# SOVEREIGNTY UNDER SIEGE: CORPORATE CHALLENGES TO DOMESTIC INTELLECTUAL PROPERTY DECISIONS

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## 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 a landmark international agreement concluded twenty years ago in conjunction with the World Trade Organization (WTO) 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 the WTO, policy makers and scholars have strived to preserve domestic flexibilities to consider domestic policies such as public health. However, those flexibilities may quickly evaporate if companies can bring claims against countries for compromising their 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.

Although investor-state arbitration claims have been broadly criticized in recent years, there are unique issues associated with expanding this remedy to domestic actions consistent with the WTO agreement. If Eli Lilly's claim were to succeed, it would disrupt internationally agreed 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 offers both an explanation of why Eli Lilly's claims should be rejected, as well as a prediction of other 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 the predicted harms.

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## I INTRODUCTION

Is a company entitled to compensation from a country that declines to provide it 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] In particular, Eli Lilly claims that two of its patents were investments that Canada unduly interfered with when the country's courts invalidated the patents for failing to meet a Canadian patentability requirement.[2]

This is the first time that domestic patent laws have been challenged on the ground that they violate an international agreement protecting foreign investments. Eli Lilly's demand for substantial financial compensation may have a chilling effect on the ability of countries to fine-tune their patent laws consistent with a separate international agreement. Importantly, since patented drugs are inevitably expensive, nations have historically been reluctant to patent drugs.[3] Some countries only permitted *methods* of making drugs, and not the drugs themselves to be patentable to ensure that drugs would not be subject to a patent premium.[4] After centuries of limited patent protection of drugs, most countries must now provide patents on drugs pursuant to the Trade Related Intellectual Property Agreement (TRIPS), to which over one hundred and fifty countries are members.[5] However, that

[1] Alternatively, these are referred to as investor state dispute settlements (ISDS).
[2] Eli Lilly v. Canada, Notice of Arbitration (12 September 2013) [hereinafter Eli Lilly Notice of Arbitration].
[3] *E.g.*, SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS AND DEVELOPING COUNTRIES 59 (2005).
[4] 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.
[5] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27, 1869 UNTS 299, 33 ILM 1143 (1994)[hereinafter TRIPS]. However, WTO member countries that are designated Least Developed Countries by the UN do not need to provide patent protection on drugs until 2022. WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition Period Under Article 66.1 For Least Developed

agreement 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] Developing countries that have recently considered modifying their laws to take advantage of these flexibilities may now have second thoughts – especially if the arbitration panel finds in Eli Lilly's favor.

In addition, countries at all levels of development are potentially impacted by Eli Lilly's challenge at a critical juncture. The pharmaceutical industry is plagued by an innovation crisis in conjunction with patent expiration of highly profitable drugs, resulting in a struggle to sustain revenue.[7] In response, the industry has been patenting drugs that are merely minor variations of existing drugs and that offer no significant improvement in treatment.[8] Even though the new drugs may not be a substantial improvement over older drugs, patent protection permits companies to charge a premium. 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.[9] Given an environment where many nations face financial constraints, providing patents on drugs of minimal therapeutic value seems especially questionable. Countries should have the ability to tailor their patent laws within existing international

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Country Members, Decision of the Council for TRIPS of 11 June 2013, IP/C/64, ¶ 1 (2013).

[6] TRIPS, art 1.

[7] *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 REV. DRUG DISCOVERY 428, 429 (2011); Charlotte Harrison, *The Patent Cliff Steepens*, 10 NATURE REV. DRUG DISCOVERY 12, 12–13 (2011); Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. TIMES, Mar. 19, 2013, at A1.

[8] *E.g.*, EC Dir. Gen for Competition, Pharmaceutical Sector Inquiry Final Report (2009)[hereinafter EC Pharmaceutical Sector Inquiry]; John R. Thomas, Patent Evergreening: Issues in Innovation and Competition, Congressional Research Service (2009). 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 Report, *supra*, at 351-52.

[9] *E.g.*, Peter Bach et al., *In Cancer Care, Cost* Matters, NY TIMES, Oct. 14, 2012; *see also* Stephen S. Hall, *The Cost of Living*, New York, Oct. 20, 2013.

flexibilities to avoid expending resources on drugs of questionable value.

Although Eli Lilly's claim is one of first impression, it actually contributes to a broader trend. International investment agreements are being increasingly used to challenge domestic laws; for example, only one suit was filed in 1982, but over 50 new cases were filed in 2012, and there are currently 500 claims pending in over fifty countries.[10] Many have noted that such provisions threaten the ability of nations to regulate in areas of traditional domestic competence such as environment and public health[11] because the financial stakes are often substantial – there are currently over one hundred pending actions worth more than $1 billion *each*.[12] Against this backdrop, Eli Lilly's suit can be seen as the latest expansion of investor claims that challenge domestic laws. Moreover, although Eli Lilly is the first company to bring such a case, there could be many more.[13] Even before Eli Lilly brought suit, the multinational law firm Jones Day published a report in which it proclaimed that investment treaty protection was "a new way forward" for multinational pharmaceutical companies to address an "assault" against their patents in the developing world that rejected or restricted patent rights.[14]

Concurrent with the increase in investor-state suits and expansive claims, such suits have recently begun to attract increased attention and criticism. Although scholars have

[10] United Nations Conference on Trade and Development (UNCTAD), Recent Developments in Investor-State Dispute Settlement (ISDS): Updated for the Multilateral Dialogue on Investment 2-3 (2013)[hereinafter UNCTAD, Recent Developments].

[11] *E.g.*, Shawn Donnan, *Disputes Clause Heaps Pressure on Trade Deal,* FIN. TIMES, Mar. 11, 2014 (noting that use has soared in recent years); Jane Kelsey & Lori Wallach, *"Investor-State" Disputes in Trade Pact Threaten Fundamental Principles of National Judicial Systems*," PUBLIC CITIZEN 3 (Apr. 2012); Samrat Ganguly, *The Investor-State Dispute Mechanism (Isdm) and A Sovereign's Power to Protect Public Health*, 38 COLUM. J. TRANSNAT'L L. 113 (1999); Stephen J. Brynes, *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.103 (2007).

[12] Arbitration Scorecard 2013, AM. LAW. (June 24, 2013); *see also* Shawn Donnan, *Disputes Clause Heaps Pressure on Trade Deal,* FIN. TIMES, Mar. 11, 2014 (noting that use has soared in recent years).

[13] *E.g.*, Brian King & Viren Mascarenhas, *Investment Treaty Protection for IP Rights*, BNA PATENT TRADEMARK & COPYRIGHT L. DAILY, Aug. 5, 2013.

[14] Jones Day, Treaty Protection for Global Patents: A Response to A Growing Problem for Multinational Pharmaceutical Companies 2 (2012)

criticized such actions for years, some of the criticisms are now being echoed in the popular press.[15] Some claim that tribunals seem to favor companies in making broad rulings that unduly interfere with traditional government regulation. Moreover, many note that problems are exacerbated because decisions are decided not by an independent court, but a panel of private arbitrators, with no appellate review. Increased criticism has resulted in concern about including such investment provisions in pending agreements. Even the Cato Institute, which usually promotes corporate interests has suggested that it would be preferable to eliminate an investment chapter from agreements the United States is currently negotiating given that there are not only concerns about domestic sovereignty, but that it is "ripe for exploitation by creative lawyers."[16] Strong public criticism has stalled or threatens to stall discussions of the Trans Pacific Partnership Agreement involving a dozen countries, as well as two bilateral agreements involving the EU.[17] In addition, although both the United States and the EU at one point defended investment chapters against critics, in the past year, the EU has stopped doing so.[18] The EU is now engaging in public consultations as well as proposing modified language with the hope of minimizing concern.[19]

Eli Lilly's suit brings to light the problems with permitting an expansive interpretation of investment chapters to cover intellectual property claims that have been canceled consistent with

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[15] *E.g.*, Barrie McKenna, *Canada Must Learn from NAFTA Legal Battles*, GLOBE & MAIL (Nov. 24, 2013); Elizabeth Olson, *Growth in Global Disputes Brings Big Paychecks for Law Firms,* NY TIMES*,* Aug. 26, 2013); Sabrina Tavernise*, Tobacco Firms' Strategy Limits Poorer Nations' Smoking Laws*, NY TIMES, (Dec 13, 2013); *Investor-State Arbitration System Needs 'Complete Overhaul*," Bilaterals.org, May 12, 2014.

[16] Daniel Ikenson, *Purge Negotiations on Investor-State Dispute Settlement* (Mar. 4, 2014)

[17] *E.g.*, Shawn Donnan & James Politi, *Official Warns EU-US Trade Deal at Risk over Investor Cases*, FIN. TIMES, Mar. 27, 2014); EU, Canada Fail to Close CETA: Stuck Over Issue Related to Eli Lilly Case, Inside US Trade, May 8, 2014; George Monblot, *This Transatlantic Trade Deal is a Full-Frontal Assault on Democracy*, GUARDIAN, Nov. 4, 2013.

[18] *E.g.* European Commission, Incorrect Claims about Investor-State Dispute Settlement (Oct. 3, 2013).

[19] *E.g.*, European Commission, Press Release, Commission to Consult European Public on Provisions in EU-US Trade Deal on Investment and Investor-State dispute Settlement, Jan 21, 2014.

domestic and international law.[20] This Article aims to not only evaluate the merits of and the policy problems raised by Eli Lilly's specific suit, but also highlight other ways that domestic attempts to balance interests of multinational drug companies with public health might be compromised, as well as how to best avoid these problems in existing and pending agreements. Notably, these issues are *in addition* to the many previously noted problems with investor-state arbitrations, such that the case for excluding such intellectual property issues is particularly strong.

This Article argues that permitting companies to use investor-state arbitration whenever they disagree with domestic decisions concerning the issuance and scope of intellectual property is unprincipled. Fundamentally, a cancelled intellectual property right is not a right at all. Moreover excluding such rights from the scope of arbitration is particularly appropriate because intellectual property is unlike most other types of property in that its very existence is only justified if it promotes desired policy as determined by each country.

TRIPS permits member countries discretion and flexibility in shaping intellectual property rights, cognizant of other policy goals, including public health. A country that is arguably complying 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 dispute filed within the World Trade Organization (WTO) that handles disputes of its agreements, such as TRIPS. The possible interference with an international agreement that permits such policy is unlike other areas typically subject to investor-state arbitrations.[21] Moreover, permitting such challenges would not further the historical justifications of protecting investments in international investment agreements. In particular, companies are not induced to invest in countries solely due to protection of intellectual property norms.

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[20] 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 their inability to be used pursuant to plain packaging laws for tobacco, these raise additional issues beyond the scope of a single article.

[21] At most, there are aspirations, such as agreements from the World Health Organization concerning tobacco. *E.g.*, WHO Framework Convention on Tobacco Control, Jun. 29, 2004.

This Article also provides a detailed analysis of Eli Lilly's central claims - that its patents were "expropriated," and also that Canada failed to provide "fair and equitable treatment" to its investments.[22] The Article hopes to show why Eli Lilly should not recover on *any* of its claims, but nonetheless explains which issues are most vulnerable for Canada in light of some prior expansive rulings. Recognizing the potential problems is important to understanding how to properly cabin such claims not only in Eli Lilly's case, but in future cases as well.

This Article proceeds in three parts. Part II provides a summary of patent law, including the importance of territoriality. In addition, it provides necessary background on the genesis of investor-state disputes that is relevant to assess whether application of such disputes to the new arena of intellectual property rights is appropriate. Part III then turns to the specifics of Eli Lilly's claims against Canada and explains why an arbitration panel should reject Eli Lilly's claims. Part IV goes beyond the specifics of Eli Lilly's claims to raise other related laws that are permissible under TRIPS, but in danger of challenge through investor-state disputes. This Part concludes with specific proposals for how to preserve the existing policy space of countries pursuant to TRIPS in pending and future agreements that aim to provide rights for investors.

## II BACKGROUND

### *A. Patent Landscape*

To understand Eli Lilly's claims against Canada, a bit of background on patents and how they operate is important.

[22] Although Eli Lilly also asserts that Canada violated the nondiscrimination agreement, that provision will not be addressed because it lacks any merit. In particular, national treatment simply requires a country to treat foreign investors "no less favorable" than its domestic investors. North American Free Trade Agreement, Dec. 17, 1992, ch. 11, art. 1102, 35 I.L.M. 605, 639 (1993)[hereinafter NAFTA]. Eli makes two claims that seem unmoored to this standard. Eli Lilly claims that Canadian law disadvantages foreign nationals with requirements "not required by the foreign applicants' own national jurisdictions." Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 106. However, nondiscrimination does not guarantee an investor laws *identical* to its home state. In addition, Eli Lilly claims that it is treated less favorably than domestic generic competitors that can benefit from making the now invalidated patented drugs. *Id.* ¶ 118. 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.

Accordingly, this section provides some detail on domestic and international laws concerning patents.

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 the patented invention within the boundaries of the patent-granting country.[23] As most consumers know, a drug that is patented is generally expensive because the patent owner can exclude all others from making the identical drug during the patent term, such that the patent owner can charge a substantial premium.

Patents are fundamentally tools of social policy. The reward of a patent is given to induce disclosure of information to society so that others can learn from and build upon that innovation.[24] 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.

The social harm of higher prices on patented goods is mediated by patent requirements, as well as the term of patent protection. Patents are generally awarded a limited term of protection of less than twenty years to minimize the period during which consumers must pay patent-inflated prices.[25] In addition, patent requirements are intended to restrict harm to only the most valuable inventions. There are two basic types of requirements that patent applications must establish to persuade a national patent office that a patent is deserved. First, the invention must meet certain requirements, typically that it is patentable subject matter that is useful, new and not obvious.[26] Second, the application itself must meet certain disclosure requirements, such as fully describing the invention and enabling others to properly make and use it.[27]

The patentability standards aim to ensure that patents are only granted on socially worthy inventions. 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 what is considered a use. The United States, for example, has one of the broadest interpretation of

[23] *E.g.*, 35 U.S.C. § 271; TRIPS, art. 28.
[24] *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 164-65 (1989).
[25] *E.g.*, 35 U.S.C. § 154; TRIPS art. 33.
[26] *E.g.*, 35 U.S.C. §§ 101-103; TRIPS art. 27(1).
[27] *E.g.*, 35 U.S.C. § 112.

usefulness; not only may an invention be considered useful for simple entertainment, rather than commercial use, but it may also be useful even if the use is to promote an activity that is deceptive or illegal.[28] Most European countries, on the other hand, bar an invention that violates morality.[29]

In addition, patentability requirements must be satisfied at the time of patent filing to foster fundamental patent policy goals. In particular, applicants are prevented from filing claims for inventions that have not been fully developed since that would unduly reward speculative claims while barring research as well as imposing costs. This is an important backdrop to Canada's implementation of when patents are "useful." As the Canadian Supreme Court has recognized, costs of patent protection are particularly important in the area of pharmaceuticals. As the court noted, "were 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."[30]

One traditional feature of patents is that they are territorially limited. Patents are awarded by individual nations and patent rights are generally only enforceable against actions that occur in that nation.[31] There is no such thing as a global patent enforceable in all countries. An inventor must seek patent protection in individual countries. However, protection in all desired countries is often not possible due to differing domestic patent laws. Indeed, these differences have always been permissible. Prior to conclusion of TRIPS in 1994, international agreements governing patents simply focused on ensuring fairness to domestic and foreign applicants and facilitating the process of obtaining patents in multiple countries *if* a nation elected to grant patents. In addition, one agreement explicitly noted that the grant or denial of a patent on an invention in one country does *not*

[28] *E.g. Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F. 3d 1364, 1366 (Fed. Cir. 1999).
[29] Convention on the Grant of European Patents, art. 53(a), Oct. 5 1973, 1065 U.N.T.S. 57 [hereinafter European Patent Convention].
[30] Apotex v. Wellcome Foundation, 2002 4 SCR 153, ¶ 80.
[31] *E.g.*, 35 U.S.C. § 271(a).

impact the decision of another country.[32] This agreement remains in force today, such that this principle remains valid.

Even though the landmark TRIPS agreement now requires many countries to provide patents, the agreement sets minimum, rather than uniform standards, such that there remains an intended diversity in domestic laws.[33] TRIPS gives states substantial flexibility in complying with TRIPS. For example, although TRIPS requires nations to grant patents on "inventions" that meet standards, it does not define what constitutes an invention.[34] Accordingly, nations can properly exclude software, for example, from patentability if they do not consider software to be an invention.[35] Similarly, although TRIPS requires nations to provide patents on inventions that are useful, new and nonobvious, it does not define any of these terms.[36] At the time that TRIPS was negotiated, 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.[37] Accordingly, although member countries must provide some protection to drug patents, they can define TRIPS patentability criteria to minimize harm. For example, a country could consider a newly discovered use of a known compound to not be "new" because TRIPS does not provide a definition of new.

### *B. Investor-State Disputes*

Before analyzing the specific claims of Eli Lilly, it may be helpful to provide the broader context of the type of agreements under which such a claim is examined.

#### *1. Overview*

There are a number of 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. These agreements are either bilateral

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[32] Paris Convention, art. 4bis.
[33] *Id.* art. 1(1).
[34] TRIPS art. 27.
[35] *Id.*
[36] *Id.*
[37] *E.g.*, Carlos Correa, *Patent Rights*, *in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189, 198-200 (1998).

investment agreements, or free trade agreements with an investor chapter aimed at promoting investment by foreign investors.[38] Typically, they provide investors a guarantee of compensation for any expropriation of investments, promise of freedom from unreasonable or discriminatory measures, guarantee of fair and equitable treatment, and assurance that foreign investments will not be treated less favorably than domestic ones.

An important issue is *how* these new rights may be enforced. The investor rights are decided not by a domestic or international court, but by a panel 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 recognize any claims, or refused to enforce domestic judgments in favor of foreign investors.[39]

Multiple aspects of investor-state arbitrations are widely criticized. A major issue is that the suits are seen 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.[40] This problem is compounded by the fact that arbitrators lack independence and impartiality of typical domestic or international tribunals.[41] Moreover, the proceedings and decisions lack transparency. Interested parties may be excluded from participation and

[38] Although scholars have questioned whether any of these agreements in fact impact decisions to invest, that is nonetheless the goal. *E.g.*, Susan Franck, *Foreign Direct Investment, Investment Treaty Arbitration, and the Rule of Law*, 19 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).

[39] Susan D. Franck, *The Legitimacy Crisis in Investment Arbitration: Privatizing Public International Law Through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521, 1537 (2005).

[40] *E.g.*, European Parliamentary Research Service, Investor-State Dispute Settlement (ISDS) Briefing 5 (2014).

[41] *E.g.*, Gus Van Harten, *Arbitrator Behaviour in Asymmetrical Adjudication: An Empirical Study of Investment Treaty Arbitration,* 50 OSGOODE HALL L J. 211 (2012); Elizabeth Olson, Growth in Global Disputes Brings Big Paychecks for Law Firms, NY TIMES, Aug. 26, 2013; Pia Eberhardt & Cecilia Olivet, Corporate Europe Observatory; Profiting from Injustice: How Law Firms, Arbitrators and Financiers are Fuelling an Investment Arbitration Boom (2012).

decisions do not even need to be public; although there are rules that increase transparency, these rules only apply prospectively to new agreements, rather than to the many that already exist.[42] In addition, a major complaint is that the system results in inconsistent decisions because provisions are broadly interpreted[43] and there is no appeal system to ensure consistency, such that similar situations may result in different determinations.[44]

There have been many proposals to reform the current system.[45] Many have suggested some type of appellate body to address the problem of inconsistent as well as expansive interpretations of identical provisions.[46] Alternatively, some suggest replacing private arbiters with an international investment court to promote impartiality and independence.[47] Other proposals do not involve drastic changes to the form of disputes, but nonetheless aim to cabin problematic decisions. For example, some suggest requiring exhaustion of domestic remedies, limiting the scope of claims, or requiring arbitrators to consider other areas of international law, such as human rights and environmental obligations.[48]

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[42] UNCITRAL Rules on Transparency in Treaty-based Investor-State Arbitration.

[43] *E.g.*, Elizabeth Olson, *Growth in Global Disputes Brings Big Paychecks for Law Firms,* NY TIMES*,* Aug. 26, 2013.

[44] Productivity Commission, Bilateral and Regional Trade Agreements: Final Report 273 (2010); UNCTAD, Recent Developments, *supra* note 10, at 26.

[45] An alternative approach is to renegotiate or withdraw from such agreements entirely. *E.g.*, *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 Arbitration Blog, Sept. 3, 2010.

[46] *E.g.*, Asif H. Qureshi, *An Appellate System in International Investment Arbitration?*, *in* THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW 1154 (Peter Muchlinski et al., 2008).

[47] *E.g.*, Gus Van Harten, Commentary: A Case for an International Investment Court, Investment Treaty News, Aug. 7, 2008; UNCTAD, Reform of Investor-State Dispute Settlement: In search of a Roadmap (2013).

[48] *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 Solorzano, A Comprehensive Approach to Investment Protection 2 (2013); Stephen Schill, Enhancing International Investment Law's Legitimacy 52, 69 (2011).

### *2. Eli Lilly's Case*

As noted earlier, 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 patent standard of utility[49] and is challenging a common law interpretation of utility that applies when a patent sets out a "promise," such that it is called the "promise doctrine."[50] Pursuant to this doctrine, a patent is useful if it does what it "promises," so that following the directions of a patent should result in the desired effect. This can either be demonstrated in the patent, or soundly predicted. In the many cases where promise relies on a sound prediction, there are three components to satisfy. First, there must be 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.[51]

Since 2005, courts have applied the promise doctrine in evaluating whether patents are invalid for failing the utility requirement and invalidated roughly a dozen patents.[52] Eli Lilly, as well as other companies, criticize the promise doctrine as improper and discriminatory since most of the patents held invalid have been pharmaceutical patents.[53] However, the doctrine is not limited to pharmaceuticals. The Canadian Manual for Patent Practice in fact has a non-pharmaceutical example involving a golf club.

Although the promise doctrine has been criticized as being without basis, the Canadian Supreme Court has provided a firm foundation 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

[49] This is sometimes also referred to as the "doctrine of sound prediction."
[50] When a patent does not make a promise, it will satisfy utility with any "mere scintilla" of utility.
[51] Eli Lilly v. Novopharm, 2010 FCA 197, 85 CPR (4th) 413, ¶70, revg. 2009 FC 1018, 78 CPR (4th) 1.
[52] Norman Siebrasse, The False Doctrine of False Promise 36-37 (2012).
[53] *E.g.,* PHRMA, SPECIAL 301 SUBMISSION 2014 76-77 (2014); *see also* USTR, 2013 Special 301 Report at 46 (noting "serious concerns about the impact of the heightened utility requirements for patents").

interest in avoiding … granting monopoly rights in exchange for misinformation."[54] 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, or for the statement of any mere scientific principle or abstract theorem."[55]

In the case of Eli Lilly's patents on the drugs sold as Strattera and Zyprexa, they were both found to promise certain treatments, yet fail to soundly predict them, such that they were found to be invalid for lack of utility. In particular, the patent on the drug sold as Strattera was invalidated because the Court found that it had an implied promise to treat ADHD as a chronic condition, but the patent lacked evidence that it was effective for long-term use because it only disclosed a short-term study.[56] Similarly, Eli Lilly's patent relating to the drug sold as Zyprexa to treat schizophrenia was found to have an implied promise of superiority with respect to improved side effects over existing antipsychotics for long-term treatment, but inadequate evidence to show this.[57]

Eli Lilly asserts that Canada improperly invalidated its patents on an interpretation of the law that did not exist when the patents were examined.[58] 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.[59] Accordingly, Eli Lilly asserts that Canada was wrong to "re-interpret a core patentability requirement enshrined in NAFTA in a way that contracts the standard accepted by the NAFTA parties at the time the treaty was negotiated."[60]

Eli Lilly also suggests that the promise doctrine is inconsistent with the Patent Cooperation Treaty (PCT) because the PCT prohibits countries from "imposing requirements as to the

[54] Appotex, 2002 4 SCR, ¶ 66.
[55] *Id.*
[56] Novopharm v. Eli Lilly, 2010 FC 915.
[57] Eli Lilly v. Novopharm, 2011 FC 1288 ¶ 84.
[58] *Id.* ¶¶ 69, 41.
[59] Eli Lilly Notice of Arbitration, supra note 2, ¶¶ 28-34.
[60] *Id.* ¶ 68.

form or contents" of the original PCT application.[61] In particular, it asserts that the promise doctrine "would defeat the single application objective."[62] However, the PCT focuses solely on procedural issues to enable inventors to more easily obtain patents in over one hundred member countries with a single application that is evaluated by individual countries[63] and does not govern what countries consider patentable.[64] 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.[65]

## III 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." Then, this Part argues that tribunals should not find revoked rights to be either an expropriation or violation of fair and equitable treatment. Although there are strong reasons for rejecting such claims, this analysis simultaneously highlights how a tribunal could nonetheless find otherwise to set the stage for the need for proposed reforms presented in Part IV.

### *A. Invalidation of Intellectual Property Rights Should Not Be a Covered Investment*

This section explains why existing investment agreements should be interpreted to exclude canceled intellectual property rights as a covered investment. Intellectual property rights are fundamentally different than other types of property because they can and often are later canceled; in such cases, there should be no

[61] Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 45; *see also* Patent Cooperation Treaty, June 19, 1970, art 27(1), 28 U.S.T. 7645, 1160 U.N.T.S. 231 [hereinafter PCT].
[62] *Id.* art. 5.
[63] PCT art. 27(5).
[64] *Id.*
[65] *Id.* art. 27(5)-(6).

investment because canceled rights mean there were no legitimate rights to begin with.

*1. Canceled Intellectual Property is Not Property*

Intellectual property rights are the only type of property whose existence may be canceled. Indeed, patents do not even exist without an initial state determination to grant it. However, this determination is made after a brief administrative review, such that they are only presumptively valid; they can and often are later canceled or revoked if it is found that the rights should not have been issued in the first instance.[66] Accordingly, a patent that is invalidated for failure to satisfy one of the stated standards should not be constitute intangible property pursuant to an investment agreement since the invalidation means it never should have existed. Rather, in that case, it could be considered more akin to an application for patent rights, for which there has never been a recognized property right and there should not be.[67]

This traditional practice is reflected in Canadian patent law. 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.[68] 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.[69]

Eli Lilly argues that because its patents were consistent with Canadian law at the time of application, a change in the law *after* issuance that invalidated its patents was improper. In particular, Eli Lilly asserts 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.[70] Eli Lilly bases this statement on the fact that the

[66] *See, e.g.*, 35 U.S.C. §§ 311, 321; Canada Patent Act §§ 42, 43(2), 60(1).

[67] 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.*, US-Jamaica BIT, art. I.1(a)(iv). 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.

[68] Canada Patent Act § 43(2).

[69] *Id.* § 42.

[70] Eli Lilly Notice of Arbitration, *supra* note 2, ¶¶ 8-9.

guidelines for Canadian patent office when it applied had a different standard that considered inventions to be satisfy the standard unless the invention is "totally useless."[71] 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.[72]

Although Eli Lilly seems to suggest that it is improper to retroactively apply law, that is typical patent law practice. In the United States, for example, after the Supreme Court modified the obviousness standard to make it more difficult to meet, this impacted the validity of existing patents.[73] More recently, after the Supreme Court modified what types of genes may be patentable subject matter, the validity of some patents is in question.[74] Moreover, this phenomenon is common to all areas of common law doctrine that have both prospective and retrospective application.[75]

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

There are unique policy problems with permitting investors to challenge domestic decisions denying or revoking intellectual property rights that are permissible under international agreements. These problems are *in addition* to the many criticisms of all investor-state arbitration disputes previously noted. Permitting challenges to domestic decisions canceling intellectual property rights is problematic because unlike other investments, intellectual property rights are granted solely to effectuate domestic social

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[71] *Id.* ¶ 8

[72] 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, ¶ 46, Eli Lilly v. Canada (June 30, 2014).

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

[74] *E.g.*, Ariosa Diagnostics, Inc. v. Sequenom, Inc., 2013 U.S. Dist. LEXIS 156554 (N.D. Cal 2013); *see also* Sherman Kahn, *Will Patents Be the Next Wave in Investor-State Arbitration?,* 7 NY DISPUTE RESOLUTION LAW. 53, 56 (2014).

[75] *See, e.g.,* Harold 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).

policies, such that if those policies do not exist, there is no basis to have an intellectual property right. Intellectual property rights are also different than traditional investments in that they are governed by international agreements that represent negotiated norms such that a decision by an investor-state tribunal, or even simply the filing of such an action would have a chilling effect on these negotiated norms and could also result in inconsistent decisions. Moreover, intellectual property is also fundamentally different than traditionally protected investments, such that the usual justification for protection of investments does not apply.

*a. Intellectual Property Policy Issues Support Deferring to States*

Intellectual property rights are inherently different than most other types of investments protected by investment chapters. Unlike most types of property, intellectual property exists to promote *underlying policy goals*. 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 affordable medicine. Accordingly, although TRIPS requires most countries of the world to provide some degree of patent protection on drugs, it explicitly recognizes the importance of considering public health and other policies; moreover, an agreement by WTO member countries since TRIPS further reinforces this fundamental principle. [76]

Not only is there a strong policy component to all drug patents, but also there may be a particular need to recalibrate patent laws in light of current business realities. Facing a "crisis" in pharmaceutical innovation where innovation has been stagnant despite exponentially increased 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.[77] 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

[76] TRIPS arts. 7-8; World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/1, ¶4 (2001).
[77] *E.g.*, *supra* note 8 and accompanying text.

a drug, or the metabolized version in a patient's stomach. Both of these practices have been dubbed "ever greening" by critics because the patent term seems "ever green."[78] Indeed, companies recognize that some of the patents are of dubious validity,[79] 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.[80]

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 they 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.[81] The drug marketed as Zyprexa similarly already enjoyed a full term of patent protection. Both of these cases could be considered examples of ever greening profitable patents. Indeed, Eli Lilly's two inventions at issue would likely be invalid in India where there is a complete bar on patents that simply claim a new utility for a known compound to help address this very type of problem.[82] Moreover, other countries including Brazil, Australia and member states of the EU similarly recognize that current patent laws impacting drugs need to be recalibrated to better balance promoting optimal innovation with less social cost.[83]

### *b. International Agreements Permit Nations to Decide on the Scope of Intellectual Property Rights*

Permitting investment arbitration disputes to decide domestic decisions concerning intellectual property rights is

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[78] *E.g.*, Thomas, *supra* note 7.

[79] *E.g.*, EC Pharmaceutical Sector Inquiry, *supra* note 8, at 192 (noting companies admitting a strategy to seek patents which "might not be rock solid").

[80] Mary Alazarki, *The Ten Biggest-Selling Drugs That are About to Lose their Patent,* Daily Finance, Feb. 27, 2011 (noting that companies can lose up to 90% 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.*

[81] Canada, Statement of Defense, ¶ 53.

[82] India Patent Law § 3d.

[83] *E.g.*, EC Pharmaceutical Sector Inquiry, *supra* note 8; Brazil, Report Innovation Towards National Competitiveness (2013); Australian Government, Pharmaceutical Patents Review: Background and Suggested Issues Paper (2012).

different than most other investment disputes because of an important separate international agreement: TRIPS.[84] As noted earlier, well over one hundred countries, including Canada, must comply with TRIPS. However, it sets *minimum, but not uniform* standards, such that nations are understood to have substantial flexibility.[85] In particular, although patents must be granted on all inventions that satisfy traditional criteria, including that the invention be useful, the agreement notably does not define what that term means, such that countries have discretion to decide this themselves.[86] In addition, TRIPS expressly contemplates that patent rights can be revoked and simply requires that there be judicial review of any such decision.[87]

TRIPS is fundamentally different than most international agreements that have been implicated in investor-state disputes thus far. Traditionally, investor-state challenges that invoke some international agreement involve agreements that are primarily aspirational. For example, in the pending suits concerning plain packaging tobacco laws, there is a WHO framework convention that supports domestic laws at issue,[88] but legally, no member countries must apply the guidelines.[89] Similarly, although some commentators have suggested that arbitrators should consider international human rights norms, these norms are notably vague and are more aimed at protection of individuals, rather than clarifying what countries can do.[90] In contrast, TRIPS represents internationally agreed upon domestic policy space in the context of intellectual property.

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[84] 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.
[85] TRIPS art. 1(1).
[86] *Id.* art. 27.
[87] *Id.* art. 32.
[88] *E.g.*, Philip Morris v. Uruguay, ICSID Case No. ARB/10/7, Request for Arbitration, P 3 (Feb. 19, 2010); Philip Morris Asia Ltd. v. Austl., UNCITRAL, PCA Case. No. 2012-12, Written Notification of Claim (Jun. 27, 2011).
[89] *Eg.,* Susy Frankel & Daniel Gervais, *Plain Packagin and the Interpretation of the TRIPS Agreement*, 46 VAND. J. TRANSNAT'L L. 1149, 1163 (2013).
[90] *E.g.*, James D. Fry, *International Human Rights Law in Investment Arbitration: Evidence of International Law's Unity*, 18 DUKE J. COMP. & INT'L. L. 77 (2007); Todd Weiler, *Balancing Human Rights and Investor Protection: A New Approach for A Different Legal Order,* 27 BC INT'L & COMP. L REV. 429 (2004).

In addition, 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, there were none that involved intellectual property at the time the WTO and TRIPs were negotiated, such that negotiators likely did not see the need to include such a provision. However, there is language to prohibit countries from taking unilateral action for violations.[91] 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.[92] There is a strong possibility of inconsistent rulings, especially because investor-state arbitrations have no appellate review.

Permitting arbitrations to overrule internationally agreed upon domestic flexibilities under TRIPS seems particularly unfair since TRIPS already encroaches on traditional state authority in the area of intellectual property rights. Notably, although TRIPS requires all countries to provide some level of patent protection, this was a monumental change to the prior international landscape that had never mandated countries grant any intellectual property rights. The idea of global rules requiring patent protection was the brainchild of multinational pharmaceutical companies who successfully lobbied the US 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 focused exclusively on mandating intellectual property rights.[93]

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[91] WTO, Understanding on rules and procedures governing the settlement of disputes, Art. 23:2 33 I.L.M. 1226, 1241 (1994).

[92] Indeed, some suggest that past tribunals have struggled to properly interpret and apply WTO law. *E.g.,* Jurgen Kurtz*, The Use and Abuse of WTO Law in Investor-State Arbitration: Competition and its Discontents*, 20 EUR. J. INT'L L. 749 (2009); Bryan Mercurio, *Awakening the Sleeping Giant*: *Intellectual Property Rights in International Investment Agreements*, 15 J. INT'L EC. L. 871, 905 (2012).

[93] *E.g.*, SUSAN SELL, PRIVATE POWER, PUBLIC LAW (2003).

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 that membership in the WTO would bring.[94] In addition, some developing countries may have agreed to TRIPS assuming that this would forestall unilateral pressure from countries concerning their intellectual property laws.[95] 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.

Importantly, if cases such as Eli Lilly's are allowed, they could have a chilling effect on an important trend where 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 most common "new" drugs that are in fact only modest variations of old drugs with no improved benefit to patients.[96] Since India adopted its law in 2005, other countries have either copied India's laws, or are contemplating doing so.[97] For example, Brazil aims to amend its patent standards to mirror India's.[98] However, Brazil's ability to do so would be completely compromised if Brazil signed an agreement permitting investor-state arbitration. Although that would seem contrary to Brazil's interest, the inclusion of investment clauses are based on many

[94] *E.g.*, PETER DRAHOS WITH JOHN BRAITHWAITE, INFORMATION FEUDALISM 10 (2002).

[95] *E.g.*, Peter Yu, *TRIPS and its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 372-73 (2006).

[96] Indian Patent Act, No. 39 of 1970, § 3(d)(amended 2005).

[97] *E.g.*, Universally Accessible Cheaper and Quality Medicines Act of 2008 and Implementing Rules and Regulations of Republic Act 9502. S1-S2 (Philippines provision); Divya Rajagopal, *EU, Australia, Canada May Follow India's Patent Law*, ECON. TIMES, April 4, 2013.

[98] Brazil, Innovation Towards National Competitiveness 114 (2013); *see also* 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 Study 41-46 (2013).

issues and preserving domestic policy space for intellectual property laws is not always at the forefront of negotiations. Moreover, even if this is simply a theoretical possibility for Brazil, it is a distinct possibility for the many countries that already have agreements permitting investor-state arbitrations.

### *c. Considering Intellectual Property an Investment Does Not Foster Traditional Investment Goals*

IP should be excluded from investor-state arbitration because providing enhanced protection of IP does not satisfy traditional justifications of investment arbitrations. Such provisions arose as a means to both encourage investors to invest in countries that they might be hesitant to invest in, and also to provide a remedy to investors who might otherwise have no recourse. As explained below, neither of these justifications is relevant to Eli Lilly's case or to IP in general.

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 necessarily invest in countries based on intellectual property laws. For example, countries known to have weak intellectual property rights, such as India and China, nonetheless have substantial foreign direct investment;[99] in addition, there is no definitive empirical support for claims that strengthening intellectual property rights result in increased investment.[100]

This is particularly true for pharmaceutical companies and patent rights. Given extensive infrastructure for drug development and even manufacture, local laws are unlikely to result in investing

[99] 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 $billion in Pharma in April-June,* EC. TIMES, Sept. 1, 2013. Notably, although South Africa increased patent protection to comply with TRIPS, this *reduced* foreign direct investment from pharmaceutical companies that instead consolidated their operations. C.M. Naude & J.M.Luiz, *An Industry Analysis of Pharmaceutical Production in South Africa,* 44 AFR. J BUS. MANAGEMENT 44 (2013); David Kaplan, Intellectual Property Rights and Innovation in South Africa: A Framework (2009).

[100] *E.g.* Sisule F.Musungu, Rethinking innovation, development and intellectual property in the UN: WIPO and beyond (2005); Mila Kascheeva, The role of foreign direct investment in the relation between intellectual property rights and growth (2013).

a new country. Generally, multinational companies develop patentable inventions where they have research labs, primarily in the US 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.

If multinational companies are not going to invest in a country due to its intellectual property laws, providing a remedy when the intellectual property laws are considered undesirable does not seem appropriate. 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 that it sought Canadian patent protection on. 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.

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 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 a robust appellate process. It is now simply seeking another "bite at the apple" that would be unavailable to a domestic Canadian company.

### *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 nonetheless not constitute expropriation. Eli Lily's case may involve a situation that is exempt from expropriation analysis. Alternatively, the situation may not be completely exempt, but based on prior decisions as well as policy grounds, Canada should not be found to have engaged in either direct or indirect expropriation.

### *1. Analysis of an Expropriation Claim Against Canada May Be Unnecessary*

An initial question is whether there is any need to even address the details of an expropriation claim. There are two possible reasons. First, the situation could fall under an exception from expropriation. Alternatively, the Canadian decisions may not constitute "state action" that is a fundamental pre-requisite to expropriation claims. Ultimately this section concludes that although there are arguments for excluding Eli Lilly's claims under either or both of these grounds, a tribunal could reasonably find otherwise, such that continued analysis is necessary.

#### *a. This Case May Be Explicitly Excluded*

The most obvious reason that an expropriation analysis may be unnecessary is that the situation may be exempt from consideration as expropriation. Eli Lilly's case is brought pursuant to NAFTA, which excludes certain issues from consideration as expropriation.[101] In particular, although article 1110 generally prohibits member states from expropriating foreign investments, paragraph 7 states that it does not apply to "revocation, limitation or creation of intellectual property rights" if consistent with the NAFTA provision on patents.[102] This seems to preclude expropriation claims of intellectual property, such as patents, that are revoked *if* consistent with NAFTA.

There are two NAFTA sections on patents that are relevant to Eli Lilly's situation. 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.[103] Notably, NAFTA does not define what it means to be "useful," such that member states, such as Canada, should be permitted to define this as they wish, even if different than the laws

[101] 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.*, US-Singapore art.15.6.5 (2003); TPP Draft Investment Chapter art.12.2(5). Notably, TRIPS is a different agreement than NAFTA, but both have similar language concerning patentability requirements. *Compare* TRIPS art. 27(1) *with* NAFTA art. 1709(1).

[102] NAFTA art. 1110(7).

[103] *Id.* 1709(1).

of other NAFTA member states. However, article 1709(8) states that countries may only revoke a patent when "grounds exist that would have justified a refusal to grant the patent."[104]

In the Eli Lilly case, the issue is whether the revocation provision of NAFTA prevents countries from revoking patents based on a ground that existed at the time the patent was issued, but for which its *interpretation* has since been modified. Eli Lilly asserts that this is impermissible. However, NAFTA's language does not explicitly support this conclusion and doing so would be contrary to recognized principles of how common law operates. As noted earlier, courts do modify patent law standards and retroactively apply them. Given this reality, it seems reasonable to interpret NAFTA "grounds exist" clause to mean that countries cannot revoke patents on a *new* ground that never previously existed, rather than an expectable modification of an existing ground. Nonetheless, it is unclear how a panel will in fact interpret this NAFTA provision, such that it is not clear that Eli Lilly's claim is exempt from expropriation claims.

### *b. Canadian Court Decisions Should Not Constitute State Action Necessary for an Expropriation Claim*

Another issue is whether the Canadian decisions constitute state action that would give rise to an expropriation claim. Unlike most investment arbitration cases where the complained of action is a legislative or regulatory measure, Eli Lilly's case involves solely the judiciary. Although there are only a handful of arbitration decisions involving actions of domestic court actions, they uniformly affirm that such actions can constitute state action.[105] Notably, even though actions of state courts *may*

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[104] *Id.* 1709(8).

[105] Azinian v. United Mexican States, ICSID Case No. ARB(AF)/97/2, 14 ICSID Review-FILJ 538, 567; Saipem S.p.A. v. People's Republic of Bangladesh, ICSID Case No. ARB/05/7, Award, ¶¶ 189-90 (June 30, 2009); *see also* Loewen Group v. US, ICSID Case No. ARB(AF)/98/3 (2001), Decision on hearing of Respondent's objection to competence and Jurisdiction, ¶ 70 ("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, ¶ 191 (no expropriation found); Azinian, ¶ 10 (state action was simply affirmance of city council decision); Loewen, ¶¶ 148, 241 (dismissing all claims both because

constitute state action, that seems to only be the case when the court ruling is clearly incompatible with a rule of international law, a denial of justice or the state is responsible for a judicial decision "contrary to municipal law."[106]

The only possible basis for considering Canadian court actions against Eli Lilly to be state action is that those actions violate international law; the other bases for state action do not involve second guessing a domestic court applying its own substantive laws. There are two separate international agreements that Eli Lilly claims are violated – NAFTA as well as the PCT. The NAFTA claims will first be explained, followed by the PCT claim.

Eli Lilly alleges that the promise doctrine is inconsistent with NAFTA requirements concerning utility and nondiscrimination.[107] 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.[108] However, that is irrelevant because NAFTA does not require member countries to have identical laws. Although NAFTA does require countries to grant patents that meet the standard of utility, it provides no definition, such that nations are permitted to self-define it.[109] 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.[110] In particular, Eli Lilly asserts that pharmaceutical patents have been "almost exclusively" impacted by the promise doctrine.[111] However, the doctrine applies to all inventions, such that this argument seems questionable. This is especially true given that similar language in TRIPS was interpreted to mean that actions that impact some areas of the law more than others are not discriminatory when the standard is neutrally worded.[112] Moreover, the WTO panel specifically noted that even if one industry is impacted more, that

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claimant was not a qualifying investor and also because the claim was an attempt to use arbitration in lieu of a domestic appeal).

[106] Azinian, ¶ 98; Loewen, ¶ 47.

[107] Eli Lilly Notice of Arbitration, *supra* note 2, ¶¶ 69-70.

[108] *Id.* ¶ 9.

[109] NAFTA art. 1709(1).

[110] *Id.*

[111] Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 69.

[112] Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (March 2000).

is a permissible *differentiation*, rather than discrimination if there is an issue unique to a certain industry.

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 should not bar a country from revoking a patent based on modification of a long-standing requirement.

Eli Lilly's claim that Canada violates international obligations under the PCT is that the utility requirement violates the 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.[113] In particular, Eli Lilly asserts that the promise doctrine essentially requires certain information be disclosed in the patent application, such that they are a matter of form and content governed by the PCT and for which a nation can not make additional requirements.[114] However, as noted earlier, the PCT is an international 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 US requires that patent applicants disclose best mode in the patent application, even though that is not a requirement of the PCT.[115]

Accordingly, Canada's promise doctrine is not incompatible with international law. In fact, Eli Lilly's challenge to the substance of Canadian law is unprecedented. 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 limit[116] as well as judicial interference with a contractually permitted arbitration.[117]

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[113] Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 45; PCT art. 27(1).
[114] Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 46.
[115] 35 U.S.C. § 112(1).
[116] 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. Bacari, *The Loewen Claim: A*

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

Although there are legitimate reasons why Eli Lilly's case should be completely excluded 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 Canada directly and indirectly expropriated its patent rights in an unusual case that is not typical of either claims. As explained below, Eli Lilly should be found to have committed neither type of expropriation.

#### *a. Canada Should Not be Found to Have Directly Expropriated Eli Lilly's Patents*

Direct expropriation claims involve outright and overt taking of property by the state, such as by transferring title to the state; the reason for the taking is not important.[118] The property must be property within the scope of an investment agreement, which typically includes not only tangible, but also intangible property of economic value. There are relatively few such claims in recent times since states want to attract foreign direct investment.[119]

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

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*Creative Use of NAFTA's Chapter 11*, 34 U. MIAMI INTER-AM. L. REV. 465, 468-69 (2003).

[117] Saipem, ¶¶ 35-37, 39.

[118] For example, when Venezuela seized oil installations of foreign companies, that resulted in a series of direct expropriation cases. *E.g.*, P.G. Caracas, *Venezuela and International Arbitration: Ick-SID*, ECONOMIST, Jan. 19, 2012.

[119] *E.g.*, Anne K. Hoffmann, *Indirect Expropriation*, *in* STANDARDS OF INVESTMENT PROTECTION (August Reinisch, ed., 2008); August Reinisch, *Expropriation*, *in* OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW 408 (Muchinski et al., eds. 2008).

physical property seized by the state in terms of the *benefit* to the state. 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 that want to use Eli Lilly's former patents that are now free for the taking. Still, given that no one technically owns legal title to the intellectual property and transfer of title to the state is a fundamental part of a direct expropriation claim, this claim should be rejected.

### *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.[120] This seems to better-fit Eli Lilly's case. It technically still owns the patents at issue; however, they have no economic value to Eli Lilly because without valid patents, Eli Lilly cannot charge a premium price because there will be other competitors. However, as will be shown below, Canada should not be considered to have indirectly expropriated Eli Lilly's investments.

An important issue is how to interpret indirect expropriation. Many agreements, including NAFTA do not provide criteria for evaluating indirect expropriation, there are two basic approaches.[121] 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.[122]

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[120] Reinisch, *supra* note 119, at 422. Accordingly, even if the investor continues to own legal title, there still may be indirect expropriation. *E.g.*, Metalclad Corporation v. United Mexican States, ICSID Case No. ARB(AF)/91/1, Decision, ¶103 (Aug. 30, 2000), 5 ICSID Rep. 212 (2001).

[121] *E.g.,* NAFTA art. 1110*; see also* Susy Nikiema, Best Practices: Indirect Expropriation, IISD at 5 (2012).

[122] Andrew Newcomb, T*he Boundaries of Regulatory Expropriation in International Law*, 20 ICSID REV. INVESTMENT L. J. 1, 9-11 (2005) [hereinafter

As explained below, Eli Lilly's strongest 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.[123] Generally, panels 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."[124] 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.[125]

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

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Newcomb, *Boundaries*]; Nikiema, *supra* note 121, at 13. In addition, some 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.*, SEBASTIAN LOPEZ ESCARCENA, INDIRECT EXPROPRIATION IN INTERNATIONAL LAW 10 (2014).

[123] *E.g.*, Consortium RFCC v. Kingdom of Morocco (ARB/00/6), award of Dec. 22, 2003, 20 ICSID Rev-FILJ, ¶ 68 (2005).

[124] Starett Housing Corporation v. Starrett Housing Int'l v. Iran, award of Dec 19, 1983, p. 14; *see also* Pope & Talbot, ¶ 102 (considering whether state interference is "sufficiently restrictive to support a conclusion that the property has been taken from the owner … under international law, expropriation requires a substantial deprivation); Metalclad, ¶ 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); Tecnicas Medioambientales Tecmed v. United Mexican States, ICSID Case No. ARB(AF)/00/2 ¶ 115 (May 29, 2003)[hereinafter Tecmed] ("radically deprived of the economical use and enjoyment of its investments, as if the rights related thereto .. had ceased to exist.").

[125] Newcomb, *Boundaries, supra* note 121, at 11-12; Metalclad, ¶ 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* Tippets v. Tams-Affa, award of June 29, 1984, Iran-US CTR, 6, 1986, at 225-26 (government intention is less important than effect of measure on owner of assets).

invalidated.[126] 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 patent exists, but the ability to exclusively determine how to exploit it is limited.[127]

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.[128] In particular, tribunals weigh harm to the investment against the state interest. In addition, although typically an element in fair and equitable treatment standards, tribunals are increasingly also incorporating legitimate expectations of investors into their analysis of indirect expropriation claims. Recent agreements tend to explicitly enumerate these factors for consideration, which notably mirror the factors that the United States Supreme Court utilizes to determine whether there has been a regulatory taking.[129] Accordingly, analyzing Eli Lilly's claims pursuant to these factors seems strong policy, as well as predictive of future agreements that explicitly note these factors. As this section will explain, Eli Lilly has a much weaker claim when these factors are considered.

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[126] 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."

[127] *E.g.*, Peter Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. IN'TL 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 152 (2009).

[128] *E.g.*, U. Kriebaum, *Expropriation*, *in* INTERNATIONAL INVESTMENT LAW 38-41 (M. Bungenberg et al, eds. 2013)

[129] *E.g.*, US Model BIT Annex B, Expropriation; US-Uruguay BIA, Annex b.2 (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); ASEAN Compressive Investment Agreement of 2009, Annex 2(c) (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.* ¶ 4(a)(i).

### 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.[130] Even for panels 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.[131]

An important issue is what constitutes 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.[132] Nonetheless, recent agreements may shed light on what subject matter within the scope of police powers. For example, 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*."[133] This is also consistent with prior tribunal decisions, such as *Methanex*, in which a law that barred use of a petrol additive deemed carcinogenic was considered a bona fide regulation that served legitimate public interest, such that it was not compensable.[134]

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

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[130] *E.g.*, Saluka, ¶ 262; Methanex Corp. v. U.S.A., NAFTA/UNICITRAL Arb.,Final Award of the Tribunal on Jurisdiction and Merits, part IV, ch. D, ¶ 7; Continental Casualty Company v. Argentine Republic, ICSID Case No. ARB/03/9, Award, ¶ 276 (Sept. 5, 2008); Marvin Feldman v. United Mexican States, ICSID Case No. ARB(AF)/99/1, Award, ¶105 (Dec. 16, 2002); SD Myers v. Canada, NAFTA Arbitration/UNCITRAL, Award, ¶ 281 (Nov. 13, 2000).

[131] *E.g.*, Tecmed, ¶ 122.

[132] *E.g.*, Saluka, ¶ 63 ("international law has yet to identify in a comprehensive and definitive fashion precisely what regulations are considered … within the police or regulatory power of states.").

[133] US Model BIT, Annex B, Expropriation, ¶ 4(b).

[134] Methanex, Part IV(D), ¶7.

exchange through proper disclosure of the invention. The promise doctrine that Eli Lilly challenges aims to ensure that this fundamental patent bargain is satisfied.

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 panel would agree.

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 panels are deferential to self-declared state interests and find no expropriation so long as the state action is non-discriminatory and in accordance with due process.[135] However, other panels 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 tribunal applies this standard. For example, in *Tecmed v. Mexico,* the tribunal found that even if there is a valid state interest, it can not 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.[136] In that case, the panel 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. [137]

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

[135] *E.g.*, Chemtura Corp v. Canada, UNCITRAL, Award of Aug. 2, 2010, ¶ 266.
[136] Tecmed, ¶ 122.
[137] *Id.* ¶ 151.

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 suggests that it may not be necessary to apply the law in this manner.

### iii. Eli Lilly Has No Legitimate Investor Expectations that Have Been Violated

The best consideration for rejecting Eli Lilly's claim is to consider whether it had any legitimate expectations. Importantly, the only legitimate expectations are those that are based on *specific assurances* from the state. These were found to exist in *Metalclad* to support an indirect expropriation claim where the investor relied on representations of the Mexican government that the investor would be issued the required permits for its business. On the other hand, in *Methanex*, the tribunal found no specific state representations to induce the investor to make commitments that would be harmed by subsequent regulatory measures, such that the investor should not have been surprised that environmental and health protection laws might change and adversely impact its interests.[138]

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 Eli Lilly complains that it was shocked by Canada's change in the law, this is inadequate grounds for a claim of legitimate investor expectations given no specific assurance provided to Eli Lilly. In addition, although Eli Lilly seems to believe that an issued patent should be considered an assurance that it will remain valid, that is fundamentally inconsistent with patent law in Canada and other countries. As noted earlier, an issued patent is only presumptively valid, but can 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 were relied upon to the investor's detriment in *Metalclad*.[139] Whereas the investor in *Metalclad* expended funds

[138] Methanex, Part IVD, ¶ 10.
[139] Metalclad, ¶ 4108.

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, it can alternatively recover compensation if Canada failed to provide "fair and equitable treatment" to its investment.[140] This claim is very important to Eli Lilly and all other investors since panels tend to take a flexible interpretation, such that this is the most common[141] and successful type of investment claim[142] and often prevails even when there is no indirect expropriation.[143] Nonetheless, this section explains why Eli Lilly should not be

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[140] NAFTA art. 1105(1).

[141] UNCTAD, Fair and Equitable Treatment, UNCTAD Series on Issues in International Investment Agreements II, A Sequel 10 (2012)[hereinafter UNCTAD, Fair and Equitable Treatment]; RUDLOPH DOLZER & CHRISTOPH SCHREUER, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 130 (2008). 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)

[142] In 2012 alone, of the twelve published decisions finding state liability, six found a violation of FET, which was the most common ground for state liability. UNCTAD, Recent Developments, *supra* note 9, at 5; *see also* AUGUST REINISCH, STANDARDS OF INVESTMENT PROTECTION, Oxford University Press (2008)(FET account for 62% of successful awards between 2006-2008). 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 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." FA Mann, *British Treaties for the Promotion and Protection of Investments,"* 52 BRIT. YBK. INT'L L. 241 (1981).

[143] *E.g.,* Matthew 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. 160, 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 141, at 112.

considered to have a valid claim against Canada for violation of the fair and equitable treatment standard because it had no legitimate expectations that were violated, which is the crux of this standard, as explained below.

A key question is what constitutes "fair and equitable treatment." Technically, there are differences in treaty language. Some, such as NAFTA, link the phrase to only minimum standards of conduct pursuant to customary international law,[144] whereas others have no reference for what constitutes "fair and equitable treatment."[145] However, in practice, tribunals seem to treat all claims similarly.[146] Essentially, tribunals as well as scholars consider whether there is a violation is based on a number of factors.[147] These include (a) defeating investors' legitimate expectations (sometimes in balance 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;[148] not all of these factors need be

[144] NAFTA art. 1105(1). This should technically limit violations to situations where the action is "shocking, egregious and outrageous." *E.g.*, JJ Coe, *Fair and equitable Treatment under Nafta's Investment Chapter*, ASIL 9, Proceedings of the 9 Annual Meeting (2002).

[145] *E.g.*, China-Switzerland Bilateral Treaty, art. 4 (2009); Belgium-Luxembourg Economic Union-Tajikistan Bilateral Treaty, art. 3 (2009); *see also* Mahnaz Malik, Best Practices Series Bulletin – Fair and Equitable Treatment (Sept. 2009); UNCTAD, Fair and Equitable Treatment, *supra* note 141, at 6-7.

[146] Notably, even where tribunals are interpreting the standard pursuant to an agreement that requires it 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.*, RDC v. Guatemala, ICSID Case No. ARB/07/23, Award (June 29, 2012); *see* also UNCTAD, Fair and Equitable Treatment, *supra* note 141, xv, 11; Matthew 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.

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

[148] *E.g.*, UNCTAD, Fair and Equitable Treatment, *supra* note 141, at 62; TUDOR, *supra* note 146, at 155; Choudhury, *Evolution or Devolution? Defining Fair and Equitable Treatment in International Investment Law*, 6 J WORLD INVEST & TRADE 297 (2005); Yannaca-Small, *supra* note 141, at 129. Alternatively, panels cite a quote from Waste Management v. Mexico that addresses similar factors. *E.g.,* GAMI Investments v. United Mexican States, NAFTA/UNCITRAL Arb., Final Award, ¶ 89 (Nov. 15, 2004); Methanex, part IV, ch. C, ¶ 26; Siemens A.G. v. Arg. Republic, ICSID Case No. ARB/02/8,

present in every case, but legitimate investor expectations are considered key to a violation.[149]

Of these factors, the only relevant factor to consider is whether Eli Lilly had a legitimate expectation that was defeated.[150] 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." This essential term is generally not defined in agreements, but there are essentially two views of legitimate expectation that have been applied by tribunals. The broadest and most investor-friendly approach is that a state must ensure a stable legal and business environment. The other approach only finds legitimate expectations if those expectations arise from a *specific state representation* that the investor relies on and the investor expectation is *balanced* against state interests. Although this author believes that the standard grounded in state representation is preferable as a matter of policy, both standards are discussed to predict how a tribunal might rule in Eli Lilly's

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Award, ¶ 297 (Feb. 6, 2007); Azurix Corp. v. Arg. Republic , ICSID ARB/01/12, Award, ¶ 370 (July 14, 2006). Waste Management No. 2 v. Mexico ¶ 98, ICSID Case N° ARB(AF)/ 00/3

[149] *E.g.*, Electrabel v. Hungary, ICSID Case No. ARB/07/19, Decision on Jurisdiction, Applicable Law and Liab., ¶ 7.75 (Nov. 30, 2012) ("most important function" of standard is to protect legitimate expectations); *see also* Rudolph Dolzer, *Fair and Equitable Treatment: Today's Contours,* 12 *S*ANTA CLARA J. INT'L L. 10 (2013)(noting that "protection of legitimate expectations "is the central pillar" of the standard)

[150] 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 act that shocks judicial propriety and cannot even include a country failing to follow its own laws. Sicula S.p.A. (ELSI) (US v. Italy) ICJ Rep. 1989, Judgment (20 July 1989), ¶ 128 (requiring conduct that "shocks or at least surprises a sense of juridical propriety); Cargill, Incorporated v. United Mexican States, ICSID Case No. ARB(AF)/5/2, Award, para. 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 US 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 141, at 82. Eli Lilly has not made any such argument.

case and also to underscore the problems with the broader standard of stable legal and business environment.

### *1. Eli Lilly Has No Legitimate Expectation in a "Stable Legal Environment" that has No Changes to Common Law*

Eli Lilly does 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. A frequently cited definition is that the "host State act in a consistent manner, free from ambiguity and totally transparent 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 such with regulations."[151] However, panels have cautioned that even the broad term "stable legal and business environment" should not be read overly broadly.[152]

Specific cases help to put this in context. For example, in *Tecmed v. Mexico,* the tribunal there found FET violated because Mexican authorities failed to renew a necessary landfill permit they had previously promised to renew.[153] 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 that had induced foreign investments.[154] In *Occidental v. Ecuador*, the tribunal found FET violated based on Ecuador's "manifestly wrong" interpretation of a

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[151] Tecmed, ¶ 154; Metalclad ¶ 99, MTD v. Chile ¶ 112; Siemens, ¶ 297, GAMI, ¶ 88; *see also* Occidental Exploration & Prod. Co. v. Republic of Ecuador, LCIA, UN 3467, Final Award, ¶ 185 (July 1, 2004).

[152] EDF v. Romania, ICSID Case No. ARB/05/13, Oct. 8, 2009 Award, ¶ 217*(*"the idea that legitimate expectations, and therefore FET, imply the stability of the legal and business framework may not be correct if stated in an overly broad and unqualified formulation. The FET 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).

[153] *Id.* ¶ 165-66.

[154] CMS Gas Transmission Co. v. Argentina, ICSID Case No. ARB/01/8, Award (May 12, 2005); Enron Corp. v. Argentina, ICSID Case No. ARB/01/3, Award (May 22, 2007). 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, ¶ 274; Enron, ¶¶ 259-60.

contract with the investor, as well inconsistent and unclear value added tax laws that negatively impacted the investor, such that the business and legal framework were disrupted.[155] In *PSEG v. Turkey*, the tribunal found that Turkey violated the fair and equitable treatment standard because it engaged in inconsistent administrative acts that included ignoring legal rights, as well as a "roller coaster" of continuing legislative changes that negatively impacted the investor's power plant.[156] 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.[157]

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,[158] 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 situations where domestic law induced an investor to make investments that were then negatively impacted by a change in law. Indeed, Eli Lilly has made no allegation that Canada's prior law induced it to make any investments. In addition, Canada's proper application of current law 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 existing law. Moreover, the *one* modification to the common law definition of utility required for all patents is a far cry from the multitude of changes considered a problem in *PSEG.*

[155] Occidental, ¶ 184.
[156] PSEG Global Inc. v. Republic of Turkey, ICSID Case No. ARB/02/5, Award, ¶¶ 246-250 (Jan. 17, 2007).
[157] *Id.* ¶ 254.
[158] *Id* ¶ 82.

### *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 stable legal and business framework as unrealistic[159] and unfair[160] and instead only recognize claims based on legitimate investor expectations if those expectations outweigh state interests. As stated in *Saluka v. Czech Republic*, "no investor may reasonably expect that the circumstances prevailing at the time the investment made remain totally unchanged… the host state's legitimate right subsequently to regulate domestic matters in the public interest must be taken into consideration as well."[161] Under such an approach, tribunals focus on *justified* expectations of the investor, such that there is no claim unless it arises from (a) a state's specific representations or commitments to an investor which have been relied on and only after (b) investor's expectations are balanced against legitimate regulatory activities of host countries.[162] As this section will explain, applying this standard shows even more clearly why Eli Lilly has no legitimate claim because there is no specific state representation that Eli Lilly was justified in relying on, and Canada had legitimate interests in modifying its law.

#### *a. A Patent is Not a State Representation of Guaranteed Validity*

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[159] *See, e.g.*, Zachary Douglas, *Nothing if not Critical for Investment Treaty Arbitration: Occidental, Eureko and Methanex,* 22 ARB. IN'TL 27, 28 (2006)(the Tecmed 'standard' is actually not a standard at all; it is 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); El Paso Energy Int'l Company v. Argentine Republic, ICSID Case No. ARB/03/15, Award, ¶¶ 352, 371 (Oct. 31, 2011) (noting that "economic and legal life is by nature evolutionary" such that it is important to consider whether changes to a legal framework "are "unreasonably or contrary to a specific commitment").

[160] UNCTAD, Fair and Equitable Treatment, *supra* note 141, 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, such that it decided that even where the agreement's preamble noted the importance of the stability of a legal framework, it declined to apply this standard. Continental Casualty v. Argentina, ICSID Case ARB/03/9, Award of Sept 5, 2008, ¶ 258.

[161] Saluka, ¶¶ 304-08.

[162] *E.g.*, Duke Energy v. Ecuador, ICSID Case No. ARB/04/19, Award, Aug. 18, 2008, ¶ 340; Continental Casualty, ¶ 261.

An initial question is what constitutes a state representation. The most typical situation is a specific state commitment to the investor at issue. As with expropriation claims, the state commitment generally requires some action attributable to the state, such as representation from a government official.[163] In addition, this state action must be either a specific commitment to the particular investor, or else general rules put in place to induce foreign investment upon which the investor relied.[164] There is no suggestion that prior Canadian law was intended to induce foreign investment, such that it will not be discussed here.[165]

The only issue here is whether there was a specific commitment to Eli Lilly. A commitment is considered specific if its "precise object was to give a real guarantee of stability to the investor."[166] Accordingly, general statements in treaties or legislation do not suffice.[167] Similarly, they do not apply to political statements, even if made by the president.[168] On the other hand, a specific commitment could include a commitment made in a contract or letter,[169] or an explicit promise or guarantee from the state.[170]

Importantly, a mere expectation that the law will not change would not constitute a specific commitment made by the state.[171] For example, in *Methanex*, the panel held no violation of the standard of fair and equitable treatment standard when California changed its laws to ban certain carcinogenic additives to methanol that essentially destroyed the investors market because

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[163] Metaclad, ¶ 73 (noting that it was unchallenged that state and local government acts were attributable to the state); Stephen Fietta, *Expropriation and the 'Fair and Equitable' Standard: The Developing Role of Investor 'Expectations' in International Arbitration,* 23 J. INT. ARB 375 (2006).

[164] *E.g.*, Glamis Gold Ltd v. United States, UNCITRAL (NAFTA), June 8, 2009, ¶ 627.

[165] *E.g.*, Enron v. Argentina, Award, May 22, 2007, ¶¶ 264-67; LG&E v. Argentina, Award, July 25, 2007, ¶¶ 132-139.

[166] El Paso, ¶ 377.

[167] *E.g.*, Continental Casualty Company, ¶ 261; *see also* El Paso, ¶ 394 (noting that this would "immobilize the legal order and prevent any adaptation to circumstances.").

[168] El Paso, ¶ 395.

[169] *E.g.*, El Paso, ¶ 376. However, breach of a contract is not per se a violation of a specific commitment. UNCTAD, Fair and Equitable Treatment, *supra* note 141, at 87.

[170] Parkerings-Compagniet A.S. v. Lithuania, ICSID Case No. ARB/05/8, Final Award, Sept 11, 2007, ¶ 331.

[171] El Paso, ¶ 396.

there was no representation that regulatory laws would not change.[172] Similarly, a tribunal found that Canadian company Glamis had no legitimate expectation that the US (through California) would not pass legislation that would impact its mining investment, even when California's action was a significant change from settled practice where there were no specific statements made by California to induce investment.[173] Also, in *ADF v. USA*, the investor was found to have no legitimate expectation that the law would remain unchanged when the state made no representation and it instead simply relied on advice by private counsel.[174]

A key question with respect to Eli Lilly's claims, is thus whether Canada made any *specific* representations to Eli Lilly that were 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 it will never be revoked.[175] However, unlike a contract that 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 patentability criteria.[176] Moreover, as noted earlier, even a breached contract with a state is not necessarily enough for a violation of the fair and equitable standard.[177] Eli Lilly may have *assumed* that its patent would remain valid in Canada, but its assumption was not a legitimate expectation, should that it is irrelevant.

### *b. There Has Been No Negative Reliance upon State Representation*

Even if there is a state representation, it is important that there be *reliance* on that representation to the investor's detriment

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[172] Methanex, Part IV(D), ¶ 7.

[173] Glamis Gold, ¶¶ 766-767, 801-02; *see also* Parkerings-Compagniet ¶¶ 334–338 (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).

[174] ADF vs. US, ICSID Case No. ARB(AF)/00/1, Final Award, Jan 9, 2003.

[175] Eli Lilly Notice of Arbitration, *supra* note 2, ¶ 82.

[176] *Cf.* NAFTA article 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).

[177] *E.g.*, Parkerings, ¶ 344; Hamester v. Ghana, ICSID Case No. ARB/07/24, Award of June 18, 2010, ¶ 337.

due to induced investments.[178] For example, in *Metalclad*, the investor relied on the representation of officials that it had all necessary federal and state permits to construct a hazardous waste landfill and expended capital in constructing the landfill,[179] such that the denial of the municipal construction permit violated its legitimate expectations.[180]

Eli Lilly has no viable argument that it relied on commitments that led to induced investments. Eli Lilly seems to complain that it could not have expected Canada to modify its standards when it applied for a patent. However, there was not only no specific representation that Canadian law would not change when Eli Lilly applied, but also, 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 patent in any and all countries that will provide such patents. In addition, even if Eli Lilly were to claim 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 it will remain valid.

### *c. Eli Lilly Has No Legitimate Expectation that Outweighs Canada's Interests*

The final consideration of legitimate expectations requires balance of legitimate investor expectations against legitimate state policy. The facts of some past tribunal cases may help to shed light on how this balance applies. For example, although *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.[181] 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 claimant's investments since it applied equally to all operators.[182] In addition, some panels suggest that

[178] *E.g.*, El Paso, ¶ 376.
[179] Metalclad, ¶¶ 85-88.
[180] *Id.* ¶¶ 89-90, 99-101.
[181] Saluki v. Czech Republic, ¶¶ 304-08.
[182] *Id.* ¶¶ 293-94; *see also* EDF v. Romania ICSD Case No. ARB(AF)/05/13, Award, ¶ 219 (Sept. 30, 2009), (noting that legitimate expectations cannot be

there should be a high level of deference to states to regulate matters within their own borders.[183]

Canada's interest in the current promise doctrine compares favorably with the facts of past tribunals. First, Canada does have a bona fide interest in promoting fundamental patent policy, including ensuring that patents are only issued when there is adequate disclosure to justify the social cost of a patent. In addition, Canada's law applies equally to all foreign and domestic companies. Even though all pharmaceutical companies are implicated, that is no different than the *Saluka* situation where all owners of duty-free operations were impacted. In addition, just as Romania was found to respond reasonably to a contraband problem by enacting a law that impacted all owners of duty free operations, so too Canadian courts appropriately responded to the problem of how to ensure that its patents serve the traditionally recognized policy ground of ensuring proper disclosure of an invention before burdening the public with a patent.

## IV 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 investment-state claims. After explaining likely claims, this Part provides specific proposals that can be incorporated in pending agreements to minimize these problems.

### *A. Public Health Issues in Danger of Disruption*

A number of controversial issues concerning the balance of pharmaceutical interests and public health are threatened by investor-state disputes. These issues include patentability criteria beyond the one challenged in Eli Lilly's case, issuance of

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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)

[183] SD Myers v. Canada, UNCITRAL (NAFTA), First Partial Award, Nov. 13, 2000, ¶ 263; GAMI v. Mexico, ¶ 93.

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 Likely To Be Challenged*

One patent standard that is especially vulnerable to challenge is a criteria that exclude from patentability drugs that are similar to existing drug if they lack improved efficacy.[184] Companies and lawyers alike have suggested that this is inconsistent with TRIPS.[185] In 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 disputes in the WTO due to political considerations and concern with possibly undesirable precedent, companies do not share these issues in seeking investment remedies. Accordingly, India's law, as well as other similar laws, are ripe for challenge 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.

If challenged, this patent standard would likely be subject to an expropriation claim, 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 have an exception that technically excludes denials of intellectual property rights *if* consistent with TRIPS. However, companies have suggested India's provision imposes an *additional* patentability requirement not permitted by TRIPS, thus violating TRIPS.[186] This is incorrect. Just as Canada is permitted to define what is "useful" for its patents laws, India is permitted to define what is an "invention," as well as what is "new," such that a number of scholars and policy makers consider India's laws to be consistent with TRIPS. Nonetheless, just as Eli Lilly has incorrectly challenged Canada as violating NAFTA with an

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[184] India Patent Law §3d.

[185] *E.g.*, Jones Day, *supra* note 14, at 3.

[186] This was a claim Novartis made, but the Indian Supreme Court rejected. Novartis v. Union of India (2013); *see also Intellectual Property Issues Dominate the USITC Public Hearing on India*, Third World Network, Feb. 13, 2014.

investment agreement, companies are likely to similarly 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 they 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 changed 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 claims, such that any potential claim could chill pending proposals for reform of patent laws.

Another likely target of an investor-state arbitration would be a compulsory license. A compulsory license is a traditionally recognized state-mandated license to use a patented invention in certain instances; although the patent is still valid, the patent owner cannot exclude the licensee and must accept the government dictated royalty.[187] 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, including a desire to ensure that patents on medical products were not unduly costly.[188] The ability to issue compulsory licenses is especially important now because countries no longer have the freedom to completely deny patents on drugs.

Although compulsory licenses are permissible under TRIPS, they are likely to be challenged as expropriation. Notably, public statements by pharmaceutical companies often talk about compulsory licenses as either "breaking" their patents, or even *expropriating* their patent rights.[189] Scholars have been expecting

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[187] *E.g.*, JEROME H. REICHMANN WITH CATHERINE HASENZAHL, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS 6 (2003).

[188] *E.g.*, *Id.* at 11-12.

[189] *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, News Release, May 4, 2007, *available at* http://www.businesswire.com/news/home/20070504005566/en/Merck-Statement-Brazilian-Governments-Decision-Issue-Compulsory#.U-oMUFZqphM (last visited Aug. 12, 2014) (referring to compulsory license as expropriation); *see also* Jones Day, *supra* note 14 (referring to compulsory license as expropriation).

such claims.[190] 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 they consider the TRIPS requirements, as well as domestic laws implementing them to be inadequate.

Although compulsory licenses consistent with TRIPS should technically be exempt from indirect expropriation claims, given great controversy concerning what TRIPS requires, it is highly likely that an arbitration tribunal could rule on what TRIPS demands. There are likely multiple aspects of compulsory licenses that could give rise to an indirect expropriation claim. Two particularly likely issues based on past global controversy include the TRIPS requirement of what constitutes "adequate remuneration," as well as the ground for issuing a license in the first instance.[191]

Companies are likely to challenge royalty rates of compulsory licenses as not TRIPS compliant because TRIPS does not provide a clear definition of 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 is still less than half of what the patent owner sought.[192] Although Bayer strongly contested the royalty rate, it was completely within the guidelines issued by the World Health Organization and the United Nations Development Programme.[193] Moreover, one law firm suggested that Bayer should be entitled to market value based on expropriation definitions, rather than TRIPS requirements.[194]

Another aspect of compulsory licenses that could be challenged under TRIPS is the ground for issuing a compulsory

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[190] *E.g.*, Peter Rutledge, *TRIPS and BITs: An Essay on Compulsory Licenses, Expropriation, and International Arbitration*, 13 NC J. L. & TECH. 149, 161 (2012); Gibson, *supra* note 127, at 359

[191] TRIPS art. 31.

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

[193] *See* James Love, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, WHO and UNDP (2005).

[194] Jones Day, *supra* note 14, at 3.

license in the first instance. TRIPS permits countries to decide the basis for issuing compulsory licenses and only governs procedural aspects of license. 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.[195] Countries have complete discretion to decide the grounds for issuing compulsory licenses – contrary to improper suggestions that these are only appropriate in the case of an emergency, such as an epidemic. This is very important for countries, such as India, that have unusual bases of compulsory license, such as a drug not being available at a "reasonably affordable price" from the patent owner.[196]

Notably, even if an arbitration panel were to properly find that the above two issues were consistent with TRIPS, such that an indirect expropriation claim was defeated, a panel might still find a violation of fair and equitable treatment claims. Unlike indirect expropriation claims, there is no intellectual property exception for even TRIPS consistent measures. 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 view of this 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 this was unexpected and unfair. Given that such claims are unpredictable and highly successful for claimants, there is a serious risk that a TRIPS consistent license would nonetheless be found to be a violation.

*2. Domestic Regulation of Clinical Data At Risk*

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 challenge countries that permit generic applicants to immediately rely on clinical data without providing a period of "data exclusivity" before generic companies

[195] *E.g.*, Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact From Fiction under TRIPS*, NC J. INT'L L & COMM. REG. 373 (2009)
[196] Indian Patent Act, § 84.

can do so. Second, companies may challenge domestic laws that require 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 TRIPS issues of interpretation.

*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 United States' Food and Drug Administration before they can be sold. Most countries grant such approval when a company can establish that its proposed new drug is safe and effective for its proposed use based on clinical data.[197] It can take many years and millions of dollars to compile the requisite data.[198]

In contrast, manufacturers of proposed generics can gain approval with a more limited set of clinical data. Most countries will approve generic versions based solely on clinical studies that show "bioequivalence" to a previously approved drug; such that the proposed generic is presumed to be just as safe and effective as the previously approved drug.[199] The time and investment needed to establish clinical data of bioequivalence is a mere fraction of the data of the earlier drug.[200] 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 can not 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.[201]

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[197] *E.g.*, Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 355(b)(1) (2006) (US standard); Food and Drug Regulations, C.R.C., ch. 870, § C.08.0002(2) (2010) (Canadian standard).

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

[199] *E.g.*, 21 U.S.C. § 355(j)(4)(F) (2006); 21 C.F.R. § 314.92(a)(1) (2010).

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

[201] Indeed, this was the situation in the US before laws were amended to permit

The issue with data exclusivity is *when* generic companies can rely on clinical data of the drug it is copying. In a country that provides data exclusivity, the generic manufacturer is barred from relying on that data for a certain period of years, ranging from five to ten years from approval of the prior drug.[202] Data exclusivity, when available, is completely separate from patent protection such that it 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.[203]

Companies are likely to bring an investment challenge against countries that do not provide data exclusivity. Companies and some countries already believe that countries must provide such protection pursuant to TRIPS, although as explained below, this interpretation is questionable, such that their claims should be rejected.

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 in a substantial and unreasonable interference with this investment. A company would likely believe that this is the case and might succeed in persuading a tribunal that only considered investment value, even though strong public policy should suggest otherwise. Developing countries in particular would seem to have legitimate state interest to permit generic companies to rely on this

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generic drug approvals based on the abbreviated process. *See* Gerard J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

[202] *E.g.*, IPhRMA, Encourage of New Clinical Drug Development: The Role of Data Exclusivity (2000).

[203] *E.g.,* EC Pharmaceutical Sector Inquiry, *supra* note 8, at 501; Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration 20 (2002).

data to promote faster entry of low cost drugs. Accordingly, an important issue is whether domestic decision to reject data exclusion could be exempt from consideration as an expropriation claim, and if not, how a panel would likely rule.

An initial issue is whether such a claim could be excluded under clauses that exempt certain intellectual property issues from indirect expropriation claims.[204] There is a question concerning whether lack of data exclusivity should be considered a "limitation" of "intellectual property rights" pursuant to agreements that exclude such 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.[205] Accordingly, it is conceivable that this would be covered as intellectual property.

However even if data exclusivity were considered a type of intellectual property right that could fall 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.[206] TRIPS requires that countries "protect" data submitted to government for approval of pharmaceuticals from "unfair commercial use" without specifying what this means.[207] 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

[204] Arguably, another reason that this 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, such that this is still possible.

[205] Indeed, there are some free trade agreements that require countries to provide data exclusivity under intellectual property chapters. *E.g.,* US-Singapore FTA, art. 16.8; US-Austl. FTA, art. 17.10

[206] *E.g.*, CYNTHIA HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 76-80 (2011).

[207] TRIPS art. 39(3).

the data.[208] The rejection of this earlier language means that it is *not* the current standard – contrary to what some companies have suggested.[209] Accordingly, a number of scholars and policy makers consider that the provision does not require data exclusivity.[210]

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 that has never recognized data exclusivity. Since India has never recognized this type of protection, 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 an investor-state arbitration could prevent countries from abandoning data exclusivity laws in favor of India's approach, even if the countries believe 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 would 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*

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[208] Brussels Draft, ¶4A, *reprinted in* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 421 (3d 2008) *see also* Bayer v. Canada, 1999 1 FC 53 (FCTD), 84 CPR (3d) 129, *affd by* 87 CPR (3d) 293 (FCA).

[209] *E.g.*, Organisation of Pharmaceutical Producers of India, OPPI Opposition Paper, Regulatory Data Protection (2008).

[210] *E.g.*, CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 383-92 (2007); Brook Baker, *Ending Drug Registration Apartheid*, 316 AM. J.L. & MED. 303, 315-16 (2008); Jerome Reichman, Undisclosed Clinical Test Data under the TRIPS Agreement and its Progeny: A Broader Perspective 10 (2004).

Companies are also likely to challenge domestic regulations concerning disclosure of clinical data supporting approved drugs. The EU 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.[211] In particular, a new EU regulation requires that all clinical data for drugs approved by the EU be made publicly available.[212] Companies strongly oppose disclosing clinical data, claiming that they are entitled to keep such data as a trade secret. Although the regulation is not yet in full effect, companies are likely to contest transparency once it does come into effect.

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 company, but by the very company seeking approval. In addition, although the company must submit the data to the government, the public is not entitled to access. There are a few cases where independent researchers obtain access to the data either because a country has a policy for doing so in limited circumstances[213] or because a company responds to public pressure.[214] Without mandatory transparency, not only doctors and patients, but also

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[211] *E.g.*, Gardiner Harris, *Diabetes Drug Maker Hid Test Data, Files Indicate*, N.Y. TIMES, July 13, 2010, at A1.

[212] EU, Regulation of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive, 2001/20/EC (April 4, 2014).

[213] For example, the European Medicines Agency previously granted access to clinical data concerning Abbvie's drug Humira and Intermune's Esbriet based on 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. Abbvie v. EMA, Case T-44/13, OJ C79/53 (2013); Intermune v. EMA, Case T-73/13R, PK C114/60 (2013); *see also* Trudo Lemmens, EMA's Proposed Data Release Policy: Promoting Transparency or Expanding Pharma Control Over Data?, PLOS Blogs, Aug. 4, 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).

[214] *E.g.*, *Full Disclosure Needed for Clinical Drug Data*, NY TIMES, July 4, 2013.

governments must rely on industry's claims concerning the value of new drugs. However, companies selectively publish positive results;[215] and are more likely to conclude that their drugs are safe and effective than independent researchers.[216] They also over-estimate benefits while minimizing risks in published studies.[217] As a result, there may be unnecessary expenditures on expensive new drugs based on questionable data[218] that can also result in negative public health outcomes that could have been avoided.[219] There are a number of examples where new drugs were later found to result in health risks after independent research.[220] 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 there is no disclosure that could be used by a competitor. In addition, the exceptions to date of expropriation would not seem to cabin such claims.

Even though a nation should have the right to decide whether or not to recognize data protected as an intellectual property right, there is an open issue concerning whether TRIPS requires this to be protected. In particular, there is a currently untested exception to the TRIPS requirement to protect data from

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[215] *E.g.*, Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trial 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 7.

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

[217] *E.g.*, Justin 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).

[218] The antiviral drug to treat influenza sold as Tamiflu was stockpiled by governments 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 Phrma,* GUARDIAN, April 9, 2014.

[219] *E.g.*, Hai Europe, Protecting Citizens' Health: Transparency of Clinical Trial Data on Medicines in the EU, Policy Paper 5 (Oct. 2013).

[220] *E.g.*, Cynthia Ho, *How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 501-05 (2014).

unfair commercial use; TRIPS explicitly states that "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."[221] 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 EU may believe that it falls within the TRIPS exception that permits disclosure for public interest, a company would likely believe otherwise.

If a panel did not extend the traditional definition of intellectual property to include data exclusivity, such claims could alternatively be exempt from a claim for indirect expropriation based on wording under some agreements that does not provide a complete exception to expropriation claims, but 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. [222]

In addition, an investor that believes that it is entitled to compensation when a country fails to provide data exclusivity raises unique challenges even though public health is involved. Most cases involving public welfare have been cases that directly impact health or environment, such as a regulation that aims to protect sea turtles, or a regulation that aims to reduce carcinogens. In contrast, the public health protected in countries that decline to impose data exclusivity is more attenuated. Some public health scholars consider it obvious that there is not only a universal right to health, but also a right to access to affordable medicine, such that any law that promotes this goal should legitimately protect public health. However, there is no universally recognized right to access affordable medicine.

Countries may face even more problems with a claim for fair and equitable treatment. Not only is this standard often read broadly, but also a country that imposes transparency requirements could be considered to be making a substantial change to the legal

[221] TRIPS art. 39(3).

[222] *E.g.,* US-Australia Free Trade Agreement, Annex 11-B, art. 4(b) (2004); US-Chile Free Trade Agreement, Annex 10-D (2003); US-Central America Free Trade Agreement, Annex 10-C (2004); CETA, Expropriation Annex ¶ 3.

and business environment. Notably, the EU regulation is not a complete surprise. The EU has been engaging in increased transparency over the years. As with all such claims, the EU's interests are better protected under the cabined standard that only recognizes claims based on *legitimate* expectations based on specific reliance. It is doubtful that the EU would have ever represented 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.[223] 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, specific proposals to cabin expropriation and fair and equitable treatment claims that would otherwise interfere with internationally permissible regulation of intellectual property rights are suggested.

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

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

[223] 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 – namely, 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 FET 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.

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.[224] Importantly, the definition of an investment cannot simply omit the word intellectual property right if it covers intangible investments. After all, that is what NAFTA does and Eli Lilly has made a claim; even those who oppose Eli Lilly's claim would need to concede that intellectual property rights are generally considered intangible investments.[225] 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 not change the scope of covered investments, but 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 from the scope of the treaty.[226] 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."[227]

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[224] *E.g.*, Brook Baker, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines – Eli Lilly and the TPP,* PJIP Research Paper Series 36, at 13 (2013).

[225] *E.g.* 35 U.S.C. § 261 (patents have attributes of personal property); *see also* Mercurio, *supra* note 92, at 878 (noting that it is "beyond doubt" that granted intellectual property rights are investments).

[226] *E.g.,* NAFTA arts. 2102, 2103.

[227] NAFTA arts. 103, 2102; Korea-Chile Free Trade Agreement art. 20.3(3); *see also* Guillermo Alvarez &William Park, *The New Face of Investment Arbitration: NAFTA chapter 11*, 28 YALE J. IN'TL L. 365, 390 (2003); Jennifer Heindl, *Toward a History of NAFTA's Chapter Eleven*, 24 BERK. J. INT'L L. 672(2006).

However, unlike these clauses that are primarily conflict of law principles that state which agreement should prevail in the event of inconsistency, this proposal goes further to ensure that panels are not unnecessarily deciding whether there is an inconsistency in the first instance. This is necessary to prevent commercial arbitrators form usurping the process for determining TRIPS compliance and potentially resulting in inconsistent judgments. [228]

The above suggestions are strongly preferable to the draft TTIP text that purports to address situations where there are competing agreements. The draft TTIP text states that in *some* situations, the tribunal shall "stay its proceedings," or "otherwise, the tribunal can continue the proceedings and simply take a separate proceeding "into account." [229] However, not only does this still give a tribunal too much authority to impinge on another international agreement, but it would still not address the situation raised by *Eli Lilly* where there is no other proceeding initiated. This may often be the case with TRIPS claims because only governments can bring WTO disputes and governments seem much more circumspect in bringing WTO disputes than investors are in seeking compensation under investor-state arbitrations.

Moreover, the TTIP provision is unduly narrow in that it does not apply in all cases where there is an international agreement, but only in cases where there is potential for overlapping compensation or the other claim could have a "significant impact" on the arbitration claim. WTO claims would not result in overlapping compensation both because investors have no standing to assert such claims and also because WTO proceedings are only intended to force countries to comply with WTO rules, but not result in compensation.[230] In addition, the "significant impact" clause may not apply even if the identical TRIPS provision were at issue in both a WTO and investment chapter proceeding. First of all, the phrase "significant impact" is very vague, such that an arbitration tribunal could easily decide that the WTO proceeding had no significant impact. Also, although a WTO panel has expertise in its own agreements, that would not necessarily result in an investor-state tribunal deferring to the WTO decision. Accordingly, investment chapters should

[228] *E.g.*, Brooks E. Allen and Tommaso Soave, *Jurisdictional Overlap in WTO Dispute Settlement and Investment Arbitration*, 30 ARB. INT'L 1, 7 (2014).
[229] TPP Draft Investment Chapter art. X-23.
[230] DSU art. 3.7 (compensation as a matter of last resort)

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 for 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."[231] This would at first glance seem to easily bar claims such as 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 also make expropriation more in line with domestic taking law that does not recognize a taking when courts simply apply slightly modified

[231] Draft CETA Investment Text art. X.11(CAN:5)(Nov. 2013).

common law doctrine.[232] 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, better 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 to asserting such a claim.[233] 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.[234] The idea of cabining expropriation claims based on domestic revocation of intellectual property rights is a sound one. To prevent possible inconsistent decisions, expropriation claims based on state action that is arguably inconsistent with TRIPS should be barred unless there is a decision 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 EU's proposed language to clarify what types of regulatory action should not constitute indirect expropriation. Although the EU 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.[235] In particular, while it singles out nondiscriminatory measures to "protect legitimate public welfare objectives such as health," it notes that in "rare circumstances" these can nonetheless constitute indirect expropriation if the impact of the measure "is so severe in light of its purpose that it appears manifestly excessive."[236] This proposal

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[232] *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 NYU L. REV. 30 (2003).
[233] NAFTA art. 2103(6).
[234] *Id.*
[235] EU, Public Consultation on Modalities for Investment Protection and ISDS in TIIP, 6-7.
[236] Draft CETA Investment Text, Annex: Expropriation ¶ 3.

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 of interests, this is notably done by a tribunal of private arbitrators who are essentially second-guessing a balance already done by a nation.

*b. Limit Fair and Equitable Treatment Claims*

The best approach to cabining 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 and these claims have posed the most significant intrusions into domestic regulatory authority, as well as 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. Considering that some countries consider that this standard does not provide foreign investors with better treatment than domestic ones, there would seem to be no need for this claim at all where domestic remedies exist. Moreover, this would avoid the problem of unduly expansive rulings concerning FET that the US has tried, but failed to cabin in NAFTA.[237]

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

[237] 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 Arbitration Blog, Oct. 30, 2013.

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-which would include TRIPS -- does not establish a violation of the fair and equitable treatment standard.[238] Notably, this clause also does not state that *compliance* with another international agreement will immunize state action from being subject to such claims, such that 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 minimum standard pursuant to customary international law, that has clearly been inadequate in cabining 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 *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 and 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 and that this was relied upon.[239] 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 it 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.

## V CONCLUSION

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[238] *E.g.*, TPP Draft Investment Chapter art. 12.6(3).
[239] *See* EU, Public Consultation on Modalities for Investment Protection and ISDS in TIIP, at 5 (Mar. 2014).

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 panel *should* deny Eli Lilly's claims, investor-state tribunals often make broad and unpredictable rulings. Moreover, even if a panel ruled properly, public health may still be compromised if other companies follow Eli Lily's lead in challenging other domestic decisions concerning intellectual property rights. Although some are wisely beginning to question the wisdom of creating more opportunities 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.