 Countries That Had Signed GATT by 1994*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/gattmem_e.htm. However, WTO member countries that the UN designates Least Developed Countries do not need to provide patent protection on drugs until at least 2016. Decision of the Council for TRIPS of June 27 2002, *Extension of the Transition Period Under Article 77.1 of the Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, para. 1, IP/C/25 (July 1, 2002). However, there are pending proposals for the WTO to further extend this timeline. E.g., Request for an Extension of the Transitional Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members With Respect to Pharmaceutical Products and for Waivers from the Obligation of Articles 70.8 and 70.9 of the TRIPS Agreement, *Communication from Bangladesh on behalf of the LDC Group*, IP/C/W/605 (Feb. 23, 2015).

4. E.g., SUDIP CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* 59 (2005). Indeed, Switzerland, home to major multinational pharmaceutical companies such as Novartis, only patented drug products in the late 1970s. PATENTVERORDNUNG [PatV], Patent Regulation [PatV] Oct. 19, 1977, SR 232.141 (Switz.). The Swiss Constitution originally barred any patents on drugs and only later were patents permitted on chemical processes. See, e.g., MICHELE BOLDRIN & DAVID K. LEVINE, *AGAINST INTELLECTUAL MONOPOLY* 216 (2008).

making drugs, and not the drugs themselves, to ensure that drugs would not be subject to a patent premium.⁵ After centuries of limited patent protection of drugs, most countries must now provide patents on drugs pursuant to TRIPS. However, TRIPS notably only requires minimum, but not uniform, standards of protection, such that countries still have some flexibility to tailor patent standards to their respective interests.⁶ Since the conclusion of TRIPS, scholars and policymakers have recommended that developing countries with limited resources embrace TRIPS flexibilities to ensure that citizens in these countries are not unduly harmed by the inevitably higher cost of patented drugs.⁷ Although some developing countries recently considered modifying their laws to take advantage of these flexibilities, they may now have second thoughts—especially if the arbitration tribunal finds in Eli Lilly’s favor.⁸

Eli Lilly’s challenge impacts countries at a critical juncture. For more than a decade, the pharmaceutical industry has suffered from an innovation crisis in conjunction with the expiration of patents on highly profitable drugs, resulting in a struggle to sustain revenue.⁹ In response, the industry has increasingly patented drugs that are merely minor variations of existing drugs

5. After all, if only one company could make a drug, that company would likely charge high prices. On the other hand, if multiple companies can make the same drug, albeit with different methods, that should cause competition that reduces drug costs.

6. TRIPS, *supra* note 3, art. 1; *see also infra* Subsection II.B.1 (discussing flexibility under TRIPS).

7. *See infra* notes 150, 157.

8. *See infra* notes 149–50 and accompanying text (discussing Brazil and South Africa).

9. *E.g.*, PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., REPORT TO THE PRESIDENT ON PROPELLING INNOVATION IN DRUG DISCOVERY, DEVELOPMENT, AND EVALUATION 9–10 (2012); Fabio Pammolli et al., *The Productivity Crisis in Pharmaceutical R&D*, 10 NATURE REVIEWS DRUG DISCOVERY 428, 429 (2011); Charlotte Harrison, *The Patent Cliff Steepens*, 10 NATURE REVIEWS DRUG DISCOVERY 12, 12–13 (2011); Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. TIMES, Mar. 18, 2013, at A1. Although some have contested that there is no innovation crisis, they are outliers. *See, e.g.*, Donald W. Light & Joel R. Lexchin, *Pharmaceutical Research and Development: What Do We Get for All That Money?*, BRIT. MED. J., Aug. 7, 2012, at 1 (claiming the innovation crisis is a myth used as a ploy to get government benefit, but nonetheless arguing that there is a crisis with respect to an inadequate number of new drugs that represent a true therapeutic advance); Bernard Munos, *Lessons from 60 Years of Pharmaceutical Innovation*, 8 NATURE REVIEWS DRUG DISCOVERY 959, 959–60 (2009) (concluding no decline in productivity, using an unduly restrictive data set). Indeed, many have noted that innovation has been stagnant for years. *E.g.*, Jeff Hewitt et al., *Beyond the Shadow of a Drought: The Need for a New Mindset in Pharma R&D*, OLIVER WYMAN 1, 3–4 (2011), http://www.oliverwyman.com/insights/publications/2011/nov/beyond-the-shadow-of-a-drought-the-need-for-a-new-mindset-in-ph.html#.VEP2e_nF90A; *Measuring the Return From Innovation: Is R&D Earning its Investment?*, DELOITTE 1, 9 (2011), https://www.deloitte.com/assets/Dcom-Poland/Local%20Assets/Documents/Raporty,%20badania,%20rankingi/pl_raport_chemiczny_2011.pdf.

and that offer no significant improvement in treatment.¹⁰ Even though these newer drugs may not be a substantial improvement over older drugs, patent protection permits companies to charge a premium.¹¹ In one extreme example, Sanofi introduced a new cancer drug at \$11,000 a month—over twice the cost of existing drugs—even though it was not more effective.¹² Given the financial constraints many nations face, providing patents on drugs of minimal therapeutic value seems especially questionable.

Although there is generally no market for expensive new products that are not a significant improvement, the pharmaceutical market is unique. Consumers generally lack expertise to assess whether new products are better, such that advertising can be particularly influential. In addition, although most patented drugs are drugs prescribed by doctors with expertise to understand the value of these drugs, their ability to effectively determine whether a new drug is worthwhile is still compromised. Doctors generally make decisions based on data by self-interested drug companies since no independent data concerning the value of a new drug generally exists. At times, the company data concerning an “improvement” is later discovered to be unsubstantiated.¹³ In addition, doctors are also influenced by

10. See, e.g., EUR. COMM’N DIR.-GEN. FOR COMPETITION, PHARMACEUTICAL SECTOR INQUIRY: FINAL REPORT 33, 351–65 (2009) [hereinafter EC PHARMACEUTICAL SECTOR INQUIRY]; JOHN R. THOMAS, PATENT EVERGREENING: ISSUES IN INNOVATION AND COMPETITION, CONGRESSIONAL RESEARCH SERVICE (2009); CHAN PARK ET AL., USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA: AN ANALYSIS OF PATENT, COMPETITION AND MEDICINES LAW, UNITED NATIONS DEVELOPMENT PROGRAMME 42 (2013). Although incremental innovation is common in all industries, what happens in the pharmaceutical industry is likely unique. The practice of patenting follow-on drugs is done in combination with substantial and usually successful marketing to consumers and doctors to ‘switch’ to a newly patented drug immediately before expiration of the patent for the first drug. E.g., EC PHARMACEUTICAL SECTOR INQUIRY, *supra* note 10, at 351–52. Although manufacturers of other new products, such as consumer electronics, may also market new products heavily, consumers generally cannot effectively evaluate whether a new drug is worthwhile; in addition, doctors often decide on drugs, yet are vulnerable to advertising even though they may not be conscious of this.

11. Not only can patent holders charge a premium, but they can increase the premium at any time during the patent term. This seems to be more of a problem in recent years. E.g., Robert Langreth, *Big Pharma’s Favorite Prescription: Higher Prices*, BLOOMBERG BUSINESSWEEK, May 8, 2014.

12. E.g., Peter B. Bach et al., *In Cancer Care, Cost Matters*, N.Y. TIMES, Oct. 14, 2012, at A25; see also Stephen S. Hall, *The Cost of Living*, N.Y. MAG. (Oct. 20, 2013), <http://nymag.com/news/features/cancer-drugs-2013-10/>.

13. E.g., Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 502–05 (2014).

pharmaceutical marketing.¹⁴ Given these issues, permitting minimally improved drugs to be patentable is problematic. Accordingly, countries should have the ability to tailor their patent laws to avoid expending resources on drugs of questionable value. Though they technically retain the right to modify domestic patent laws consistent with TRIPS, countries may consider the threat of investor-state litigation pursuant to investor-state arbitration agreements to essentially eliminate this option.

Although Eli Lilly's claim is one of first impression, it actually contributes to a broader trend. Companies are increasingly challenging domestic decisions pursuant to bilateral and multilateral agreements that provide protection to foreign investors and permit them to bring investor-state disputes. For example, investors filed only one dispute in 1982, over fifty new cases in 2012, and today there are currently five hundred claims pending in over fifty countries.¹⁵ Many have noted that such provisions threaten the ability of nations to regulate in areas of traditional domestic competence such as environmental law and public health¹⁶ because the financial stakes are often substantial—there are currently over one hundred pending actions worth more than \$1 billion each.¹⁷ Against this backdrop, Eli Lilly's suit is arguably the latest expansion of investor claims that challenge domestic laws. Moreover, many more suits challenging domestic intellectual property decisions may follow.¹⁸ Even before Eli Lilly brought suit, the multinational law firm Jones Day published a report proclaiming that investment treaty protection was “a new way forward” for multinational pharmaceutical

14. Although physicians recognize this problem, they seem to always assume that this is only a problem for *other* physicians, but that they themselves are immune from this phenomenon. *E.g.*, *id.* at 503–04.

15. U.N. Conference on Trade & Dev., *Recent Developments in Investor-State Dispute Settlement (ISDS): Updated for the Multilateral Dialogue on Investment*, at 2–3, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/3/REV (May 28–29, 2013) [hereinafter UNCTAD, *Recent Developments*].

16. *See, e.g.*, Stephen J. Byrnes, *Balancing Investor Rights and Environmental Protection in Investor-State Dispute Settlement Under CAFTA: Lessons from the NAFTA Legitimacy Crisis*, 8 U.C. DAVIS BUS. L.J. 102, 109–112 (2007); Samrat Ganguly, Note, *The Investor-State Dispute Mechanism (ISDM) and a Sovereign's Power to Protect Public Health*, 38 COLUM. J. TRANSNAT'L L. 113, 116, 123–26 (1999); Jane Kelsey & Lori Wallach, “Investor-State” Disputes in Trade Pact Threaten Fundamental Principles of National Judicial Systems, PUB. CITIZEN 3 (Apr. 2012), <http://www.citizen.org/documents/isds-domestic-legal-process-background-brief.pdf>.

17. *Arbitration Scorecard 2013*, AM. LAW. (June 24, 2013), <http://www.americanlawyer.com/id=1202608198051/Arbitration-Scorecard-2013>; *see also* Shawn Donnan, *Disputes Clause Heaps Pressure on Trade Deal*, FIN. TIMES (LONDON), Mar. 11, 2014 (noting that use has soared in recent years).

18. *E.g.*, Brian King & Viren Mascarenhas, *Investment Treaty Protection for IP Rights, PATENT, TRADEMARK & COPYRIGHT L. DAILY*, Aug. 5, 2013; Sherman Kahn, *Will Patents be the Next Wave in Investor-State Arbitration?*, 7 N.Y. DISP. RESOL. LAW. 53 (2014).

companies to address an “assault” against their patents in the developing world.¹⁹

The increase in investor-state disputes and expansive claims has attracted increased attention and criticism. Although scholars have criticized such actions for years, the popular press and policymakers are now also highlighting such challenges as problematic for interfering with traditional government regulation.²⁰ Moreover, critics of investor-state disputes include developed as well as developing countries—Germany recently expressed concern even though it is a party to one hundred existing agreements that provide this remedy.²¹ Commentators also have expressed concern about including such investment provisions in pending agreements. Even the Cato

19. BAIJU S. VASANI ET AL., JONES DAY, TREATY PROTECTION FOR GLOBAL PATENTS: A RESPONSE TO A GROWING PROBLEM FOR MULTINATIONAL PHARMACEUTICAL COMPANIES 1–2 (2012) [hereinafter JONES DAY].

20. E.g., Barrie McKenna, *Canada Must Learn From NAFTA Legal Battles*, GLOBE & MAIL (Nov. 24, 2013), <http://www.theglobeandmail.com/report-on-business/economy/canada-must-learn-from-nafta-legal-battles/article15579209/>; Elizabeth Olson, *Growth in Global Disputes Brings Big Paychecks for Law Firms*, N.Y. TIMES, Aug. 26, 2013, at B1; Sabrina Tavernise, *Tobacco Firms' Strategy Limits Poorer Nations' Smoking Laws*, N.Y. TIMES, Dec. 13, 2013, at A1; James Traub, *Trading Up: Why a Massive Trade Deal is the Key to the Asia Pivot—and to America's Future*, FOREIGN POLICY (Feb. 21, 2014), http://www.foreignpolicy.com/articles/2014/02/21/trading_up/; Elizabeth Warren & Rosa De Lauro, *Who is Writing the TPP?*, BOSTON GLOBE (May 11, 2015), <http://www.bostonglobe.com/opinion/2015/05/11/elizabeth-warren-and-rosa-de-lauro-who-writing-tpp/2FQZAV6uz9GGQI6pe3cd0K/story.html>; see also *infra* notes 71–72, 75–86 and accompanying text (describing criticisms by scholars and policymakers).

21. E.g., Peter Clark, *Germany Throws Down Gauntlet in CETA Investor-State Negotiations*, IPOLITICS (July 27, 2014), <http://www.ipolitics.ca/2014/07/27/germany-throws-down-gauntlet-in-ceta-investor-state-negotiations/>. In addition, Australia took the bold position in 2011 that it would not include such provisions in future trade agreements. DEP'T OF FOREIGN AFFAIRS AND TRADE, AUSTL. GOV'T, GILLARD GOVERNMENT TRADE POLICY STATEMENT: TRADING OUR WAY TO MORE JOBS AND PROSPERITY (2011); see also *Australia to Reject Investor-State Dispute Resolution in TPPA*, INV. TREATY NEWS (Apr. 13, 2012), <http://www.iisd.org/itn/2012/04/13/news-in-brief-7/>. Its current position is that it will consider such provisions on a case-by-case basis. See, e.g., Mike Secombe, *Big Tobacco's Plan to Stub Out Plain Packaging*, SATURDAY PAPER (Mar. 8, 2014), <https://www.thesaturdaypaper.com.au/opinion/topic/2014/03/08/big-tobaccos-plan-stub-out-plain-packaging/1394197200/>. However, academics suggest that Australia should not include such provisions. E.g., MATTHEW RIMMER, TROJAN HORSE CLAUSES: INVESTOR-STATE DISPUTE SETTLEMENT (2014), available at http://works.bepress.com/matthew_rimmer/178 (submission to the Australian Parliament). Also, some countries, such as South Africa and Indonesia, have terminated or failed to renew agreements with such provisions. E.g., U.N. Conference on Trade & Dev., *International Investment Policymaking in Transition: Challenges and Opportunities of Treaty Renewal*, at 2–3, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/9 (June 2013); Ben Bland & Shawn Donnan, *Indonesia to Terminate More than 60 Bilateral Investment Treaties*, FIN. TIMES (Mar. 26, 2014), <http://www.ft.com/cms/s/0/3755c1b2-b4e2-11e3-af92-00144feabdc0.html>.

Institute, which usually promotes corporate interests, has suggested that a current U.S. trade initiative involving a dozen countries, the Transatlantic Trade and Investment Partnership, should not include an investment chapter not only because of concerns about domestic sovereignty, but also because investment chapters are “ripe for exploitation by creative lawyers.”²² Strong public criticism has stalled—or threatens to stall—discussions of the Trans-Pacific Partnership, as well as two bilateral agreements involving the European Union.²³ Although both the United States and the European Union at one point defended investment chapters against critics, in the past year, the European Union has stopped doing so.²⁴ The European Union is now engaging in public consultations as well as proposing modified language with the hope of minimizing concern.²⁵

Eli Lilly’s suit brings to light the problems with permitting an expansive interpretation of investment chapters to cover intellectual property “rights” that have been denied or cancelled under domestic law and are consistent with international law, such as TRIPS.²⁶ In particular, Eli Lilly’s suit highlights

22. Daniel J. Ikenson, *A Compromise to Advance the Trade Agenda: Purge Negotiations of Investor-State Dispute Settlement*, CATO INST. (Mar. 4, 2014), <http://www.cato.org/publications/free-trade-bulletin/compromise-advance-trade-agenda-purge-negotiations-investor-state>; see also *Investor-State Arbitration System Needs ‘Complete Overhaul,’* BILATERALS.ORG (May 12, 2014), <http://www.bilaterals.org/?investor-state-arbitration-system> (a prominent international lawyer who has himself served as counsel in several cases also suggested a problem with the system in delivering the keynote address to the annual Investment Treaty Arbitration Counsel).

23. E.g., Clark, *supra* note 21; Shawn Donnan & James Politi, *Official Warns EU-US Trade Deal at Risk over Investor Cases*, FIN. TIMES (Mar. 27, 2014), <http://www.ft.com/intl/cms/s/0/58ee2da0-b5dc-11e3-b40e-00144feabdc0.html>; Matthew Schewel, *EU, Canada Fail to Close CETA: Stuck Over Issue Related to Eli Lilly Case*, INSIDE U.S. TRADE, May 8, 2014; George Monbiot, *Comment, This US Trade Deal is a Full-Frontal Assault on Democracy*, GUARDIAN, Nov. 5, 2013; Brent Patterson, *Fast-Track authority stalls the Trans-Pacific Partnership*, RABBLE (May 25, 2015), <http://rabble.ca/blogs/bloggers/brent-patterson/2015/05/fast-track-authority-stalls-trans-pacific-partnership/3>.

24. E.g., EUR. COMM’N, INCORRECT CLAIMS ABOUT INVESTOR-STATE DISPUTE SETTLEMENT (2013); *The Facts on Investor-State Dispute Settlement: Safeguarding the Public Interest and Protecting Investors*, OFF. U.S. TRADE REPRESENTATIVE (Mar. 27, 2014), <http://www.ustr.gov/about-us/press-office/blog/2014/March/Facts-Investor-State%20Dispute-Settlement-Safeguarding-Public-Interest-Protecting-Investors>; *Investor-State Dispute Settlement (ISDS), Fact Sheet*, OFF. U.S. TRADE REPRESENTATIVE (Mar. 2015), <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2015/march/investor-state-dispute-settlement-isds/>.

25. E.g., Press Release, European Comm’n, Commission to Consult European Public on Provisions in EU-US Trade Deal on Investment and Investor-State Dispute Settlement (Jan. 21, 2014).

26. This article intentionally focuses on intellectual property rights that are denied or canceled, rather than any case where intellectual property rights are at issue. Although there are pending disputes concerning whether existing trademarks that have lost value due to

an important, yet unresolved tension: a country could be vulnerable to an investor-state dispute even if it complies with a separate international law concerning intellectual property rights. This Article aims to not only evaluate the merits of and the policy problems raised by Eli Lilly's specific suit, but also demonstrate other ways that domestic attempts to balance interests of multinational drug companies with public health might be compromised.²⁷ Eli Lilly's suit may prompt other companies to challenge not only patentability standards they disagree with, but also exceptions to patent rights, even where these exceptions are permissible under TRIPS. This would threaten recent and proposed patent laws that commentators have hailed as promoting a better balance of patent rights and access to medicine.

Moreover, the threat extends beyond the patent arena: pharmaceutical companies may also use investor-state disputes to challenge domestic regulatory laws that negatively impact their ability to sell even patented drugs. Domestic laws governing clinical data associated with approval of new drugs are likely an issue. Typically, nations require companies to provide clinical data to establish that a new drug is safe and effective before approving the drug for sale.²⁸ However, companies that seek to sell a new drug are the ones that create the data and often overstate benefits.²⁹ To address this problem, the European Union has an important new law that aims to ensure that doctors and patients have full information about underlying data of approved drugs, such that they are less likely to be susceptible to overstated marketing

their inability to be used pursuant to plain packaging laws for tobacco, these raise additional issues beyond the scope of a single article. In addition, this is an important issue that has thus far been overlooked by scholars, even though some scholars have previously discussed the pending trademark cases, how compulsory licenses could be challenged as expropriations, and whether intellectual property rights in general constitute investments. *E.g.*, 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* 2009–2010, at 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).

27. This article focuses on issues that have not received much academic attention and also seem currently ignored in negotiations. However, there are other public health issues that have been raised as concerns. *E.g.*, Shawn Donnan, *EU Pledges to Protect NHS in US Trade Talks*, *FIN. TIMES* (July 10, 2014), <http://www.ft.com/intl/cms/s/0/eb1e1102-085e-11e4-9380-00144feab7de.html> (asserting that decisions of the National Health Service and other European public health programmes will be exempt from investor-state challenges); Press Release, HAI Europe et al., 'Investor-to-State Dispute Settlement' in EU-US Trade Deal Risks Access to Affordable Medicines (July 14, 2014), *available at* <http://haieurope.org/wp-content/uploads/2014/07/Press-release-Joint-response-ISDS-in-TTIP.pdf>.

28. *See infra* note 316 and accompanying text.

29. *See infra* Subsection III.B.2.b); Subsection IV.A.3.b).

claims.³⁰ Although many commentators heralded this law as important, it is vulnerable to challenge by companies, as later explained.³¹

This Article argues that it is unprincipled to permit companies to use investor-state arbitration to challenge domestic decisions when they have no valid intellectual property rights. Eli Lilly, for example, is asserting that it is entitled to compensation because two of its initially issued patent were later invalidated for failing to satisfy mandatory patent law requirements. However, its invalidated patents amount to rights that never existed in the first place. It would be more analogous to a void contract, which purports to give rights but was never enforceable. Moreover, unlike most other types of property, the very existence of intellectual property is only justified if it promotes desired policy. Most recognize a utilitarian justification for intellectual property—to promote innovation while at the same time recognizing and balancing competing policy considerations, such as access for researchers, users, and consumers.³² Although some believe that intellectual property rights are inherently beneficial in promoting innovation and attracting foreign direct investment, data does not clearly support this claim.³³ Since such rights inherently reduce access and increase costs, countries should view the policy justification for providing such rights skeptically. In addition, although there are international agreements that require countries to provide equal treatment to domestic and foreign intellectual property right holders, all such agreements assume that each country has some discretion to decide how to balance intellectual property rights against other interests.

This Article also argues that permitting companies to challenge domestic decisions regarding intellectual property through investor-state disputes is problematic because they disrupt internationally agreed norms under TRIPS, and also because the historical justifications for protecting foreign investors do not apply. TRIPS permits member countries discretion in shaping intellectual property rights to advance policy goals other than promoting

30. See *infra* Subsection IV.A.3.b).

31. See, e.g., HAI EUROPE, PROTECTING CITIZENS' HEALTH: TRANSPARENCY OF CLINICAL TRIAL DATA ON MEDICINES IN THE EU (2013).

32. Of course, there are competing views on whether inventors and artists have a "natural" right to intellectual property, as well as whether these rights are protected as human rights instruments, such as the International Covenant on Economic, Social and Cultural Rights. See International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), art. 15.1(b), U.N. Doc. A/RES/21/2200 (Dec. 16, 1966). This Article agrees with the majority of commentators who reject this view. Historical and policy justifications of intellectual property rights support the majority view—patents have always served to further the societal goals of promoting and disseminating technological innovation.

33. See *infra* Subsection III.A.2.c).

innovation, including public health.³⁴ A country that arguably complies with TRIPS should not be subject to an investor-state challenge that could disrupt TRIPS norms, as well as result in a judgment inconsistent with a decision from the World Trade Organization (“WTO”)—the international body that handles TRIPS disputes. Moreover, permitting such challenges would not further the historical justification of protecting investments in international investment agreements—to promote investment from foreign companies. Unlike most other types of investments where increased protection induces foreign investment, companies do not invest in countries solely, or even primarily due to the strength of intellectual property protection; in addition, whether or not a company decides to seek more patent protection is unlikely to benefit the host country unlike the typical scenario where stronger protection for foreign companies results in direct benefit to the host country. Eli Lilly’s case uniquely threatens a country’s freedom to legislate under a separate international agreement. In contrast, prior instances of investor-state disputes that arguably relate to another international agreement have not resulted in a clear conflict pursuant to which resolution of the investor’s claim would violate the integrity of a separate international agreement. Often this is because the other international agreement only is aspirational.³⁵

This Article also provides a detailed analysis of Eli Lilly’s central claims—that Canada “expropriated” Eli Lilly’s investment in its patents, and that Canada failed to provide “fair and equitable treatment” to Eli Lilly’s investments.³⁶ The Article seeks to show why Eli Lilly should not recover on

34. TRIPS, *supra* note 3, art. 1.1; World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN01/DEC/2, ¶¶ 4–5 (2002) [hereinafter Doha Public Health Declaration]; see also *infra* Subsection II.B.1 (discussing flexibility under TRIPS).

35. See *infra* notes 138–42 and accompanying text (discussing nonbinding WHO framework convention as well as ambiguous human rights norms).

36. Although Eli Lilly originally asserted that Canada violated the nondiscrimination agreement, that provision will not be addressed because it lacks any merit; indeed, Eli Lilly’s notice of arbitration dropped this ground. In particular, national treatment simply requires a country to treat foreign investors “no less favorabl[y]” than its domestic investors. North American Free Trade Agreement, U.S.-Can.-Mex., ch. 11, art. 1102, Dec. 17, 1992, 32 I.L.M. 605, 639 [hereinafter NAFTA]. Eli Lilly made two claims that seem unmoored to this standard. Eli Lilly claimed that Canadian law disadvantages foreign nationals with requirements “not required by the foreign applicants’ own national jurisdictions.” *Eli Lilly & Co. v. Canada*, Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven, ¶ 106 (NAFTA/UNCITRAL Arb. Trib. Nov. 7, 2012). However, nondiscrimination does not guarantee an investor laws identical to its home state. In addition, Eli Lilly claimed that it is treated less favorably than domestic generic competitors that can benefit from making the now invalidated patented drugs. *Id.* ¶ 107. However, nondiscrimination is only about comparing similarly situated entities, and generic pharmaceutical companies are not similar—they have an entirely different business model, such that this claim is illogical.

any of its claims, but nonetheless explains which issues are most vulnerable for Canada. As the final Part of this Article highlights, recognizing potential problems that may arise from the decision in Eli Lilly's case is important to understanding how to properly cabin such claims in future cases.

This Article proceeds in three parts: Part II provides a background of relevant domestic and international law and policy, as well as an overview of Eli Lilly's claims to contextualize Eli Lilly's investor-state dispute. Part III then turns to the specifics of Eli Lilly's claims against Canada and explains why an arbitration tribunal should reject Eli Lilly's claims. Part IV goes beyond the specifics of Eli Lilly's claims to explain other TRIPS-consistent domestic laws that are in danger of subsequent investor-state disputes. This Part concludes with specific proposals for preserving countries' existing policy space under TRIPS in pending and future agreements concerning investor protection.

I. BACKGROUND

A. DOMESTIC PATENT LAW AND POLICY

To understand Eli Lilly's claims against Canada, some background on patent law is important. A patent is a legal document granted by a country to the creator of an invention that provides the commercially valuable ability to exclude others from making or selling the patented invention within the boundaries of the patent-granting country.³⁷ A patent is fundamentally a lever to promote social policy, offering a reward to induce inventors to disclose information to society so that others can learn from and build upon that innovation.³⁸ Because most inventions build upon prior inventions, encouraging inventors to share their knowledge is socially valuable, even if there is a temporary cost of higher prices during the period of patent protection. A patented drug is generally expensive because the patent owner can exclude all others from making the identical drug during the patent term; therefore the patent owner can and generally does charge a substantial premium.

The social harm of higher prices on patented goods is mediated by a limited term of patent protection, as well as patentability requirements. Patents generally award inventors a term of protection of no more than twenty years to minimize the period during which consumers must pay

37. *E.g.*, 35 U.S.C. § 271 (2012); TRIPS, *supra* note 3, art. 28.

38. *See* *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 164–65 (1989).

patent-inflated prices.³⁹ In addition, the patentability standards aim to ensure that patents are only granted on more socially valuable inventions so that the price premium only applies where deserved.

There are two basic types of requirements that patent applications must satisfy. First, the invention must meet certain patentability requirements, typically that it is: patentable subject matter, useful (or that it has “utility”), new, and not obvious.⁴⁰ For example, an invention that has no use at all, or only a “throw away” use, such as being used as a paperweight, would not deserve a patent. However, nations differ on the appropriate standard for utility. The United States, for example, has one of the broadest interpretations of usefulness; an invention qualifies as useful by providing simple entertainment, rather than a commercial use, and may also be useful even if its use promotes deceptive or even illegal activity in some circumstances.⁴¹ Most European countries, on the other hand, bar patents on inventions that violate morality.⁴² Second, the application itself must meet certain disclosure requirements—it must fully describe the invention and enable others to properly make and use the disclosed invention.⁴³

A patent application must satisfy these patentability requirements at the time of filing to foster fundamental patent policy goals. In particular, patentability requirements prevent applicants from filing claims for inventions that they have not fully developed to avoid unduly rewarding speculative claims, which could bar research and impose costs on the public. Notably, although Canada has a unique interpretation of the utility requirement under the “promise doctrine,” its interpretation in fact supports this fundamental patent policy. In cases where an application promises a certain use (but not if there is no such promise), an invention is only considered useful if it provides an adequate disclosure for that promise. The Canadian Supreme Court has recognized costs of patent protection to be particularly important in the area of pharmaceuticals, noting that

39. *E.g.*, 35 U.S.C. § 154(a)(2) (2012); TRIPS, *supra* note 3, art. 33.

40. *E.g.*, 35 U.S.C. §§ 101–103 (2012); TRIPS, *supra* note 3, art. 27(1).

41. *E.g.*, *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999). In addition, there are patents on inventions that may be illegal such as radar detectors and gambling devices.

42. Convention on the Grant of European Patents art. 53(a), Oct. 5, 1973, 1065 U.N.T.S. 199 (barring patents on inventions “the publication or exploitation of which would be contrary to ‘ordre public’ or morality”) [hereinafter European Patent Convention]; *see also* Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL’Y 247 (2000) (explaining cases interpreting this doctrine).

43. *E.g.*, 35 U.S.C. § 112 (2012); TRIPS, *supra* note 3, art. 29.

[w]ere the law to be otherwise, major pharmaceutical companies could . . . patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed.⁴⁴

Although Canada's interpretation of what is useful is different than the interpretations of other countries, countries widely recognize the purpose espoused by the Canadian Supreme Court. The U.S. Supreme Court has similarly stated that a patent is not a "hunting license" in interpreting the utility requirement to bar a patent on a new method of making a known steroid when the inventors had no idea what function the steroid served, other than as a tool for further research.⁴⁵

Like all types of intellectual property, patents are granted by individual nations and are territorially limited. Because a global patent does not exist, an inventor must seek patent protection in individual countries. For example, a U.S. patent gives its owner rights against others in the U.S., but does not provide any protection in other countries. To obtain protection in other countries, the inventor would have to apply for and obtain patent protection in the desired countries. However, an identical patent application filed in different countries will not result in identical patent rights, or even patentability. This is because each country has its own patentability standards. Contrary to Eli Lilly's suggestions, courts in different countries can and often do apply different domestic standards to determine whether the same invention is patentable; courts often note that other nations' decisions regarding similar, or even identical patent applications are not relevant to a domestic court's evaluation of patentability.⁴⁶

B. THE INTERNATIONAL LANDSCAPE: IP AND FOREIGN INVESTMENTS

Before addressing the specifics of Eli Lilly's claims, it may help to provide a broader context of the international landscape. As noted in the introduction, Eli Lilly's case lies at the unique intersection of separate

44. *Apotex Inc. v. Wellcome Foundation, Ltd.*, [2002] 4 S.C.R. 153, para. 80 (Can.).

45. *Brenner v. Manson*, 383 U.S. 519, 535–36 (1966).

46. *E.g., Canada (Att'y Gen.) v. Amazon.com, Inc.*, [2011] F.C.A. 328, para. 16 (Can.) ("[I]t would not be helpful . . . to explain the results of Amazon's patent applications in other jurisdictions. . . . [E]very jurisdiction has its own patent laws and administrative practices, and they are inconsistent with one another in important respects."); *Conor Medsystems Inc. v. Angiotech Pharm. Inc.*, [2008] UKHL 49, ¶ 3 (stating that "it is inevitable that [different courts] will occasionally give inconsistent decisions about the same patent"); *Apotex*, [2002] 4 S.C.R. 153, para. 40 (Can.) ("[G]iven the differences in our respective patent laws, the outcome of the U.S. litigation on this patent is of limited interest here.").

international agreements that govern intellectual property and foreign investments.⁴⁷ To better understand Eli Lilly's case, this Section first considers the traditional territorial scope of intellectual property rights, as well as how such rights are treated under international intellectual property agreements such as TRIPS. Finally, this Part provides an overview of bilateral and multilateral agreements that protect foreign direct investment.

1. *Intellectual Property: Territoriality and Treaties*

There is a long history of recognizing national boundaries of patents in the global arena. The Paris Convention was one of the earliest international agreements relating to patents (established in 1883), yet it did not require any member countries to grant patents—this was considered a domestic choice.⁴⁸ The agreement only provided rules to ensure fairness to domestic and foreign applicants, and facilitate the process of obtaining patents in multiple countries.⁴⁹ Indeed, a provision on the independence of patents specifically clarified that the grant or denial of a patent on an invention in one country does not impact the decision of another country.⁵⁰ This rule inherently recognized and reinforced that patents are tools of domestic discretion and that patent rights, if any, are restricted to the territory of the patent-granting nation. Accordingly, countries not only differed on whether or not to completely ban patents, but also on the grounds for granting patents; nations could decide to grant patents only on processes, or only in some fields of technology.

The second significant international agreement relating to patents is the Patent Cooperation Treaty ("PCT"). This agreement, concluded in 1970, provided a mechanism for inventors to more easily obtain patents in multiple countries with a uniform PCT application that could be examined in individual member states. Importantly, the PCT still firmly recognized territorial limits and domestic sovereignty. It simply made the process of filing for patents in multiple countries easier with a single application. For example, a PCT application establishes a priority filing date in all member

47. In some situations, including Eli Lilly's, there is an international agreement that simultaneously governs both intellectual property and foreign investments in separate chapters of the agreement. However, the issues are the same as if there were independent agreements.

48. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

49. For example, a nation that provided patents could not treat patent applications of its own nationals better than those of foreign applicants. Paris Convention, *supra* note 48, arts. 2–3 (national treatment).

50. Paris Convention, *supra* note 48, art. 4*bis*.

countries, but each country where the applicant ultimately files evaluates the patent according to its own patent standards.⁵¹

Today, most nations of the world are members of the WTO and, as such, must provide patent and other intellectual property rights pursuant to TRIPS. This landmark agreement, concluded in 1994, has dramatically changed the ability of nations to exercise full control over the decision to grant patent rights. Member countries are required to grant patents to all “inventions,” that meet certain standards of patentability.

Even though TRIPS now requires many countries to provide patents, because the agreement sets minimum, rather than uniform standards, it explicitly contemplates diversity in domestic laws.⁵² Although TRIPS notably requires some nations to provide patents for the first time, it gives states substantial flexibility in how to do so. For example, although TRIPS requires nations to grant patents on “inventions” that meet patentability standards, it does not define what constitutes an invention.⁵³ Accordingly, nations can properly exclude software, for example, from patentability if they do not consider software to be an invention.⁵⁴ Similarly, although TRIPS requires nations to provide patents on inventions that are useful, new, and nonobvious, it does not define any of these terms.⁵⁵ Before TRIPS, member states had different laws about some of these terms. The lack of inclusion of any specific definitions permits nations to provide their own definitions.⁵⁶ A failed attempt to create a new patent law treaty with uniform patent standards after TRIPS underscores that nations understood TRIPS not to

51. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 [hereinafter Patent Cooperation Treaty].

52. TRIPS, *supra* note 3, art. 1(1).

53. *Id.* at art. 27.

54. *Id.*

55. *Id.*

56. E.g., Carlos M. Correa, *Patent Rights*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189, 198–200 (2d ed. 1998); PARK, *supra* note 10, at 39; WORLD HEALTH ORG. ET AL., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 57 (2012); Michael N. Meller, *Principles of Patentability and Some Other Basics for a Global Patent System*, 83 J. PAT. & TRADEMARK OFF. SOC’Y 359, 359 (2001); E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CANADIAN INTELL. PROP. REV. 35, 58–59 (2014); Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 89 (2007); Expert Report of Daniel Gervais Accompanying Counter Memorial of Canada, ¶¶ 22–54.

impose such uniformity.⁵⁷ The attempt to create uniform standards shows that countries recognized that there were no uniform standards of patentability under existing agreements, such as TRIPS.

Accordingly, although member countries must provide some protection to drug patents, they can define TRIPS patentability criteria to minimize harm to social policies beyond innovation. For example, a country could consider a newly discovered use of a known compound to neither be an “invention” nor “new” because TRIPS does not define these key terms. Although the use itself may be new, arguably that was inherent in the existence of the compound, such that society does not benefit from granting a patent on this new use. Countries might also consider such a use as simply falling below the threshold inventiveness. In fact, India’s recent patent amendments take this approach in barring from patentability new uses of known compounds.⁵⁸

Countries may also decide how to satisfy the TRIPS patentability requirement that an invention be “useful.”⁵⁹ TRIPS article 27 actually states that countries must provide patents on inventions that are “capable of industrial application,” but clarifies in a footnote that this term is meant to be synonymous with “useful.” These terms refer to somewhat similar, but slightly different patentability requirements that existed in the laws of countries at the time TRIPS was negotiated. As noted by one scholar, “the deliberate inclusion of these two alternatives precludes any inference that the draftsmen of TRIPS intended to incorporate by reference or implication any single existing standard of patentability.”⁶⁰

Indeed, these differences have always been permissible. Prior to the conclusion of TRIPS in 1994, the Paris Convention simply focused on ensuring fairness to domestic and foreign applicants if a country decided to provide patents and the PCT similarly facilitated the process of obtaining

57. Reichman & Dreyfuss, *supra* note 56, at 89–90. This effort was abandoned in 2006. See *Draft Substantive Patent Law Treaty*, WIPO, http://www.wipo.int/patent-law/en/draft_splt.htm (last visited May 9, 2015).

58. The Patents (Amendment) Act, 2005, No. 15, § 3(d), Acts of Parliament, 2005 (India).

59. TRIPS, *supra* note 3, art. 27(1).

60. Christopher Wadlow, *Utility and Industrial Applicability*, in *PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH* 355, 356 (Toshiko Takenaka, ed., 2008).

patents in multiple countries.⁶¹ These agreements remain in force today, and the principle of territoriality remains valid.⁶²

2. *International Agreements Governing Foreign Direct Investments and Providing Investor-State Disputes*

There are over 3000 international agreements that provide foreign investors substantive rights to protect their investment, as well as a mechanism to protect those rights outside of domestic courts.⁶³ These agreements are either bilateral investment agreements, or free trade agreements, such as the North American Free Trade Agreement (“NAFTA”), with an investor chapter aimed at promoting foreign investment.⁶⁴ Although a free trade agreement may include a chapter on both intellectual property rights and foreign investor rights, these chapters operate independently of each other.

Most agreements protecting foreign investors provide a similar set of substantive rights. These rights build upon prior international rights and provide more clarity than prior principles of customary international law. Typically, they provide investors a guarantee of compensation for any expropriation of investments, freedom from unreasonable or discriminatory measures, fair and equitable treatment, and guarantee foreign investors that they will not be treated less favorably than domestic ones. All of these rights

61. Paris Convention, *supra* note 48, arts. 2–3; PCT, *supra* note 51 (streamlining process to file patents in multiple countries).

62. In addition, TRIPS clarifies that it is consistent with the Paris Convention. TRIPS, *supra* note 3, art. 2.

63. E.g., UNCTAD, INVESTOR-STATE DISPUTES: PREVENTION AND ALTERNATIVES TO ARBITRATION 3–4 (2010), available at http://unctad.org/en/docs/diacia200911_en.pdf; INT’L INST. FOR ENVIRON. & DEV. (IIED), INVESTMENT TREATIES AND SUSTAINABLE DEVELOPMENT: INVESTOR-STATE ARBITRATION 1 (2014), available at <http://pubs.iied.org/pdfs/17241IIED.pdf>.

64. Although scholars have questioned whether any of these agreements in fact impact decisions to invest, that is nonetheless the goal. E.g., JESWALD W. SALACUSE, THE LAW OF INVESTMENT TREATIES 121 (2009) (noting conflicting studies); Todd Allee & Clint Peinhardt, *Delegating Differences: Bilateral Investment Treaties and Bargaining Over Dispute Resolution Provisions*, 54 INT’L STUD. Q. 1 (2010); Susan D. Franck, *Foreign Direct Investment, Investment Treaty Arbitration, and the Rule of Law*, 19 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 337 (2007); Jeswald W. Salacuse & Nicholas P. Sullivan, *Do BITs Really Work?: An Evaluation of Bilateral Investment Treaties and Their Grand Bargain*, 46 HARV. INT’L L.J. 67, 75–79 (2005); Tom Ginsburg, *International Substitutes for Domestic Institutions: Bilateral Investment Treaties and Governance*, 25 INT’L REV. L. & ECON. 107, 108 (2005). But see Todd Allee & Clint Peinhardt, *Contingent Credibility: The Impact of Investment Treaty Violations on Foreign Direct Investment*, 65 INT’L ORG. 401 (2011); Jennifer L. Tobin & Susan Rose-Ackerman, *When BITs Have Some Bite: The Political-Economic Environment for Bilateral Investment Treaties*, 6 REV. INT’L ORGS. 1 (2011).

help to ensure that host governments will not subject foreign investors to inappropriate risks, and consequently induce them to invest.

Investor-state arbitrations developed simultaneously with bilateral investment treaties as a means to promote and protect investment from foreign companies. These largely began after World War II when newly independent nations wanted to encourage foreign investment and assistance with developing natural resources, as well as to generally encourage foreign investment.⁶⁵ The investor-state arbitration remedy provided an important avenue for relief to investors. Although foreign investors previously might have attempted to sue the state in its own courts, those courts could be biased; alternatively, the state might be able to claim sovereign immunity. Sometimes the investor could not even directly pursue an action. In the worst-case scenario, home states used, or at least threatened to use, military force.⁶⁶ All of these options provided the investor with limited avenues of recourse, either because no suit could be brought or because a judgment was not enforceable.⁶⁷

Investor-state arbitrations address this problem through a unique process. Investors bring claims not before a domestic or international court, but a tribunal of private arbitrators, who are generally lawyers. The state is considered to have consented to this by agreeing to the treaty provision. The ability of foreign investors to arbitrate their disputes against states obviates prior hurdles to protecting investments when domestic courts either did not

65. Germany and Pakistan signed the first such agreement in 1959. United Nations Commission on Trade and Development, *Bilateral Investment Treaties in the Mid 1990s*, UNCTAD/ITE/IIT/7, Sales No. E. 98.II.D.8, 8–10 (1998). International agreements to promote investments date back as far as the late 1700s, but mostly focused on expropriation and also did not have the same type of arbitration-based remedies as current agreements. E.g., RUDOLF DOLZER & CHRISTOPH SCHREUER, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW* 6–8 (2d ed. 2012).

66. E.g., Susan Franck, *Development and Outcomes of Investment Treaty Arbitration*, 50 HARV. INT'L L.J. 435, 442 (2009) (noting gunboat diplomacy and war); KENNETH J. VANDEVELDE, *UNITED STATES INVESTMENT TREATIES: POLICY AND PRACTICE* 7 (1992) (describing use of military force); Ray C. Jones, *NAFTA Chapter 11 Investor-to-State Dispute Resolution: A Shield to be Embraced or a Sword to be Feared?*, 2002 BYU L. REV. 527, 529 (describing gun boat diplomacy).

67. For example, even if the ICJ ruled in favor of a company, a nation might decide not to pay the investor. The only remedy in such a case was passing a UN Security Council resolution. E.g., Susan D. Franck, *The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law Through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521, 1537 (2005).

recognize any claims, or refused to enforce domestic judgments in favor of foreign investors.⁶⁸

Although the global community initially praised this process as a way to promote investment flows during a more stable global economic era, more recently, scholars, countries, and citizens have criticized multiple aspects of investor-state arbitrations.⁶⁹ Some of the criticisms build on popular anti-trade or anti-corporate sentiment.⁷⁰ However, countries as well as scholars have also expressed reservation and criticism.⁷¹ A major issue is that the suits appear to improperly encroach on domestic authority and even have a chilling effect on legitimate state regulatory functions due to substantial awards, as well as legal costs of defending such cases.⁷² One example of a substantial award occurred in July 2014 against Russia for over \$50 billion.⁷³ Although a recent study noted that states win in sixty percent of the cases,

68. *E.g., id.* at 1537; Anthea Roberts, *State-to-State Investment Treaty Arbitration: A Hybrid Theory of Interdependent Rights and Shared Interpretive Authority*, 55 HARV. INT'L L.J. 1, 15–17 (2014) (discussing gunboat diplomacy as well as broader historical context).

69. For a discussion of early praise, see David P. Riesenbergh, Note, *Fee Shifting in Investor-State Arbitration: Doctrine and Policy Justifying Application of the English Rule*, 60 DUKE L.J. 977, 985 (2011).

70. Citizens may not only object, but publicly protest. For example, in South Korea, there were physical fights and tear gas use. *E.g., South Korea Passes U.S. Free-Trade Agreement, Lawmaker Sets Off Tear Gas Canister in Protest*, FOX NEWS (Nov. 22, 2011), <http://www.foxnews.com/world/2011/11/22/south-korea-passes-us-free-trade-agreement-lawmaker-sets-off-tear-gas-canister/>.

71. *E.g.*, Joseph Stiglitz, Letter to Congress, May 18, 20015, available at <http://www.scribd.com/doc/265770405/Letter-to-Congress-Stiglitz-on-Trade-Deal>; Letter to Congress, April 30, 2015, available at <http://www.afj.org/wp-content/uploads/2015/03/ISDS-Letter-3.11.pdf>; GUS VAN HARTEN ET AL., PUBLIC STATEMENT ON THE INTERNATIONAL INVESTMENT REGIME ¶ 8 (Aug. 31, 2010) (statement by some academics suggesting that the process is “not a fair, independent and balanced method for the resolution of investment disputes”); *supra* note 21 and accompanying text (noting concern by countries); but see Hon. Charles N. Brower & Sadie Blanchard, *What's in a Meme? The Truth About Investor-State Arbitration: Why It Need Not, and Must Not, Be Repossessed by States*, 52 COLUM. J. TRANSNAT'L L. 689 (2014).

72. *E.g.*, EUR. PARLIAMENTARY RESEARCH SERV., INVESTOR-STATE DISPUTE SETTLEMENT (ISDS): STATE OF PLAY AND PROSPECTS FOR REFORM 5 (2014). The average cost of attorney fees alone has been estimated at \$5 million U.S. dollars with a mean tribunal cost of approximately \$1 million. *E.g.*, Susan D. Franck, *Using Investor-State Mediation Rules to Promote Conflict Management: An Introductory Guide*, 29 ICSID REV. 66, 77–78 (2014).

73. The Russian award is the largest award to date. See Glyn Moody, *Corporate Sovereignty Tribunal Makes \$50 Billion Award Against Russia*, TECHDIRT (Aug. 5, 2014, 12:37 AM), <https://www.techdirt.com/articles/20140801/05242228082/corporate-sovereignty-tribunal-makes-50-billion-award-against-russia.shtml>; Kavaljit Singh, *The Era of Mega-Arbitration: International Court Rules Against Russia in \$50 Billion Decision*, MADHYAM (July 30, 2014), <http://www.madhyam.org.in/the-era-of-mega-arbitration-tribunal-awards-50-billion-against-russia-in-yukos-case/>.

the average award—\$16.6 million—is nonetheless significant.⁷⁴ Although there is a huge diversity in awards, even a lower award would still be substantial for any developing country, such that a potential award, even if statistically unlikely, could have a substantial impact on domestic decisions.

A major complaint is that the system results in inconsistent decisions because there is no binding precedent,⁷⁵ tribunals interpret provisions broadly,⁷⁶ and there is no appeal system.⁷⁷ Although tribunals often rely on prior decisions⁷⁸ and awards, and counsel for parties regularly cite prior decisions, the lack of hierarchy among tribunals as compared to traditional court systems, as well as the lack of an appellate system, may result in unpredictability.⁷⁹ Some also contend that arbitrators lack the independence and impartiality of typical domestic or international tribunals.⁸⁰ Although arbitrators are clearly private parties, rather than judges, some suggest that the presumption that arbitrators will rule in favor of corporations is overstated.⁸¹ A related issue is that the proceedings and decisions may lack the same level of transparency as most judicial decisions. The rules for most proceedings do not permit interested parties to participate and do not require

74. E.g., Susan D. Franck, *Using Investor-State Mediation Rules to Promote Conflict Management: An Introductory Guide*, Washington & Lee Legal Studies Paper No. 2014-13, page 14, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2389763.

75. This is true of international law in general. E.g., Statute of the International Court of Justice art. 59, June 26, 1945, 59 Stat. 1055, T.S. 993, 3 Bevans 1179; MOHAMED SHAHABUDEEN, PRECEDENT IN THE WORLD COURT (1996); Gabrielle Kaufmann-Kohler, *Arbitral Precedent: Dream, Necessity or Excuse?*, 23 ARB. INT'L 357, 362–65 (2007); see also NAFTA, *supra* note 36, art. 1136(1) (“An award made by a Tribunal shall have no binding force except between the disputing parties and in respect of the particular case.”).

76. E.g., Elizabeth Olson, *Growth in Global Disputes Brings Big Paychecks for Law Firms*, N.Y. TIMES (Aug. 26, 2013), <http://dealbook.nytimes.com/2013/08/26/growth-in-global-disputes-brings-big-paychecks-for-law-firms/>.

77. AUSTL. GOV'T PRODUCTIVITY COMM'N, BILATERAL AND REGIONAL TRADE AGREEMENTS: PRODUCTIVITY COMMISSION RESEARCH REPORT 273 (2010); UNCTAD, Recent Developments, *supra* note 1515, at 26.

78. Christoph Schreuer & Matthew Weiniger, *A Doctrine of Precedent?*, in THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW 1196 (Peter Muchlinski et al. eds., 2008) (considering there to be a de facto practice of precedent, even if not required).

79. See Schreuer & Weiniger, *supra* note 78, at 1191–95; Jeswald W. Salacuse, *The Emerging Global Regime for Investment*, 51 HARV. INT'L L.J. 427, 460–61 (2010).

80. E.g., PIA EBERHARDT & CECILIA OLIVET, PROFITING FROM INJUSTICE: HOW LAW FIRMS, ARBITRATORS AND FINANCIERS ARE FUELLING AN INVESTMENT ARBITRATION BOOM 9 (2012); Olson, *supra* note 76; Gus Van Harten, *Arbitrator Behaviour in Asymmetrical Adjudication: An Empirical Study of Investment Treaty Arbitration*, 50 OSGOODE HALL L.J. 211, 216 (2012).

81. Gus Van Harten, *Perceived Bias in Investment Treaty Arbitration*, in THE BACKLASH AGAINST INVESTMENT ARBITRATION: PERCEPTIONS AND REALITY 433 (Michael Waibel et al. eds., 2010).

final decisions to be made public. Although there are recent rules that increase transparency, these rules only apply prospectively to new agreements, rather than to the many that already exist.⁸² These disputes are admittedly more transparent than general commercial arbitration, but there is a major distinction in that investor-state disputes involve actions against sovereign nations. Even though nations consent to this process in a manner analogous to private parties, the consent is for a broad range of claims whereas commercial arbitration generally involves claims arising from a contractual clause limited to a specific situation.

To combat these shortcomings there have been many proposals to reform the current system for investor-state disputes.⁸³ Many have suggested some type of appellate body to address the problem of inconsistent as well as expansive interpretations of identical provisions.⁸⁴ Alternatively, some suggest replacing private arbiters with an international investment court to promote impartiality and independence.⁸⁵ Other proposals do not involve drastic changes to the dispute resolution process but nonetheless aim to cabin problematic decisions. For example, some suggest requiring that claimants first exhaust domestic remedies; limiting the scope of claims; or

82. UNCITRAL Rules on Transparency in Treaty-based Investor-State Arbitration art. 1 (2014), available at <http://www.uncitral.org/pdf/english/texts/arbitration/rules-on-transparency/Rules-on-Transparency-E.pdf> (mandatory application only for disputes under treaties concluded on or after 2014).

83. An alternative approach is to renegotiate or withdraw from such agreements entirely. E.g., Ben Bland & Shawn Donnan, *Indonesia to Terminate More than 60 Bilateral Investment Treaties*, FIN. TIMES, Mar. 26, 2014; Andrew Newcombe, *A Brief Comment on the "Public Statement on the International Investment Regime,"* KLUWER ARB. BLOG (Sept. 3, 2010), <http://kluwarbitrationblog.com/blog/2010/09/03/public-statement-on-the-international-investment-regime/>; see also Gus Van Harten et al., *Public Statement on the International Investment Regime*, BILATERALS.ORG (Aug. 30, 2010), <http://bilaterals.org/?public-statement-on-the> (statement from academics asserting that "[t]here is a strong moral as well as policy case for governments to withdraw from investment treaties and to oppose investor-state arbitration, including by refusal to pay arbitration awards").

84. E.g., APPEALS MECHANISMS IN INTERNATIONAL INVESTMENT DISPUTES (Karl P. Sauvant ed., 2009); Asif H. Qureshi, *An Appellate System in International Investment Arbitration?*, in THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW 1154 (Peter Muchlinski et al. eds., 2008); Mark Kantor, *ICSID SECRETARIAT, POSSIBLE IMPROVEMENTS OF THE FRAMEWORK FOR ICSID ARBITRATION*, TRANSNATIONAL DISPUTE MANAGEMENT (2004), <http://www.transnational-dispute-management.com/article.asp?key=307> (suggesting consideration of an appeals facility at ICSID). But see Schreuer & Weiniger, *supra* note 78, at 1203–05 (suggesting that appeals may not be the best way to provide consistent interpretation and instead suggesting preliminary rulings on questions of law instead).

85. E.g., Gus Van Harten, *Commentary: A Case for an International Investment Court*, INV. TREATY NEWS, Aug. 7, 2008; U.N. Conference on Trade & Dev., *Reform of Investor-State Dispute Settlement: In Search of a Roadmap*, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/4 (June 26, 2013).

requiring arbitrators to consider other areas of international law, such as human rights and environmental obligations.⁸⁶

C. ELI LILLY'S CASE

Eli Lilly has filed a notice of arbitration against Canada, alleging violations of NAFTA's investment chapter. Eli Lilly claims that Canadian courts improperly invalidated its patents for failing the utility requirement and challenges the Canadian "promise doctrine"—a common law interpretation of utility that applies when a patent sets forth, or is perceived to set forth, a "promise." The promise doctrine dates back to early patent law in the UK, as well as older Canadian decisions; however, Canadian courts only recently invalidated patents under this doctrine.⁸⁷ Since 2005, Canadian courts have invalidated roughly a dozen patents for failing to satisfy this doctrine.⁸⁸ Pursuant to this doctrine, a patent that promises something is only useful if it does what it "promises." If the patent does not make a promise, a scintilla of utility can establish usefulness.⁸⁹ For patents and patent applications that make a promise, whether the promise is fulfilled can either

86. *E.g.*, THOMAS McDONAGH, UNFAIR, UNSUSTAINABLE, AND UNDER THE RADAR: HOW CORPORATIONS USE GLOBAL INVESTMENT RULES TO UNDERMINE A SUSTAINABLE FUTURE 7, 15 (2013); JONAS PARELLO-PLESNER & ELENA ORTIZ DE SOLÓRZANO, A COMPREHENSIVE APPROACH TO INVESTMENT PROTECTION 2 (2013); Stephan W. Schill, *Enhancing International Investment Law's Legitimacy: Conceptual and Methodological Foundations of a New Public Law Approach*, 52 VA. J. INT'L L. 57, 69 (2011).

87. The promise doctrine has its origins in British law prior to 1977 (after that date utility was eliminated as a requirement and the requirement of "industrial application" was substituted). *E.g.*, Gold & Shortt, *supra* note 56, at 50. The promise doctrine in Canadian law can arguably be found as early as the 1960s. *E.g.*, New Process Screw Corp. v. P.L. Robertson Mfg Co. Ltd. (1961), 39 C.P.R. 31 (Can. Ex. Ct.) (patent promising a process of making screws of many sizes depending on certain pitch angles in fact failed to create the types of screws promised); *see also* Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd., [1981] 1 S.C.R. 504 (Can.) (stating that an invention is not useful either if it will not operate at all or if "it will not do what the specification promises that it will do"); *see also* Gold & Shortt, *supra* note 56, at 38. *But see* Norman Siebrasse, *The False Doctrine of False Promise*, CANADIAN INTELL. PROP. REV. 3, 8–9 (2012).

88. Siebrasse, *supra* note 87, 36–37. For the purpose of analyzing Eli Lilly's investment claims, this article assumes that Eli Lilly is correct in asserting that the promise doctrine modifies Canadian patent law to consider the legal and policy implications; however, if Canada's laws have not changed at all, Eli Lilly's claims are weaker. Although it is currently unknown how the tribunal will decide, Canada as well as some scholars dispute that Canada's law has changed. *E.g.*, Eli Lilly & Co. v. Canada, Statement of Defense, ¶ 12, (NAFTA/UNCITRAL Arb. Trib. June 30, 2014) [hereinafter Canada, Statement of Defense]; Gold & Shortt, *supra* note 56, at 53–57, 61–77 (arguing that the promise doctrine is not new to Canada and that other countries also require similar evidence, even if they do so under other patent law requirements).

89. *E.g.*, Eli Lilly Canada Inc. v. Novopharm Ltd., [2012] 1 F.C.R. 349, para. 76 (Can.).

be demonstrated in the patent or “soundly predicted.” In the many cases where the promise relies on a sound prediction, there are three components to satisfy. First, there must be a factual basis for the prediction. Tested compounds can supply this. Second, the inventor must have a sound basis from which the desired result can be inferred from the factual basis as of the date of the application. Third, there must be proper disclosure in the patent application to justify the quid pro quo of a patent monopoly.⁹⁰

An important issue is where a court (or the patent office) should look to find a promise in the patent or in the patent application. Some courts and commentators argue that only promises found entirely or mostly in the claims are relevant, but not those found in the specification.⁹¹ The majority of cases do not restrict promises to those found in patent claims.⁹² This is consistent with claim drafting; patent prosecutors generally do not restrict claims by stating the claims’ utility. Rather, prosecutors draft claims to simply cover the structural elements of the invention. More typically, a patent or patent application will state in its specification the invention’s intended purpose, as well as how the invention is an improvement over prior inventions, thus leading to a promise. Courts have not found promises based solely on abstract tables of data or drawings and instead generally look to an actual statement in the specification.⁹³ However, even focusing on statements in the specification can lead to different results, with some recent decisions since Eli Lilly filed its notice of arbitration seeming to take a more restrained view of what constitutes a promise.⁹⁴

90. *Id.* at para. 70.

91. *E.g.*, Fournier Pharma Inc. v. Canada (Health), 2012 FC 740, para. 126 (Can.); Teva Canada Ltd. v. Novartis AG, 2013 FC 141, paras. 76–77 (Can.); Fiona E. Legere, *The Pitfalls of “the Promise of the Patent,”* 29 CANADIAN INTELL. PROP. REV. 57, 60–61 (2013). However, some courts assert that claims control but actually look at the specification. *E.g.*, Bauer Hockey Corp. v. Eaton Sports Canada Inc., 2010 FC 361, para. 289 (Can.).

92. *See* Gold & Shortt, *supra* note 56, at 44. Some Canadian cases decided after Eli Lilly’s notice of arbitration have taken a more restrained view of the promise doctrine. *E.g.*, Sanofi-Aventis v. Apotex Inc., 2013 FCA 186, para. 49 (Can.) (finding that there should only be a promise if “the inventor makes an explicit promise of a specific result” in a case involving the drug sold as Plavix).

93. *E.g.*, Apotex Inc. v. H Lundbeck A/S, 2013 FC 192, paras. 244–53 (Can.) (rejecting promise based simply on table of data); Pfizer Canada Inc. v. Canada (Health), [2009] 1 F.C.R. 253, paras. 54–55 (Can. Fed. Ct. App.) (reversing trial court finding of promise based solely on data in a table); Gold v. Serratus Mountain Prods. Ltd., 2004 FC 815, para. 53 (Can.) (drawings alone inadequate).

94. *E.g.*, Sanofi-Aventis v. Apotex Inc., 2013 FCA 186 (Can.) (concluding that the lower court had erred in finding a promise for use in humans based on inferences regarding the drug sold as Plavix); Pfizer Canada Inc. v. Mylan Pharm. ULC, 2014 FC 38, para. 60 (Can.) (finding the patent relating to the drug marketed as Celebrex did not promise reduced

Eli Lilly and other companies criticize the promise doctrine as discriminatory since courts have mostly invalidated pharmaceutical patents under it.⁹⁵ However, the doctrine is technically not limited to pharmaceuticals. The Canadian Manual for Patent Practice in fact has a non-pharmaceutical example involving a golf club. In addition, a court has recently applied the doctrine to a mechanical invention.⁹⁶ Even though the promise doctrine applies to all areas, it may be harder to satisfy a promise of an improved medical treatment than an improved mechanical device—especially if the patent promises that the invention is superior for long-term treatment, since proving that claim involves clinical data. However, this does not necessarily support Eli Lilly’s claim of discrimination since a number of neutrally worded patent standards are more difficult to meet for certain areas of technology, yet are not considered discriminatory.

Some also criticize the promise doctrine as being unpredictable. For example, in *Apotex Inc. v. Pfizer Canada Inc.*, the court found the patent application promised to treat glaucoma with minimal side effects; because the court determined that glaucoma was a chronic disease, it invalidated the patent for lacking any long-term data on treatment, even though the patent claims did not refer to a chronic condition or long-term treatment.⁹⁷ This decision also conflicted with an earlier court decision holding the same patent valid.⁹⁸ Although these different decisions may seem to indict the doctrine, courts have come to different conclusions concerning the same

side effects in humans); *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 250, paras. 60–70 (Can.) (rejecting the suggestion that there was a promise of utility in treating inflammation or a promise of reduced side effects in a patent covering the drug marketed as Celebrex in contrast to an earlier decision by a different drug concerning the same patent); *Pfizer Canada Inc. v. Apotex Inc.*, 2014 FC 314 (Can.). But see *Alcon Canada Inc. v. Cobalt Pharm. Co.*, 2014 FC 149 (Can.) (finding implied promise of enhanced physical stability of solution). Of course, it could also be that some promises alleged to exist by a company desiring to invalidate the patent were farfetched. For example, in one case, the defendant claimed a passage suggested that a patent promised rapid absorption of the drug in vivo based on language that simply noted that this was a possible mechanism, such that the court rejected this argument. *Bayer Inc. v. Cobalt Pharm. Co.*, 2013 FC 1061 (Can.). Nonetheless, the court stated that “[c]ourts should not strive to defeat otherwise valid patents,” which could be seen as an intent to take a more restrained view of applying the promise doctrine. *Id.* at para. 93.

95. *E.g.*, PHRMA, SPECIAL 301 SUBMISSION 2014 76–77 (2014); see also OFFICE OF THE U.S. TRADE REPRESENTATIVE, EXEC. OFFICE OF THE PRESIDENT, 2013 SPECIAL 301 REPORT 46 (2013) (noting “serious concerns about the impact of the heightened utility requirements for patents”).

96. *Bell Helicopter Textron Canada Limitée v. Eurocopter*, 2013 FCA 219 (Can.).

97. 2011 FCA 236 (Can.).

98. *Pharmascience Inc. v. Pfizer Canada Inc.*, 2011 FCA 102 (Can.).

patent in applying other patentability standards. In fact, for some issues, such as claim construction, reversals are quite common.

Although commentators have criticized the promise doctrine for being without basis, the Canadian Supreme Court has provided a firm foundation for the doctrine in public policy. The court explained that it “balances the public interest in early disclosure of new and useful inventions, even before their utility has been verified by tests . . . and the public interest in avoiding . . . granting monopoly rights in exchange for misinformation.”⁹⁹ Noting that patent monopolies are associated with higher prices, the court stated that the “public should not be expected to pay an elevated price in exchange for speculation.”¹⁰⁰

In the case of Eli Lilly’s patents on the drugs sold as Strattera and Zyprexa, courts found the patents on both drugs promised certain treatments, yet failed to soundly predict them, such that the patents were invalid for lack of utility. Moreover, in both cases, Eli Lilly appeared to be attempting to obtain additional patent protection beyond the term of its original patents. In other words, Eli Lilly was engaging in the common practice of “evergreening” by pharmaceutical companies; as noted earlier, some scholars and policymakers suggest that this is precisely the situation where countries should decline to provide patents. The facts of Eli Lilly’s patents further underscore this.

A federal court invalidated Eli Lilly’s improvement patent, which allegedly covered the drug sold as Strattera, because it had an implied promise to treat ADHD as a chronic condition, but the patent only disclosed a short-term study and did not demonstrate efficacy for long-term use.¹⁰¹ The invalidated patent claimed a new use—treating ADHD—for a known compound, and specifically suggested in the specification that the compound was effective without disclosing any studies or working examples. Importantly, Eli Lilly had previously obtained a patent for the broader “genus” (group) of compounds, as well as a second Eli Lilly patent for treatment for depression.¹⁰² Eli Lilly later developed data to establish that the drug was in fact useful for treating ADHD, but not until long after filing the patent application. Admittedly, it is difficult for a patent applicant to have

99. *E.g.*, NAFTA, *supra* note 36, art. 1100; *see also* Apotex Inc. v. Wellcome Found., Ltd. [2002] 4 S.C.R. 153, para. 66 (Can.).

100. *Id.* at para. 37.

101. Novopharm Ltd. v. Eli Lilly & Co., 2010 FC 915 (Can.).

102. Canada Patent No. 1,051,034 (Filing date Jan 1, 1975); Canada Patent No. 1,181,430 (Filing date Nov. 12, 1981); *see also* Canada, Statement of Defense, *supra* note 88, ¶ 53.

clinical data at the time an invention is disclosed. However, the invention at issue here did not involve a new compound; rather, it was a new use of an old compound. Moreover, as noted earlier, patent policy dictates that the public should not be burdened with the social cost of a patent unless, at the time of filing, the inventor has made an adequate disclosure; otherwise, the patent becomes a mere hunting license, which imposes substantial costs for the public while rewarding applicants for making a lucky guess.

Similarly, a different federal court invalidated Eli Lilly's patent claiming use of the drug sold as Zyprexa to treat schizophrenia because the patent implied a promise of superiority. In that case, the court found the patent promised the drug would have fewer side effects than existing antipsychotics for long-term treatment, but the specification provided inadequate disclosure to support this promise.¹⁰³ Importantly, the patent at issue was a "selection" patent that Eli Lilly sought after obtaining a patent on a broader "genus" patent for use in the treatment of certain psychotic conditions, including schizophrenia.¹⁰⁴ However, Canadian patent law, consistent with other countries, generally only permits patents on selections of a previously patented genus if the narrower claim has an advantage over the previously disclosed genus. Eli Lilly's invalidated patent attempted to demonstrate such an advantage; it in fact stated that the invention had "marked superiority and a better side effects profile than prior known antipsychotic agents."¹⁰⁵ However, it did not disclose data to support this claim.

Eli Lilly asserts that Canada improperly invalidated its patents based on an interpretation of the law that did not exist when the patents were examined.¹⁰⁶ Eli Lilly notes that Canada's law is currently different than that of other NAFTA parties (the United States and Mexico) but that when NAFTA was enacted, Canadian law was more similar to other NAFTA parties, such that the promise doctrine could not have been anticipated.¹⁰⁷ Accordingly, Eli Lilly asserts that Canada was wrong to "re-interpret a core patentability requirement enshrined in NAFTA in a way that contradicts the standard accepted by the NAFTA parties at the time the treaty was negotiated."¹⁰⁸

103. *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, para. 218 (Can.).

104. *See* Canadian Patent No. 1,075,687. A selection patent is a subset of the previously and more broadly disclosed genus.

105. Canada Patent 2,041,113, p. 5; *see also* Canada, Statement of Defense, *supra* note 88, ¶ 69 (citing patent specification).

106. *Eli Lilly Notice of Arbitration*, *supra* note 2, ¶ 69.

107. *Id.* ¶¶ 28–34.

108. *Id.* ¶ 68.

Eli Lilly also suggests that the promise doctrine is inconsistent with the PCT because the PCT prohibits countries from “imposing ‘requirements as to the form or contents . . .’” of the original PCT application.¹⁰⁹ In particular, it asserts that the promise doctrine “would defeat the single application objective.”¹¹⁰ Eli Lilly seems to make two separate, but both invalid, claims about the PCT. First, Eli Lilly suggests that the promise doctrine is inconsistent with the PCT requirement that bars countries from imposing requirements on the form of the original PCT application.¹¹¹ Although there is such a rule, it notably only governs the actual PCT application and not patent standards of individual countries. The PCT explicitly states that it does not “limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires.” Utility is in fact a substantive condition of patentability, and the PCT states that national laws may require the applicant to furnish evidence of any substantive condition of patentability.¹¹²

Eli Lilly’s claim that the promise doctrine “would defeat the single application objective” is also flawed. Eli Lilly seems to presume that if one nation has a patent standard that differs from others it would be impossible for applicants to comply with this standard in the PCT application, such that this inconsistent standard would defeat the purpose of the PCT—to provide a streamlined method of applying for patents in multiple countries. However, given that the PCT does not govern patentability standards, this claim is unfounded. This argument seems especially unjustified since there are prior situations where nations have had different laws that implicate what is disclosed in the PCT application. For example, the United States is unique in requiring patent applicants to disclose the “best mode” of using an invention.¹¹³ Although other countries have not adopted the best mode requirement, foreign applicants have used PCT applications to seek U.S.

109. *Id.* ¶ 45; *see also* Patent Cooperation Treaty, *supra* note 51, art. 27(1).

110. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 45.

111. Patent Cooperation Treaty, *supra* note 64, art. 27(5).

112. *Id.* art. 27(5)–(6).

113. 35 U.S.C. § 112 (2012); *see also* NAT’L RESEARCH COUNCIL OF THE NAT’L ACADEMIES, A PATENT SYSTEM FOR THE 21ST CENTURY 121 (Stephen A. Merrill et al. eds., 2004) (“[O]nly the United States imposes a best mode requirement.”); Donald S. Chisum, *Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, A Review of Recent Federal Circuit Cases and a Plea for Modest Reform*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 277, 279 (1997) (noting the standard is “virtually unique to U.S. law” without counterparts in European or Japanese law). However, although this requirement still technically exists for granting of patents, failure to meet this requirement is no longer a basis for invalidation after the most recent amendments to patent laws. 35 U.S.C. § 282(b)(3)(A) (2012).

patents for years. Admittedly, some suggest that this may be unfair to foreign applicants who might forget to consider U.S. patent laws when they file a PCT application. Yet even those that criticize the best mode as unfair to foreign applicants do not cite any problems with PCT applications.¹¹⁴ This criticism differs from Eli Lilly's claim that the promise doctrine is an actual violation of the PCT or that the doctrine completely defeats the single application objective. For example, the best mode requirement does not defeat the single application objective because an applicant's PCT application can still result in a U.S. patent if the applicant discloses the information appropriate for complying with U.S. law.

Although Eli Lilly correctly considers a patent to be a possible investment covered by investor-state agreements, there are multiple challenges to its claims that this Article will detail in subsequent Parts. First, although valid intellectual property rights are unquestionably investments, an intellectual property "right" that is canceled for failing to meet the applicable standards should not be considered an investment that is within the scope of such agreements. Eli Lilly obviously contests this issue in making its claims that invalidating a patent is tantamount to "expropriation" of its investment and a violation of the requirement that all investments be provided "fair and equitable treatment."

II. REVOCATION OF INTELLECTUAL PROPERTY RIGHTS SHOULD NOT BE A BREACH OF INVESTMENT OBLIGATIONS

Eli Lilly's case illustrates why revocation of patent rights should not constitute a breach of investment obligations. First, this Part explains why there is no covered "investment" and thus no grounds for an investor-state dispute. Then, this Part argues that tribunals should not find revoked rights to be either an expropriation or a violation of fair and equitable treatment. Although there are strong reasons for rejecting such claims, this analysis also highlights how a tribunal could nonetheless find otherwise, which underscores the need for the reforms proposed in Part IV.

114. *E.g.*, NAT'L RESEARCH COUNCIL, *supra* note 113, at 121; Chisum, *supra* note 113, at 279. In particular, these criticisms focus on the situation where an applicant relies on the PCT application, but reliance on a previously filed domestic application in the foreign inventor's home country for obtaining an earlier filing date. *See* 35 U.S.C. § 119 (2012). However, those who complain about the unfairness of the best mode for foreign applicants mostly focused not on PCT applications, but applicants who rely on the date of a patent application in their *own country*. *E.g.*, Lee Petherbridge & Jason A. Rantanen, *The Pseudo-Elimination of Best Mode: Worst Possible Choice?*, 59 UCLA L. REV. DISCOURSE 170, 171 (2012).

A. CANCELED INTELLECTUAL PROPERTY RIGHTS SHOULD NOT BE A COVERED INVESTMENT THAT WOULD ENABLE AN INVESTOR-STATE DISPUTE

Existing investment agreements should be interpreted to exclude canceled intellectual property rights as a covered investment. Intellectual property rights are different than other types of property because they can be and often are later canceled. The cancellation of the rights means there were no legitimate rights to begin with, so in these cases there should be no recognized investment that would trigger the ability to file an investor-state dispute.

1. *Intellectual Property is Different from Real Property*

Intellectual property rights are fundamentally different from real property rights with respect to their existence; intellectual property may be canceled and has a different creation process.¹¹⁵ This is inherently different from real property, which is never canceled; in the rare case where an action to quiet title succeeds, the property itself still exists. In addition, unlike most forms of real property, which exist without state intervention, some types of intellectual property only exist if granted by the state and states can even cancel many types that exist without state intervention.¹¹⁶ For example, a patent right does not exist without a state agency such as the U.S. Patent and Trademark Office reviewing an application to evaluate whether a patent is deserved.¹¹⁷ But this determination occurs after only a brief administrative review, so patents are at most presumptively valid;¹¹⁸ they can be and often

115. Although not all intellectual property rights may be canceled, this is definitely true of patents, as well as trademarks and copyrights. *E.g.*, 15 U.S.C. § 1064 (2012) (trademarks); 37 C.F.R. § 201.7 (2001) (copyright).

116. The only types of intellectual property rights that cannot be canceled are rights of publicity and trade secrets. However, these are often considered less valuable to companies than the traditional types of intellectual property that can be canceled, such as patents, copyrights, and trademarks.

117. *E.g.*, 35 U.S.C. §§ 111, 131 (2012). This is obviously different than other types of intellectual property rights, such as trademarks, trade secrets, and rights of publicity, which not only exist, but which a rights holder can enforce without a state determination to grant. *E.g.*, 15 U.S.C. § 1125 (2012) (permitting enforcement of unregistered trademarks). Copyrights can also exist without state determination, but U.S. law still requires registration of a copyright before a rights holder can file suit. 17 U.S.C. § 411 (2012).

118. *E.g.*, 35 U.S.C. § 282 (2012) (presumption of validity); Canada Patent Act, R.S.C. 1985, c. P-4, § 43(2). In India, patents do not enjoy an initial presumption of validity; they only acquire such a presumption after six years, after the opposition period has elapsed. *E.g.*, The Patents Act, No. 39 of 1970, INDIA CODE § 13.4 (2005) (as amended by The Patents Act 2005, No. 15, Acts of Parliament, 2005) (patent examination does not “warrant the validity of any patent”); 3M Innovative Props. Co. v. M/S Venus Safety & Health Pvt Ltd.,

are canceled or revoked if it is found that the agency should not have issued the rights in the first instance.¹¹⁹ In most countries, there are a variety of cancellation and revocation mechanisms, including proceedings at the patent office as well as invalidation in a court.¹²⁰ For example, Canada's patent laws state that an issued patent is assumed valid in the absence of evidence to the contrary, thus expressly contemplating that issued patents can be found invalid.¹²¹ Canada's patent laws also provide that the usual patent right to exclude is "subject to adjudication" by Canadian courts, which means that those rights are contingent on a Canadian court determining whether the patent is valid.¹²² Accordingly, a patent that is invalidated for failure to satisfy one of the stated standards should not constitute intangible property pursuant to an investment agreement since the invalidation means the patent never should have existed.

Rather, invalidating a patent is more akin to an application for patent rights, for which there has never been a recognized property right.¹²³ In particular, whereas the owner of a patent can exclude others from use of the patented invention, the owner of a mere patent application has no such rights.¹²⁴ Nonetheless, there is one prior case that is somewhat analogous to

(2014) (India), *available at* <http://lobis.nic.in/dhc/MAN/judgement/05-06-2014/MAN30052014S25582013.pdf>; *see also* TABREZ AHMAD & INDRANIL GHOSH, PRESUMPTION OF PATENT VALIDITY: A COMPARATIVE STUDY IN THE LIGHT OF INDIAN AND U.S. SITUATIONS (2011), *available at* <http://ssrn.com/abstract=1978918>; Lakshmikumaran & Sridharan, *International Report- Delhi High Court Rules on Presumption of Validity Under Indian Patent Law*, IAM (July 2, 2014) <http://www.iam-magazine.com/reports/Detail.aspx?g=2805840f-8901-40ac-b907-e2ef68e69ceb/>.

119. *See, e.g.*, 35 U.S.C. §§ 311, 321 (2012); Canada Patent Act, R.S.C. 1985, c. P-4, §§ 42, 43(2), 60(1).

120. In the United States, patents may be invalidated pursuant to re-examination, inter partes review, and a relatively new post-grant review for patents filed after March 2013. 35 U.S.C. §§ 301 (re-examination), 311 (inter partes review), 321 (post-grant review) (2012).

121. Canada Patent Act, R.S.C. 1985, c P-4, § 43(2).

122. *Id.* § 42.

123. Although some agreements consider patent applications to be investments, they notably limit such claims to applications for *patentable* inventions, which means that they still must meet the basic patentability requirements. *E.g.*, Bilateral Investment Treaty, U.S.-Jam., art. I.1(a)(iv), Feb. 4, 1994, S. TREATY DOC. No. 103-35 (1997). However, including an application as an investment seems questionable based on intellectual property laws because there are no rights unless and until they are granted. *But see* Mercurio, *supra* note 26, at 878–80 (arguing that an application for an intellectual property right could be considered an investment, in part because the European Court of Human Rights held that an application for a trademark is a property right for purposes of the European Convention on Human Rights).

124. *See* 35 U.S.C. § 271(a) (2012) (only providing enforcement rights to patent owner). Although Congress recently amended the Patent Act to provide limited retroactive damages

the situation of cancelled intellectual property. A recent decision held that an application to sell a generic drug was not a property right that would qualify as an investment because, even though the FDA granted tentative approval, the FDA retained the right to revoke the approval.¹²⁵ Although an application to sell a drug is obviously different than an application for a patent, in both situations there is no “right” (whether to sell a drug or exclude others from making it) unless and until a government agency makes a determination. In addition, in both cases, a positive government decision is tentative and subject to reversal. Since a revocable decision that would confer some proper rights is not an investment, a right that has already been revoked is even less likely to qualify. Of course, this is only one tribunal decision, and other decisions need not follow it. However, given that the decision simply further supports long-standing patent policy, there is a firm foundation for a tribunal to consider cancelled intellectual property rights not to be a type of covered investment.

In addition, canceled intellectual property rights, including those canceled based on a common law modification of long-standing patent criteria should be considered to never have existed. This highlights yet another difference between intellectual property law and real property. As noted earlier, real property is not dependent on state determinations, so what constitutes valid real property is unlikely to change. This difference is an important nuance for Eli Lilly’s case. Eli Lilly argues that because its patents were consistent with Canadian law at the time of application, it was improper for a change in the law after issuance to invalidate its patents.¹²⁶ However, contrary to Eli Lilly’s assertion, it is common for case law to modify patent law and retroactively invalidate previously granted patent rights. In the United States, for example, the Supreme Court’s modification of the obviousness standard to make it

to a patent owner for infringement that occurred while the application was pending, such rights only issue if a patent is ultimately awarded. *See id.* § 154(d).

125. *Apotex Inc. vs. United States*, Award on Jurisdiction and Admissibility, ¶¶ 209–10, 222–23 (NAFTA/UNCITRAL Arb. Trib. June 14, 2013).

126. Eli Lilly Notice of Arbitration, *supra* note 2, ¶¶ 8–9 (asserting that the Canadian judiciary has “created a new doctrine” to assess utility that is a “dramatic departure from the standard” prevailing in Canada when its patents were filed and granted). Eli Lilly bases this statement on the fact that when it applied, the Canadian patent office guidelines used a different utility standard that considered inventions to satisfy unless the invention is “totally useless.” *Id.* ¶ 8. However, the very guidelines that Eli Lilly uses as its sole source of authority for this issue in fact state that only courts have authority to interpret patent law. *Manual of Patent Office Practice*, Consumer and Corporate Affairs Canada, Patent Office, Forward (1977). This is true of all subsequent guidelines. Canada, Statement of Defense, *supra* note 88, ¶ 46.

more difficult to meet impacted the validity of existing patents.¹²⁷ More recently, after the Supreme Court modified what types of genes may be patentable subject matter, the validity of some previously issued patents is in question.¹²⁸ Moreover, this phenomenon is common to all areas of common law doctrine that have both prospective and retrospective application.¹²⁹ In addition, there is even a prior tribunal decision rejecting the suggestion that retroactive application of a domestic law would be inappropriate and explicitly noting that it is “normally a matter of local courts to determine” whether to apply new decisional law retrospectively.¹³⁰

2. *Canceled Intellectual Property Should Be Excluded from Investment Agreements Based on Policy Grounds*

In addition to the criticisms of investor-state arbitration disputes previously noted, these disputes present unique policy problems when investors challenge IP rights that are permissible under international agreements. First, unlike most types of investments subject to investor-state disputes, international treaties, such as TRIPS, govern intellectual property. These international agreements represent negotiated norms among states, and a decision by an investor-state tribunal interpreting these treaties, or even simply the filing of an action challenging them, would have a chilling effect on these negotiated norms and could also result in inconsistent decisions. Second, intellectual property rights are granted to effectuate domestic social policies, and permitting challenges to domestic decisions canceling intellectual property rights undermines these policies. Third, intellectual property is also fundamentally different from traditionally protected investments in that the traditional rationale for permitting investors to challenge states does not apply to intellectual property.

127. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 407 (2007); see also Christopher M. Holman, *Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645, 681–84 (2011).

128. *E.g.*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938 (N.D. Cal. 2013); see also Sherman Kahn, *Will Patents Be the Next Wave in Investor-State Arbitration?*, 7 N.Y. DISP. RESOL. LAW. 53, 56 (2014).

129. See, e.g., Harold J. Krent, *The Puzzling Boundary Between Criminal and Civil Retroactive Lawmaking*, 84 GEO. L.J. 2143, 2156 (1996); see also Donald T. Hornstein, *Resiliency, Adaptation, and the Upsides of Ex Post Lawmaking*, 89 N.C. L. REV. 1549, 1551 (2011) (noting that retroactivity is not only tolerated but sometimes celebrated).

130. *Mondev Int'l Ltd. v. United States*, ICSID Case No. ARB(AF)/99/2, Award, ¶¶ 137–38 (Oct. 11, 2002) (rejecting the suggestion that retrospective application of a rule by a court would constitute violation of NAFTA article 1105 regarding minimum standard of treatment).

- a) International Agreements Permit Nations to Decide on the Scope of Intellectual Property Rights; Investment Arbitrations Should Not Disrupt This Norm

Investment arbitration disputes that affect domestic decisions concerning intellectual property rights are different than most other investment disputes because they can undermine the goals of the separate international agreement, TRIPS; accordingly, investor-state disputes should exclude domestic intellectual property decisions consistent with TRIPS.¹³¹ As noted earlier, well over one hundred countries, including Canada, must comply with TRIPS. However, TRIPS sets minimum, but not uniform standards, such that nations have substantial flexibility to define these standards.¹³² In particular, while patents must be granted on all inventions that satisfy traditional criteria, including that the invention be useful, TRIPS notably does not define the term, so countries have discretion to decide the applicable standard.¹³³ In addition, TRIPS expressly contemplates that patent rights can be revoked and simply requires that there be judicial review of any such decision.¹³⁴ As explained below, TRIPS is fundamentally different from other international agreements implicated in investor-state disputes to date, which involve more ambiguous criteria and do not create a direct conflict. In addition, if investor-state disputes could challenge TRIPS-consistent decisions, there is a risk of decisions inconsistent with the built-in dispute resolution process of TRIPS. Moreover, considering that TRIPS is already an encroachment on traditional state sovereignty, permitting investor-state disputes to challenge TRIPS-consistent actions would seem particularly unfair and would have a chilling effect on TRIPS-permissible laws that would promote better access to affordable medicine. Given these issues, investor-state tribunals should not consider TRIPS-consistent domestic decisions as violations of investor rights.

Although investor-state tribunals have previously addressed conflicts with other international agreements, those agreements are fundamentally different than TRIPS. Only in limited situations has another international agreement been arguably relevant to investment-specific claims.¹³⁵ These

131. Although there are agreements since TRIPS that set even higher standards, this section will focus only on TRIPS because it has the most extensive membership of any international agreement concerning intellectual property.

132. TRIPS, *supra* note 3, art. 1(1).

133. *Id.* art. 27(1); *see also supra* notes 53–60 and accompanying text (noting that this proposition is well supported by scholars and policymakers).

134. TRIPS, *supra* note 3, art. 32.

135. This excludes the use of “umbrella” clauses in international agreements that permit an investor to enforce other commitments or reliance on other international agreements as

situations involve direct conflicts with another international agreement where arguably only one agreement can apply,¹³⁶ and a situation where an agreement that generally provides for investor-state arbitration explicitly exempts under certain environmental treaties.¹³⁷ TRIPS, however, is a unique international agreement because its standards allow for flexibility. An investor-state tribunal could find that a state has violated the investment-based rights of a foreign investor when the state is in compliance with TRIPS because TRIPS only provides a minimum standard of protection. Although this may seem to suggest there is no conflict, such a finding would undermine the ability of countries to use flexibilities under TRIPS. As a policy matter, it is inappropriate to impose liability under an investment chapter on a country that is complying with a separate international agreement.

In no other prior situations have investor-state disputes had the potential to create liability for nations that are complying with a separate international agreement. Indeed, in most cases, there is not a true conflict with a separate international agreement. The closest situation that has arisen involves the

part of customary international law. *See, e.g.,* Roger Alford, *Using Investment Arbitration to Enforce WTO Commitments*, KLUWER ARB. BLOG (Apr. 18, 2014), <http://kluwerarbitrationblog.com/blog/2014/04/18/using-investment-arbitration-to-enforce-wto-commitments/> (noting that umbrella clauses in BITS could permit enforcement of WTO and other trade agreement commitments); *see also* Charles Owen Verrill, Jr., *Are WTO Violations Also Contrary to the Fair and Equitable Treatment Obligations in Investor Protection Agreements?*, 11 ILSA J. INT'L & COMP. L. 287 (2005); S.D. Myers, Inc. v. Canada, Partial Award, ¶¶ 234, 256 (NAFTA/UNCITRAL Arb. Trib. Nov. 12, 2000), 40 I.L.M. 1408 (2001) [hereinafter S.D. Myers Partial Award] (suggesting in dicta that minimum standard of treatment under NAFTA take into account “the letter or spirit of widely, though not universally accepted international agreements like those in the WTO system”).

136. Even when raised, tribunals do not always need to address a possible conflict since sometimes the competing international agreement is found to have come into force too late to be relevant. *E.g.,* Micula v. Romania, ICSID Case No. ARB/05/20, Award (Dec. 11, 2013) (finding no conflict because non-investment agreement was concluded *after* the investment agreement). *See also* Abba Kolo, *Transfer of Funds: The Interaction between the IMF Articles of Agreement and Modern Investment Treaties: A Comparative Law Perspective*, in INTERNATIONAL INVESTMENT LAW AND COMPARATIVE PUBLIC LAW 345, 355 (Steven Schill ed., 2010) (suggesting that if there is a conflict between a capital transfer provision of an investment agreement and the IMF, the investment agreement should apply as more specific under *lex specialis*).

137. Canada argued that investment claims were inconsistent with its international environmental obligations under the Basel Convention and the U.S.-Canada Transboundary Agreement on Hazardous Waste, such that these agreements should prevail over investment claims. The tribunal found no actual conflict. S.D. Myers Partial Award, *supra* note 135, ¶ 150. This situation is also different in that NAFTA has a specific clause for possible inconsistency with other environmental agreements and states that those obligations shall prevail to the extent of inconsistency, but where a party has a choice between equally effective and reasonably available means, the party must choose the least inconsistent measure. NAFTA, *supra* note 36, art. 104.

actual or proposed use of other international agreements as defenses where those agreements are largely aspirational. For example, in the pending suits concerning plain packaging tobacco laws, there is a WHO framework convention that supports domestic laws at issue,¹³⁸ but legally, no member countries must apply the guidelines.¹³⁹ Similarly, although some commentators have suggested that states should rely on international human rights norms as a defense, these norms are notably vague and generally do not clearly indicate what countries can do.¹⁴⁰ For example, although some have suggested that there is an international right to affordable and equitably distributed water that could be relevant, no state has attempted to clearly rely on such rights.¹⁴¹ This could be because international rights are to citizens, rather than countries. Moreover, there is no firm requirement; any such right is based on a General Comment to the UN Committee on Economic, Social and Cultural Rights, and the UN agreement actually only requires that states “take steps” with the caveat that those steps be based on “available resources.”¹⁴² Accordingly, as human rights treaties simply reflect a general desire to promote certain activity, they provide no firm criteria, whereas TRIPS expressly states that countries must provide certain patent standards while at the same time permitting nations flexibility in interpreting these standards.

138. *E.g.*, Philip Morris Brands Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Request for Arbitration, ¶ 3 (Feb. 19, 2010); Philip Morris Asia Ltd. v. Australia, PCA Case. No. 2012-12, Written Notification of Claim (BIT/UNCITRAL Arb. Trib. June 27, 2011).

139. *E.g.*, Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46 VAND. J. TRANSNAT'L L. 1149, 1163 (2013); *see also* WORLD HEALTH ORG., WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (2004), available at <http://whqlibdoc.who.int/publications/2003/9241591013.pdf>.

140. *E.g.*, LUKE ERIC PETERSON & KEVIN R. GRAY, INT'L INST. FOR SUSTAINABLE DEV., INTERNATIONAL HUMAN RIGHTS IN BILATERAL INVESTMENT TREATIES AND IN INVESTMENT TREATY ARBITRATION 27–32 (2003) (suggesting that states that are member to ICESCR and other covenants consider using these as defenses); Ursula Kriebaum, *Privatizing Human Rights: The Interface Between International Investment Protection and Human Rights*, in THE LAW OF INTERNATIONAL RELATIONS 165, 173–77 (A. Reinisch & U. Kriebaum eds., 2007); Todd Weiler, *Balancing Human Rights and Investor Protection: A New Approach for a Different Legal Order*, 27 B.C. INT'L & COMP. L. REV. 429 (2004).

141. Indeed, one commentator has suggested that the vagueness of these obligations is an explanation for why nations do not suggest a conflict with human rights. James D. Fry, *International Human Rights Law in Investment Arbitration: Evidence of International Law's Unity*, 18 DUKE J. COMP. & INT'L L. 77, 93–96 (2007).

142. International Covenant on Economic, Social and Cultural Rights art. 2, Dec. 16, 1966, 993 U.N.T.S. 3 (“[E]ach State Party to the present Covenant undertakes to take steps, . . . with a view to achieving progressively the full realization of the rights recognized.”); *see also* arts. 11–13 (right to water). In addition, the General Comment is itself nonbinding.

Investor-state dispute tribunals should also decline to address intellectual property issues that are consistent with international agreements concerning intellectual property when these agreements already provide a mechanism for addressing alleged inconsistencies to prevent inconsistent decisions. For example, there is a built-in forum for adjudicating alleged TRIPS violations pursuant to the robust WTO dispute settlement process. If investors were permitted to usurp this process, it could both result in inconsistent decisions and undermine the negotiated international norms pursuant to TRIPS. Notably, the WTO dispute settlement process is intended to be the sole means to settle violations of its agreements such as TRIPS. Although there is no language expressly excluding investor-state arbitrations, no such arbitrations involved intellectual property at the time the WTO and TRIPS were negotiated, so negotiators likely did not see the need to include such a provision. However, these agreements do contain language prohibiting countries from taking unilateral action for violations.¹⁴³ Permitting investors to engage in a form of self-help through investor-state arbitrations seems one step beyond countries taking unilateral actions. Moreover, there are issues with having investor-state arbitrations decide TRIPS issues when they lack familiarity with either intellectual property or WTO agreements.¹⁴⁴ There is a strong possibility of inconsistent rulings, especially because investor-state arbitrations have no appellate review.

Beyond interfering with an existing dispute resolution process and producing potentially inconsistent decisions, permitting investor-state arbitrations to overrule internationally agreed upon domestic flexibilities under TRIPS seems particularly unfair to countries since TRIPS already encroaches on traditional domestic authority in the area of intellectual property rights. Notably, the TRIPS requirement that all countries provide some level of patent protection was a monumental change to the prior international landscape, where countries previously did not have to grant any intellectual property rights. The idea of global rules requiring patent protection was the brainchild of multinational pharmaceutical companies. They successfully lobbied the United States and EU member states to advocate this in the context of an agreement that would include issues of interest to developing countries that would otherwise oppose an agreement

143. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 23:2 Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 33 I.L.M. 1226, 1241.

144. Indeed, some suggest that past tribunals have struggled to properly interpret and apply WTO law. *E.g.*, Jürgen Kurtz, *The Use and Abuse of WTO Law in Investor-State Arbitration: Competition and its Discontents*, 20 EUR. J. INT'L L. 749 (2009) (focusing on misuse of WTO law concerning national treatment); Mercurio, *supra* note 26, at 905.

focused exclusively on mandating intellectual property rights.¹⁴⁵ Developing countries may have capitulated to including intellectual property norms because they were interested in enhancing the ability to market agricultural products to other countries, which membership in the WTO would allow.¹⁴⁶ In addition, some developing countries may have agreed to TRIPS assuming that this would forestall unilateral pressure from countries concerning their intellectual property laws.¹⁴⁷ Accordingly, agreement to TRIPS requirements, including providing patents on drugs, does not reflect uniform agreement that patents are desirable as a matter of policy. Given this historical context, permitting an individual investor to further encroach on the limited domestic flexibilities under TRIPS seems particularly unfair to developing countries.

Importantly, if tribunals allow cases such as *Eli Lilly's*, these cases could have a chilling effect on an important trend where developing countries are beginning to finally use their full flexibility under TRIPS. Notably, although TRIPS has always provided states discretion to define the minimum patentability standards, some nations were initially hesitant to do so and simply copied the patent standards of countries such as the United States, even though such laws were not necessarily in their interest. India was the first country to use its full flexibility under TRIPS to create a unique law that bars patents on “new” drugs that are in fact only modest variations of old drugs with no improved benefit to patients.¹⁴⁸ Since India adopted its law in 2005, other countries have either copied India’s laws, or are contemplating doing so.¹⁴⁹ For example, there is a proposal for Brazil to amend its patent standards to mirror India’s.¹⁵⁰

145. *E.g.*, SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (2003).

146. *E.g.*, PETER DRAHOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* 10 (2002).

147. *E.g.*, Peter K. Yu, *TRIPS and its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 372–73 (2006).

148. The Patents (Amendment) Act, 2005, No. 15, § 3(d), Acts of Parliament, 2005 (India).

149. *E.g.*, Universally Accessible Cheaper and Quality Medicines Act of 2008, Rep. Act No. 9502, §§ 1–2 (2008) (Phil.); Divya Rajagopal, *EU, Australia, Canada May Follow India's Patent Law*, ECON. TIMES, Apr. 4, 2013. In addition, Argentina’s patent guidelines impose an even higher standard—new forms are not patentable even if they have an increase in efficacy. Joint Resolution Nos. 118/20012, 546/2012 and 107/2012, May 2, 2012, B.O. 08/05/12 (Arg.), *available at* http://www.wipo.int/wipolex/en/text.jsp?file_id=288443; Park et al., *supra* note 10, at 43 n.7.

150. BRAZIL CENTER FOR STRATEGIC STUDIES AND DEBATES, *BRAZIL'S PATENT REFORM: INNOVATION TOWARDS NATIONAL COMPETITIVENESS* 114 (2013), *available at* http://infojustice.org/wp-content/uploads/2013/09/Brazilian_Patent_Reform.pdf. In addition, there is a policy proposal recommending that South Africa either copy India’s law

In light of these negative policy implications, tribunals that end up evaluating cases such as Eli Lilly's should at a minimum take TRIPS—including the inherent domestic flexibilities in its implementation—into account. A recent arbitral decision suggests that a tribunal might be willing to do so. In *Ioan Micula v. Romania*, although the majority of the tribunal rejected the notion that the investment agreement was in direct conflict with the EU Agreement, it was willing to consider EU law in evaluating the investment claims.¹⁵¹ In addition, even if a tribunal were to consider TRIPS, the outcome is unclear because TRIPS does not necessarily result in a conflict with any investment provision. Any possible “conflict” would be more with respect to whether an investment tribunal interpreted TRIPS provisions differently than a WTO panel or scholar would. Different interpretations are possible since companies and even countries have been known to suggest TRIPS violations where there are none.¹⁵² Indeed, Eli Lilly's claims are one example—Eli Lilly alleges that Canada's promise doctrine is inconsistent with the utility standard because of a supposed “shared understanding” between signatories.¹⁵³ However, this is irrelevant to interpreting international treaties; the final text, rather than presumed unstated understandings, controls. Eli Lilly ignores this fact, as well as the fact that utility is undefined in the pertinent treaty, rendering Canada free to define it.

b) Domestic Policy Underlying Intellectual Property Supports
Deferring to States

Intellectual property rights are inherently different than most other types of investments protected by investment chapters. The underlying policy goals that justify providing intellectual property rights are distinct from the goals behind other types of property. For example, patents are the primary policy tool to promote innovation and encourage sharing of inventions, rather than keeping them secret. However, it is well recognized that desired policy goals must be balanced against other competing social goals, such as access to

or an even more stringent approach adopted by Argentina. CHAN PARK ET AL., *supra* note 10, at 46.

151. *Micula v. Romania*, ICSID Case No. ARB/05/20, Final Award (Dec. 11, 2013).

152. *E.g.*, *infra* Subsection IV.A.1 (discussing improper suggestions that India's patent law fails to comply with TRIPS).

153. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 40; *see also id.* ¶¶ 7–9 (arguing that Canada's changed interpretation of utility is inconsistent with NAFTA's utility requirement without acknowledging that the term is nowhere defined in NAFTA). Technically Eli Lilly claims that Canada's patent standards are inconsistent with NAFTA, rather than TRIPS, but the standards are identical. *Compare* TRIPS, *supra* note 3, art. 27(1), *with* NAFTA, *supra* note 36, art. 1. Indeed, Eli Lilly does not dispute this. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 42.

affordable medicine. Most other property rights do not inherently compromise these other social goals; indeed, traditional property rights generally do not result in higher prices for goods. Accordingly, although TRIPS requires most countries to provide some degree of patent protection for drugs, it explicitly recognizes the importance of considering public health and other policies; in addition, member states subsequently reaffirmed this principle in a WTO Ministerial Declaration referred to as the Doha Public Health Declaration.¹⁵⁴

Although most countries must provide patents on drugs under TRIPS, it is especially important to defer to domestic decisions concerning TRIPS-consistent patent laws now. First, patents on drugs inherently limit short-term access, but nations are no longer at liberty to completely deny such patent protection even if they value access to low cost medicine more than promoting possible future innovation. Moreover, the patent policy of promoting innovation in the drug arena with patent rights should be considered in light of current business realities. Facing a “crisis” in pharmaceutical innovation where innovation has been stagnant despite exponential increases in expenditures on research, drug companies have developed patent and innovation strategies that aim to extend their profits with minimal innovation. For example, companies are patenting slight modifications of existing drugs, such as extended releases, or new uses that are easier to identify than a brand new compound.¹⁵⁵ In addition, companies are also obtaining patents on multiple aspects of a drug including not just the traditionally patented active ingredient, but also the coating of a drug, or the metabolized version in a patient’s stomach. Critics have dubbed both of these practices “evergreening” because the patent term seems perpetual.¹⁵⁶ In addition, policymakers in both developing and well-developed countries have criticized the handling of these patents; for example, Europe issued a substantial report concerning these patents and recent policy reports suggest that developing countries should modify their patent laws to deny these types of questionable innovations.¹⁵⁷ Companies actually recognize that some of

154. TRIPS, *supra* note 3, arts. 7–8; Doha Declaration on Public Health, *supra* note 34, ¶ 4 (2001).

155. *E.g.*, *supra* note 10 and accompanying text.

156. *E.g.*, THOMAS, *supra* note 10.

157. *E.g.*, EC PHARMACEUTICAL SECTOR INQUIRY, *supra* note 10; BRAZIL CTR. FOR STRATEGIC STUDIES & DEBATES, *supra* note 150; AUSTL. GOV’T, PHARMACEUTICAL PATENTS REVIEW: BACKGROUND AND SUGGESTED ISSUES PAPER (2012); *see also* DECLARATION ON PATENT PROTECTION AND REGULATORY SOVEREIGNTY UNDER TRIPS (2014), *available at* <https://www.mpg.de/8132986/Patent-Declaration.pdf> (signed by forty scholars from over twenty-five countries to reinforce TRIPS flexibilities).

the patents are of dubious validity,¹⁵⁸ but nonetheless seek such patents in hopes of stemming revenue losses as patents on profitable innovative drugs of prior years such as Lipitor and Prozac increasingly expire.¹⁵⁹ Accordingly, although there could theoretically be a policy justification that patent rights promote innovation even if this negatively impacts short-term access through higher prices, that justification seems more theoretical than real in cases where companies are creating minor improvements. Although companies often argue that basic market principles make such concerns irrelevant because consumers would not buy inferior drugs, as noted earlier, the pharmaceutical market is unique, such that general market principles do not apply. So, countries should be able to use their discretion under TRIPS to minimize the social harm of expensive drugs to only those drugs that they deem are more innovative and thus worth the “cost.”

The contested Eli Lilly patents are the very type of patents that policymakers question. In both cases, Eli Lilly is seeking to obtain additional patent protection when it had at least one patent already. In the case of the drug marketed as Strattera for attention deficit disorder, Eli Lilly was already awarded two different patents before it sought the third patent that Canada invalidated.¹⁶⁰ The drug marketed as Zyprexa similarly already enjoyed a full term of patent protection. Both of these instances could be considered examples of evergreening profitable patents. Indeed, Eli Lilly’s two inventions at issue would likely be invalid in India where, to help address this very type of problem, there is a complete bar on patents that simply claim a new utility for a known compound.¹⁶¹ Moreover, other countries including Brazil, Australia, and member states of the European Union similarly

158. *E.g.*, EC PHARMACEUTICAL SECTOR INQUIRY, *supra* note 10, at 192 (noting companies admitting a strategy to seek patents which “might not be rock solid”).

159. Melly Alazraki, *The 10 Biggest-Selling Drugs That are About to Lose their Patent*, DAILY FIN. (Feb. 27, 2011), <http://www.dailyfinance.com/2011/02/27/top-selling-drugs-are-about-to-lose-patent-protection-ready/> (noting that companies can lose up to ninety percent of sales when patents expire). Notably, although Eli Lilly suggests that Canada improperly invalidated a patent pertaining to Zyprexa, which was one of the top five best selling drugs in 2011, in most countries, Zyprexa lost patent protection in 2012. *Id.*; ELI LILLY & CO., 2012 ANN. REP. 12 (2012), *available at* <http://files.shareholder.com/downloads/LLY/3538664350x0x648089/D3A84E25-2AE1-4E41-8E25-A1AE41DA09BB/English.PDF> (noting Zyprexa sales decreased eighty-three percent in the United States and forty-five percent outside the United States due to loss of patent exclusivity).

160. Canada, Statement of Defense, *supra* note 88, ¶ 53.

161. The Patents (Amendment) Act, 2005, No. 15, § 3(d), Acts of Parliament, 2005 (India).

recognize that current patent laws impacting drugs need to be recalibrated to better balance promoting optimal innovation with less social cost.¹⁶²

c) Considering Intellectual Property an Investment Does Not Foster Traditional Policy Justifying Investor-State Disputes

Intellectual property should be excluded from investor-state arbitration because providing enhanced protection of IP does not satisfy traditional justifications for investment arbitrations. Such provisions arose as a means both to encourage investors to consider countries that they might be hesitant to invest in, and to provide a remedy to foreign investors who might otherwise have no recourse if a state took action that reduced the value of their investments.¹⁶³ As explained in this Section, neither of these justifications is relevant to Eli Lilly's case or to intellectual property in general. First, increased protection of intellectual property through investor-state disputes is unlikely to result in greater investment by owners of intellectual property rights in these countries. Second, it is also not necessary to provide adequate recourse. To the contrary, providing such rights would give foreign investors more recourse than domestic investors.

Permitting intellectual property, including denial of intellectual property rights pursuant to domestic law, to be a covered investment is unlikely to encourage companies to invest in particular countries. Multinational companies do not invest in countries solely based on intellectual property laws. A number of studies indicate that other factors, such as tax incentives, infrastructure, and skills are more relevant than intellectual property laws.¹⁶⁴ Indeed, countries known to have weak intellectual property rights, such as India and China, nonetheless have substantial foreign direct investment.¹⁶⁵ In addition, scholars have noted that especially for impoverished countries,

162. *E.g.*, EC PHARMACEUTICAL SECTOR INQUIRY, *supra* note 10; BRAZIL, CENTER FOR STRATEGIC STUDIES & DEBATES, *supra* note 150; AUSTL. GOV'T, *supra* note 157.

163. *E.g.*, Salacuse, *supra* note 64, at 109–10.

164. *E.g.*, Carsten Fink, *Intellectual Property Rights and U.S. and German International Transactions in Manufacturing Industries*, 9 DUKE J. COMP. & INT'L L. 163 (1997); Claudio R. Frischtak, *Harmonization Versus Differentiation in Intellectual Property Right Regimes*, in GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 89, 103–05 (Mitchel B. Wallerstein et al. eds., 1993); Jeong-Yeon Lee & Edwin Mansfield, *Intellectual Property Protection U.S. Foreign Direct Investment*, 78 REV. ECON. & STAT. 181, 181–85 (1996).

165. For example, India had \$1 billion in foreign direct investment in three months of 2013 despite controversial patent laws that have been noted as inadequate by many companies. *E.g.*, *India Receives Highest FDI Worth \$ 1 billion in Pharma in April–June*, ECON. TIMES (Sept. 1, 2013), http://articles.economictimes.indiatimes.com/2013-09-01/news/41663407_1_pharmaceuticals-sector-highest-fdi-fdi-policy/.

foreign direct investment is unlikely because of a lack of infrastructure or a viable domestic market.¹⁶⁶

This is particularly true for pharmaceutical companies and patent rights. Given the extensive infrastructure already present for the development and manufacture of a drug, local laws are unlikely to encourage investment in a new country. Generally, multinational companies develop patentable inventions where they have research labs, primarily in the United States and Europe, but seek patent rights in all nations where they can market their inventions, including nations where they may have made no investments.

Although some claim that stronger patent rights may promote foreign direct investment, there is no robust empirical evidence to support this claim.¹⁶⁷ A number of scholars have noted that macroeconomic factors such as infrastructure and skills are more important than intellectual property protection,¹⁶⁸ and there are specific studies that note this for patents in particular.¹⁶⁹ Historical evidence supports this argument. For example, Brazil and Thailand received substantial foreign direct investment in the 1970s and 1980s despite low levels of intellectual property protection.¹⁷⁰ One scholar found that foreign direct investment even increased in Korea's pharmaceutical industry after abolition of protection of drugs.¹⁷¹ More recently, although South Africa increased patent protection to comply with TRIPS, this reduced foreign direct investment from pharmaceutical

166. KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 199–205 (2000).

167. E.g., SISULE F. MUSUNGU, RETHINKING INNOVATION, DEVELOPMENT AND INTELLECTUAL PROPERTY IN THE UN: WIPO AND BEYOND (2005); Mila Kashcheeva, *The Role of Foreign Direct Investment in the Relation Between Intellectual Property Rights and Growth*, 65 OXFORD ECON. PAPERS 699 (2013); Rajnish Kumar Rai, *Effect of TRIPS-Mandated Intellectual Property Rights on Foreign Direct Investment in Developing Countries: A Case Study of the Indian Pharmaceutical Industry*, 11 J. WORLD INTELL. PROP. 404, 411 (2009).

168. See *supra* note 164; see also Wolfgang E. Siebeck, *Conclusions and Recommendations, in* STRENGTHENING OF INTELLECTUAL PROPERTY RIGHTS IN DEVELOPING COUNTRIES 89 (Wolfgang E. Siebeck ed., 1990); Marco C.E.J. Bronckers, *The Impact of TRIPS: Intellectual Property Protection in Developing Countries*, 31 COMMON MARKET L. REV. 1245 (1994); Carlos A. Primo Braga, *Trade-Related Intellectual Property Issues: The Uruguay Round Agreement and its Economic Implications, in* URUGUAY ROUND AND THE DEVELOPING ECONOMIES 381 (Will Martin & L. Alan Winters eds., 1996).

169. E.g., EDWIN MANSFIELD, INTELLECTUAL PROPERTY PROTECTION, DIRECT INVESTMENT, AND TECHNOLOGY TRANSFER, INTERNATIONAL FINANCE CORPORATION, THE WORLD BANK, DISCUSSION PAPER NO. 27 (1994).

170. CARLOS CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 27 (2000).

171. Arman S. Kirim, *Reconsidering Patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry*, 13 WORLD DEV. 219, 219–36 (1985).

companies that instead consolidated their operations.¹⁷² This is also consistent with a classic study that showed that stronger patent protection in Italy did not result in increased domestic or foreign direct investment.¹⁷³ Also, some have suggested that even if stronger intellectual property rights might attract some foreign direct investment, the corresponding loss in jobs erodes that benefit. Furthermore, stronger intellectual property rights could create higher local prices that may be cost-prohibitive in developing countries.¹⁷⁴

If intellectual property laws will not encourage multinational companies to invest in a country, providing a remedy when the intellectual property laws are considered undesirable does not seem appropriate because the remedy will not result in substantial investments. In addition, it is fundamentally different than the traditional rationale of protecting induced investments. For example, even though Eli Lilly claims that it could not have anticipated that Canada would change its patent laws, those laws did not induce Eli Lilly to develop the inventions on which it sought Canadian patent protection. Rather, Eli Lilly was developing those inventions for any country that would provide protection and does not appear to have made any specific investments in Canada based on Canadian patent law. Admittedly, an issued patent could have induced Eli Lilly to begin to market its drug. However, unlike other investments for which the investor-state dispute challenge is granted, a granted patent can be legally canceled, so the claim for inducement is weak. Moreover, the “investment” of marketing a drug does not provide the same value to a country as the types of investment that the laws initially contemplated. For example, although marketing a drug may involve some investment in local advertisement and possibly employment of local citizens, it would likely pale in comparison to the capital investments that are more typical with real property such as building structures in a country in response to incentive programs.

In addition, investor-state arbitrations originally developed to provide foreign investors an ability to protect assets when they had no other means to do so. Typically, this was because they could not bring a claim before

172. C. te W. Naudé & J.M. Luiz, *An Industry Analysis of Pharmaceutical Production in South Africa*, 44 S. AFR. J. BUS. MGMT. 33 (2013); David Kaplan, *Intellectual Property Rights and Innovation in South Africa: A Framework*, in *THE ECONOMICS OF INTELLECTUAL PROPERTY IN SOUTH AFRICA* (WORLD INT’L PROP. ORG. ed., 2009).

173. F.M. Scherer & Sandy Weisburst, *Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy*, 26 INT’L REV. INDUS. PROP. & COPYRIGHT L. 1009 (1995).

174. E.g., Paul J. Heald, *Moving the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 MINN L. REV. 249 (2003); Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 32 CASE W. RES. J. INT’L L. 471, 480–81 (2000).

domestic courts where the government might be immune from suit or because court systems were corrupt. However, neither of these situations apply to Eli Lilly's case. It was already able to directly challenge Canada's decision to revoke its patents through an appellate process.¹⁷⁵ In addition, Eli Lilly does not even contest that there was any procedural irregularity with the manner in which it was able to challenge the undesirable court decisions. However, Eli Lilly is now simply seeking another bite at the apple that would be unavailable to a domestic Canadian company. This is not within the traditional justification of investor-state disputes, which are supposed to provide a means for foreign investors that are otherwise without recourse. In fact, Eli Lilly's situation falls within one of the current criticisms of such disputes—that they unfairly provide more benefits to foreign investors than are available to domestic investors.

B. INVALIDATION OF PATENT RIGHTS SHOULD NOT CONSTITUTE
EXPROPRIATION

Assuming that Eli Lilly has a covered investment, this Section explains why invalidation of Eli Lilly's patent rights should not constitute "expropriation" under the relevant investment chapter. This Section first demonstrates how Eli Lilly's case may involve a situation that is exempt from expropriation analysis. Alternatively, this Section examines how, although the situation may not be completely exempt based on prior decisions as well as policy grounds, the arbitration tribunal should not find that Canada has engaged in either direct or indirect expropriation.

Before addressing the specific legal claims, it is important to first clarify what expropriation means. All international agreements protecting foreign investments provide a claim against states that expropriate (take) investments covered by the agreement; such investments typically include not only tangible, but also intangible property of economic value. It is roughly analogous to U.S. takings law in terms of involving state action, but expropriations may exist in situations that would fail under U.S. takings law. In general, agreements recognize that there are some situations where countries should be allowed to expropriate investments, but only if there is a public purpose, the action is nondiscriminatory, and there is just compensation.

A foreign investor may have a claim for either direct or indirect expropriation. Direct expropriation claims involve outright and overt taking of property by the state, such as by transferring title to the state; the reason

175. In addition, although the Supreme Court of Canada denied Eli Lilly review, that was within the discretion of the Court.

for the taking is not important.¹⁷⁶ Indirect expropriation, on the other hand, can exist even if the investor maintains ownership of the investment, but because of “unreasonable interference” the investor loses all, or a significant part, of its investment.¹⁷⁷ Although the two types of expropriation are fairly straightforward to explain, there are few direct expropriation claims in recent times¹⁷⁸ and indirect expropriation analysis is complicated because tribunals use several different tests.

1. *Canada’s Actions May Be Exempt from an Expropriation Claim*

An initial question is whether there is any need to even address the details of an expropriation claim. There are two possible ways Canada could avoid the claim altogether. First, the situation could fall under a specific NAFTA intellectual property exception that prevents foreign investors from raising a claim for expropriation. Alternatively, the Canadian decisions may not constitute the “state action” that is a fundamental prerequisite to expropriation claims. Although there are arguments for excluding Eli Lilly’s claims under either of these grounds, a tribunal could reasonably find otherwise, as explained below.

First, Eli Lilly’s case is brought pursuant to NAFTA, which expressly excludes certain issues from consideration as expropriation that might otherwise qualify.¹⁷⁹ Article 1110 generally prohibits member states from expropriating foreign investments. However, paragraph seven states that it does not apply to “revocation, limitation or creation of intellectual property

176. For example, when Venezuela seized oil installations of foreign companies, it resulted in a series of direct expropriation cases. *E.g.*, P.G., *Venezuela and International Arbitration: Ick-SID*, *ECONOMIST* (Jan. 20, 2012, 6:03 PM), <http://www.economist.com/blogs/americasview/2012/01/venezuela-and-international-arbitration/>.

177. *E.g.*, August Reinisch, *Expropriation*, in *THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW* 407, 422 (Peter Muchlinski et al. eds., 2008). Accordingly, even if the investor continues to own legal title, there still may be indirect expropriation. *E.g.*, *Metalclad Corp. v. United Mexican States*, ICSID Case No. ARB(AF)/91/1, Award, ¶ 103 (Aug. 30, 2000), 5 ICSID Rep. 212 (2001) [hereinafter *Metalclad Award*].

178. *E.g.*, Anne K. Hoffmann, *Indirect Expropriation*, in *STANDARDS OF INVESTMENT PROTECTION* 151 (August Reinisch ed., 2008); Reinisch, *supra* note 177, at 408.

179. In addition, a similar analysis applies to many other existing and pending agreements that contain similar language about excluding as expropriation denial of intellectual property rights consistent with TRIPS. *E.g.*, U.S.-Singapore Free Trade Agreement, U.S.-Sing., art. 15.6.5, May 6, 2003; Trans-Pacific Partnership Agreement, Wikileaks Investment Chapter art. 11.7(5) (2015) [hereinafter draft TPP investment chapter]. Notably, TRIPS is a different agreement than NAFTA, but both have similar language concerning patentability requirements. *Compare* TRIPS, *supra* note 3, art. 27(1), *with* NAFTA, *supra* note 36, art. 1709(1).

rights” if consistent with the NAFTA provision on patents.¹⁸⁰ This seems to preclude expropriation claims of intellectual property, such as patents, that are revoked in a manner consistent with NAFTA.

In the Eli Lilly case, the issue is whether the revocation provision of NAFTA prevents countries from revoking patents because the interpretation of an existing patent law ground, utility, has changed since the patent was issued. Eli Lilly asserts that such a revocation is impermissible under NAFTA, which would mean that the paragraph seven exemption does not apply. However, NAFTA’s language does not explicitly support this conclusion and doing so would be contrary to recognized principles of how common law operates. There are two NAFTA sections on patents that are relevant to Eli Lilly’s situation. First, the most fundamental patent provision is article 1709(1), which requires each party to provide patents on inventions that satisfy the criteria of being new, useful, and non-obvious.¹⁸¹ Notably, NAFTA does not define what it means to be “useful,” so member states such as Canada should be able to define this as they wish, even if different than the laws of other NAFTA member states. Second, article 1709(8) states that countries may only revoke a patent when “grounds exist that would have justified a refusal to grant the patent.”¹⁸²

As noted earlier, courts do modify patent law standards and retroactively apply them. Given this reality, it seems reasonable to interpret the NAFTA “grounds exist” clause to mean that countries cannot revoke patents on a *new* ground that never previously existed, rather than modification of an existing ground. In Eli Lilly’s case, the patents were invalidated for failing to satisfy the utility doctrine—a long-existing ground for patentability. Although interpretation of the utility doctrine to incorporate the promise doctrine may be new, it is simply a modification of the existing ground. Nonetheless, it is unclear how a tribunal will in fact interpret this NAFTA provision, so it is not clear whether this exempts Canada’s actions from an expropriation claim.

The other issue is whether the Canadian decisions constitute state action, because state action is a fundamental requirement for expropriation. If Canada’s decisions are not a state action, then Eli Lilly has no expropriation claim. Unlike most investment arbitration cases where the action in question is a legislative or regulatory measure, Eli Lilly’s case involves solely the judiciary. Although there are only a handful of arbitration decisions involving domestic court actions, those decisions uniformly affirm that such actions

180. NAFTA, *supra* note 36, art. 1110(7).

181. *Id.* art. 1709(1).

182. *Id.* art. 1709(8).

can constitute state action.¹⁸³ Notably, even though actions of state courts *may* constitute state action, tribunals have stated this is only the case when the court ruling is clearly incompatible with a rule of international law, when there is a denial of justice, or when the state is responsible for a judicial decision “contrary to municipal law.”¹⁸⁴ There are no prior challenges to the substance of judicial decisions as expropriation. Rather, situations involved racial discrimination against an investor that a court failed to limit¹⁸⁵ as well as judicial interference with a contractually permitted arbitration.¹⁸⁶

The only possible basis for considering Canadian court actions against Eli Lilly to be state action is that those actions violate international law; Eli Lilly does not allege that the Canadian court decision was a denial of justice or that that judicial decision was contrary to municipal law. Eli Lilly claims that the judicial decision violated two separate international agreements—NAFTA and the PCT.

Eli Lilly alleges that the promise doctrine is inconsistent with NAFTA requirements concerning utility and nondiscrimination.¹⁸⁷ In particular, Eli Lilly asserts that a “dramatic and unanticipated shift” in Canada’s definition of utility is “significantly out of step” with its NAFTA partners.¹⁸⁸ However, that is irrelevant because NAFTA does not require member countries to have identical laws. Although NAFTA does require countries to grant patents that

183. *Azinian v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award (Nov. 1, 1999), 14 ICSID REV.-FOR. INV. L.J. 538, 567 [hereinafter *Azinian Award*]; *Saipem S.p.A. v. People’s Republic of Bangl.*, ICSID Case No. ARB/05/7, Award, ¶¶ 189–90 (June 30, 2009) [hereinafter *Saipem Award*]; see also *Loewen Grp., Inc. v. United States*, ICSID Case No. ARB(AF)/98/3, Decision on Hearing of Respondent’s Objection to Competence and Jurisdiction, ¶ 70 (Jan. 5, 2001) [hereinafter *Loewen Decision*] (“The modern view is that conduct of an organ of the State shall be considered as an act of the State under international law, whether the organ be legislative, executive or judicial.”). However, these assertions are generally made in cases where *no* expropriation is found, and possibly cases where state action wasn’t even limited to the judiciary, such that they are dicta. *E.g.*, *Saipem Award*, *supra*, ¶ 191 (no expropriation found); *Azinian Award*, *supra*, ¶ 10 (state action was simply affirmance of city council decision); *Loewen Decision*, *supra*, ¶¶ 148, 241 (dismissing all claims both because claimant was not a qualifying investor and also because the claim was an attempt to use arbitration in lieu of a domestic appeal).

184. *Azinian Award*, *supra* note 183, ¶ 98; *Loewen Decision*, *supra* note 183, ¶ 47.

185. In *Loewen*, the investor claimed that racial and other inappropriate suggestions were made against it that resulted in the largest ever state verdict of over \$500 million for contracts worth less than \$5 million that when combined with a 125% bond requirement threatened to bankrupt the company, such that it could not realistically appeal. *E.g.*, Jake A. Baccari, *The Loewen Claim: A Creative Use of NAFTA’s Chapter 11*, 34 U. MIAMI INTER-AM. L. REV. 465, 468–69 (2003).

186. *Saipem Award*, *supra* note 183, ¶¶ 35–37, 39.

187. Eli Lilly Notice of Arbitration, *supra* note 2, ¶¶ 69–70.

188. *Id.* ¶ 9.

meet the standard of utility, it provides no definition, so nations are permitted to self-define it.¹⁸⁹ In addition, NAFTA does not state that countries are precluded from modifying its definition.

Eli Lilly also asserts that Canada has violated the NAFTA obligation to grant patents without discrimination as to field of technology.¹⁹⁰ In particular, Eli Lilly asserts that the promise doctrine has “almost exclusively” impacted pharmaceutical patents.¹⁹¹ However, the doctrine applies to all inventions, so this argument seems questionable. There are many facially neutral patent law standards that actually apply differently to different areas of technology.¹⁹² In addition, as explained by one WTO panel, a neutrally worded law does not de facto discriminate against a field of technology because it does not impact all fields equally.¹⁹³ In particular, the WTO panel stated that discrimination “does not prohibit bona fide exceptions to deal with problems that may only exist in certain product areas.” Such action is considered a permissible *differentiation*, rather than discrimination.¹⁹⁴

Eli Lilly also alleges that Canada’s action is inconsistent with NAFTA article 1709(8), which states that a country may revoke a patent only when “grounds exist that would have justified a refusal to grant the patent.” However, as noted earlier, this should be interpreted to mean that a country cannot revoke a patent on a new patentability requirement, but it should not bar a country from revoking a patent based on modification of the long-standing patent requirement of utility.

Eli Lilly claims that Canada’s modified utility requirement violates the international PCT rule barring countries from imposing “requirements as to the form or contents of the international application different from or additional to” those provided for in the PCT.¹⁹⁵ In particular, Eli Lilly asserts that the promise doctrine essentially requires certain information be disclosed in the patent application, and that these applications are a matter of form and content governed by the PCT for which a nation cannot make additional requirements.¹⁹⁶ However, as noted earlier, the PCT is an international

189. NAFTA, *supra* note 36, art. 1709(1).

190. *Id.*

191. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 69.

192. *E.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003).

193. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R, ¶ 7.94 (Mar. 17, 2000).

194. *Id.* ¶ 7.92

195. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 45; Patent Cooperation Treaty, *supra* note 51, art. 27(1).

196. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 46.

agreement intended to simplify patent filings on a global basis without restricting *substantive* patentability conditions in individual countries, such as utility. However, even with respect to disclosures in the application, there is prior precedent for nations requiring additional disclosures beyond what is in the PCT. For example, the United States requires that patent applicants disclose best mode in the patent application, even though that is not a requirement of the PCT.¹⁹⁷

Accordingly, there are reasonable arguments for considering Canada's actions as not expropriation. Nonetheless, the explicit exemption from NAFTA expropriation claims involving "revocation" of intellectual property rights consistent with the separate NAFTA section on patents is sufficiently ambiguous, such that it is not clear how a tribunal would rule, even though this author believes Eli Lilly should be within this exclusion. Similarly, a tribunal could find for the first time that a domestic court decision modifying existing common law is a state action based on a violation of international law, even though this author believes that is incorrect.

2. *Canada Could Be Found to Not Have Expropriated Eli Lilly's Patents*

Although there are legitimate reasons why a tribunal should exclude Eli Lilly's case from an expropriation analysis as noted in the above section, this section will consider whether Eli Lilly has expropriation claims based on traditional expropriation concepts since it is unclear how a tribunal would rule. Eli Lilly has alleged that Canada directly and indirectly expropriated its patent rights in an unusual case that is not typical of either claim. As explained below, a tribunal should find that Canada committed neither type of expropriation under NAFTA's investment chapter. Although this Section analyzes both types, there is substantially more to analyze with indirect expropriation claims because there are several independent tests that tribunals use.

a) *Canada Should Not Be Found to Have Directly Expropriated Eli Lilly's Patents*

The first question is whether Canada directly expropriated Eli Lilly's investment. Canada did remove Eli Lilly's title to previously granted patents, which is typical of direct, rather than indirect expropriation claims. However, unlike in most direct expropriation claims, ownership of those patent rights were not transferred to Canada or any other party; rather, what was in those patents is now in the public domain and freely useable by anyone. There is a possible argument that patent invalidation is tantamount to physical property

197. 35 U.S.C. § 112(1) (2012).

seized by the state in terms of the benefit to the state—even though benefit is not necessary for direct expropriation. Similar to the situation where direct expropriation of tangible property would benefit the state, invalidation of Eli Lilly's property rights arguably benefits all Canadian citizens. For example, other companies can now make and sell generic versions of Eli Lilly's drugs in Canada because there is no valid patent to bar them; this obviously benefits these companies. Moreover, since such companies are likely generic companies that compete based on price, Canadian citizens benefit from the lower cost of drugs. Nonetheless, since benefit is not required for direct expropriation, this argument is weak. The important issue here is that unlike direct expropriation cases, the titles to Eli Lilly's investments—its patents—were not transferred to the state since no one owns them at all.

b) Canada Should Not Be Found to Have Indirectly Expropriated Eli Lilly's Patents

The next issue is whether Canada has committed indirect expropriation through invalidation of Eli Lilly's patents. Usually, indirect expropriation claims mean that the investor retains title, but there is "unreasonable interference" as well as "deprivation" of property rights, such that the investor loses all, or a significant part of its investment.¹⁹⁸ This theory seems to better fit Eli Lilly's case. Eli Lilly could assert that while it technically still owns the patents at issue, they have no economic value because without valid patents, Eli Lilly cannot charge a premium price because there will be other competitors. However, as will be shown below, the tribunal should not find that Canada indirectly expropriated Eli Lilly's investments.

An important issue is how to analyze indirect expropriation. Although many agreements, including NAFTA do not provide criteria for evaluating indirect expropriation, there are two basic approaches.¹⁹⁹ First, indirect expropriation may exist based solely on the effect of the interference with the investment, such that it is called the "sole effect doctrine." However, many tribunals and scholars consider this approach unfair and instead weigh economic impact on an investment against other factors including legitimate state interest, proportionality between state interest and investor harm, as well as reasonable expectations.²⁰⁰ As explained below, Eli Lilly's stronger

198. Reinisch, *supra* note 177, at 422. Accordingly, even if the investor continues to own legal title, there still may be indirect expropriation. *E.g.*, *Metalclad Award*, *supra* note 177, ¶ 103.

199. *E.g.*, NAFTA37, art. 1110; *see also* SUSY H. NIKIEMA, INT'L INST. FOR SUSTAINABLE DEV., BEST PRACTICES: INDIRECT EXPROPRIATION 5 (2012).

200. Andrew Newcombe, *The Boundaries of Regulatory Expropriation in International Law*, 20 ICSID REV.-FOR. INV. L.J. 1, 9–11 (2005); NIKIEMA, *supra* note 199, at 13. In addition, some

claim is under the sole effect doctrine, but utilizing that doctrine seems fundamentally unfair.

i) Sole Effect Doctrine Favors Lilly But Should Not Be Applied

Under the sole effect doctrine, significant and irreversible damage to enjoyment of property is the sole criterion for finding indirect expropriation.²⁰¹ Generally, tribunals speak of damage that is so severe that there is no longer any economic interest to the investor; for example, one tribunal stated that rights must be “rendered so useless that they must be deemed to have been expropriated.”²⁰² Accordingly, economic activity that is made more difficult, but not impossible will likely not constitute indirect expropriation. The state intent or possible benefit is not relevant pursuant to this doctrine.²⁰³

If the sole effect test is applied, Eli Lilly seems to have a strong claim. Invalidation of a patent is an absolute and permanent interference since the patent owner has no rights after it is invalidated.²⁰⁴ Indeed, prior commentators have noted that actions short of invalidation of patents would meet this standard, such as a compulsory license of a patent in which the

have noted that the sole effect doctrine has been primarily recognized until recently when wealthy countries have become more subject to investor-state disputes and thus interested in emphasizing legitimate state interest. *E.g.*, SEBASTIÁN LÓPEZ ESCARCENA, *INDIRECT EXPROPRIATION IN INTERNATIONAL LAW* 10 (2014).

201. *E.g.*, *Consortium R.F.C.C. v. Kingdom of Morocco*, ICSID Case No. ARB/00/6, Award, ¶ 68 (Dec. 22, 2003), 20 ICSID REV.-FOR. INV. L.J. 391 (2005).

202. *Starrett Hous. Corp. v. Iran*, Interlocutory Award No. ITL 32-24-1, 4 Iran-US Cl. Trib. Rep. 122, 154 (Dec. 19, 1983); *see also* *Pope & Talbot Inc. v. Canada*, Interim Award, ¶ 102 (NAFTA Arb. Trib. June 26, 2000), 40 I.L.M. 258 (2001) (considering whether state interference is “sufficiently restrictive to support a conclusion that the property has been taken from the owner”); *Metalclad Award*, *supra* note 177, ¶ 103 (requiring action that “has the effect of depriving the owner, in whole or in significant part, of the use or reasonably-to-be-expected economic benefit of property”); *Técnicas Medioambientales Tecmed S. A. v. United Mexican States*, ICSID Case No. ARB(AF)/00/2, Award, ¶ 115 (May 29, 2003), 10 ICSID Rep. 134 (2006) [hereinafter *Tecmed Award*] (“[R]adically deprived of the economical use and enjoyment of its investments, as if the rights related thereto . . . had ceased to exist.”).

203. *E.g.*, *Newcombe*, *supra* note 200, at 11–12; *Metalclad Award*, *supra* note 177, ¶ 103 (asserting no need to consider “motivation or intent” of state action because indirect expropriation can exist “even if not necessarily to the benefit of the host state”); *see also* *Tippetts v. TAMS-AFFA Consulting Eng’rs of Iran*, Award No. 141-7-2, 6 Iran-US Cl. Trib. Rep. 219, 225–26 (June 29, 1984) (government intention is less important than effect of measure on owner of assets).

204. Once a patent is invalidated, there is no prospect for obtaining a new patent because the original patent would preclude a subsequent application for the same invention from satisfying the requirement of being “new.” *See* 35 U.S.C. § 102(b) (2012).

patent exists, but the ability to exclusively determine how to exploit it is limited.²⁰⁵

However, a number of commentators and tribunals in recent years have suggested that the sole effect doctrine is unfair and inappropriate. Although the sole effect test was the primary test applied by tribunals since the 1980s and even through the early 2000s, more recent tribunals have shifted away from this doctrine.²⁰⁶ In particular, tribunals have shifted toward weighing harm to the investment against the state interest. In addition, although typically an element in fair and equitable treatment standards, tribunals are also increasingly incorporating legitimate expectations of investors into their analysis of indirect expropriation claims.²⁰⁷ Recent agreements as well as model agreements tend to explicitly enumerate these as factors for consideration, which notably mirror the factors that the U.S. Supreme Court utilizes to determine whether there has been a regulatory taking.²⁰⁸ Accordingly, analyzing Eli Lilly's claims pursuant to these factors seems to represent strong policy. As this section will explain, Eli Lilly has a much weaker claim when these factors are considered.

205. E.g., Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT'L L. REV. 357, 386 (2010); Tsai-Yu Lin, *Compulsory Licenses for Access to Medicines, Expropriation and Investor-State Arbitration Under Bilateral Investment Agreements—Are there Issues Beyond the TRIPS Agreement?*, 40 IIC: INT'L REV. INTELL. PROP. & COMPETITION L. 152 (2009).

206. E.g., Ursula Kriebaum, *Expropriation*, in INTERNATIONAL INVESTMENT LAW 38–41 (Marc Bungenberg et al. eds., 2015), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2295979.

207. E.g., DOLZER & SCHREUER, *supra* note 65, at 115–17; see also 2004 Canadian Model BIT Annex B 13(1)(b)(ii) (expressly noting the “extent to which the measure or series of measures interfere with distinct, reasonable investment-backed expectations” is a factor that should be considered in whether there is an indirect expropriation).

208. E.g., US Model BIT Annex B, Expropriation; Agreement on the Encouragement and Reciprocal Protection of Investments, U.S.-Uruguay, Annex B, para 4(a), Nov. 5, 2005, T.I.A.S. No. 06-1101 (considering economic impact of government action, the extent to which the government action interferes with distinct, reasonable, investment based expectations, and the character of the government action); 2004 Canadian Model BIT Annex B 13(1)(b); ASEAN Comprehensive Investment Agreement of 2009, Annex 2 (3) (considering whether a binding written commitment by the government has been breached and also considering the character of the government action and whether it is disproportionate to its public purpose). Importantly this specifically rejects the sole effect doctrine by stating that adverse effect on the economic value of an investment is not on its own adequate to establish indirect expropriation. *Id.*

ii) Legitimate State Interest Should Outweigh Eli Lilly's Interest

Although all expropriations must be for a public purpose, considering the purpose behind the state action is nonetheless important for two possible reasons. Some tribunals consider that when a state action is pursuant to its regulatory police powers, there should be no compensable expropriation, so long as the action is done on a nondiscriminatory basis and pursuant to due process.²⁰⁹ Even for tribunals that do not completely exclude state action from the scope of compensable expropriation, the type of state interest is relevant in considering whether the state action is proportional to investor harm.²¹⁰

An important issue is what constitutes a legitimate interest of the state. Although this is often considered to be synonymous with regulatory police powers, there is no internationally agreed definition of such powers.²¹¹ Nonetheless, the 2012 US Model BIT explicitly noted that legitimate public welfare objectives that would usually not constitute indirect expropriation include public health, safety, and the environment.²¹² This is also consistent with prior tribunal decisions, such as *Methanex*, in which the tribunal found that a law barring use of a petrol additive deemed carcinogenic was a bona fide regulation that served legitimate public interest, such that it was not compensable.²¹³

Countries have strong policy interests in limiting the scope of intellectual property rights to situations where the rights result in more benefits than harm. As noted earlier, it would be unfair to impose the economic cost of higher prices attendant with patent protection unless the inventor of the patent provided an adequate exchange through proper disclosure of the invention. The promise doctrine that Eli Lilly challenges aims to ensure that this fundamental patent bargain is satisfied.

209. *E.g.*, *Saluka Invs. B.V. v. Czech Republic*, Partial Award, ¶ 262 (Perm. Ct. Arb. Mar. 17, 2006) [hereinafter *Saluka Partial Award*]; *Methanex Corp. v. United States*, Final Award of the Tribunal on Jurisdiction and Merits, Part IV.D, ¶ 7 (NAFTA/UNCITRAL Arb. Trib. Aug. 3, 2005), 16 ICSID Rep. 40 (2012) [hereinafter *Methanex Final Award*]; *Cont'l Cas. Co. v. Arg. Republic*, ICSID Case No. ARB/03/9, Award, ¶ 276 (Sept. 5, 2008) [hereinafter *Cont'l Cas. Co. Award*]; *Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award, ¶ 105 (Dec. 16, 2002), 7 ICSID Rep. 341 (2005); *S.D. Myers Partial Award*, *supra* note 135, ¶ 281.

210. *E.g.*, *Tecmed Award*, *supra* note 202, ¶ 122.

211. *E.g.*, *Saluka Partial Award*, *supra* note 209, ¶ 263 (“[I]nternational law has yet to identify in a comprehensive and definitive fashion precisely what regulations are considered . . . within the police or regulatory power of States.”).

212. US Model BIT, Annex B, Expropriation, ¶ 4(b).

213. *Methanex Final Award*, *supra* note 209, at Section IV.D, ¶ 15.

Although this author thinks there is a clear case for considering the design of intellectual property rights to be a legitimate state interest, this is admittedly different than traditionally listed public welfare objectives. The closest common public welfare objective is the state interest in promoting public health. Arguably, this is promoted by denying patents on drugs that would increase the cost of medicine and thereby negatively impact public health for those could not afford the drugs. However, it is unclear if a tribunal would agree. Indeed, many would suggest that denying patents on drugs to reduce the cost of medicine is poor policy since that would reduce the incentive to create new drugs. Basically, the argument is that expensive drugs for the short-term are better than no new drugs in the long term. On the other hand, the proper balance between incentivizing new drugs that are expensive to consumers and potentially also impede subsequent research is a thorny question to which there are no uniform answers. This is fundamentally a policy determination that nations previously were able to decide based on their domestic preferences for promoting innovation versus access prior to TRIPS. Importantly, it is not simply an issue of developed versus developing countries; some developed countries, such as Italy and Portugal only granted patents on drug patents recently. In addition, before Canada concluded NAFTA, which has similar patent requirements as TRIPS, it granted drug patents, but permitted them to be broadly licensed by generic companies. Although the United State has traditionally provided expansive scope of patentability with little regard for impacts on access, other countries bar patents that reduce access to treatment, such as patents on methods of medical treatment.²¹⁴ Given that there is broad disagreement concerning whether there is a public health interest in reducing the cost of medicine by denying some patents on drugs, it is unclear how a tribunal would rule.

Assuming that Canada has a legitimate interest in tailoring its patent laws to best promote access to affordable medicine while consistent with international law, the next step is to consider whether that interest unduly harms Eli Lilly's investment. Some tribunals are deferential to self-declared state interests and find no expropriation so long as the state action is nondiscriminatory and in accordance with due process.²¹⁵ However, other tribunals apply a proportionality test, balancing the public purpose against the investor's expectations. This can be tricky because although a balancing test is more reasonable than the sole effect doctrine, it depends on how a

214. *E.g.*, European Patent Convention, *supra* note 42, art. 53(c); *see also* TRIPS, *supra* note 3, art 27(3) (permitting exclusion of such inventions from the scope of patentability).

215. *E.g.*, Chemtura Corp. v. Canada, Award, ¶ 266 (NAFTA/UNCITRAL Arb. Trib. Aug. 2, 2010).

tribunal applies this standard. For example, in *Tecmed*, the tribunal found that even if there is a valid state interest, it cannot outweigh the investor interest unless the state action is necessary to achieve the intended public interest, which it defined as the only measure available to achieve the objective, or the least detrimental among a number of effective solutions.²¹⁶ In that case, the tribunal found that the state's refusal to renew a license for a hazardous waste treatment plant was indirect expropriation because even though the license was denied for the legitimate interest of resolving local complaints concerning health and safety, there were less detrimental solutions possible, such as relocation of the plant.²¹⁷

Eli Lilly's situation seems somewhat similar to *Tecmed*'s in that its entire interest (in its patents) was vitiated when there arguably could have been a less detrimental solution. Just as the *Tecmed* tribunal suggested that the state could have taken a different action that would not have entirely terminated the investor's interest, so too Canada's law may seem unduly severe. In particular, although the policy reason for Canadian law is well established, given that Canada is the only country to have this law, a tribunal could find that it may not be necessary to apply the law in this manner.²¹⁸ However, some commentators note that although Canada is the only country to consider patent promises with respect to the utility requirement, other countries, including Australia and New Zealand have similarly invalidated patents that fail to achieve what they promise, despite having some basic utility.²¹⁹

iii) Eli Lilly Has No Legitimate Investor Expectations That Have Been Violated

The best consideration for rejecting Eli Lilly's claim for indirect expropriation is that it did not have any legitimate expectations that were violated. Recent agreements specifically note analysis of legitimate expectations of an investor as a way to assess indirect expropriation, but tribunals have also considered legitimate expectations pursuant to agreements that do not explicitly require this method of assessment. In both cases, the

216. *Tecmed Award*, *supra* note 202, ¶ 122.

217. *Id.* ¶ 51.

218. This is particularly true if the tribunal is sympathetic to Eli Lilly's position, even though there are competing expert reports about whether Canada's law is in fact unique. *Compare* Memorial of Claimant Eli Lilly, ¶¶ 145–60 (citing experts that allege that Canada's law is unique) *with* Counter Memorial of Canada, ¶¶ 170–99 (noting lack of international harmony in standards and functional similarity between US and Canadian law).

219. E.g., *Pracdes Pty. Ltd. v. Stanilite Electronics Pty. Ltd.* (1995) 35 IPR 259, 273–75 (Austl.); *Hammar Maskin A.B. v Steelbro N.Z. Ltd.* [2010] NZCA 83, ¶ 76 (Austl.).

focus is on whether the investor had a legitimate expectation that was violated. The legitimacy of the investor's expectations generally depends on specific assurances by the state.²²⁰ This is consistent with the interpretation of legitimate expectations in the context of violation of the standard of "fair and equitable treatment" from which the concept is derived.²²¹ The facts of prior cases may help to put this standard in context.

Metalclad v. United Mexican States provides a helpful example of legitimate investor expectations to support an indirect expropriation claim. In that case, there were multiple assurances that were specifically relied upon in making investments.²²² Investor Metalclad obtained a state construction permit for a hazardous waste landfill and assurances from federal agents that all necessary permits had been required.²²³ However, after construction begun, the local government ordered construction to stop because Metalclad had not obtained a municipal construction permit.²²⁴ At that point, federal agents once again assured Metalclad that if it applied for such a permit, it would be granted.²²⁵ However, it was not²²⁶ and thus Metalclad could not operate the landfill and the state later declared the land a Natural Area for protection of a rare cactus thereby terminating any possibility of Metalclad operating its facilities.²²⁷ The tribunal found that Metalclad had reasonably relied on assurances by the federal government and had a reasonable expectation to construct and operate the landfill that was thwarted.²²⁸

In contrast, in a more recent decision, a different NAFTA tribunal took a different approach to indirect expropriations in *Methanex v. United States*. In that case, the Canadian methanol producer asserted that a California law banning a carcinogenic gasoline additive resulted in an indirect expropriation of its investments in the California and U.S. market and improperly benefited

220. E.g., Reinisch, *supra* note 177, at 448. This is also consistent with the fair and equitable treatment standard from which the concept of legitimate expectations are derived.

221. E.g., Katia Yanaca-Small, *Fair and Equitable Treatment Standard: Recent Developments, in* STANDARDS OF INVESTMENT PROTECTION 111, 126 (Reinisch, ed. 2008) ("legitimate expectation is assumed more readily if an individual investor receives specific formal assurances" from the government official that the official should perceive the investor to reasonably rely upon); CAMPBELL McLACHLAN, LAURENCE SHORE & MATTHEW WEINIGER, *INTERNATIONAL INVESTMENT ARBITRATION: SUBSTANTIVE PRINCIPLES* ¶ 7.99 (2007).

222. Metalclad Award, *supra* note 177, ¶¶ 37–44.

223. *Id.*

224. *Id.* ¶ 40.

225. *Id.* ¶ 41.

226. *Id.* ¶¶ 45–50.

227. *Id.* ¶¶ 45, 69.

228. *Id.* ¶ 104.

the domestic ethanol industry.²²⁹ Although the tribunal dismissed the case on other grounds,²³⁰ it made findings that a state measure prohibiting use of a petrol additive considered carcinogenic was not an indirect expropriation because it was a bona fide regulation to serve the public interest on a nondiscriminatory basis and that there were no specific state representations to induce the investor.²³¹ In particular, the tribunal found that the investor should not have been surprised that environmental and health protection laws might change and adversely impact its interests.²³²

If Eli Lilly's legitimate expectations were considered, there should be no expropriation because Eli Lilly was given no specific assurance that either the law would not change, or that its patent would remain forever valid. Although there is a presumption of validity for issued Canadian patents, the fact that it is a presumption, rather than an ironclad right, suggests that there is no reasonable expectation that it will be immune from cancelation.²³³ Indeed, patent scholars have previously noted that the public should not expect issued patents to be valid based on the current system which in fact relies on litigation challenges as a more efficient mechanism to weed out improper patents, than to have patent offices spend more time preventing invalid patents from issuing.²³⁴ Although Eli Lilly complains that it was

229. Methanex Final Award, *supra* note 209, Part III.A, ¶ 1, Section IV.D, ¶ 2.

230. *Id.* at Section IV.F, ¶ 1.

231. *Id.* at Section IV.D, ¶ 7.

232. *Id.* at Section IV.D, ¶ 10; *see also* Parkerings-Compagniet A.S. v. Republic of Lith., ICSID Case No. ARB/05/8, Final Award, ¶ 331–35 (Sept. 11, 2007) [hereinafter Parkerings Final Award] (affirming that explicit promise or assurance is necessary and without that investor's assertion that changes to domestic law were unfair did not constitute violation of fair and equitable treatment, especially given that investor knew that the country was in a state of transition from being part of the Soviet Union to part of the EU, such that changes were likely).

233. This is underscored not only by the fact that Canadian patent law permits issued patents to be challenged (subject to the presumption of validity), but also provides mechanisms for such patents to be challenged.

234. *E.g.*, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. (2001). *But see* F. Scott Kieff, *The Case for Preferring Patent-Validity Litigation Over Second-Window Review and Gold-Plated Patents: When One Size Doesn't Fit All, How Could Two Do the Trick?*, 157 U. PENN. L. REV. 1937 (2009). In addition, although there have been proposals to more closely scrutinize certain patent applications where the inventor desires a stronger presumption of validity, no such proposals have been enacted. *E.g.*, Alan Devlin, *Revisiting the Presumption of Patent Validity*, 37 SW. U. L. REV. 323 (2008); Mark A. Lemley et al., *What to Do About Bad Patents*, REG., Winter 2005–06, at 10; Vincent M. De Grandpré, *United States: U.S. Looks at 'Gold-plating' to Enhance Patents*, MONDAQ, <http://www.mondaq.com/unitedstates/x/70826/Patent/US+Looks+At+GoldPlating+To+Enhance+Patents/> (last updated Dec. 2, 2008) (noting that President Obama proposed this during his presidential campaign). *But see* F. Scott Kieff, *supra* (arguing against such proposals).

shocked by Canada's change in the law, this is an inadequate ground for a claim of legitimate investor expectations given that Canada provided no specific assurance to Eli Lilly. In addition, although Eli Lilly seems to believe that an issued patent should be considered an assurance that the patent will remain valid, Eli Lilly's assumption is fundamentally inconsistent with patent law in Canada and other countries. As noted earlier, an issued patent is only presumptively valid, but can be and often is subsequently invalidated if it is later found not to meet patentability requirements. In addition, the mere grant of a patent seems very different than the multiple assurances given to the investor that the investor then relied upon to its detriment in *Metalclad*.²³⁵ Whereas the investor in *Metalclad* expended funds in building a hazardous landfill in reliance on the multiple investments, there is no claim that Eli Lilly developed its drugs in reliance on Canadian law. To the contrary, Eli Lilly developed its drugs as any multinational pharmaceutical company does—to sell worldwide.

C. INVALIDATION OF PATENT RIGHTS SHOULD NOT CONSTITUTE A VIOLATION OF THE FAIR AND EQUITABLE TREATMENT STANDARD

Assuming that Eli Lilly has an appropriate “investment” under NAFTA, even if it cannot establish an expropriation claim, it can alternatively recover compensation if Canada failed to provide “fair and equitable treatment” to Eli Lilly's investment.²³⁶ This claim is very important to Eli Lilly and all other investors since tribunals tend to take a flexible interpretation of what constitutes “fair and equitable treatment.” Claims based on a violation of the fair and equitable treatment standard are currently the most common²³⁷ and successful type of investment claim,²³⁸ and often prevail even when there is

235. *Metalclad Award*, *supra* note 177, ¶ 4108.

236. NAFTA, *supra* note 36, art. 1105(1).

237. UNCTAD, FAIR AND EQUITABLE TREATMENT: UNCTAD SERIES ON ISSUES IN INTERNATIONAL INVESTMENT AGREEMENTS II, A SEQUEL 10 (2012) [hereinafter UNCTAD, FAIR AND EQUITABLE TREATMENT]; Rudolf Dolzer, *Fair and Equitable Treatment: Today's Contours*, 12 SANTA CLARA J. INT'L L. 7, 10 (2013); *see also* Mercurio, *supra* note 26, at 894 (noting that although the standard was traditionally “rarely invoked” and only applicable where action was “egregious and shocking,” it is now commonly invoked due to a significantly broadened interpretation of the standard since the early 2000s). Most BITs and trade agreements include such standards, although a few BITs with Asian countries do not. Katia Yannaca-Small, *Fair and Equitable Treatment Standard: Recent Developments*, in STANDARDS OF INVESTMENT PROTECTION 110, 113 (August Reinisch ed., 2008).

238. In 2012 alone, six of the twelve published decisions finding state liability did so based on a violation of fair and equitable treatment. Violation of the fair and equitable treatment standard was the most common ground for state liability. UNCTAD, RECENT DEVELOPMENTS, *supra* note 15, at 5. A prescient professor noted in 1981 that “the right to fair and equitable treatment goes much further than the right to most favored-nation and to

no indirect expropriation.²³⁹ Nonetheless, this section explains why a tribunal should find that Eli Lilly does not have a valid claim against Canada for violation of the fair and equitable treatment standard because Eli Lilly had no legitimate expectations that were violated, which is the crux of this standard.

A key question is what constitutes “fair and equitable treatment.” Technically, there are differences in treaty language governing foreign investments that use the phrase “fair and equitable treatment.” Some, such as NAFTA, link the phrase to only minimum standards of conduct pursuant to customary international law,²⁴⁰ whereas others have no reference for what constitutes “fair and equitable treatment.”²⁴¹ However, in practice, tribunals seem to treat all claims similarly.²⁴² Essentially, tribunals as well as scholars consider whether there is a violation based on a number of factors.²⁴³ These include (a) defeating investors’ legitimate expectations (sometimes in balance

national treatment . . . so general a provision is likely to be almost sufficient to cover all conceivable cases and it may well be that provisions of the Agreements affording substantive protection are not more than examples of specific instances of this overriding duty.” F. A. Mann, Note, *British Treaties for the Promotion and Protection of Investments*, 52 BRIT. Y.B. INT’L L. 241 (1981).

239. E.g., Matthew C. Porterfield, *State Practice and the (Purported) Obligation Under Customary International Law to Provide Compensation for Regulatory Expropriations*, 37 N.C. J. INT’L L. & COM. REG. 159, 168–70 (2011); Marcela Klein Bronfman, *Fair and Equitable Treatment: An Evolving Standard*, 10 MAX PLANCK Y.B. UNITED NATIONS L. 609, 648 (2006); Yannaca-Small, *supra* note 237, at 112.

240. NAFTA, *supra* note 36, art. 1105(1). This should technically limit violations to situations where the action is “shocking, egregious and outrageous.” E.g., Jack J. Coe, *Fair and Equitable Treatment Under NAFTA’s Investment Chapter*, 96 ASIL PROC. 17 (2002).

241. E.g., Free Trade Agreement, China-Switz., art. 4, July 6, 2013, *available at* <http://www.seco.admin.ch/themen/00513/00515/01330/05115/index.html>; Agreement on the Reciprocal Promotion and Protection of Investments, BLEU-Taj., art. 3, Feb. 12, 2009, *available at* <http://investmentpolicyhub.unctad.org/Download/TreatyFile/418>; *see also* MAHNAZ MALIK, IISD, BEST PRACTICES SERIES BULLETIN: FAIR AND EQUITABLE TREATMENT 3 (Sept. 2009); UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 6–7.

242. Notably, even where tribunals are interpreting the standard pursuant to an agreement that requires the standard to be linked to customary international law, panels do not necessarily do so and may instead simply rely on other tribunal decisions that do not require consideration of international law. E.g., R.R. Dev. Corp. v. Republic of Guad., ICSID Case No. ARB/07/23, Award, ¶ 219 (June 29, 2012); *see also* UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at xv, 11; Matthew C. Porterfield, *A Distinction Without a Difference? The Interpretation of Fair and Equitable Treatment Under Customary International Law by Investment Tribunals*, INVESTMENT TREATY NEWS (Mar. 22, 2013), <http://www.iisd.org/itn/2013/03/22/a-distinction-without-a-difference-the-interpretation-of-fair-and-equitable-treatment-under-customary-international-law-by-investment-tribunals/>.

243. Alternatively, some suggest that there is no stable or fixed content to this standard. E.g., IOANA TUDOR, THE FAIR AND EQUITABLE TREATMENT STANDARD IN THE INTERNATIONAL LAW OF FOREIGN INVESTMENT 133 (2008).

with the host state's right to regulate), (b) denial of justice and due process, (c) manifest arbitrariness in decision making, (d) undue discrimination, or (e) outright abusive treatment.²⁴⁴ Not all of these factors need be present in every case, but legitimate investor expectations are considered key to establishing a violation.²⁴⁵

For that reason, the only relevant factor to consider is whether Eli Lilly had a legitimate expectation that was defeated.²⁴⁶ In particular, the issue is whether Canada unexpectedly changed its law such that Eli Lilly's legitimate expectations when it made its investment were violated. Obviously, the critical question is what constitutes "legitimate expectations."

244. *E.g.*, UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 62; TUDOR, *supra* note 243, at 155; Barnali Choudhury, *Evolution or Devolution?: Defining Fair and Equitable Treatment in International Investment Law*, 6 J. WORLD INVESTMENT & TRADE 297, 302–15 (2005); Yannaca-Small, *supra* note 237, at 129. Alternatively, panels cite a quotation from *Waste Management v. Mexico* that addresses similar factors. *E.g.*, GAMI Invs., Inc. v. United Mexican States, Final Award, ¶ 89 (NAFTA/UNCITRAL Arb. Trib. Nov. 15, 2004) [hereinafter GAMI Final Award]; Methanex Final Award, *supra* note 209, at Part IV.C, ¶ 26; Siemens A.G. v. Arg. Republic, ICSID Case No. ARB/02/8, Award, ¶ 297 (Feb. 6, 2007); Azurix Corp. v. Arg. Republic, ICSID Case No. ARB/01/12, Award, ¶ 370 (July 14, 2006); Waste Mgmt., Inc. v. United Mexican States, ICSID Case No. ARB(AF)/00/3, Award, ¶ 98 (Apr. 30, 2004).

245. *E.g.*, Electrabel S.A. v. Republic of Hung., ICSID Case No. ARB/07/19, Decision on Jurisdiction, ¶ 7.75 (Nov. 30, 2012) ("most important function" of standard is to protect legitimate expectations); Saluka Partial Award, *supra* note 209, ¶ 302 ("[T]he standard of fair and equitable treatment is . . . closely tied to the notion of legitimate expectations which is the dominant element of the standard."); EDF (Servs.) Ltd. v. Romania, ICSID Case No. ARB/05/13, Award, ¶ 216 ("one of the major components of the [fair and equitable treatment] standard is the parties' legitimate and reasonable expectations") [hereinafter EDF (Servs.) Ltd.]; *see also* Dolzer, *supra* note 237, at 17 (noting that "protection of legitimate expectations . . . 'is the central pillar' " of the standard).

246. At first glance, "manifest arbitrariness" or "discrimination" may seem relevant to Eli Lilly's claim that Canada breached its obligation to "refrain from conduct that is arbitrary, unfair, unjust and discriminatory" in invalidating its two patents. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 81. However, this is unlikely since manifest arbitrariness without direct targeting of a foreign investor requires an act that shocks judicial propriety and cannot even include a country failing to follow its own laws. Case Concerning Elettronica Sicula S.p.A. (ELSI) (U.S. v. It.), Judgment, 1989 I.C.J. 15, ¶ 128, (July 20) (requiring conduct that "shocks, or at least surprises, a sense of juridical propriety"); Cargill, Inc. v. United Mexican States, ICSID Case No. ARB(AF)/05/2, Award, ¶ 303 (Sept. 18, 2009) (finding manifestly arbitrary conduct where Mexico imposed an import permit for high fructose corn syrup with the express intent of damaging U.S. producers of such syrup and where there were no objective criteria for how to obtain such permits). Similarly, *undue* discrimination generally requires treating an investor differently because of impermissible categories such as race and gender, or at a minimum, treating the investor differently than domestic investors. UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 82. Eli Lilly has not made any such argument.

Although agreements generally do not define “legitimate expectations,” there are essentially two approaches.²⁴⁷ The broadest and most investor-friendly approach is that a state must ensure a stable legal and business environment.²⁴⁸ The other approach only finds legitimate expectations if those expectations arise from a specific state representation that the investor relies on.²⁴⁹ Indeed, one tribunal cautioned against an unduly broad reading of legitimate expectations that would inappropriately constrain states.²⁵⁰ Accordingly, a number of tribunals and scholars suggest not only that there should be a specific state representation, but also that state interests should be balanced against investor expectations.²⁵¹ This author believes that the standard grounded in state representation is preferable as a matter of policy. Other commentators also endorse this balancing approach, and arguably tribunals have recently trended toward it. In particular, commentators as well as some tribunals have noted that it is difficult to find and justify legitimate expectations solely on the basis of a preexisting legal regime and that this standard should not serve the same purpose as stabilization clauses.²⁵² Nonetheless, both standards are discussed below to predict how a tribunal

247. Arguably, there are other variations of legitimate expectations, but the two approaches outlined here represent the extremes.

248. *E.g.*, UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 64; Dolzer, *supra* note 237, at 24–25.

249. *E.g.*, UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 67–70; Dolzer, *supra* note 237, at 24–25.

250. EDF (Servs.) Ltd., *supra* note 245, ¶ 217 (“The idea that legitimate expectations, and therefore [fair and equitable treatment], imply the stability of the legal and business framework, may not be correct if stated in an overly broad and unqualified formulation. The [fair and equitable treatment] might then mean the virtual freezing of the legal regulation of economic activities, in contrast with the State’s normal regulatory power and the evolutionary character of economic life.”).

251. After all, although agreements aim to protect investments, investors arguably benefit the host state, such that public policy concerns of the host state should be considered. *E.g.*, Abhijit P.G. Pandaya & Andy Moody, *Legitimate Expectations in Investment Treaty Arbitration: An Unclear Future*, 15 TILBURG L. REV. 93, 96 (2010–11). In addition, some suggest that in applying this standard, tribunals should be deferential to host states.

252. *E.g.*, CAMPBELL MCLACHLAN ET AL., INTERNATIONAL INVESTMENT ARBITRATION: SUBSTANTIVE PRINCIPLES 238 (2008); Pandaya & Moody, *supra* note 251, at 114; EDF (Servs.) Ltd., *supra* note 245, ¶ 218 (fair and equitable treatment should not serve same function as stabilization clauses); Michele Potestà, *Legitimate Expectations in Investment Treaty Law: Understanding the Roots and the Limits of a Controversial Concept*, 28 ICSID REV. 88, 114 (2013) (noting that it would be “illogical” to permit fair and equitable treatment to provide the same type of protection as a stabilization clause that an investor bargained for); Elizabeth Snodgrass, *Protecting Investors’ Legitimate Expectations: Recognizing and Delimiting a General Principle*, 21 ICSID REV.-FOR. INV. L.J. 1, 35, 56–57 (2006); Yannaca-Small, *supra* note 237 at 126.

might rule in Eli Lilly's case and also to underscore the problems with the broader standard of a stable legal and business environment.

1. *Eli Lilly Has No Legitimate Expectation that Common Law Interpretations Will Not Change*

Eli Lilly should not have a claim for violation of fair and equitable treatment under even the broadest standard—that the state maintain a stable legal and business environment—based on prior cases. A frequently cited definition of what constitutes a stable legal and business environment is:

[T]he host State [must] act in a consistent manner, free from ambiguity and totally transparently in its relations with the foreign investor, so that it may know beforehand any and all rules and regulations that will govern its investments, as well as the goals of the relevant policies and administrative practices or directives, to be able to plan its investment and comply with such regulations.²⁵³

This definition has encountered substantial criticism for being impossible to meet.²⁵⁴ It will nonetheless be discussed as a standard that could be applied to establish that even under this overly broad and criticized standard, Eli Lilly should not have a valid claim for violation of fair and equitable treatment.²⁵⁵ Although it is true that the common definition seems to prevent a state from ever changing any laws that may impact a foreign investor without adequate notice, tribunals citing this definition seem to apply it more narrowly.

Specific cases help to put this in context. For example, in *Tecmed v. Mexico*, the tribunal found a violation of fair and equitable treatment because Mexican authorities failed to renew a necessary landfill permit they had

253. *Tecmed Award*, *supra* note 202, ¶ 154; *Metalclad Award*, *supra* note 177, ¶ 99; *MTD Equity Sdn Bhd. v. Republic of Chile*, ICSID Case No. ARB/01/7, Decision on Annulment, ¶ 107 (Mar. 21, 2007); *Siemens A.G. v. Arg. Republic*, ICSID Case No. ARB/02/8, Award, ¶ 297 (Feb. 6, 2007); *GAMI Final Award*, *supra* note 244, ¶ 91; *Occidental Exploration & Prod. Co. v. Republic of Ecuador*, LCIA Case No. UN3467, Final Award, ¶ 185 (BIT/UNCITRAL Arb. Trib. July 1, 2004); *see also* UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 64 (referring to quoted provision from *Tecmed* as the “classic statement” of this investor-friendly approach).

254. *E.g.*, Zachary Douglas, *Nothing if Not Critical for Investment Treaty Arbitration: Occidental, Eureko and Methanex*, 22 ARB. INT'L 27, 28 (2006) (stating that this is “actually not a standard at all,” but, rather, “a description of perfect public regulation in a perfect world, to which all states should aspire but very few (if any) will ever attain”); *White Indus. Austl. Ltd. v. Republic of India*, Final Award, ¶ 10.3.5 (BIT/UNCITRAL Arb. Trib. Nov. 30, 2011) (noting that this statement has been subject to “valid criticism”); *MTD Equity Sdn Bhd. v. Republic of Chile*, ICSID Case No. ARB/01/7, Decision on Annulment, ¶¶ 66–78 (Mar. 21, 2007) (suggesting that this standard is questionable).

255. This is especially true given that Eli Lilly is suing under NAFTA, which links this standard to customary standards of international law.

previously promised to renew.²⁵⁶ In both *CMS v. Argentina* as well as *Enron v. Argentina*, the tribunal found a violation based on this standard where Argentina dismantled its prior regime of tariff guarantees, without which foreign companies would not have made investments in Argentina.²⁵⁷ In *Occidental v. Ecuador*, the tribunal found a violation of fair and equitable treatment based on Ecuador's "manifestly wrong" interpretation of a contract with the investor, as well as Ecuador's inconsistent and unclear value-added tax laws, which negatively impacted the investor, such that the business and legal framework were disrupted.²⁵⁸ In *PSEG v. Turkey*, the tribunal found that Turkey violated the fair and equitable treatment standard because Turkey engaged in inconsistent administrative acts that included ignoring legal rights, as well as a "roller coaster" of continuing legislative changes that negatively affected the investor's power plant.²⁵⁹ The tribunal found that these changes were the exact opposite of stability since the law as well as its interpretation and implementation were continuously changing.²⁶⁰

Although Eli Lilly claims that it was "entitled to rely on the stability, predictability and consistency of Canada's legal and business framework existing at each stage of the establishment, expansion, and development of Lilly's investment" in its drugs,²⁶¹ its claim is far different from prior situations where tribunals found a violation of fair and equitable treatment. Eli Lilly's complaint is unlike the prior decisions in which tribunals found that domestic law specifically induced an investor to make investments in the country that were then negatively impacted by a change in law. Indeed, Eli Lilly has made no allegation that Canada's prior law induced Eli Lilly to make any investments. In addition, Canada's proper application of current law on utility requiring the promise doctrine to be met is neither a "manifestly wrong" legal interpretation nor a "roller coaster" of changes. Canadian courts have not engaged in any manifestly wrong legal interpretations; to the contrary, courts have consistently and correctly ruled against Eli Lilly based on prevailing law. In addition, while this doctrine is arguably different than

256. Tecmed Award, *supra* note 202, ¶ 165–66.

257. CMS Gas Transmission Co. v. Arg. Republic, ICSID Case No. ARB/01/8, Award (May 12, 2005) [hereinafter CMS Gas Award]; Enron Corp. v. Arg. Republic, ICSID Case No. ARB/01/3, Award (May 22, 2007) [hereinafter Enron Award]. However, it may have been relevant in these cases that the tribunal was applying an agreement that specifically noted that the standard is "desirable in order to maintain a stable framework for investment. CMS Gas Award, *supra*, ¶ 274; Enron Award, *supra*, ¶¶ 259–60.

258. Occidental, *supra* note 253, ¶ 184.

259. PSEG Global Inc. v. Republic of Turk., ICSID Case No. ARB/02/5, Award, ¶¶ 246–50 (Jan. 19, 2007).

260. *Id.* ¶ 254.

261. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 82.

when Eli Lilly first applied for its patents, one modification to the common law definition of utility is a far cry from the multitude of changes considered a problem in *PSEG*. Moreover, in past cases where tribunals have applied this broad standard, the fact that the relevant agreements specifically referenced stability as a goal of the treaty may have influenced the tribunals.²⁶²

2. *An Issued Patent Is Not a State Representation of Permanent Validity That Can Be Justifiably Relied On and Must Be Balanced against State Interests*

A number of tribunals reject the broad standard of a stable legal and business framework as unrealistic²⁶³ and unfair,²⁶⁴ and instead only recognize claims based on legitimate investor expectations if those expectations outweigh state interests. As the tribunal in *Saluka v. Czech Republic* stated, “[n]o investor may reasonably expect that the circumstances prevailing at the time the investment is made remain totally unchanged. . . . [T]he host State’s legitimate right subsequently to regulate domestic matters in the public interest must be taken into consideration as well.”²⁶⁵ Under such an approach, tribunals only find a claim if it arises from (a) a state’s specific representations or commitments to an investor which the investor has relied on, and only after (b) the investor’s expectations are balanced against legitimate regulatory activities of host countries.²⁶⁶ As this section will explain, Eli Lilly has no valid claim because there was no specific representation by Canada that Eli Lilly was justified in relying on, and Canada had legitimate interests in modifying its patent laws.

262. *E.g.*, *Occidental*, *supra* note 253, ¶ 183 (referring to the preamble); *CMS Gas Award*, *supra* note 257, ¶ 274 (referring to the preamble). In addition, the Argentine cases involved licenses granted by the government which stated that they could not be modified without the licensee’s consent. These licenses may have also played a role in the tribunal’s finding of a breach of fair and equitable treatment.

263. *See, e.g.*, *Douglas*, *supra* note 254, at 28; *El Paso Energy Int’l Co. v. Arg. Republic*, ICSID Case No. ARB/03/15, Award, ¶¶ 352, 371 (Oct. 31, 2011) [hereinafter *El Paso Energy Award*] (noting that “[e]conomic and legal life is by nature evolutionary” such that it is important to consider whether changes to a legal framework are unreasonable or contrary to a “specific commitment”).

264. UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 67. Indeed, one tribunal stated it would be unconscionable for a country to promise not to change its legislation as time and needs change. Even where the agreement’s preamble noted the importance of the stability of a legal framework, the tribunal declined to apply this standard. *Cont’l Cas. Co. Award*, *supra* note 209, ¶ 258.

265. *Saluka Partial Award*, *supra* note 209, ¶¶ 304–08.

266. *E.g.*, *Duke Energy Electroquil Partners v. Republic of Ecuador*, ICSID Case No. ARB/04/19, Award, ¶ 340 (Aug. 18, 2008); *Cont’l Cas. Co. Award*, *supra* note 209, ¶ 261.

a) A Patent Is Not a State Representation of Guaranteed Validity

The first question is what constitutes a state representation. The most typical state representation is a specific state commitment to an investor. As with expropriation claims, a tribunal may find a state commitment exists if there is some action attributable to the state, such as a representation from a government official.²⁶⁷ In addition, this state action must be either a specific commitment to the investor, or a set of general rules put in place with the intention of inducing foreign investment upon which the investor relied.²⁶⁸ In this case, there is no suggestion that prior Canadian law was intended to induce foreign investment, such that inducement is not discussed.²⁶⁹

The issue here is whether Canada made a specific commitment to Eli Lilly. Tribunals and scholars consider a commitment specific if its “precise object was to give a real guarantee of stability to the investor.”²⁷⁰ Accordingly, general statements in treaties or legislation do not suffice.²⁷¹ On the other hand, a specific commitment could include a commitment made in a contract or letter,²⁷² or an explicit promise or guarantee from the state.²⁷³ However, although there are heightened expectations from a contract, not every breach of a contract necessarily violates the fair and equitable treatment standard;²⁷⁴ rather, something more is necessary, although tribunals have not

267. Metalclad Award, *supra* note 177, ¶ 73 (noting that it was unchallenged that state and local government acts were attributable to the state); *see also* Stephen Fietta, *Expropriation and the “Fair and Equitable” Standard: The Developing Role of Investors’ “Expectations” in International Investment Arbitration*, 23 J. INT’L ARB. 375 (2006).

268. *E.g.*, Glamis Gold, Ltd. v. United States, Award, ¶ 627 (NAFTA/UNCITRAL Arb. Trib. June 8, 2009) [hereinafter *Glamis Gold*].

269. *E.g.*, Enron Award, *supra* note 257, ¶¶ 264–67; LG&E Energy Corp. v. Arg. Republic, ICSID Case No. ARB/02/1, Award, ¶¶ 132–39 (July 25, 2007).

270. El Paso Energy Award, *supra* note 262, ¶ 377 (emphasis removed).

271. *E.g.*, Cont’l Cas. Co. Award, *supra* note 209, ¶ 261; *see also* El Paso Energy Award, *supra* note 259, ¶ 394 (noting that this would “immobilize the legal order and prevent any adaptation to circumstances”).

272. *E.g.*, El Paso Energy Award, *supra* note 262, ¶ 376. However, breach of a contract is not per se a violation of a specific commitment. UNCTAD, FAIR AND EQUITABLE TREATMENT, *supra* note 237, at 87.

273. Parkerings Final Award, *supra* note 232, ¶ 331.

274. *E.g.*, Duke Energy Electroquil Partners v. Republic of Ecuador, ICSID Case No. ARB/04/19, Award, ¶ 358 (Aug. 18, 2008); Gustav F W Hamster GmbH & Co KG v. Republic of Ghana, ICSID Case No. ARB/07/24, Award, ¶ 335 (June 18, 2008) [hereinafter *Hamster Award*]; Impregilo S.p.A. v. Arg. Republic, ICSID Case ARB/07/17, Final Award, ¶ 181 (June 21, 2011); *see also* Parkerings Final Award, *supra* note 232, ¶ 344 (“The expectation a party to an agreement may have of the regular fulfillment of the obligation by the other party is not necessarily an expectation protected by international law. . . . [T]he party whose contractual expectations are frustrated should . . . seek redress before a national tribunal.”).

necessarily been consistent in assessing what additional activity suffices.²⁷⁵ One tribunal suggested that there must be a denial of justice or discrimination.²⁷⁶ Another tribunal found a violation of this standard not just based on a simple breach, but the fact that the state took action inconsistent with the investment agreement for an urban development project by denying relevant permits to complete the project.²⁷⁷

Importantly, a mere expectation that the law will not change does not constitute a specific commitment made by the state that lays the groundwork for a violation of fair and equitable treatment.²⁷⁸ For example, in *Methanex*, the tribunal held there was no violation of the standard of fair and equitable treatment standard when California changed its laws to ban certain carcinogenic additives to methanol and that change essentially destroyed the investor's market because there was no representation that regulatory laws would not change.²⁷⁹ Similarly, a tribunal found that Canadian company Glamis had no legitimate expectation that the United States (through California) would not pass legislation that would impact Glamis's mining investment, even when California's action was a significant change from settled practice, where California made no specific statements to induce investment.²⁸⁰ Also, in *ADF v. United States*, the tribunal found the investor had no legitimate expectation that the law would remain unchanged when the state made no representation and the investor instead simply relied on advice by private counsel.²⁸¹ More recently, in *Total v. Argentina*, a tribunal held that the legal regime in force at the time an investment is made is not guaranteed to remain in force unless the state has explicitly assumed a legal obligation, such as a stabilization clause.²⁸² Tribunals have noted that absent unusual situations, such as a drastic or discriminatory change in laws, there should be

275. *E.g.*, Potestà, *supra* note 252, at 15–18.

276. Glamis Gold, *supra* note 268, ¶ 620.

277. MTD Equity Sdn Bhd. v. Republic of Chile, ICSID Case No. ARB/01/7, Decision on Annulment (Mar. 21, 2007).

278. El Paso Energy Award, *supra* note 262, ¶ 371.

279. Methanex Final Award, *supra* note 209, at Section IV.D, ¶ 7.

280. Glamis Gold, *supra* note 268, ¶¶ 766–67, 801–02; *see also* Parkerings Final Award, *supra* note 332, ¶ 334–38 (finding no violation of legitimate expectations that Lithuania would not change its laws given that Lithuania was transitioning from being part of the Soviet Union to becoming a candidate for EU membership).

281. ADF Grp. Inc. v. United States, ICSID Case No. ARB(AF)/00/1, Final Award (Jan. 9, 2003).

282. Total S.A. v. Arg. Republic, ICSID Case No. ARB/04/1, Decision on Liability, ¶¶ 117, 429 (Dec. 27, 2010).

no liability under the fair and equitable treatment standard when there is no stabilization clause.²⁸³

A key question with respect to Eli Lilly's claims is thus whether Canada made any specific representations to Eli Lilly that Eli Lilly relied on. The only possible representation stems from Eli Lilly's novel claim that the issued patents are a contract, such that the patent itself is a representation that the patent will never be revoked.²⁸⁴ However, unlike a contract, which can generally be canceled only in extreme circumstances, issued patents are only presumptively valid and are often canceled if found to fail to meet one of the required criteria.²⁸⁵ Moreover, as noted earlier, even a breached contract with a state is not necessarily enough to establish a violation of the fair and equitable treatment standard. Something more is usually necessary.²⁸⁶

b) There Has Been No Negative Reliance upon a State Representation

Even if there is a state representation, it is important that there be reliance on that representation to the investor's detriment due to induced investments.²⁸⁷ For example, in *Metalclad*, the investor relied on the representation of officials that the investor had all necessary federal and state permits to construct a hazardous waste landfill and expended capital in constructing the landfill.²⁸⁸ Thus the denial of the municipal construction permit violated the investor's legitimate expectations.²⁸⁹

Eli Lilly has no viable argument that it relied on commitments that induced it to invest in developing its invention and to apply for a Canadian patent. Eli Lilly seems to complain that it could not have expected Canada to modify domestic standards when it applied for a patent. However, there was no specific representation that Canadian law would not change when Eli Lilly applied. Moreover, Eli Lilly's expenditure of capital to develop the drug it sought to patent is not tied to Canadian laws. As mentioned earlier, multinational pharmaceutical companies develop drugs that they aim to

283. *E.g.*, *Toto Costruzioni Generali S.p.A. v. Republic of Leb.*, ICSID Case. No. ARB/07/12, Award, ¶ 244 (June 7, 2012).

284. Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 82.

285. *Cf.* NAFTA, *supra* note 36, art. 1110(7) (expressly recognizing invalidated patent claims as outside the realm of expropriation, which suggests that there are no legitimate expectations that a patent will never be invalidated).

286. *E.g.*, *Parkerings Final Award*, *supra* note 232, ¶ 344; *Hamester Award*, *supra* note 270, ¶ 337.

287. *E.g.*, *El Paso Energy Award*, *supra* note 262, ¶ 376.

288. *Metalclad Award*, *supra* note 177, ¶¶ 85–88.

289. *Id.* ¶¶ 89–90, 99–101.

patent in any and all countries that will provide such patents. In addition, even if Eli Lilly claimed that it was induced to invest in promoting its new drug, this claim should also fail because an issued patent is not a guarantee that the patent will remain valid. Given that it is common for issued patents to be invalidated, the existence of a patent should not induce investment in promoting a drug.

c) Eli Lilly Has No Legitimate Expectation That Outweighs
Canada's Interests

The final method of determining legitimate expectations requires balancing investor expectations against state policy. The facts of some past tribunal cases may help to shed light on how this balance applies. For example, although the tribunal in *Saluka* recognized the importance of considering legitimate regulatory action, the tribunal found that the Czech Republic had no legitimate reason to protect similarly situated domestic, but not foreign, banks.²⁹⁰ In contrast, in *EDF v. Romania*, the tribunal found that a statute passed to abolish duty-free operations in Romanian airports was a reasonable response to the legitimate problem of contraband and did not disproportionately or discriminatorily impact the claimant's investments since it applied equally to all operators.²⁹¹ In addition, some tribunals suggest that there should be a high level of deference to states to regulate matters within their own borders.²⁹²

Past decisions favor a finding that Canada has a legitimate interest in the current promise doctrine. First, Canada does have a bona fide interest in promoting fundamental patent policy that ensures patents are only issued when there is adequate disclosure to justify the social cost of a patent.²⁹³ In addition, Canada's law applies equally to all foreign and domestic companies. Even though all pharmaceutical companies are implicated, the impact on this single industry is no different than the situation in *Saluka* where all owners of duty-free operations were impacted. In *Saluka*, the tribunal found that Romania responded reasonably to a contraband problem by enacting a law that impacted all owners of duty free operations. Here, Canadian courts appropriately responded to the problem of how to ensure that Canadian

290. *Saluka Partial Award*, *supra* note 209, ¶¶ 304–08.

291. *Id.* ¶¶ 293–94; *see also* *EDF (Servs.) Ltd.*, *supra* note 245, ¶ 219 (noting that “[l]egitimate expectations cannot be solely the subjective expectations of the investor” and that proper consideration of “the host State’s power to regulate its economic life in the public interest” should be taken into account).

292. *S.D. Myers Partial Award*, *supra* note 135, ¶ 263; *GAMI Final Award*, *supra* note 244, ¶ 93.

293. *See supra* Section II.A (explaining the importance of patent disclosures).

patents serve the traditional purpose of requiring proper disclosure of an invention before burdening the public with a patent by creating a doctrine that arguably impacts pharmaceutical innovations more. Although the expropriation doctrine provides some protection to foreign investors, it is not intended to provide better protection than that afforded to domestic investors.

III. BEYOND ELI LILLY'S CASE: PENDING PROBLEMS AND HOW TO ADDRESS THEM

This Part goes beyond the *Eli Lilly* case to highlight other domestic laws at the intersection of intellectual property and public health vulnerable to challenge in investor-state arbitration proceedings. In particular, this Part explains TRIPS-consistent domestic actions that might nonetheless result in investor-state claims. After explaining claims that companies (which qualify as foreign investors) are likely to make in investor-state proceedings, this Part provides specific proposals that can be incorporated in pending agreements to minimize these problems.

A. PUBLIC HEALTH ISSUES IN DANGER OF DISRUPTION

Eli Lilly's suit may portend the beginning of a trend towards investor challenges to a number of controversial issues concerning the balance of pharmaceutical interests and public health. These issues include patentability criteria beyond the one challenged in *Eli Lilly*, issuance of compulsory licenses on patents, and domestic regulations concerning protection of clinical data submitted to obtain approval to sell drugs.

1. Patentability Standards and Compulsory Licenses

One patent standard that is especially vulnerable to challenge under investor-state arbitration is a criteria that makes new drugs that are very similar to existing drugs unpatentable unless they show improved efficacy.²⁹⁴ Companies and lawyers alike have improperly suggested that section 3(d) of India's patent law barring patents on drugs that are very similar to existing drugs without providing increased efficacy is inconsistent with TRIPS.²⁹⁵ In

294. *E.g.*, The Patents (Amendment) Act, 2005, No. 15, § 3(d), Acts of Parliament, 2005 (India) (clarifying that inventions do not include "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant").

295. *E.g.*, JONES DAY, *supra* note 19, at 19; *see also* PHRMA, SPECIAL 301 SUBMISSION 2014, at 26 (referring to 3(d) as an "additional hurdle"); K. M. Gopakumar, *Intellectual Property*

the eight years since India pioneered this law there have been no challenges to its TRIPS consistency in the WTO forum. However, while countries tend to be hesitant to bring WTO disputes due to political considerations and concern with possibly undesirable precedent, companies do not share these concerns in seeking investment remedies.²⁹⁶ Accordingly, India's and other similar laws are ripe for challenge by foreign companies to the extent that there is an applicable investment agreement. Even in the absence of a specific challenge, Eli Lilly's suit alone could make a country hesitant to adopt such laws given the potential cost of a challenge,²⁹⁷ in addition to potential awards granted as compensation to foreign investors who establish violation of investment claims.²⁹⁸

A company could claim that India's section 3(d) patent standard results in improper expropriation, including a claim that the law is not consistent with TRIPS in a manner similar to Eli Lilly's case. As noted earlier, most agreements technically exclude from the definition of expropriation any domestic denial of intellectual property rights if the denial is consistent with TRIPS. However, some have suggested India's section 3(d) provision imposes an additional patentability requirement not permitted by TRIPS, and thus violates TRIPS.²⁹⁹ This is incorrect given that India has not imposed a

Issues Dominate the USITC Public Hearing on India, THIRD WORLD NETWORK (Feb. 13, 2014), <http://www.twinside.org.sg/title2/health.info/2014/hi140201.htm> (noting PhRMA claim that 3d adds additional requirements).

296. *E.g.*, Ermiyas Tekeste Biadgleng, IP Rights under Investment Agreements: The TRIPS-Plus Implications for Enforcement and Protection of Public Interest, South Centre Research Paper No. 8, at 30 (2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=943013. Moreover, law firms seem to encourage such action. *E.g.*, JONES DAY, *supra* note 19; Nandan S. Nelivigi et al., *Indian Patent Office Grants Compulsory License for Bayer's Nexavar: Implications for Multinational Drug Companies*, WHITE & CASE (Apr. 2012), <http://www.whitecase.com/alerts-04022012/>.

297. *See, e.g.*, SCOTT SINCLAIR, CAN. CTR. FOR POLICY ALTS., NAFTA CHAPTER 11 INVESTOR-STATE DISPUTES 24–25 (2010), *available at* <https://www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2010/11/NAFTA%20Dispute%20Table.pdf> (noting that whereas the cost of simply administering a panel can be \$ 1 million or more, legal costs can be substantially higher and even with respect to frivolous claims that never get a full hearing can still cost several hundred thousand dollars).

298. For example, Mexico was ordered to pay compensation of nearly \$170 million (plus interest) in 2009 for three decisions involving a Mexican tax on high fructose corn syrup. This exceeded the total annual GDP of the poorest sixteen Mexican states. SINCLAIR, *supra* note 297. In 2010, the Philippines spent nearly \$60 million to defend two cases against a German investor. Kim Arveen M. Patria, *Study Investment Provisions Before an FTA Says Advocacy Group*, FOCUS ON THE GLOBAL SOUTH, <http://focusweb.org/content/study-investment-provisions-fta-says-advocacy-group> (last visited Dec. 15, 2014).

299. *E.g.*, *supra* note 295 and accompanying text; *see also In re Natco Pharma. Ltd. & Bayer Corp.*, C.L.A. No. 1 of 2011 (Controller of Patents Mar. 9, 2012) (India); Bayer Corp.

new requirement of patentability; rather, India has simply provided a different definition of patentability that is permissible and in fact contemplated by TRIPS. Just as TRIPS permits Canada to define what is “useful” for Canada’s patents laws, TRIPS permits India to define what is an “invention,” as well as what is “new,” such that a number of scholars and policymakers consider India’s laws to be consistent with TRIPS.³⁰⁰ Nonetheless, just as Eli Lilly has incorrectly challenged Canada as violating NAFTA with an investment agreement, companies are similarly likely to challenge India’s TRIPS-consistent standard.

A possibly even bigger problem is that countries that want to copy India’s law may face claims by companies that the companies have been denied fair and equitable treatment due to an undesirable change in the law. An unduly broad interpretation of such claims might permit an investor to recover if a country changed its laws in a way that altered the legal environment. As noted earlier, there should not be any legitimate expectation that the law will never change. Nonetheless, companies win the vast majority of these cases, such that any potential claim—including an unsubstantiated one—could chill pending proposals for reform of patent laws.

2. *Compulsory Licenses*

Another likely target for investor-state arbitration is a compulsory license. A compulsory license is a traditionally recognized, state-mandated license to use a patented invention in certain instances; the patent is still valid, but the patent owner cannot exclude the licensee and must accept the government dictated royalty.³⁰¹ Although this situation seems inapposite of the patent right to exclude, one of the reasons compulsory licenses have historically been granted is to promote public interest on a number of grounds, including access to medicine.³⁰² The ability to issue compulsory licenses is especially important now to developing countries with limited resources; previously, they could promote access to low-cost drugs by declining to issue patents,

v. Natco Pharma. Ltd., Order No. 45/2013, ¶ 54 (Intellectual Property Appellate Board, Chennai Mar. 4, 2013).

300. E.g., CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 95–96 (2011); Amy Kapczynski, *Harmonization and its Discontents: Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1597–98 (2009).

301. E.g., JEROME H. REICHMAN & CATHERINE HASENZAH, UNITED NATION CONFERENCE ON TRADE & DEV. & INT’L CENTRE FOR TRADE & SUSTAINABLE DEV., NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS 6 (2003).

302. E.g., *id.* at 11–12.

but now that they must issue some patents under TRIPS, compulsory licenses are one of the few tools available to promote lower-cost drugs.³⁰³

Although compulsory licenses are permissible under TRIPS, they are likely to be challenged by patent owners as expropriation. Notably, public statements by pharmaceutical companies often talk about compulsory licenses as either “breaking” their patents, or even expropriating their patent rights.³⁰⁴ Scholars have been expecting such claims.³⁰⁵ This makes sense because a compulsory license may be a prototypical situation where an investor believes that it needs and deserves the additional protection of investor-state arbitration because the investor considers the TRIPS requirements, as well as domestic laws implementing those requirements, inadequate.

Although compulsory licenses that are consistent with TRIPS should technically be exempt from indirect expropriation claims in most cases,³⁰⁶ an

303. See TRIPS, *supra* note 3, art. 27(1). Although nations can impose heightened patentability requirements, it is highly unlikely that this will result in the pre-TRIPS situation of zero patents on any drugs. Indeed, although India has been at the forefront of imposing new restrictions on patentability, the vast majority of pharmaceutical patents have in fact been granted. E.g., C.H. Unnikrishnan, *Foreign Drug Makers Won 77% of All Patents in Last 3 Years*, LIVE MINT (Sept. 15, 2014), <http://www.livemint.com/Industry/H0ZID9XSP78ESv1MAUuZZN/Foreign-drug-makers-won-77-of-all-patents-granted-in-last-3.html>; Broo Baker, *Pharmaceutical Patents Granted by Indian Patent Office (IPO)*, TECH CORP LEGAL LLP, http://techcorplegal.com/Indian_Law_Firm/foreign-pharmaceutical-companies-granted-pharmaceutical-patents-by-indian-patent-office-ipo/ (indicating that over two thirds of pharmaceutical patent applications were granted). The most up to date list of granted and pending applications since July 2012, is available from the Indian patent office at <http://164.100.176.38/tk/> (select “pharmaceutical” from dropdown menu).

304. E.g., Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 Hous. L. Rev. 1047, 1069–70 (2009); see also Merck & Co., Inc. *Statement on Brazilian Government's Decision to Issue Compulsory License for STOCRIN*, BUSINESS WIRE (May 4, 2007, 12:11 PM), <http://www.businesswire.com/news/home/20070504005566/en/Merck-Statement-Brazilian-Governments-Decision-Issue-Compulsory/> (last visited Aug. 12, 2014) (referring to compulsory license as expropriation); see also JONES DAY, *supra* note 18 (referring to compulsory license as expropriation).

305. E.g., Peter B. Rutledge, *TRIPS and BITs: An Essay on Compulsory Licenses, Expropriation, and International Arbitration*, 13 N.C. J. L. & TECH. ONLINE 149, 161 (2012), available at http://digitalcommons.law.uga.edu/fac_artchop/827/; Gibson, *supra* note 205, at 359.

306. See, e.g., NAFTA, *supra* note 36, art. 1110(7) (excluding compulsory licenses granted consistent with NAFTA, which has provisions similar to TRIPS); U.S.-Singapore Free Trade Agreement, *supra* note 179, art. 15.6.5 (excluding compulsory licenses granted consistent with TRIPS); Dominican Republic–Central America–U.S. Free Trade Agreement art. 10.7.5, Aug. 5, 2004, 43 I.L.M. 514 (2004) [hereinafter CAFTA] (excluding compulsory licenses consistent with TRIPS); see also HOWARD MANN ET AL., IISD MODEL INTERNATIONAL AGREEMENT ON INVESTMENT FOR SUSTAINABLE DEVELOPMENT art. 8(G) (2005)

investor-state dispute would likely still be initiated to assess whether the license in fact complies with TRIPS because TRIPS requirements for compulsory licenses are highly controversial and contested. Part of the problem is that determining whether the licenses comply with TRIPS requires an interpretation of undefined, yet key, terms. For example, TRIPS permits compulsory licenses when a state provides “adequate remuneration,” without any definition of what would be “adequate.” In addition, although TRIPS provides many procedural requirements a state must follow to issue an appropriate license, there is some controversy concerning the ground for issuing a license in the first instance.³⁰⁷

Companies are likely to challenge royalty rates of compulsory licenses as not TRIPS compliant because TRIPS does not clearly define what compensation is “adequate” and companies believe that any compulsory license fails to provide adequate compensation. This is aptly illustrated in the recent case concerning India’s compulsory license on Bayer’s cancer drug sold as Nexavar. Bayer sought a royalty rate of fifteen percent of net sales whereas the court granted a royalty of six percent. Although a subsequent appeal raised the royalty to seven percent, that rate is still less than half of what the patent owner sought.³⁰⁸ Even though Bayer strongly contested the royalty rate, that rate was completely within the guidelines issued by the World Health Organization and the United Nations Development Programme.³⁰⁹

One law firm suggested that the six percent royalty rate constituted indirect expropriation that failed to provide adequate compensation to Bayer pursuant to a typical investment agreement that requires compensation “equivalent to the value of the expropriated . . . investment immediately before the date on which such expropriation . . . became publicly known.”³¹⁰ Although some might suggest that there is no conflict between this expropriation standard and the ambiguous TRIPS requirement of “adequate”

(excluding from expropriation compulsory licenses granted consistent with “applicable international agreements on intellectual property”).

307. TRIPS, *supra* note 3, art. 31.

308. *In re Natco Pharma. Ltd. & Bayer Corp.*, C.L.A. No. 1 of 2011 (Controller of Patents Mar. 9, 2012) (India); *Bayer Corp. v. Natco Pharma. Ltd.*, Order No. 45/2013, ¶ 54 (Intellectual Property Appellate Board, Chennai Mar. 4, 2013).

309. See JAMES LOVE, WORLD HEALTH ORGANIZATION, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES (Robert Weissman ed., 2005).

310. JONES DAY, *supra* note 19, at 3.

compensation, scholars generally believe that “adequate” compensation under TRIPS is not intended to be market rate.³¹¹

Another TRIPS-consistent aspect of compulsory licenses that foreign investors could challenge is the grounds for issuing a compulsory license in the first instance. TRIPS permits countries to decide the basis for issuing compulsory licenses and only governs procedural aspects of compulsory licensing. However, there have been many misstatements concerning permissible grounds for issuing compulsory licenses made not only by companies, but also by scholars and government officials.³¹² Contrary to the common claim by companies that compulsory licenses are only appropriate in case of an emergency or if the patent owner cannot provide adequate supply of the needed drug,³¹³ countries have complete discretion to decide the grounds for issuing compulsory licenses.³¹⁴ This is very important for countries like India that have unusual legal criteria for issuing a compulsory license, such as a drug not being available at a “reasonably affordable price” from the patent owner.³¹⁵

Notably, even if an arbitration tribunal were to properly find that the above two issues were consistent with TRIPS, and thus not indirect expropriation, a tribunal might still find a violation of fair and equitable treatment. There is no intellectual property exception to fair and equitable treatment claims for even TRIPS-consistent measures in any existing agreement. A company might argue that it applied for a patent to its detriment because it did not expect that a country would issue a compulsory license that demolished the value of its patent. A tribunal that took a broad

311. E.g., HO, *supra* note 300, at 138; Tsai-Yu Lin, *Compulsory Licenses for Access to Medicines, Expropriation and Investor-State Arbitration Under Bilateral Investment Agreements—Are There Issues Beyond the TRIPS Agreement?*, 40 IIC: INT'L REV. INTELL. PROP. & COMPETITION L. 152, 163–64 (2009); Antony Taubman, *Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927, 951–55, 957 (2008) (explaining that this is not necessarily equivalent to full market value); Biadgleng, *supra* note 296, at 18; see also Gibson, *supra* note 205, at 415 (suggesting that it is unclear whether a TRIPS consistent license would constitute expropriation under an investment agreement).

312. E.g., Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact From Fiction under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371 (2009); see also James Love, USPTO “Clarifies” June 27, 2012 Testimony on Biologics Exclusivity and India Compulsory License, KNOWLEDGE ECOLOGY INT'L, (July 3, 2012), available at <http://www.keionline.org/node/1452>.

313. E.g., JONES DAY, *supra* note 19, at 3.

314. TRIPS, *supra* note 3, art. 31; Doha Public Health Declaration, *supra* note 34, ¶ 5(b) (“Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”); see also HO, *supra* note 300, at 128–29.

315. The Patents (Amendment) Act, 2005, No. 15, § 84, Acts of Parliament, 2005 (India).

view of the fair and equitable treatment standard to demand a stable legal environment might be sympathetic to such a claim. Even if there is no technical change in domestic laws, if a country had simply not previously issued compulsory licenses, or rarely issued such licenses, a company might nonetheless complain that an unexpected issuance of a compulsory license was inconsistent with fair and equitable treatment. Given that such claims are unpredictable and highly successful for claimants, there is a serious risk that tribunals deciding investor-state claims would nonetheless find that a TRIPS-consistent license is an expropriation or a violation of fair and equitable treatment.

3. *Domestic Regulation of Clinical Data*

In addition, nations may be subject to investment claims concerning domestic regulations governing clinical data relating to new drugs. There are two related issues that could be subject to challenge. First, companies may bring challenges against countries that permit generic applicants to immediately rely on clinical data without providing a period of “data exclusivity” for the initial drugmaker. Second, companies may challenge domestic laws requiring that all clinical trials of approved drugs be made publicly available. Although both potential challenges relate to the same data, they will be discussed separately because they involve separate issues (reliance versus disclosure), as well as different issues of interpretation under TRIPS.

a) Countries That Do Not Provide “Data Exclusivity” Will Likely Be Challenged

To best understand the data exclusivity issue, some background concerning the regulatory drug approval process is necessary. Unlike most other patented items, patented drugs need regulatory approval by a domestic agency such as the U.S. Food and Drug Administration before the drugs can be sold. Most countries grant such approval when a company can establish that the proposed new drug is safe and effective for its proposed use based on clinical data.³¹⁶ It can take many years and millions of dollars to compile the requisite data for regulatory review.³¹⁷

In contrast, manufacturers of proposed generics can gain approval with a more limited set of clinical data. Most countries will approve generic versions

316. *E.g.*, Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) (2012) (U.S. standard); Food and Drug Regulations, C.R.C., c. 870, § C.08.0002(2) (Can.) (Canadian standard).

317. *E.g.*, Salomeh Keyhani et al., *Are Development Times for Pharmaceuticals Increasing or Decreasing?*, 25 HEALTH AFF. 461, 463 (2006).

based solely on clinical studies that show “bioequivalence” to a previously approved drug; the proposed generic is then presumed to be just as safe and effective as the previously approved drug.³¹⁸ The time and investment needed to establish clinical data of bioequivalence is a mere fraction of the time and investment required to produce data for the earlier drug’s regulatory approval process.³¹⁹ This is an intentional policy decision. After all, a company that is a second or later entrant to the market with no possible patent protection cannot charge high prices to recoup an expensive investment. Moreover, if generic companies are not provided a less costly regulatory approval process, original companies can continue to sell their drugs at premium prices long after a patent has expired due to lack of competition.³²⁰

The issue with data exclusivity is when generic companies can rely on clinical data of the drug they are copying. In a country that provides data exclusivity, the generic manufacturer is barred from relying on that data for a certain period, ranging from five to ten years from approval of the prior drug.³²¹ Data exclusivity, when available, is completely separate from patent protection and can provide substantial commercial advantage for even unpatentable products. In contrast, a country that does not recognize data exclusivity will permit other companies to immediately rely on this data. This means that as soon as a patented drug is approved for sale, a generic manufacturer can apply to sell a lower-cost equivalent. Importantly, this does not mean that the patent is not valid. However, it does permit the manufacturer of a generic to enter the market while simultaneously challenging the patent. Although this may seem like a formidable challenge, the vast majority of challenged drug patents are in fact found invalid or not infringed.³²²

318. *E.g.*, 21 U.S.C. § 355(j)(4)(F) (2012); 21 C.F.R. § 314.92(a)(1) (2010); *Notice: Release of the Health Canada Draft Guidance Document: Quality (Chemistry and Manufacturing): New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)*, HEALTH CANADA (Jan. 24, 2014), http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/consultation/drug-medic/qual_ndsands_draft_pdnpadn_ebauche-eng.pdf.

319. *E.g.*, Henry G. Grabowski et al., *Entry and Competition in Generic Biologics*, 28 *MANAGERIAL & DECISION ECON.* 439, 443 (2007).

320. Indeed, this was the situation in the United States before laws were amended to permit generic drug approvals based on the abbreviated process. *See, e.g.*, Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 *FOOD & DRUG L.J.* 187, 187 (1999).

321. *E.g.*, 21 U.S.C. § 314.108 (2012) (five-year exclusivity); Council Directive 2004/27/EC. Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, 2004 O.J. (L 136) 34, 39 art. 10.1 (ten-year maximum exclusivity).

322. *E.g.*, EC PHARMACEUTICAL SECTOR INQUIRY, *supra* note 10, para. 501 (finding that in over half of cases where patent was challenged by a generic company, the patent was

A patent-owning company such as Eli Lilly may assert that in a country without data exclusivity, its right to prevent other companies from using its data was indirectly expropriated. Clinical data that is expensive to develop seems to easily fall within the definition of an investment. The expropriation issue is whether permitting generic companies to rely on clinical data results is a substantial and unreasonable interference with this investment. A company would likely believe that this is the case if it cannot completely exclude competitors from using its proprietary data. This seems somewhat analogous to a compulsory license of a patent in that, although the company can still use its data (or patent), lack of exclusivity results in a substantial interference with the expected value. A developing country should have a strong policy argument for denying data exclusivity to permit generic companies to more quickly rely on this data and promote faster entry of low cost drugs. However, it is unclear how a tribunal would balance interests or whether it would instead use the “sole effect” test, which would clearly favor only corporate interests. Accordingly, an important issue is whether a domestic decision to reject data exclusivity could be exempt from consideration as an expropriation claim.

An initial question is whether such a claim could be excluded under clauses that exempt certain intellectual property issues from indirect expropriation claims.³²³ The issue is whether lack of data exclusivity should be considered a “limitation” of “intellectual property rights” pursuant to agreements that exclude such limitations of intellectual property rights from the scope of expropriation. Although data exclusivity is not a traditional intellectual property right, many companies as well as countries consider it to be one in contexts beyond investor-state disputes.³²⁴ However, the phrase

invalidated); FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 20 (2002)* (finding that generic companies win in seventy-three percent of challenges, with twenty-eight percent of patents found invalid, thirty-five percent of the cases finding lack of infringement, and ten percent of cases abandoned by the patent owner before a judicial finding); see also Wullianallur Raghupathi, *Pharmaceutical Patent Validity: An Empirical Study of the Recent Decisions of the U.S. Court of Appeals for the Federal Circuit (2008-2011)*, 18–19 (Fordham Univ., Working Paper), available at http://ghimc.org/pdf/patent_enforcement.pdf (finding that during the period 2005–2006 about half of patents challenged by generics were held invalid).

323. Arguably, another reason the expropriation claim should be excluded is that lack of implementation of a desired law may not constitute state action that is fundamental to an expropriation claim. Generally, expropriation claims are based on an affirmative act, rather than an omission. However, as Eli Lilly’s case shows, companies are not afraid to make new claims in the area of investment arbitrations.

324. Indeed, there are some free trade agreements that require countries to provide data exclusivity under intellectual property chapters. See, e.g., U.S.-Singapore Free Trade

“limitations of intellectual property” suggests that there must be a recognized intellectual property right that can be limited, such that a country that completely denied a right might not fall under this language. Nonetheless, it is at least conceivable that data exclusivity or lack of data exclusivity would be covered as intellectual property.

Even if data exclusivity is considered a type of intellectual property right that falls within the intellectual property exception to expropriation, it is not necessarily immune to challenge. In particular, this exception only applies to intellectual property rights consistent with TRIPS and there is significant controversy concerning what TRIPS requires. In particular, although some companies and countries believe that TRIPS requires data exclusivity, a proper interpretation of TRIPS pursuant to the customary rules of interpretation of international agreements establishes that this view is incorrect.³²⁵ TRIPS requires that countries “protect” data submitted to government for approval of pharmaceuticals from “unfair commercial use” without specifying what this means.³²⁶ Although companies suggest that it is unfair to allow other companies to rely on their data, negotiators rejected language that specifically stated that there could be no reliance on the data.³²⁷ The rejection of this earlier language means that it is not the current standard—contrary to what some companies have suggested.³²⁸ Accordingly, a number of scholars and policymakers consider that the provision does not require data exclusivity.³²⁹

Lack of data exclusivity could also be challenged as a violation of the fair and equitable treatment standard. Although this is recognized as the broadest and most frequently successful claim in investment disputes, it is unlikely to be successful against a country like India. Since India has never recognized

Agreement, *supra* note 179, art. 16.8; Australia-U.S. Free Trade Agreement, U.S.-Austl., art. 17.10, May 18, 2004, 43 I.L.M. 1248 (2004) [hereinafter AUSFTA].

325. *E.g.*, Ho, *supra* note 314, at 76–80.

326. TRIPS, *supra* note 3, art. 39(3).

327. Brussels Draft, ¶4A, reprinted in DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 421 (3d ed., 2008); see also *Bayer Inc. v. Canada* (Att’y Gen.) (1998), [1999] 1 F.C. 553 (Can.).

328. See generally ORG. OF PHARM. PRODUCERS OF INDIA, OPPI POSITION PAPER: REGULATORY DATA PROTECTION—A BUILDING BLOCK FOR PHARMACEUTICAL R&D (2008).

329. *E.g.*, CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 383–92 (2007); JEROME REICHMAN, UNDISCLOSED CLINICAL TEST DATA UNDER THE TRIPS AGREEMENT AND ITS PROGENY: A BROADER PERSPECTIVE 10 (2004); Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 315–16 (2008).

protection for data exclusivity, there would be no legitimate expectation for it to do so even under the broadest standard of maintaining a stable legal and business environment. After all, a stable environment would be the same legal environment.

However, the bigger issue is that the threat of investor-state arbitration could prevent countries from abandoning data exclusivity laws in favor of India's approach, even if a country believes that India's approach is better policy in promoting access to lower-cost drugs. Although tribunals have repeatedly noted that investors should not expect that laws will be frozen in time, a company could claim that they did not expect an existing protection to be dismantled. Some claims could be cabined if tribunals use the more robust standard that only finds violations when an investor relies on a specific state representation since it is unlikely that any country would promise to keep data exclusivity laws. However, that possibility may be too large a risk to take for a developing country with limited funds.

b) Domestic Data Transparency Requirements Are Vulnerable to Challenge

Companies are also likely to challenge domestic regulations concerning disclosure of clinical data supporting approved drugs. The European Union is at the forefront of requiring what is referred to as data "transparency," but if it is challenged, other countries may be hesitant to enact laws that public health scholars uniformly applaud as desirable.³³⁰ In particular, a new EU regulation requires that all clinical data for drugs approved by the European Union be made publicly available.³³¹ Companies strongly oppose disclosing clinical data, claiming that they are entitled to keep such data as a trade secret.³³² Although the regulation is not yet in full effect, companies are likely to contest it once it is.

Before addressing possible claims, it is important to explain the rationale for transparency laws in the context of the regulatory structure for approval of new drugs. As noted earlier, a new drug will be approved for sale based on clinical data that it is safe and effective. Notably, such data is developed not by an independent organization, but by the very company seeking approval.

330. See generally Gardiner Harris, *Diabetes Drug Maker Hid Test Data, Files Indicate*, N.Y. TIMES, July 13, 2010, at A1 (describing problems when drug companies are not required to publicly disclose all relevant data).

331. Regulation 536/2014 of the European Parliament and of the Council on Medicinal Products for Human Use, and Repealing Directive, 2001/20/EC, 2014 O.J. (L 158).

332. Aaron S. Kesselheim & Michelle M. Mello, *Confidentiality Laws and Secrecy in Medical Research: Improving Public Access to Data on Drug Safety*, 26 HEALTH AFF. 483, 483 (2007); see also, e.g., *infra* note 333 (noting AbbView objection).

In addition, although the company must submit the data to the government, the public is not entitled to access it. There are a few cases where independent researchers obtained access to the data either because a country had a policy for doing so in limited circumstances³³³ or because a company responded to public pressure.³³⁴ However, without mandatory transparency, not only doctors and patients, but also governments must rely on industry claims concerning the value of new drugs. Because companies have an interest in selectively publishing positive results,³³⁵ they are more likely to conclude that their drugs are safe and effective than independent researchers.³³⁶ They also overestimate benefits while minimizing risks in published studies.³³⁷ As a result, there may be unnecessary expenditures on expensive new drugs based on questionable data³³⁸ that can also result in negative public health outcomes that could have been avoided.³³⁹ There are a number of examples where new drugs were later found by independent

333. For example, the European Medicines Agency previously granted access to clinical data concerning Abbvie's drug Humira and Intermune's drug Esbriet based on a 2010 policy that such data be provided upon request. European Medicines Agency, European Medicines Agency Policy on Access to Documents (Related to Medicinal Products for Human and Veterinary Use), EMA/110196/2006 (2010). The companies subsequently challenged this decision. Case T-44/13, *AbbVie, Inc. v. European Meds. Agency* (July 17, 2014), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=155902&doclang=en>; Case T-73/13R, *InterMune UK Ltd v. European Meds. Agency* (Apr. 25, 2013), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=137242&doclang=en>; see also Trudo Lemmens, *EMA's Proposed Data Release Policy: Promoting Transparency or Expanding Pharma Control Over Data?*, PLOS BLOGS (May 30, 2014), <http://blogs.plos.org/speakingofmedicine/2014/05/30/emas-new-data-release-policy-promoting-transparency-expanding-pharma-control-data/> (last visited Aug. 12, 2014).

334. E.g., Editorial, *Full Disclosure Needed for Clinical Drug Data*, N.Y. TIMES, July 5, 2013, at A16.

335. E.g., Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38 AM. J.L. & MED. 63, 93–94 (2012); Nicholas Bakalar, *Review Finds Drug Makers Issue More Positive Studies*, N.Y. TIMES, Feb. 27, 2007, at F7.

336. E.g., Fujian Song et al., *Dissemination and Publication of Research Findings: An Updated Review of Related Biases*, 14 HEALTH TECH. ASSESSMENT (2010).

337. E.g., Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 J. AM. MED. ASSOC. 454 (2003); Joel Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 BRIT. MED. J. 1167 (2003).

338. Governments stockpiled the antiviral drug to treat influenza sold as Tamiflu based on unverified effectiveness claims by the company that independent researchers only recently determined to be unsubstantiated. E.g., Ben Goldacre, *What the Tamiflu Saga Tells Us About Drug Trials and Big Pharma*, GUARDIAN (Apr. 9, 2014), <http://www.theguardian.com/business/2014/apr/10/tamiflu-saga-drug-trials-big-pharma/>.

339. E.g., HAI EUROPE, *supra* note 31.

research to result in harmful health risks.³⁴⁰ Even though independent researchers can ultimately discover issues, it is expensive, inefficient, and poor public policy to bar them from considering existing data that could result in better public outcomes.

There is a serious concern that transparency requirements would constitute an expropriation. Mandatory disclosure of data would seem to constitute a substantial interference with the expectation that a company's data will not be accessed by a competitor. In addition, the current exceptions of expropriation do not seem to cabin such claims.

A nation should have the right to decide whether to recognize protected data as an intellectual property right. But there is an open issue concerning whether TRIPS requires this data to be protected. In particular, there is a currently untested exception to the TRIPS requirement to protect data from unfair commercial use; TRIPS explicitly states: "Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."³⁴¹ In other words, TRIPS seems to contemplate that there are in fact some situations where members may not need to protect data against disclosure if necessary to protect the public. Although the European Union may believe that it falls within the TRIPS exception that permits disclosure for public interest, a company would likely believe otherwise.

If a tribunal does not extend the traditional definition of intellectual property to include data exclusivity, such claims could be exempt from a claim for indirect expropriation. This exemption could be based on the language of certain agreements that does not provide a complete exception to expropriation claims, but rather suggests that regulation for public welfare be treated differently. For example, a number of agreements suggest that nondiscriminatory regulatory measures "designed and applied to protect legitimate public welfare objectives, such as public health" do not generally constitute indirect expropriation "except in rare circumstances."³⁴²

In addition, an investor that believes it is entitled to compensation when a country fails to provide data exclusivity raises unique challenges even when public health is involved. Most cases involving public welfare have been

340. *E.g.*, Ho, *supra* note 13, at 501–05.

341. TRIPS, *supra* note 3, art. 39(3).

342. *E.g.*, AUSFTA, *supra* note 324, Annex 11-B, art. 4(b); U.S.-Chile Free Trade Agreement, U.S.-Chile, Annex 10-D, June 6, 2003, 42 I.L.M. 1026; CAFTA, *supra* note 306, Annex 10-C; Draft, CETA Investment Text, EU-Can., Annex X.11(3): *Expropriation*, http://www.tradejustice.ca/wp-content/uploads/2013/08/EU-Canada-FTA-Negotiations-Investment-chapter-4-April-2014_clean.pdf [hereinafter Draft CETA Investment Text].

cases that directly impact public health or the environment, such as a regulation that aims to protect sea turtles, or a regulation that aims to reduce carcinogens.³⁴³ In contrast, the public health interest protected in countries that decline to impose data exclusivity is more attenuated. Some consider it obvious that there is not only a universal right to health, but also a right to access to affordable medicine.³⁴⁴ However, there is no universally recognized right to access to affordable medicine; indeed, this is the crux of frequent international tension between companies that want strong patent protection and those that want less patent protection to promote access to affordable drugs.³⁴⁵

343. *E.g.*, *supra* note 213 and accompanying text (discussing how the California ban of an arguable carcinogen should be considered lawful regulation and not expropriation in *Methanex*); KYLA TIENHAARA, *THE EXPROPRIATION OF ENVIRONMENTAL GOVERNANCE: PROTECTING FOREIGN INVESTORS AT THE EXPENSE OF PUBLIC POLICY* 239–43 (2009); Benjamin W. Jenkins, *The Next Generation of Chilling Uncertainty: Indirect Expropriation Under CAFTA and Its Potential Impact on Environmental Protection*, 12 OCEAN & COASTAL L.J. 269 (2007). Notably, such claims of public welfare do not always succeed in thwarting a claim for expropriation. For example, Mexico was found to have indirectly expropriated Metalclad's investment, and Costa Rica was required to pay \$ 4 million for expropriating land to protect sea turtles. *E.g.*, *Metalclad Award*, *supra* note 177; Joyce Gomez, *Expropriation to Protect Turtles Costs Government \$4 Million*, COSTA RICA NEWS, <http://www.costaricanewssite.com/expropriation-to-protect-turtles-costs-government-4-million/> (last visited Dec. 13, 2014).

344. *E.g.*, *Minister of Health v. Treatment Action Campaign* 2002 (5) SA 721 (S. Afr.) (right to affordable HIV drugs); Further Initiatives for Social Development, G.A. Res. S-24/2, ¶ 101, U.N. Doc. A/RES/S-24/2 (July 1, 2000); Commission on Human Rights, Res. 2001/33, *Access to Medication in the Context of Pandemics Such as HIV/AIDS* (Apr. 23, 2001) (asserting right to ARV treatment as part of the right to enjoy the "highest attainable standard of physical and mental health"); High Commissioner of the Comm'n on Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, Comm'n on Human Rights, U.N. Doc. E/CN.4/Sub.2/2001/13, ¶¶ 10–15, 27–58 (June 27, 2001); Joanne Csete, *Several for the Price of One: Right to AIDS Treatment as Link to Other Human Rights*, 17 CONN. J. INT'L L. 263, 265 (2002); Lisa Forman, *From TRIPS-Plus to Rights-Plus? Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights Through the Thai Experience*, 7 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 347 (2012); Melissa McClellan, *"Tools for Success": The TRIPS Agreement and the Human Right to Essential Medicines*, 12 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 153 (2005); Simon Walker, *A Human Rights Approach to the WTO's TRIPS Agreement*, in *INTERNATIONAL TRADE AND HUMAN RIGHTS: FOUNDATIONS AND CONCEPTUAL ISSUES* 171, 176 (Frederick M. Abbott et al. eds., 2006) ("The right to health . . . includes a right to affordable, essential drugs, as set out in the WHO's essential drug list."); Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. INT'L L.J. 325 (2003).

345. *E.g.*, Doha Public Health Declaration, *supra* note 34, para. 4 (recognizing that nations should have the ability to promote access to medicine, but without creating a complete exception to patent rights); Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 852–53 (2008) (describing the use of "frameworks of international rights discourse and corporate malfeasance" for access to medicine, which necessarily suggests that no such universal right currently exists). Although

Countries may face even more problems with a claim for fair and equitable treatment. This standard is often read broadly, and a country that imposes transparency requirements could be considered to be making a substantial change to the legal and business environment. Notably, the EU regulation is not a complete surprise. The European Union has been engaging in increased transparency over the years. As with all such claims, the European Union's interests are better protected under the standard that only recognizes claims based on legitimate expectations due to specific reliance. It is doubtful that the European Union would ever represent that it would not change its laws. However, considering that past cases have broadly interpreted this standard, the EU regulations could still be vulnerable.

B. PROPOSALS TO PRESERVE FLEXIBILITY UNDER TRIPS

This Section provides concrete proposals to address the unique policy issues raised by permitting investors to challenge domestic decisions concerning the proper scope—if any—of intellectual property rights when those decisions are arguably permissible under international agreements such as TRIPS.³⁴⁶ In particular, this Section advocates ideally excluding such issues from international agreements governing investments, or limiting challenges in the dispute settlement system. If this is not possible, this Section suggests specific proposals to cabin expropriation and fair and equitable treatment claims that would otherwise interfere with internationally permissible regulation of intellectual property rights.

the WHO and UN have urged nations to try to expand access to drugs, this remains an issue. See U.N. Secretary General, *Review of the Problem of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome in All Its Aspects*, ¶ 101, U.N. Doc. A/55/779 (Feb. 16, 2001) (urging states to use compulsory licenses and other means to expand access to lower cost generics). Even those that suggest that corporations be more sensitive to drug prices as a matter of human rights are often cautious to only suggest access for life-saving drugs, and not all drugs. E.g., Chuan-Feng Wu, *Transnational Pharmaceutical Corporations' Legal and Moral Human Rights Responsibilities in Relation to Access to Medicines*, 7 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 77 (2012).

346. Although this Section focuses on proposals that stem from the policy issues raised here, there is one issue raised by the Eli Lilly case that impacts all cases: whether procedurally proper decisions of domestic courts should ever be challenged in investor-state disputes. As explained in Part III, there is no precedent or policy reason for enabling investors to obtain compensation using either expropriation or fair and equitable treatment claims when they simply disagree with substantive domestic law. The proposals to limit claims that attempt to challenge substantive law regarding intellectual property equally apply to all other areas.

1. *Exclude Intellectual Property from Investor-State Disputes*

The simplest way to avoid above-noted problems is by narrowing the scope of what constitutes a covered investment. Alternatively, an exception to investor-state disputes could be created to avoid policy problems. In considering these solutions, this Article considers intellectual property to be broadly defined to include not only patents but also any regulatory protection of drugs, such as data exclusivity, since companies themselves consider both to be intellectual property.

There are several approaches to modifying the definition of investment. The most efficient way to eliminate noted problems is to modify the definition of what constitutes an “investment” to explicitly exclude intellectual property rights in their entirety. Not surprisingly, some have suggested doing this.³⁴⁷ It is not adequate for an agreement to simply not mention intellectual property as covered since most agreements cover intangible investments. Even those who oppose Eli Lilly’s claim would need to concede that intellectual property rights are generally considered intangible investments.³⁴⁸ Accordingly, there needs to be an explicit statement that intangible investments do not include intellectual property rights. Alternatively, if intellectual property rights are included as an investment, there should be a clarification that such rights do not include those that have been canceled pursuant to domestic law. Moreover, it may be wise to clarify that domestic law includes common law modifications to the law. This would thus obviate Eli Lilly’s objection that Canada was unjustified in modifying and retroactively applying this standard.

Another possibility is to maintain the scope of covered investments, and instead change the scope of investor-state disputes. In particular, claims that require adjudication of rights under another international agreement, such as TRIPS, could be excluded entirely. Agreements have previously excluded some subject matter, such as national security and tax measures,

347. E.g., Brook K. Baker, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines—Eli Lilly and the TPP*, PJIIP RESEARCH PAPER SERIES PAPER 36, at 13 (2013). Although this is obviously a current issue, some countries astutely noted this problem earlier and tried unsuccessfully to eliminate IP from the definition of investments. E.g., OECD, REPORT TO THE NEGOTIATING GROUP ON INTELLECTUAL PROPERTY, NEGOTIATING GROUP ON THE MULTILATERAL AGREEMENT ON INVESTMENT (MAI) 4 (1997), available at <http://www1.oecd.org/daf/mai/pdf/ng/ng9732e.pdf> (noting that some experts recommend excluding intellectual property rights entirely from the definition of “investment”).

348. E.g., 35 U.S.C. § 261 (2012) (patents have attributes of personal property); see also Mercurio, *supra* note 26, at 878 (noting that it is “beyond doubt” that granted intellectual property rights are investments).

from the scope of the treaty.³⁴⁹ Alternatively, agreements could include language that states “[n]othing in this agreement shall affect the rights and obligations of any party to TRIPS or any other international intellectual property agreement; no party may bring an issue requiring adjudication of a TRIPS provision unless it has been previously determined to be in violation of TRIPs pursuant to the WTO.” This would be somewhat similar to existing exceptions in some agreements concerning either tax or environmental agreements.³⁵⁰ However, unlike these clauses, which are primarily conflict of law principles that state which agreement should prevail in the event of inconsistency, this proposal goes further to ensure that tribunals do not unnecessarily decide whether there is an inconsistency in the first instance. This is necessary to prevent commercial arbitrators from usurping the process for determining TRIPS compliance, which could lead to inconsistent judgments.³⁵¹

The above suggestions are strongly preferable to the draft text to address situations where there are competing agreements under CETA that is being used as a basis for the pending Transatlantic Trade and Investment Partnership (“TTIP”). In particular, the CETA draft states that if there is a potential for “overlapping compensation” or the other claim could have a “significant impact” on the arbitration claim, the tribunal shall “stay its proceedings,” or otherwise, the tribunal can continue the proceedings and simply take a separate proceeding “into account in its decision, order or award.”³⁵² However, this approach still not only gives a tribunal too much authority to impinge on another international agreement, but it also does not address the situation raised by Eli Lilly where no other proceeding has previously been initiated. This may often be the case with TRIPS claims because only governments can bring WTO disputes and governments seem circumspect in doing so. Moreover, WTO claims would not result in overlapping compensation both because investors have no standing to assert such claims, and because WTO proceedings are only intended to force

349. *E.g.*, NAFTA, *supra* note 36, arts. 2102, 2103.

350. *Id.* arts. 103, 2103; Korea-Chile Free Trade Agreement, Kor.-Chile, art. 20.3(3), Feb. 15, 2003, *available at* http://www.sice.oas.org/Trade/Chi-SKorea_e/ChiKoreaInd_e.asp; *see also* Guillermo Aguilar Alvarez & William W. Park, *The New Face of Investment Arbitration: NAFTA Chapter 11*, 28 YALE J. INT’L L. 365, 390 (2003); Jennifer A. Heindl, *Toward a History of NAFTA’s Chapter Eleven*, 24 BERKELEY J. INT’L L. 672 (2006).

351. *E.g.*, Brooks E. Allen & Tommaso Soave, *Jurisdictional Overlap in WTO Dispute Settlement and Investment Arbitration*, 30 ARB. INT’L L. 7 (2014).

352. Draft CETA Investment Text, *supra* note 342, art. x-23; EUR. COMM’N TRADE, PUBLIC CONSULTATION ON MODALITIES FOR INVESTMENT PROTECTION AND ISDS IN TIIP, Question 7 (Mar. 2014) (citing CETA art. x-23), *available at* http://trade.ec.europa.eu/doclib/docs/2014/march/tradoc_152280.pdf.

countries to comply with WTO rules, but do not result in compensation.³⁵³ Accordingly, investment chapters should exclude from the scope of arbitrations any claims that challenge internationally agreed upon standards for state action.

2. *Limit the Scope of Investment Claims Based on International Agreements Such as TRIPS*

If intellectual property issues cannot be entirely excluded from investment arbitration disputes, the next best alternative is to cabin the most likely claims—expropriation and fair and equitable treatment claims. This section explains how to limit such claims and why existing proposals thus far are inadequate.

a) Limit Expropriation Claims

The optimal method of limiting challenges to domestic laws consistent with international intellectual property standards is to explicitly bar expropriation claims in this area. Technically, this is already recognized in existing agreements, including NAFTA. However, as the Eli Lilly case illustrates, that language is inadequate since parties may disagree on whether certain conduct is permissible under an international intellectual property agreement.

Canada has proposed that there is no indirect expropriation in the case of a decision by a court, administrative tribunal, or other governmental intellectual property authority limiting or creating an intellectual property right, except where “the decision amounts to a denial of justice or an abuse of right.”³⁵⁴ This would at first glance seem to easily bar claims like Eli Lilly’s without needing to evaluate whether there is a violation of a separate international agreement. However, a company, such as Eli Lilly, could claim a denial of justice or abuse of right. Although no prior tribunal has found similar facts to fit these circumstances, past expansive rulings suggest this is a possibility. Accordingly, any exception to expropriation for intellectual property rights should clarify that there is no denial of justice or abuse of right if there is a common law modification of laws that are retroactively applied. This would not only prevent the Eli Lilly situation, but would also make expropriation more in line with domestic taking law that does not

353. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 3.7 Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 33 I.L.M. 1226, 1241 (providing that compensation should only be awarded as a matter of last resort), available at http://www.wto.org/english/docs_e/legal_e/28-dsu.pdf.

354. Draft CETA Investment Text, *supra* note 342, art. X.11(5).

recognize a taking when courts simply apply slightly modified common law doctrine.³⁵⁵ Of course, there is no requirement that international expropriation must be consistent with domestic taking law. However, given that expropriation is a remedy only available to foreign investors, unless there is a sound policy reason to provide a broader scope of expropriation to only foreign investors, closer alignment in treatment of all investors seems most appropriate.

Another possibility is to bar expropriation claims based on intellectual property rights in a manner similar to expropriation claims based on taxation. For example, NAFTA states that tax measures may in some cases constitute expropriation, but imposes unique procedural requirements for asserting such a claim.³⁵⁶ In particular, before a claim can be adjudicated, both the country accused of expropriation as well as the investor's own country must decide whether there is an expropriation claim that is permitted to go forward.³⁵⁷ The idea of cabining expropriation claims based on domestic revocation of intellectual property rights is a sound one. To prevent potential inconsistent decisions, expropriation claims based on state action that is arguably inconsistent with TRIPS should be barred unless there is a finding of TRIPS inconsistency by a WTO panel. This would obviate inconsistent decisions and also allow TRIPS issues to be decided by arbitrators with expertise in WTO agreements, including TRIPS.

These proposals would be a significant improvement over the European Union's proposed language to clarify what types of regulatory action should not constitute indirect expropriation. Although the European Union shares a desire with many others to "avoid claims against legitimate public policy measures," its proposed clarification is no better than language in existing treaties.³⁵⁸ In particular it notes that in "rare circumstances," nondiscriminatory measures to protect "legitimate public welfare objectives such as health" can nonetheless constitute indirect expropriation if the impact of the measure "is so severe in light of its purpose that it appears manifestly excessive."³⁵⁹ This proposal introduces new language in need of interpretation, such as what would be "manifestly excessive" or "severe in light of its purpose." In addition, although it may seem fair to have a balance

355. E.g., Vicki Been & Joel C. Beauvais, *The Global Fifth Amendment? NAFTA's Investment Protections and the Misguided Quest for an International "Regulatory Takings" Doctrine*, 78 N.Y.U. L. REV. 30, 80–82 (2003).

356. NAFTA, *supra* note 36, art. 2103(6).

357. *Id.*

358. EU Comm'n, Public Consultation on Modalities for Investment Protection and ISDS in TTIP, at 6–7 (Mar. 2014).

359. Draft CETA Investment Text, *supra* note 342, Annex X.11: Expropriation ¶ 3.

of interests, a tribunal of private arbitrators does the balancing, and in doing so the arbitrators are essentially second guessing the balance already determined by a nation.

b) Limit Fair and Equitable Treatment Claims

The best approach to cabin fair and equitable treatment claims would be to eliminate them altogether in cases where the agreement is solely between countries with strong legal systems. Although it may seem radical to jettison a traditional component of investment chapters, there are some existing chapters where tribunals have no authority to litigate such claims. These claims have posed the most significant intrusions into domestic regulatory authority and have resulted in inconsistent rulings. Moreover, this standard was initially intended to provide a remedy as a back up to the non-discrimination provision in the exceptional situation where the host country's political and legal systems disintegrate to the extent that investors cannot be adequately protected. There seems to be no need for this claim at all where domestic remedies exist. In addition, this would avoid the problem of unduly expansive rulings concerning fair and equitable treatment that the United States has tried, but failed to cabin in NAFTA.³⁶⁰

If fair and equitable treatment claims must remain within the scope of investment arbitrations, adding clear exceptions would be the next best alternative. For example, just as intellectual property rights denied or canceled under domestic law should never be considered expropriation, a similar clause could exist for fair and equitable treatment claims. In addition, as noted earlier with expropriation claims, it may be better to exclude any fair and equitable treatment claim based on state law denying or canceling an intellectual property right on substantive grounds unless that state law is found by a WTO panel to be inconsistent with TRIPS. Even if there were a TRIPS violation, there should not necessarily be a fair and equitable treatment claim. Many existing and pending agreements state that breach of a separate international agreement—including TRIPS—does not establish a

360. For example, after some broad interpretations of this standard under NAFTA, the NAFTA Free Trade Commission issued an interpretation that aimed to clarify that the standard be linked to customary international law to cabin rulings. NAFTA Free Trade Comm'n, Notes of Interpretation of Certain Chapter 11 Provisions, ¶ B (July 31, 2001). However, this was of little utility since tribunals simply interpreted customary international law broadly. *E.g.*, Patrick Dumberry, *The Emergence of a Consistent Case Law: How NAFTA Tribunals Have Interpreted the Fair and Equitable Treatment Standard*, KLUWER ARB. BLOG (Oct. 30, 2013), <http://kluwarbitrationblog.com/blog/2013/10/30/the-emergence-of-a-consistent-case-law-how-nafta-tribunals-have-interpreted-the-fair-and-equitable-treatment-standard/>.

violation of the fair and equitable treatment standard.³⁶¹ Notably, this clause also does not state that compliance with another international agreement will immunize state action from being subject to such claims. Thus, additional language is necessary.

This could be accomplished by including language defining what qualifies as fair and equitable treatment. Although some agreements limit the term to the minimum standard pursuant to customary international law, such limits have clearly been inadequate in cabinining intrusive claims. Accordingly the term could be stated to never exist simply because the legal or business environment has changed. This would importantly be helpful not only for the intellectual property issues that this Article focuses on, but also for all investor-state claims that have resulted in undue encroachment on domestic regulatory authority. In addition, an investment chapter could mandate that fair and equitable treatment claims must be based on whether a party made a specific representation to induce investment that created a legitimate expectation. Furthermore, it could mandate that there is never a legitimate expectation that laws will remain frozen in time. This would go farther than the current EU proposal that suggests that tribunals may consider whether a country made a specific representation relied upon by the investor.³⁶² In addition to requiring—rather than permitting—tribunals to consider specific representation, it may be important to define what constitutes such a representation. For example, Eli Lilly incorrectly believes that an intellectual property right granted by the state is a representation that the right can never be invalidated. Accordingly, it could be helpful to clarify that intellectual property rights issued by a nation are not representations of permanent validity.

IV. CONCLUSION

Eli Lilly's case against Canada exposes important policy problems with permitting investors to use investor-state arbitrations to challenge domestic intellectual property decisions. Although a tribunal should deny Eli Lilly's claims, investor-state tribunals often make broad and unpredictable rulings. Moreover, even if a panel rules properly, public health may still be compromised if other companies follow Eli Lilly's lead in challenging other domestic decisions concerning intellectual property rights. Although some are wisely beginning to question the wisdom of creating more opportunities

361. Draft, TPP, Investment chapter, *supra* note 179, art. II.6: Minimum Standard of Treatment.

362. See EU COMM'N TRADE, *supra* note 352, ques. 3.

through additional agreements, this Article hopes to provide a roadmap for how to combat likely claims in the thousands of existing agreements, as well as how to cabin claims in any future agreements.