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Corporate Power Unbound: Investorstate Arbitration of IP Monopolies on Medicines—Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement

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CORPORATE POWER UNBOUND: INVESTOR-STATE ARBITRATION OF IP MONOPOLIES ON MEDICINES—*ELI LILLY V. CANADA* AND THE TRANS-PACIFIC PARTNERSHIP AGREEMENT

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I. INTRODUCTION

So-called free trade agreements and investment treaties are currently more about instantiating corporate power than they are about leveling the field for competitive trade and encouraging direct foreign investment in productive capacity.[1] The historic and now neo-liberal justifications for free trade are that it leverages comparative advantage so that countries produce and export raw materials and industrial goods with which they are naturally endowed or are relatively more efficient in manufacturing while importing cheaper, more efficiently produced goods from abroad.[2] The goal is to reduce trade barriers, especially tariffs and non-tariff barriers that protect local producers and manufacturers from more efficient foreign competitors while allowing comparatively efficient domestic exporters the same advantages abroad. In a fictional world of full employment and full utilization of domestic resources, of internationally immobile labor and capital, and of perfect competition, comparative advantage purportedly increases economic efficiency, lowers the cost of living, and produces a win-win trading system when trade is balanced. Similarly, the historic justification for the protection of foreign investment is that investors need reassurance to invest in other countries, particularly less developed economies where their fixed investments might be expropriated or their investment returns held hostage. Moreover, foreign investors need to be able to pursue their own self-interest rather than wait on their governments to protect them, and thus investors should be empowered to directly bring claims against confiscatory state action.

The high-theory appeal and canonical incantation of free-trade and investor-protection orthodoxies hides the brutal realities of ascendant corporate power, most especially for the purposes of this Article, the power of the innovator pharmaceutical industry that relies on the golden-goose of globalized intellectual property (IP) protections to extract monopoly profits from the sale of what are essentially global public goods. This industry has relentlessly pursued global minimum standards of patent and data protections within what became the World Trade Organization and now seeks longer, stronger, and broader forms of protection via bilateral, regional, and multilateral trade and economic partnership agreements. At the same time, there has been a proliferation of bilateral and regional investment treaties, the vast majority of which give foreign investors strengthened rights to bring private arbitration claims against government for policies and decisions that thwart their investment-based

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[1] Carmen G. Gonzalez, *Deconstructing the Mythology of Free Trade: Critical Reflections on Comparative Advantage*, 17 BERKELEY LA RAZA L.J. 65 (2006).

[2] *See generally* Robert E. Prasch, *Reassessing the Theory of Comparative Advantage*, 8 REV. POL. ECON. 37 (1996).

expectations of profit, including those stemming from their asserted intellectual property rights.

Despite the deep irony of free trade agreements being subverted to codify and extend anti-competitive monopoly rights and despite the equally deep irony of foreign investors having greater enforcement rights than local investors, the combination of enhanced intellectual property rights (IPRs) and protections and strengthened investor rights is creating a wild-west opportunity for unbounded corporate power. Two current contestations show the dangers of this expanded power in sharp relief. First, in the Trans-Pacific Partnership Agreement (TPPA), at the behest of its powerful pharmaceutical lobby, the United States sought the most extreme forms of pharmaceutical patent, data, and enforcement rights that had ever been proposed at the same time that it sought enhanced IP-related investor rights.[3] Although U.S. early demands were not all fully met, the formal TPPA negotiations have been concluded and a legally scrubbed version of the final agreed text was released on January 26, 2016.[4]

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[3] For early evidence of U.S. IP demands, *see* Trans-Pacific Partnership, Intellectual Property Rights Chapter (draft Feb. 10, 2011), *available at* http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf; Trans-Pacific Partnership—Intellectual Property Rights Chapter (Selected Provisions), Sept. 2011, *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf. For an analysis of these leaks, *see* Sean M. Flynn, Brook Baker, Margot Kaminski & Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV. 105, 105–83 (2013). For early evidence of U.S. investment demands, *see* Draft TPP Investment Chapter, *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf. The most recent Investment Chapter leak was Trans-Pacific Partnership treaty: Advanced Investment Chapter working document for all 12 nations (January 20, 2015 draft, released by Wikileaks, March 25, 2015), https://wikileaks.org/tpp-investment/WikiLeaks-TPP-Investment-Chapter.pdf. *See* Trans Pacific Partnership Document Library, http://infojustice.org/resource-library/tpp (last visited Sept. 25, 2015) (providing a comprehensive collection of early TPP leaked documents and commentary between 2010 and 2014).

In terms of the history of the TPPA, On November 12, 2011, the Leaders of the nine Trans-Pacific Partnership countries—Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, Vietnam, and the United States—announced the achievement of the broad outlines of an ambitious, 21st-century Trans-Pacific Partnership (TPP) agreement that would enhance trade and investment among the TPP partner countries, promote innovation, economic growth and development, and support the creation and retention of jobs. *Outlines of TPP*, http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/united-states-trans-pacific-partnership (last visited Oct. 18, 2015). Since that time, Mexico and Canada, the U.S.'s NAFTA trade partners also joined the negotiations. Japan also elected to participate in the negotiations. *See Statement by Acting U.S. Trade Representative Demetrios Marantis on Japan's Announcement Regarding the Trans-Pacific Partnership* (Mar. 15, 2013), http://www.ustr.gov/about-us/press-office/press-releases/2013/march/amb-marantis-statement-japan-tpp.

[4] New Zealand Ministry of Foreign Trade and Affairs, Text of the Transpacific Partnership (downloadable by chapter), https://www.mfat.govt.nz/en/about-us/who-we-are/treaty-making-process/trans-pacific-partnership-tpp/text-of-the-trans-pacific-partnership.

The TPPA was signed on February 4, 2016, but formal ratification awaits.[5] Second, in *Eli Lily v. Canada*, an American pharmaceutical company is claiming $500 million in damages under the North America Free Trade Agreement (NAFTA) investment clause because Canada invalidated two medical patents that failed to meet well-established Canadian standards of patentability.[6]

This Article is not written as an abstract juxtaposition of these two current events. It is written to expose the dangers that countries face, especially low- and middle-income countries, in trade negotiations with the U.S., Europe, and Japan. These nations seek to impose stronger patent, data, and market entry protections while simultaneously expanding the armamentarium of enforcement powers available to pharmaceutical behemoths. Part II of this Article contains a brief introduction to the international IP regime, namely the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[7] and the TRIPS-plus pharmaceutical protections contained in the TPPA Intellectual Property Chapter[8] and Transparency Annex[9] recently signed by twelve Pacific rim countries. Part III gives a brief historical background on investment treaties and investor-state dispute settlement (ISDS). Part IV analyzes the TPPA Investment Chapter[10] in more depth, particularly its provisions dealing with protection for, and enforcement of, IP-related investments. Part V discusses the pending *Eli Lilly v. Canada* ISDS arbitration, including the claims and defenses of the parties. Part VI concludes with a recommendation that investment chapters be struck from the TPPA and other trade agreements or alternatively, that such chapters should not apply whatsoever to the protection

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[5] Rebecca Howard, *Trans Pacific Partnership signed but years of negotiations still to come*, FORBES (Feb. 4, 2016), http://www.reuters.com/article/us-trade-tpp-idUSKCN0VD08S; *TPP Ministers Outline Ratification Process; Mexico, Australia Aim For 2016 Approval*, INSIDE U.S. TRADE (Feb. 3, 2016), http://insidetrade.com/daily-news/tpp-ministers-outline-ratification-process-mexico-australia-aim-2016-approval.

[6] Eli Lilly and Co. v. The Gov't of Canada [hereinafter *Eli Lilly v. Canada*], UNCITRAL, ICSID Case No. UNCT/14/2, https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx? CaseNo=UNCT/14/2&tab=DOC (last visited Sept. 25, 2015).

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[8] TPPA Chapter 18 Intellectual Property, https://www.mfat.govt.nz/assets/_securedfiles/Trans-Pacific-Partnership/Text/18.-Intellectual-Property.pdf [hereinafter IP Chapter]. Previous versions of this chapter were leaked in 2010, 2011, 2012, 2013, and 2014.

[9] TPPA Chapter 26 Transparency, Annex 26-A on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices, https://www.mfat.govt.nz/assets/_securedfiles/Trans-Pacific-Partnership/Text/26.-Transparency-and-Anti-Corruption-Chapter.pdf [hereinafter Transparency Annex].

[10] TPPA Chapter 9 Investment, https://www.mfat.govt.nz/assets/_securedfiles/Trans-Pacific-Partnership/Text/9.-Investment-Chapter.pdf [hereinafter Investment Chapter].

or enforcement of IPRs given the many other enforcement powers available to patent holders. This Article claims that extending boundless corporate power to Big Pharma through adoption of ISDS for IPRs presents a grave danger to the communal right to health and the right of access to affordable medicines for all.[11]

II. THE BIRTH OF GLOBALIZED IP PROTECTION FOR PHARMACEUTICALS AND ITS PROPOSED EXPANSION IN THE TPP IP CHAPTER

Although scholars trace the history of IPRs back several centuries, the first efforts to set any global standards with respect to patents occurred with the adoption of the 1883 Paris Convention for the Protection of Industrial Property (Paris Convention),[12] the 1986 Berne Convention for the Protection of Literary and Artistic Works (Berne Convention),[13] and with the imposition of colonial IP regimes.[14] The strictures of the Paris Convention were quite limited; in terms of patents, it principally required non-discrimination against patent applicants from other countries; provided for rights of priority, division of patents, and identification of the inventor; restricted the grounds for revocation; and expanded permissible uses of compulsory licenses. In Africa, Asia, and the Pacific, the parallel introduction of colonial IP laws began in the late nineteenth century after the 1884 Congress of Berlin.[15] Nonetheless, despite these partial successes, rich countries and IP-based industries were interested in extending the scope of IP protections beyond the Paris and Berne Conventions because both Conventions lacked effective enforcement measures and because their reach was not yet truly global.

In 1967, during a period of development-oriented contestation over IPRs by newly independent states, developed countries succeeded in establishing the World Intellectual Property Organization (WIPO), which was empowered to administer the Paris and Berne Conventions and also to promote harmonization of intellectual property legislation. "Within WIPO, developed countries conducted a protracted campaign to deepen, strengthen, and extend

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[11] For an articulation of the communal right to health and of access to affordable medicines, see, Yousuf A. Vawda & Brook K. Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate: Realising the Goal of Access to Medicines*, 13 AFR. HUM. RTS. L.J. 55, 57–84 (2013).

[12] Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

[13] The Berne Convention for the Protection of Literary and Artistic Works, September 9, 1886, as revised at Paris on July 24, 1971 and 25 amended Sept. 28, 1979, 102 Stat. 285 3, 1161 U.N.T.S. 31.

[14] Brook K. Baker & Tenu Avafia, *The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-Plus Era: Implications for Treatment Access* 8–9 (Global Commission on HIV and the Law, Working Paper for the Third Meeting of the Technical Advisory Group, 2011).

[15] *Id.*

the scope and application of IP, but a resilient coalition of developing countries, led by Brazil and India, was steadfast in opposing such measures."[16] As a consequence of their failure to secure global standards of IP protection within WIPO, IP-based industries pushed their countries' trade negotiators to establish a harmonized system of IPRs and IP enforcement within the General Agreement on Tariffs and Trade (GATT).[17]

> The pharmaceutical industry played a particularly active role in initiating and consolidating a robust coalition of IP industries that persuaded trade negotiators, first in the U.S. and then in Europe and Japan to champion a comprehensive and enforceable international IP regime, and to do so within the context of GATT negotiations. Pfizer in particular played a leading role ideologically throughout the 1970s and 1980s, especially in forging the Intellectual Property Committee, an international business coalition whose paper became the blueprint for IP demands by high-income countries in the GATT negotiations. The pharmaceutical industry was primarily interested in eliminating what it felt was unfair discrimination against the patenting of medicines, but it was also motivated to try to gain control over uses of its clinical and regulatory data to delay registration of generic equivalents, in essence seeking another form of exclusive rights.[18]

Ultimately, with a mixture of trade sanctions, threats, and agricultural and textile inducements, the TRIPS Agreement was adopted as one of the primary texts of the newly established WTO. The TRIPS Agreement established a global floor of substantive protections and enforcement measures for pharmaceuticals through patents and registration-related data rights. Pursuant to TRIPS, member states are obliged to grant product and process patents to all applicants on an equal basis without discrimination with respect to the domicile of the inventor, the field of technology, or the eventual importation of the invention.[19] Patents must be granted for a minimum of twenty years[20] and

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[16] *Id.* at 6.

[17] *See* PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY (Earthscan Publications Ltd. 2003) (providing a detailed history of the political and strategic genesis of the TRIPS Agreement as engineered by U.S. knowledge industries); *see also* DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS – THE TRIPS AGREEMENT (Routledge 2002).

[18] Baker & Avafia, *supra* note 14, at 6–7.

[19] TRIPS Agreement, *supra* note 7, art. 27.1.

allow the patent holder to exclude others from "making, using, offering for sale, selling, or importing" patent-infringing products.[21] In addition to granting exclusive patent rights, the TRIPS Agreement also provides limited protections for pharmaceutical data submitted for the purpose of obtaining marketing approval.[22] Such confidential data, at least with respect to new chemical entities and data, which required considerable effort to originate, is to be protected against unfair commercial use.[23] The pharmaceutical industry and trade representatives from wealthy countries have persistently claimed that TRIPS's data protection clause actually requires data exclusivity—a monopoly right that would prevent a country from referencing or relying on regulatory data previously submitted in order to grant marketing approval for a generic equivalent.[24]

Despite the passage of TRIPS, member states retained important interpretative freedom and specific flexibilities to protect public interests, including the right to health. These reserved rights include

- to strictly define baseline patentability rules (novelty, inventive step, and industrial applicability),[25] to compel disclosures,[26] and to allow pre- and post-grant oppositions[27] to ensure only high quality patents are granted and to prevent "evergreening;"
- to exclude patents for certain subjects, such as patents on surgical, diagnostic and therapeutic methods, and plants and animals;[28]

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[20] *Id.* art. 33.

[21] *Id.* art. 28.1.

[22] *Id.* art. 39.3.

[23] *Id.*

[24] *See generally* Carlos M. Correa, *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69 (2002); Aaron X. Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement*, 45 HARV. INT'L L.J. 443 (2004); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1 (2009); Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303 (2008).

[25] Article 1.1 gives countries considerable interpretive freedom to implement the Agreement within their own legal system and practice. TRIPS Agreement, *supra* note 7. Article 27.1 states the basic required standards of patentability but does not define them further.

[26] *Id.* art. 29.

[27] *Id.* art. 62.4; *see* WIPO Standing Comm. on the Law of Patents, OPPOSITION SYSTEMS AND OTHER ADMINISTRATIVE REVOCATION AND INVALIDATION MECHANISMS (Apr. 2012), http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_4.pdf.

[28] TRIPS Agreement, *supra* note 7, art. 27.3.

- to adopt limited exceptions including Bolar/early-working and experimental/research use;[29]
- to issue compulsory licences and government use orders;[30]
- to parallel import goods placed lawfully on the market;[31]
- to regulate and prevent abusive practices that unreasonably restrain trade and adversely affect the transfer of technology;[32] and
- to make use of transitional periods and waivers.[33]

Because the U.S. and Europe persisted post-TRIPS in trying to coerce low- and middle-income countries not to use their TRIPS flexibilities, developing countries, led by the Africa Group, fought for clarification of those flexibilities. The historical Doha Declaration on the TRIPS Agreement and Public Health provided this clarification.[34]

The battle over pharmaceutical IPRs has continued since the Doha Declaration. European, American, and Japanese negotiators have shifted forums away from the WTO to conclude bilateral and regional "free trade" agreements (FTAs) and economic partnership agreements (EPAs) with extensive TRIPS-plus protections that have a negative effect on public health and access to medicines.[35] The TPPA is perhaps the most troubling and

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[29] *Id.* art. 30; *see* Christopher Garrison, *Exceptions to Patent Rights in Developing Countries* (Aug. 2006), http://www.unctad.org/en/docs/iteipc200612_en.pdf; Evans Misati & Kyoshi Adachi, *The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda* (2010), http://www.ictsd.org/downloads/2011/12/the-research-and-experimentation-exceptions-in-patent-law-jurisdictional-varations-and-the-wipo-development-agenda.pdf.

[30] TRIPS Agreement, *supra* note 7, art. 31; *see* Cecilia Oh, *Compulsory Licenses: Recent Experiences in Developing Countries*, 1 INT'L J. INTELL. PROP. MGMT. 22, 22–36 (2006); Jerome H. Reichman & Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* (June 2003), http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf; *see generally* Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613, 613–715 (2004).

[31] TRIPS Agreement, *supra* note 7, art. 6; *see* Frederick M. Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, 1 J. INT'L ECON. L. 607, 607–36 (1998).

[32] TRIPS Agreement, *supra* note 7, arts. 8.2, 40.

[33] *Id.* arts. 65, 66 and extensions thereof.

[34] World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002).

[35] Peter Drahos, *Expanding Intellectual Property's Empire: the Role of FTAs* (2003), *available at* http://www.ictsd.org/down102ds/2608/08/drahos-fta-2003-en.pdf; Francisco Rossi, *Free trade agreements and TRIPS-plus measures*, 1 INT'L J. INTELL. PROP. MNGT. 150 (2006); UNDP/UNAIDS ISSUE BRIEF,

advanced example. The final text contains the following TRIPS-plus provisions, most based on proposals from the United States:

- Requiring countries to ease standards for granting secondary patents by requiring patents on new uses or methods of use of known substances;[36]
- Lowering standards for the definition of "inventive step";[37]
- Eliminating certain exclusions for invention derived from plants[38] and requiring ratification or accession to the International Convention for the Protection of New Varieties of Plants;[39]
- Providing extensions of patent terms beyond the TRIPS-required 20 years to compensate for regulatory delays in granting patents[40] or marketing approvals;[41]
- Requiring periods of data exclusivity, including successive periods, that prevent medicines regulatory authorities from referencing or relying on clinical trial data submitted by originators to grant marketing approval for generic equivalents;[42]
- Requiring drug regulatory authorities to link marketing approval to the absence of any claimed patents or to provide notice of marketing approval application and opportunity to adjudicate validity or infringement;[43] and
- Enhancing enforcement measures including mandatory injunctions,[44] heightened damages,[45] and confiscatory border measures.[46]

THE POTENTIAL IMPACTS OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH (2012), *available at* http://unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf.

[36] IP Chapter, *supra* note 8, art. 18.37.2.

[37] *Id.* art. 18.37.1, n.30 (obviousness to a person skilled or having ordinary skill in the art in light of the prior art).

[38] *Id.* art. 18.37.4.

[39] *Id.* art. 18.7.2(d).

[40] *Id.* arts. 18.46.3–.4.

[41] *Id.* art. 18.48.2.

[42] *Id.* arts. 18.50.1, 18.50.2, 18.54 (five plus three years for non-biologic pharmaceuticals); *id.* arts. 18.52.1(a), 18.51.1(b) (eight years or five years plus comparable market protection for biologics).

[43] *Id.* arts. 18.51.1–.2.

[44] *Id.* arts. 18.74.2.

Unsurprisingly, Article 18.6.1 references the Doha Declaration at the same time that it reiterates the parties' commitment to the IP Chapter.

> The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.[47]

Article 18.6 also references the TRIPS/health solution and commits parties to notifying the WTO of their acceptance of the same.[48]

The Transparency Annex[49] gives pharmaceutical companies multiple opportunities to influence medical product listings for reimbursement though not the level of such reimbursement. If adopted, the Transparency Annex would require parties to render listing decisions within a specified time period, to afford applicants timely opportunities to provide comments and materials in support of their applications, to provide written justifications for their decisions, and to grant a review or reconsideration process for aggrieved applicants.[50]

These TPPA provisions, individually and collectively, can adversely impact access to medicines in TPPA parties.[51] More patents might be granted on a particular medicine extending the time period of monopoly control and delaying

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[45] *Id.* art. 18.74.4 (requiring that judicial authorities consider the market price or suggested retail price as am proper measure of damages for patent infringements).

[46] *Id.* art. 18.76 (applying to copyright and trademark infringements, including transshipment of confusingly similar trademark goods).

[47] *Id.* art. 18.6.1(a).

[48] *Id.* arts. 18.6.1(b), 18.6.2.

[49] Transparency Annex, *supra* note 9.

[50] *Id.* para. A.2.

[51] *See, e.g.*, Buruc Kilic, Hannah Brennan & Peter Maybarduk, *What is Patentable under the Trans-Pacific Partnership? An Analysis of the Free Trade Agreement's Patentability Provisions from a Public Health Perspective*, 40 YALE J. INT'L L. ONLINE (2015), http://www.yjil.org/docs/pub/o-40-killic.pdf; *The Foundation for AIDS Research*, *Issue Brief: Trans-Pacific Partnership: Curbing Access to Medicines Now and in the Future* (2015), http://www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2015/IB_TPP_Brief_RC_050615.pdf. For an access-to-medicines critique of earlier draft IP Chapter provisions, *see* Flynn, Baker, Kaminski & Koo, *supra* note 3, at 149–83; Ruth Lopert & Deborah Gleeson, *Symposium: Global Health & Law – The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines*, 41 J.L. MED. & ETHICS 199, 206–10 (2013); *see generally* UNITAID, TRANS-PACIFIC PARTNERSHIP AGREEMENT: IMPLICATIONS FOR ACCESS TO MEDICINE AND PUBLIC HEALTH (2014), *available at* http://www.unitaid.eu/images/marketdynamics/publications/TPAA-Report_Final.pdf.

generic competition. The duration of exclusive rights can also be prolonged because of patent term extensions that compensate for patenting and regulatory delays. In addition, new forms of monopoly protection are erected that delay marketing approval of generic equivalents, namely data exclusivity and patent-registration linkage.[52] Patent holders will also have additional enforcement powers and deterrent remedies against alleged infringers and will have new opportunities to insist that their products be listed on therapeutic formularies and that their medicines be reimbursed at a high rate. However, pharmaceutical companies are gaining more than the power to pursue enhanced private enforcement rights, or to seek governmental support in guarding borders and confiscating alleged infringing products, or even to seek state-state dispute resolution if their IPRs are not adequately protected. They also will have greatly expanded IP-enforcement rights directly against governments if their well-grounded expectations of profits are frustrated by adverse patent or regulatory rulings. The importance of IP-investor Rights cannot be overstated.

III. BRIEF HISTORICAL BACKGROUND ON INVESTMENT TREATIES AND INVESTOR-STATE DISPUTE SETTLEMENT

Free trade agreements and bilateral investment treaties (BITs) typically contain investment clauses designed to attract direct foreign investment and protect the interests of foreign investors against grossly unfair, confiscatory, or discriminatory treatment.[53] In addition to defining the types of foreign investment entitled to protection, investment chapters typically allow for both interstate dispute settlement and investor-state dispute settlement; the latter means that if a foreign investor believes that its investment has been unlawfully devalued by government action it can either induce its government to seek resolution on its behalf or directly launch arbitral proceedings against the offending government before a private panel of trade lawyers.[54] Typical claims under investment clauses address: (1) alleged violations of ***minimum standards of treatment*** for foreign investors, i.e., fair and equitable treatment and full protection and security—basically policy protection and adjudicative due process; (2) ***direct or indirect expropriation***, including what we call in the U.S. "regulatory takings"; and (3) ***national treatment and most favored nation*** principles requiring host governments to afford foreign investors

[52] IP Chapter, *supra* note 8, arts. 18.51, 18.52; *see* Baker, *supra* note 30, at 613–715.

[53] Jeswald W. Salacuse & Nicholas P. Sullivan, *Do BITRs Really Work?: An Evaluation of Bilateral Investment Treaties and Their Grand Bargain*, 46 HARV. INT'L L.J. 67, 67–130 (2005); Zachary Elkins, Andrew T. Guzman & Beth A. Simmons, *Competing for Capital: The Diffusion of Bilateral Investment Treaties, 1960–2000*, 60 INT'L ORG. 811, 811–46 (2006).

[54] *See, e.g.*, Investment Chapter, *supra* note 10.

treatment that is no less favorable than that afforded to domestic entities in similar circumstances or no less favorable than that afforded to investors from another state that has an investment agreement with the host government. International investment treaties also frequently mandate free flow of capital and place restrictions on prudent capital controls, something now recognized as having contributed to asset bubbles and global financial insecurity. Finally, they greatly restrict performance requirements designed to promote domestic inputs as a condition of foreign investment activity.

United States Bilateral Investment Treaties are designed to ensure that investments provide six basic benefits, often referred to as the "core" BIT principles:

- First, our BITs provide that investors and their "covered investments" (that is, investments of a national or company of a Party in the territory of the other Party) are entitled to be treated as favorably as the host Party treats its own investors and their investments or investors and investments from any third country. The BITs generally afford the better of national treatment (NT) or most favored nation (MFN) treatment for the full life cycle of investment, i.e., from its establishment or acquisition, through its management, operation and expansion, to its disposition.
- Second, "BITs establish clear limits on the expropriation of investments and provide for payment of prompt, adequate and effective compensation when expropriation takes place."
- Third, "BITs provide for the transferability of funds into and out of the host country without delay using a market rate of exchange." This covers all transfers related to a covered investment and creates a predictable environment guided by market forces.
- Fourth, the circumstances in which performance requirements can be imposed are limited. The performance requirement disciplines apply to specific circumstances that would require covered investments to adopt inefficient and trade-distorting practices (e.g., local content requirements or export quotas) as a condition for establishment, acquisition, expansion, management, conduct, or operation.

- Fifth, BITs give investors from both Parties the right to submit an investment dispute with the treaty partner's government to international arbitration. There is no requirement to use that country's domestic courts.
- Sixth, BITs give covered investments the right to engage the top managerial personnel of their choice, regardless of nationality.[55]

The vast majority of investor-state dispute resolution claims are handled by the International Centre for the Settlement of Investment Disputes (ICSID), although there are alternative arbitral forums, regional and otherwise.[56] Most investment treaties allow recourse to ICSID arbitration without first exhausting local judicial or administrative remedies, a right frequently not given to domestic investors with respect to exhaustion or post-exhaustion review. Typically, a panel of three private arbitrators is chosen to establish an investor-state dispute resolution tribunal, often from a surprisingly small pool of international trade lawyers.[57] Decisions are non-reviewable except through annulment proceedings addressing a narrow range of tribunal errors and are

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[55] *Bilateral Investment Treaties*, http://www.ustr.gov/trade-agreements/bilateral-investment-treaties (last visited Oct. 17, 2015).

[56] The ICSID arbitration rules are contained in the *Convention on the Settlement of Investment Disputes between States and Nationals of Other States*, 18 March 1965, 575 U.N.T.S. 159, 4 I.L.M. 532 (entered into force 14 October 1966) [*ICSID Convention*] and the rules created by the ICSID Administrative Council pursuant to arts. 6(1)(a) to (c) of the *ICSID Convention*, *Administrative and Financial Regulations, Rules of Procedure for the Institution of Conciliation and Arbitration Proceedings*; *Rules of Procedure for Arbitration*. These rules are published in ICSID, *ICSID Convention, Regulations and Rules*, Doc. ICSID/15 (Washington: ICSID, 2006). The ICSID Additional Facility for the Administration of Conciliation, Arbitration and Fact-Finding Proceedings was created by the ICSID Administrative Council on September 27, 1978. *ICSID Additional Facility for the Administration of Conciliation, Arbitration and Fact-Finding Proceedings*, Doc. ICSID/11 (Washington: ICSID, 1979). Schedule C of the *ICSID Additional Facility*, sets out the *Arbitration (Additional Facility) Rules*. On April 5, 2006, the Administrative Council approved amendments to the *ICSID Arbitration Rules* and the *Additional Facility Rules* creating greater transparency and allowing amicus participation in ICSID proceedings for the first time, *available at* https://icsid.worldbank.org/ICSID/ICSID/RulesMain.jsp. For a critique and review of the 2006 revisions, *see* J. Anthon VanDuzer, *Enhancing the Procedural Legitimacy of Investor-State Arbitration Through Transparency and Amicus Curiae Participation*, 52 MCGILL L.J. 681 (2007).

An alternative international system for investor-state arbitration is pursuant to United National Commission on International Trade Law [UNCITRAL] Arbitration Rules (2010), *available at* http://www.uncitral.org/pdf/english/texts/arbitration/arb-rules-revised/arb-rules-revised-2010-e.pdf. There are several regional mechanisms for investor-state arbitration as well.

[57] PIA EBERHARDT & CECILIA OLIVET, TRANSNATIONAL INSTITUTE AND CORPORATE EUROPE OBSERVATORY REPORT, PROFITING FROM INJUSTICE 8 (2012), http://www.tni.org/pressrelease/exposed-elite-club-lawyers-who-make-millions-suing-states.

heard by another arbitral tribunal instead of by judges.[58] Although arbitral decisions are not precedential,[59] panels frequently cite other tribunal decisions[60] even as they also frequently ratchet up investor protections.[61]

Investor-state dispute resolution is facing a crisis of credibility given its perceived bias towards investor prerogatives. The analysis here, however, focuses not on legitimacy debates,[62] but rather on a particular threat to access to medicines posed by pharmaceutical companies pursuing investor-state claims. More specifically, the analysis focuses on the pro-investor TPPA Investment Chapter[63]—and on the first ever IP-related pharmaceutical investor-state arbitral claim by Eli Lilly against Canada that demonstrates the danger of investment claims in the pharmaceutical context.[64]

The investor-state dispute settlement regime was ostensibly established to encourage direct foreign investment and thereby facilitate the efficient and free flow of capital to its most productive uses. By allowing private investors to seek remedies before purported neutral arbiters, foreign investors could avoid

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[58] Nigel Blackaby, *Public Interest and Investment Treaty Arbitration*, *in* INTERNATIONAL COMMERCIAL ARBITRATION: IMPORTANT CONTEMPORARY QUESTIONS 355, 364 (Albert Jan van den Berg ed., 2002) (expressing early concern over the absence of appellate review in the investor-state arbitration context).

[59] Joshua Karton, *Lessons from International Uniform Law*, *in* RESHAPING THE INVESTOR-STATE DISPUTE SETTLEMENT SYSTEM: JOURNEYS FOR THE 21ST CENTURY 48, 67 (Jean E. Kalicki, Anna Joubin-Bret eds., Koninklijke Brill NV 2015).

[60] *Id.* at 65.

[61] Robin Broad, *Corporate Bias in the World Bank Group's International Centre for Settlement of Investment Disputes: A Case Study of a Global Mining Corporation Suing El Salvador*, 36 U. PENN. J. INT'L L. 851, 851–74 (2015).

[62] *Cf.* William W. Burke-White & Andreas von Staden, *Private Litigations in a Public Law Sphere: The Standard of Review in Investor-State Arbitrations*, 35 YALE J. INT'L L. 283 (2010) (arguing for a "margin of appreciation" standard of review); Alec Stone Sweet, *Investor-State Arbitration: Proportionality's New Frontier*, 4 LAW & LEGAL ETHICS OF HUM. RTS. 47 (2010) (arguing for adoption of a proportionality review balancing public and private interests); Caroline Henckels, *Indirect Expropriation and the Right to Regulate: Revisiting Proportionality Analysis and the Standard of Review of Investor-State Arbitration*, 15 J. INT'L ECON. L. 223, 223–55 (2012) (arguing for a more deferential application of proportionality review taking into account "host state authorities' greater democratic legitimacy and proximity to host state communities, and tribunals' comparatively weak institutional capacity"). For a broader discussion of possible reforms, *see* UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT (UNCTAD), WORLD INVESTMENT REPORT 2013 – GLOBAL VALUE CHAINS: INVESTING FOR DEVELOPMENT 110, 110–20 (2014) (mapping five paths to reform of investment arbitration); UNTAD, WORLD INVESTMENT REPORT 2014: INVESTMENT IN THE SDGS: AN ACTION PLAN 126, 126–33 (2015) (mapping pro-sustainable development goals approaches to investment law reform).

[63] Investment Chapter, *supra* note 10.

[64] Eli Lilly & Co. v. The Gov't of Canada, Notice of Intent to Submit a Claim to Arbitration under NAFTA (Nov. 7, 2012), http://italaw.com/sites/default/files/case-documents/italaw1172.pdf [hereinafter Notice of Intent].

asset expropriation and adjudicative injustice. Larcenous and lawless governments would be deterred from confiscating hard-earned foreign investments and become compliant with, or at least obedient, to the rule of law. In the context of a global development agenda, investment clauses were believed to provide a level of security that would incentivize foreign direct investment in the real economy and financial markets of low- and middle-income countries thereby accelerating the development of comparative advantage and lubricating participation in the expanding global economy.[65] A total of 3,271 international investment agreements (IIAs) were concluded between 1980 and 2014, of which almost 90% were bilateral investment treaties (BITs).[66] The resulting complex web of agreements allows investors to shop for investment provisions that are most advantageous to them and, if necessary, set up a subsidiary for the purpose of asserting a preferred protected foreign status. Alternatively, most favored nation rules permit an investor to argue that it is entitled to the benefit of the "best" investment clause protections that have been granted to investors from any other state.[67]

Although modern investment clauses and investor-state dispute resolution have existed since the 1950s, their use was limited during their first fifty years as only fifty investor-state claims were filed.[68] Although records are scarce, investors seem to have reserved their claims for those exceptional cases where hard investments were nationalized or transferred to others without compensation.[69] In contrast, since 2001, six hundred and eight known investor-state disputes have been filed.[70] Investors had won only $3 billion from

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[65] Eric Neumayer & Laura Spess, *Do Bilateral Investment Treaties Increase Foreign Direct Investment to Developing Countries?*, 33 WORLD DEV. 1567 (2005).

[66] UNCTAD, WORLD INVESTMENT REPORT: REFORMING INTERNATIONAL INVESTMENT GOVERNANCE 106 (2015), *available at* http://unctad.org/en/PublicationsLibrary/wir2015_en.pdf.

[67] UNCTAD, MOST-FAVOURED NATION TREATMENT (2010), *available at* http://unctad.org/en/DOCS/diaeia20101_en.pdf; Pia Acconci, *Most-Favoured-Nation Treatment*, *in* THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW (Peter Muchlinski, Federico Ortino & Christoph Schreuer eds., 2008).

[68] UNCTAD, *IIA Issues Note: Latest Developments in Investor-State Dispute Settlement* 3 (2012), http://unctad.org/en/PublicationsLibrary/webdiaeia2012d10_en.pdf. The history of protecting international investments is much longer than the history of bilateral investments treaties. *See* KENNETH J. VANDEVELD, BILATERAL INVESTMENT TREATIES: HISTORY, POLICY, AND INTERPRETATION, at Ch. 2 (Oxford University Press, New York, 2010).

[69] Six such cases, decided in the early 2000s, were based on direct expropriation claims. Roderick Abbot, Frerik Erixon & Martina Francesca Ferracane, DEMYSTIFYING INVESTOR-STATE DISPUTE SETTLEMENT, ECIPE Occasional Paper No. 5, at 14 (2014).

[70] UNCTAD, *IIA Issues Note – Investor-State Dispute Settlement: Review of Developments in 2014*, at 2 (2015), http://investmentpolicyhub.unctad.org/Upload/Documents/UNCTAD_WEB_DIAE_PCB_2015_%202%20IIA%20ISSUES%20NOTESMAY%20evening.pdf. *See Table of Foreign Investor-State Cases and Claims under NAFTA and Other U.S. Trade Deals*, PUBLIC CITIZEN (2015), http://www.citizen.org/documents/investor-state-chart.pdf. The fact that an investor-state

taxpayers in arbitral awards before last year, but a stunning $50 billion was awarded in 2014 in three closely related arbitrations involving stakeholders in the former petroleum company Yukos and the Russian Federation.[71] The amount claimed in ISDS cases in 2014 ranged from $8 million to $2.5 billion.[72] Moreover, the average cost of arbitral proceedings is nearly $8 million, although the Philippines's tribunal costs and legal costs in a single case exceeded $50 million.[73]

This sea change in investor-state claims was triggered by the belated realization that not only could investors bring claims against banana-republic confiscations but also against emerging economies and even advanced democracies whenever their expectations of profit were thwarted by shifting government regulations, adverse adjudicative decisions or other state practices.[74] Accordingly, foreign corporations have used investor-state dispute resolution to challenge a broad array of environmental and land use laws, government procurement decisions, regulatory permitting decisions, financial regulations, consumer protection laws, public health provisions, public safety laws, and a range of other public interest policies.[75] Claims in extractive industries are common. For example, Churchill Mining has filed a $2 billion claim against Indonesia relating to its mining regulations.[76] ICSID recently ordered Ecuador to pay Occidental Petroleum $1.8 billion in a disagreement over an oil concession contract in the largest investor-state award to date.[77] Claims relating to environmental and public health hazards are also common.

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arbitral award has been issued does not necessarily mean that it has yet been paid. However, $380 million has been paid out to investors under U.S. FTAs and these are only a subset of investor-state awards. Many arbitral claims are settled, post-award, and others are enforced by being reduced to a court judgment that can thereafter be executed against state property, subject to some foreign sovereign immunity issues. *See* Vincent O. Nmehielle, *Enforcing Arbitration Awards Under the International Covenant for the Settlement of Investment Disputes (ICSID Convention)*, 7 ANN. SURVEY INT'L & COMP. L. 21, 21–48 (2001). According to a 2008 PriceWaterhouseCoopers study, host states have complied with about 90% of investment arbitration awards rendered against them. *See International Arbitration: Corporate attitudes and practices*, ACADEMIA (2008), *available at* http://www.academia.edu/262767/PricewaterhouseCoopers_International_Arbitration_Corporate_Attitudes_and_Practices.

[71] *Investor-State Dispute Settlement: Review of Developments in 2014*, UNCTAD (2014), *available at* http://unctad.org/en/PublicationsLibrary/nebdiaepcb2015d2_end.pdf.

[72] UNCTAD, IIA ISSUES NOTE, RECENT TRENDS IN IIAS AND ISDS No. 1 (Feb. 2015), *available at* http://unctad.org/en/PublicationsLibrary/webdiaepcb2015d1_en.pdf.

[73] EBERHARDT & OLIVET, *supra* note 57, at 7.

[74] *Id.*

[75] *Id.*

[76] Churchill Mining PLC v. Republic of Indonesia, ICSID Case No. ARB/12/14 (2015), *available at* http://www.italaw.com/cases/1479.

[77] UNCTAD, *Recent developments in investor-state dispute settlement, IIA Issues Note* (May 2013), http://unctad.org/en/PublicationsLibrary/webdiaepcb2013d3_en.pdf.

One prominent public health example is the arbitral claim against Australia under a 1993 Australia-Hong Kong bilateral investment treaty brought by a subsidiary of Phillip Morris International (PMI) challenging plain packaging restrictions on tobacco products.[78] PMI pursued its 2011 arbitral claim despite the Australian High Court's confirmation of the constitutionality of the Tobacco Plain Packaging Act 2011.[79] Fortunately, in December 2015, the arbitral tribunal declined jurisdiction to hear the case, emboldening other countries to proceed with stalled plain packaging legislation.[80]

In the infamous *Metalclad v. Mexico* case, a U.S. toxic waste disposal firm challenged a Mexican city's refusal to grant a construction permit for a toxic waste facility until and unless the firm cleaned up pre-existing toxic waste problems of which it was aware when it purchased the property from a previous polluter. In an earlier instance, Canada reversed an environmental ban on the gasoline additive MMT, a probable carcinogen, after U.S. Ethyl Corporation filed a NAFTA investor-state claim against it.[81] More recently, in another environmental case involving Canada, *Bilcon v. Canada*, Canada's effort to thwart a mining and marine terminal project because it would violate "core community values" was found to have violated the minimum standards of treatment rule in NAFTA.[82] Bilcon is seeking $300 million in compensation from Canada.

In 2008, the government of El Salvador refused to issue mining permits to Canadian gold mining company Pacific Rim, in order to protect local communities from the contamination of water supplies with chemicals such as arsenic.[83] Pacific Rim then launched an investor-state dispute against El Salvador for $315 million for the loss of anticipated future profits.[84] Pacific

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[78] *See* Tania Voon, *Acquisition of Intellectual Property Rights: Australia's Plain Tobacco Packaging Dispute*, 2 EUR. INTELL. PROP. REV. 113 (2013); Patricia Ranald, *The Australian High Court tobacco plain packaging decision and Investor-State Dispute Settlement (ISDS)*, Paper presented at the Stakeholders Forum, Fourteenth round of Trans-Pacific Partnership negotiations in Leesburg, Virginia (Sept. 9, 2012), *available at* http://www.scribd.com/doc/105755455/Investor-state-Disputes-Settlement-and-the-TPP-Patricia-Ranald.

[79] JT International SA v. Commonwealth of Australia; British American Tobacco Australasia Limited v. Commonwealth of Australia, [2012] HCA 43 (Austl.).

[80] Daniel Hurst, *Australia wins international legal battle with Philip Morris over plain packaging*, THE GUARDIAN (Dec. 17, 2015), http://www.theguardian.com/australia-news/2015/dec/18/australia-wins-international-legal-battle-with-philip-morris-over-plain-packaging.

[81] *See NAFTA – Chapter 11 – Investment: Cases Filed Against the Government of Canada: Ethyl Corporation v. Government of Canada*, *available at* http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/ethyl.aspx?lang=eng.

[82] *Bilcon v. Canada* (U.S. v. Canada) (Perm. Ct. Arb. 2015), *available at* http://www.italaw.com/cases/documents/2984.

[83] THOMAS MCDONAGH, THE DEMOCRACY CENTER, UNFAIR, UNSUSTAINABLE AND UNDER THE RADAR (2013), *available at* http://democracyctr.org/wp/wp-content/uploads/2013/05/Under_The_Radar_English_Final.pdf.

[84] *Id.*

Rim's U.S. subsidiary brought the claim within the scope of the Central American Free Trade Agreement (CAFTA) and the ISDS clause contained within that treaty.[85] The ongoing claim has attracted the attention of more than 300 NGOs, trade unions, and civil society groups who vow to defend every last "drop of water"[86] in a country where approximately 1.5 million rural inhabitants lack access to reliable water sources.[87]

In 2010, U.S.-owned The Renco Group, Inc. filed a notice of intent to commence arbitration against the Peruvian government for denying it a third opportunity to clean up over a decade's worth of pollution from its metal smelter in La Oroya.[88] The Peruvian government shut down the metal smelter after Renco's persistent delay in implementing environmental improvements.[89] Many of La Oroya's children suffered from elevated lead levels and displayed symptoms consistent with lead poisoning, including anemia, convulsions, stunted growth and mental retardation.[90] Renco responded by bringing an investor-state dispute against Peru under the 2009 U.S.-Peru FTA, demanding $800 million in compensation for Peru's alleged "unfair treatment" of Renco's smelter-operating subsidiary.[91] The threat of expensive and protracted arbitration forced the Peruvian government to permit renewed operation of the smelter without pollution-capturing devices. This renewed smelting has already produced reports of fresh emissions.[92] Peru's inability to protect the health of its own people demonstrates the devastating impact that investor-state disputes can have on public health.

In 2011, Germany's decision to shut down its nuclear power industry in the wake of Fukushima triggered a multi-billion dollar claim by Swedish energy

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[85] Carey L. Biron, *World Bank Tribunal Weighs Final Arguments in El Salvador Mining Dispute*, IPS NEWS AGENCY (Sept. 16, 2014), *available at* http://www.ipsnews.net/2014/09/world-bank-tribunal-weighs-final-arguments-in-el-salvador-mining-dispute/.

[86] Claire Provost, *El Salvador groups accuse Pacific Rim of "assault on democratic governance,"* THE GUARDIAN (Apr. 10, 2014), http://www.theguardian.com/global-development/2014/apr/10/el-salvador-pacific-rim-assault-democratic-governance.

[87] Denis Collins, *The Failure of a Socially Responsive Gold Mining MNC in El Salvador: Ramifications of NGO Mistrust*, 88 J. BUS. ETHICS 245, 245–68 (2009).

[88] The Renco Grp., Inc. v. The Republic of Peru, Claimant's Notice of Intent to Commence Arbitration Under United States-Peru Trade Promotion Agreement (2010), *available at* http://italaw.com/documents/RencoGroupVPeru_NOI.pdf.

[89] Lori Wallach, *Brewing Storm over ISDS Clouds Trans-Pacific Partnership Talks*, KLUWER ARBITRATION BLOG (Feb. 29, 2016, 9:05 AM), http://sensiblesafeguards.org/assets/documents/kluwerblog-with-endnotes.pdf.

[90] Andrew Martin, *Coup d'Etat to Trade Seen in Billionaire Toxic Lead Fight*, BLOOMBERG (May 10, 2013), http://www.bloomberg.com/news/articles/2013-05-09/rennert-800-million-toxic-lead-fight-roils-global-trade.

[91] The Renco Grp., Inc. v. The Republic of Peru, *supra* note 88.

[92] Public Citizen, *Renco Uses U.S.-Peru FTA to Evade Justice for La Oroya Pollution* (Dec. 2012), http://www.citizen.org/documents/renco-la-oroya-memo.pdf.

company Vattenfall, which operates two nuclear plants in Germany: Krümmel and Brunsbüttel.[93] Vattenfall demanded compensation of $4.7 billion under the ISDS clause of the Energy Charter Treaty.[94] The ability of a foreign investor to hold a national government hostage over legislation designed to protect the health of its citizens highlights the extraordinary anti-democratic precedent set by investor-state disputes. ISDS provisions provide foreign nationals with greater rights than domestic citizens by virtue of their ability to bring treaty claims. Consequently, "the rights provided to foreign investors surpass the protections enshrined in Germany's basic law" which carefully balances public welfare objectives and investor rights.[95] While the public interest is a guiding principle in *Grundgesetz*, it may be completely ignored by an international investment tribunal whose priorities lie with investors.[96]

Although many investor-state cases implicate public health and safety, prior to 2012, no pharmaceutical company had filed an investor-state challenge based on intellectual property rights. That moratorium ended on 7 November 2012,[97] when Eli Lilly and Company initiated arbitration proceedings under the North American Free Trade Agreement (NAFTA) investment clause to attack Canada's invalidation of a patent on an attention deficit disorder medicine called Stattera.[98] In doing so, Eli Lilly is challenging a well-established patent rule in Canada, the so-called promise doctrine, whereby a medicine's "utility," and thus patentability, must be demonstrated or soundly predicted at the time of filing a patent.[99] Eli Lilly has made a number of specific investment chapter claims including an allegation that the Canadian ruling involved a violation of

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[93] *The Arbitration Game*, ECONOMIST (Oct. 11, 2014), *available at* http://www.economist.com/news/finance-and-economics/21623756-governments-are-souring-treaties-protect-foreign-investors-arbitration.

[94] *Id.*

[95] Natalie Bernasconi-Osterwalder & Rhea Tamara Hoffmann, INTERNATIONAL INSTITUTE FOR SUSTAINABLE DEVELOPMENT [IISO], *The German Nuclear Phase-Out Put to the Test in International Investment Arbitration? Background to the new dispute Vattenfall v. Germany (II)* (2012), http://www.tni.org/files/download/vattenfall-icsid-case_oct2013.pdf.

[96] *Id.*

[97] Notice of Intent, *supra* note 64.

[98] The challenged court decision is *Eli Lilly Co. v. Teva Canada Ltd.*, 2011 FAC 220. The investor-state claim is *Eli Lilly v. Canada*, *supra* note 6. Chapter 11 of NAFTA adopted investor-state arbitration. North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 259 (entered into force Jan. 1, 1994). Eli Lilly initiated an IP-related claim despite the fact that intellectual property rights are not directly defined as covered investments in Article 1139.

[99] *See* E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CAN. INTELL. PROP. REV. 35 (2014) (presenting a comprehensive review of the long history of the promise doctrine in Canadian and British jurisprudence and kindred utility doctrine in other jurisdictions).

minimum standards of treatment, indirect expropriation, and discrimination.[100] The analysis below will first address the provisions in the Investment Chapter and their theoretical risk to access to medicines and then examine those risks in light of the actual claims asserted by Eli Lilly against Canada.

IV. THE TPPA INVESTMENT CHAPTER IS A BOOBY-TRAP FOR ACCESS TO MEDICINES

The TPPA IP Chapter has been analyzed briefly above with respect to the dangers it poses in terms of access to medicines[101] and elsewhere with respect to its IP enforcement provisions.[102] An earlier leaked version of the TPPA Investment Chapter[103] has also been closely analyzed primarily with respect to the generic dangers of its extra-judicial investor-state dispute settlement provisions.[104] Our analysis expands on other investor-state critiques and focuses on the particular risks the Investment Chapter poses with respect to access to medicines, especially in light of the direct and indirect inclusion of IPRs in the Chapter's coverage. These risks are cumulative to existing IP enforcement risks and burdens because investor-state dispute resolution offers unique remedies beyond enhanced private enforcement mechanisms (mandatory injunctions and expanded damages) and beyond heightened enforcement undertakings by governments (state-state dispute resolution, border measures, and criminal enforcement). In essence, the inclusion of intellectual property rights granted in the TPPA IP Chapter gives IP-"investors" new substantive "investment rights" that they could now directly, selectively, and cumulatively enforce against sovereign governments' regulations, policies,

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100 Eli Lilly v. Canada, *supra* note 6.

101 *See supra* notes 36–46 and accompanying text.

102 Lise Johnson & Lisa Sachs, *The TPP's Investment Chapter: Entrenching, rather than reforming, a flawed system*, Columbia Center on Sustainable Investment Policy Paper (November 2015), *available at* http://ccsi.columbia.edu/files/2015/11/TPP-entrenching-flaws-21-Nov-FINAL.pdf; Amokura Kawharu, *TPPA: Chapter 9 on Investment*, Trans-Pacific Partnership Agreement New Zealand Expert Paper Series No. 2 (2015), *available at* https://tpplegal.files.wordpress.com/2015/12/ep2-amokura-kawharu.pdf; Public Citizen, *Secret TPP Investment Chapter Unveiled: It's Worse than We Thought* (2015), *available at* https://www.citizen.org/documents/analysis-tpp-investment-chapter-november-2015.pdf.

103 Investment Chapter, *supra* note 10.

104 *See, e.g.*, Lori Wallach & Todd Tucker, *Public Interest Analysis of Leaked Trans-Pacific Partnership (TPP) Investment Text* (June 13, 2012), http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/gtwtppinvestmentanalysis.pdf; Jane Kelsey, *New TPP Leaked Text: National Says 'Yes' to Investor Rights to Sue*, SCOOP (June 14, 2012), http://www.scoop.co.nz/stories/PO1206/S00186/national-says-yes-to-investor-rights-to-sue.htm; Lori Wallach & Ben Beachy, *Analysis of Leaked Trans-Pacific Partnership Investment Text* (Mar. 25, 2015), http://citizen.org/documents/tpp-investment-leak-2015.pdf.

and adjudicatory decisions using the Investment Chapter's investor-state dispute resolution.

There are five main dangers in the Investment Chapter that threaten access to medicines:

- First, the minimum standard of treatment rule, including fair and equitable treatment, and the indirect expropriation standard contain significant ambiguities that could greatly restrict countries' ability to enact, use, and defend lawful flexibilities that enhance access to medicines.
- Second, national treatment and most favored nation provisions can be interpreted to prevent unanticipated forms of alleged discrimination against foreign investors.
- Third, it is dangerous to cross-reference and incorporate IP rights into the investment chapter, given the extensive private and public enforcement rights that rightholders already possess and given drug companies' proclivities to bring lawsuits against governments.[105]
- Fourth, the bracketed limited exception to IP-related investment rights for compulsory licenses and patenting decisions does not provide the security against investor claims that TPPA Parties would need to truly safeguard lawful measures that promote access to affordable

[105] Using India as an example, Bayer unsuccessfully sued India to achieve judicially mandated patent-registration linkage. Bayer Corp. v. Union of India, 41 P.T.C. 634 (Del. 2009); Bayer Corp. v. Union of India, 9 Feb. 2010, LPA 443/2009; Petition(s) for Special Leave to Appeal (Civil) No(s) 6540/2010; *see* Mabel Tsui, *Access to Medicine and the Dangers of Patent Linkage: Lessons from* Bayer Corp. v. Union of India, 18 J.L. & MED. 577 (2011); Anshul Mittal, *Patent Linkage in India: Current Scenario and Need for Deliberation*, 15 J. INTEL. PROP. RGTS. 187 (2010). Bayer appealed the granting of a compulsory license on its cancer medicine, Nexavar (sorfenib tosylate) but lost and further review was denied. Samanwaya Rautray*, Nexavar Licence Case: SC dismisses Bayer's appeal against HC decision*, ECON. TIMES (Dec. 13, 2014), http://articles.economictimes.indiatimes.com/2014-12-13/news/57012244_1_bayer-s-compulsory-licence-glivec. Novartis unsuccessfully sued India in 2006 to invalidate Section 3(d) of the Indian Amended (2005) Patents Act on the grounds that it was unconstitutional and violated the TRIPS Agreement. *See* Shamnad Basheer & Prashant Reddy, *"Ducking" TRIPS In India: A Saga Involving Novartis and the Legality of Section 3(d)*, 20 NAT'L L. SCH. INDIA REV. 131 (2008). Novartis appealed the underlying denial of a patent on its cancer medicine, Glivec all the way to the Supreme Court of India, which dismissed Novartis's effort to obtain a patent on Glivec and to reinterpret section 3(d) of the India Patents Act to make it easier to evergreen patents on medicines. *Novartis v. Government of India*, Civil Appeal Nos. 2706–2716 of 2013 (Apr. 1, 2013), *available at* http://supremecourtofindia.nic.in/outtoday/patent.pdf.

medicines for all, as set forth in the TRIPS Agreement and further clarified in the Doha Declaration on the TRIPS Agreement and Public Health.[106]

- Fifth, the Investment Chapter prevents certain performance requirements that in the IP context might give developing countries leeway to develop domestic pharmaceutical capacity in order to ensure a self-sufficient and uninterrupted supply of medicines and to promote industrial development and diversification.

A. THE "MINIMUM STANDARD OF TREATMENT/FAIR AND EQUITABLE TREATMENT" STANDARD AND INDIRECT EXPROPRIATION STANDARD CONTAIN DANGEROUS INTERPRETIVE AMBIGUITIES THAT COULD NEGATIVELY IMPACT GOVERNMENT POLICIES AND DECISIONS AFFECTING ACCESS TO MEDICINES

Article 9.6.1 of the TPPA Investment Chapter requires that, as a "minimum standard of treatment," "Each Party shall accord to covered investments treatment in accordance with applicable customary international law principles, including fair and equitable treatment and full protection and security."[107] Although subparagraph 1 does not require treatment in addition to or beyond that required by customary international law, Article 9.6.2(a) interprets "fair and equitable treatment" to include "the obligation not to deny justice in criminal, civil, or administrative adjudicatory proceedings in accordance with the principle of due process embodied in the principal legal systems of the world."[108] Articles 9.6.3–5 corral the reach of the minimum standard of treatment rule: (1) Article 9.6.3 clarifies that breach of a separate provision of the TPPA or of a separate international agreement does not by itself establish a minimum standard breach; (2) Article 9.6.4 states that the mere fact that a parties actions or inactions are inconsistent with an investor's expectation does not necessarily constitute a breach; and (3) Article 9.6.5 clarifies that the mere fact that a subsidy or grant has not been issued, renewed, or maintained, or that it has been modified or reduced, does not necessary constitute a breach.[109]

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[106] Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, Nov. 9–14, 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm [hereinafter Doha Declaration].

[107] Investment Chapter, *supra* note 10.

[108] *Id.*

[109] *Id.*

However, the effectiveness of these provisions to limit increasing investor reliance on the minimum standard of treatment has been sharply questioned.[110]

Investor-state tribunals have used increasingly expansive interpretations of the "minimum standard of treatment" rule that depart further and further from the "customary international law" actually practiced by States, despite an annex defining customary international law as the "general and consistent practice of States that they follow from a sense of legal obligation."[111] Indeed, in the recent ruling on the *Railroad Development Corporation v. Republic of Guatemala* case, an investor-state tribunal explicitly rejected arguments that the minimum standard of treatment for foreign investors needed to be based on state practice, opting instead to borrow a more expansive interpretation of the standard from another tribunal.[112]

That more elastic interpretation of the minimum standard of treatment came from the 2004 NAFTA case known as *Waste Management, Inc. v. United Mexican States II*.[113] In its award, the tribunal defined a violation of the minimum standard of treatment as entailing state conduct that is "arbitrary, grossly unfair, unjust or idiosyncratic, is discriminatory and exposes the claimant to sectional or racial prejudice, or involves a lack of due process leading to an outcome which offends judicial propriety."[114] The tribunal noted that this might be the case where there has been a "manifest failure of natural justice in judicial proceedings or a complete lack of transparency and candor in an administrative process."[115] More problematically, the tribunal decided that if a state breaches "representations" that were "reasonably relied on" by investors at the time of investment, that breach constitutes evidence of unfair or inequitable conduct that violates the minimum standard of treatment.[116] Some commentators, citing other expansive tribunal decisions, argue that the minimum standard of treatment goes so far as to protect the "reasonable expectations" of an investor

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[110] Johnson & Sachs, *supra* note 102, at 4–6; Public Citizen, *supra* note 102, at 10; Kawharu, *supra* note 102, at 10–12.

[111] Investment Chapter, *supra* note 10, Annex 9-A. For a chronology of tribunals' elastic interpretations of the minimum standard of treatment, *see* Public Citizen, *Memorandum on "Fair and Equitable Treatment" and Investors' Reasonable Expectations: Rulings in U.S. FTAs & BITs Demonstrate FET Definition Must be Narrowed* (Sept. 5, 2012), http://www.citizen.org/documents/MST-Memo.pdf?iframe=true&width=100% &height=100% (detailing a chronology of tribunals' elastic interpretations of the minimum standard of treatment).

[112] *See* Public Citizen, *Railroad Development Corporation (RDC) v. Guatemala*, http://www.citizen.org/RDC-vs-Guatemala#!prettyPhoto[iframe]/0/ (last visited Oct. 20, 2015) (describing the expansive view of the minimum standard).

[113] Waste Mgmt., Inc. v. United Mexican States, Case No. ARB(AF)/00/3, Award (ICSID Apr. 30, 2004), *available at* http://www.state.gov/documents/organization/34643.pdf.

[114] *Id.* ¶ 98.

[115] *Id.*

[116] *Id.*

even in the absence of direct representations, let alone binding commitments allowing unfettered and immutable market participation or profit-making opportunities.[117] Such expansive interpretations of the "minimum standard of treatment" have made these claims an investor favorite. In nearly 75% of the investor-state cases won under U.S. trade and investment agreements, the tribunal cited a "minimum standard" violation to rule against the respondent party.[118]

In the pharmaceutical context, foreign investors might claim that the "minimum standard of treatment" rule covers their reasonable expectations for future profits arising from the granting or even filing of intellectual property claims. Changing or re-interpreting substantive IP standards or guidelines judicially, administratively deciding pre- or post-grant patent oppositions in favor of challengers, or adjudicating exceptions to granted rights might all be interpreted as violations of minimum standards of treatment. In sum, whenever foreign IP rightholders disagree with judicial or administrative decisions or view those decisions as insufficiently transparent or candid, the foreign rightholder could potentially bring investment chapter claims directly against that government without ever being required to exhaust appeal mechanisms.

These concerns are no longer purely speculative. A major international corporate law firm, Jones Day, has directly counseled pharmaceutical companies about foreign investor claims they might bring against India:

> [T]he basic patentability standards of the TRIPs agreement have been guaranteed to Novartis' investments in India ever since India agreed to become TRIPs-compliant in 2005; denying a patent in violation of those standards therefore may constitute a violation of the fair and equitable treatment standard. In Bayer's case, the sheer length of time for which the compulsory license was granted to the Indian company—i.e., the "balance term of the patent"—and the fact that no national health "emergency" exists to justify such a license over a "non-life saving drug," are

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117 *See* FIONA MARSHALL, INSTITUTE FOR SUSTAINABLE DEVELOPMENT, FAIR AND EQUITABLE TREATMENT IN INTERNATIONAL INVESTMENT AGREEMENTS, INTERNATIONAL INSTITUTE FOR SUSTAINABLE DEVELOPMENT (Oct. 1–2, 2007), http://www.iisd.org/pdf/2007/inv_fair_treatment.pdf.

118 *See* Wallach & Tucker, *supra* note 104, at 8.

> just two reasons to suggest that India has run afoul of Article 31 of TRIPs.[119]

The *Novartis v. India* case[120] involved the denial of an evergreening patent on Glivec, an important cancer medicine. The Bayer case referred to involves India's first grant of a compulsory license, also on a cancer medicine. What's striking about Jones Day's advice is its legal inaccuracy. Although TRIPS Article 31 does allow patent holders to seek termination of a compulsory license when the conditions giving rise to that license have abated, there is no stated limitation in TRIPS on the duration of a license. Even more clearly, Article 31 contains no requirement whatsoever that compulsory licenses on medicines only be granted for "emergencies" or that they are limited to lifesaving medicines. Compulsory licenses under TRIPS can be granted for non-emergency conditions routinely, but unlike licenses granted in emergencies or for public, non-commercial use or to remedy anti-competitive behavior such licenses require an attempt to negotiate a voluntary license with the patent holder on reasonable terms. Likewise, compulsory licenses can be granted on medicines that respond to any health need, not just life-saving need. Both of these points were directly addressed and clarified in the Doha Declaration.[121]

Article 9.8 of the TPPA Investment Chapter also prohibits direct and "indirect expropriation" of a covered investment, which includes failure to pay fair market value upon expropriation.[122] Although there is an exception in subparagraph 5 with respect to "compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement," this exception would not appear to cover exceptions to data exclusivity or patent-registration linkage rights nor many other patent related claims. Even the last portion of subparagraph 5, which includes an exception to the expropriation rule for "the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter 18 (Intellectual Property) and the TRIPS Agreement,"[123] as important as it may be, might not give rights to create novel exceptions to

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[119] Jones Day Commentary, *Treaty Protection for Global Patents: A Response to a Growing Problem for Multinational Pharmaceutical Companies* 3 (Jones Day Oct. 2012), http://www.jonesday.com/files/Publication/96b88f45-3c81-4e6e-b640-9ca243920ad5/Presentation/PublicationAttachment/523d7608-c58a-4bab-bd96-9e1d121287ea/Treaty%20Protection.pdf; *see also* Viren Mascarenhas & Giulia Previti, *Use Investment Treaties to Protect your Right*, MANAGING IP, 42 (Sept. 2013), http://www.managingip.com/Article/3248510/Use-investment-treaties-to-protect-your-rights.html.

[120] *See supra* note 105.

[121] *See* Doha Declaration, *supra* note 106, ¶ 5.

[122] Investment Chapter, *supra* note 10.

[123] *Id.* It is important to note that the exception in Article 9.8.5 applies only to expropriate claims and not to minimum standard of treatment claims or discrimination claims.

intellectual property rights in the absence of full remuneration. Pursuant to the indirect expropriation rule, it would be unlawful, arguably, to create a new public health exception to data exclusivity or to require disclosure of the international proprietary name of active pharmaceutical ingredients on medicine-related patents. Likewise, payment of partial liability awards or royalties would not suffice to escape indirect expropriation strictures. Finally, the subparagraph 5 language would not prevent the foreign IP-investor from advancing even more fanciful interpretations of what is "inconsistent" with the IP Chapter as evidenced by the *Eli Lilly v. Canada* investor complaint.

Possible meanings of indirect expropriation are addressed further in Annex 9-B, and clarify the imperative to protect investor expectations, by requiring a case-by-case, fact-based inquiry of the following subparagraph 3(a) factors:

> (i) the economic impact of the government action, although the fact that an action or series of actions by a Party has an adverse effect on the economic value of an investment, standing alone, does not establish that an indirect expropriation has occurred;
> (ii) the extent to which government action interferes with *distinct, reasonable investment-backed expectations*; and
> (iii) the character of the government action.[124]

Footnote 36 in Annex 9-B places some restrictions on which investment-backed expectations are reasonable, saying that the determination depends "on factors such as whether the government provided the investor with binding written assurances and the nature and extent of government regulation or the potential for government regulation in the relevant sector."[125] Subparagraph 3(b) also sets some loose boundaries on investor expectations: "Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, and the environment, do not constitute indirect expropriations, except in rare circumstances."[126] Although this public welfare exception and its public health clarification may be helpful, it is not an absolute privilege. Investors can claim: (1) that their cases are the rare ones where even non-discriminatory regulation

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[124] *Id.* (emphasis added).

[125] *Id.*

[126] *Id.* Footnote 37 in Annex 9-B further clarified that regulatory actions to protect public health "include, among others, such measures with respect to the regulation, pricing and supply of, and reimbursement for, pharmaceuticals (including biological products), diagnostics, vaccines, medical devices, gene therapies and technologies, health-related aids and appliances and blood and blood-related products."

constitutes indirect expropriation; (2) that the regulatory actions are discriminatory, e.g., targeted solely at or disproportionately applied to pharmaceutical investors; or (3) that the interests being protected are not legitimate. They can, of course, also claim that their IP rights have been violated.

To give concrete examples, if a compulsory license were granted on a medicine pursuant to the TRIPS/health solution,[127] would that be deemed confiscatory? Some commentators have suggested that compulsory licenses in general should be considered an expropriation, while others disagree,[128] but what if the compulsory license displeased the foreign patent holder's legal sensitivities in some regard? To use another example, if a compulsory licensing regime were to have a local working requirement—as is true in India and Brazil[129]—a foreign pharmaceutical investor might claim that this objective was a rare, challengeable circumstance, or evidence of discriminatory bias in favor of domestic firms, or that local working requirements violate TRIPS Article 27.1 by discriminating against imports. Likewise, if ostensibly neutral compulsory licensing rights were used more routinely to grant pharmaceutical-related licenses, as recently occurred in Indonesia with seven different hepatitis and antiretroviral medicines,[130] the pharmaceutical investor might claim field-of-technology "discrimination" in violation of Article 27.1. Finally, if the royalty rate did not adequately compensate for lost profits from a drug company's perspective, especially in comparison to the much higher absolute value of royalty rates in commercial transactions, the compulsory license might be deemed confiscatory.[131]

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[127] A special waiver was adopted by the WTO on August 6, 2003, providing for compulsory licenses permitting export/import of unlimited exportation of specified quantities of particular medicines when the importing country has insufficient manufacturing capacity to operationalize a domestic compulsory license. Baker, *supra* note 30. Although an amendment based on the Paragraph 6 waiver was proposed in 2005, Article 31bis, it has not yet been ratified by sufficient number of WTO members to become effective. I use this example because even though a compulsory license exception is proposed in the Investment Chapter it is not clear that Paragraph 6 System licenses would be judged to have been issued "in accordance with the TRIPS Agreement."

[128] *Compare* Peter B. Rutledge, *TRIPS and BITS: An Essay on Compulsory Licenses, Expropriation, and International Arbitration*, 13 N.C. J.L. & TECH. 149 (2012), *with* Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT'L L. REV. 357 (2010).

[129] India Patents Act, § 84(1)(c); Brazil Law No. 9.279, of May 14, 1996, Art. 68.

[130] Public Citizen, *Breaking News: Indonesia Licenses Patents for Seven HIV & Hepatitis B Medicines – Precedent-Setting Government Order has Extraordinary Lifesaving Potential* (2012), http://www.citizen.org/PC-statement-on-compulsory-licensing-in-Indonesia.

[131] For a discussion of royalty rates, *see* James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, WHO HEALTH ECONOMICS AND DRUGS TCM SERIES NO. 18 (2005), http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf.

Jones Day has practical advice for transnational drug companies with respect to such compulsory-license-based indirect expropriation claims:

> Because exclusivity is a central feature to an intellectual property asset like a patent, the grant of a compulsory license significantly devalues that asset, and thus arguably "ha[s] an effect equivalent to . . . [an] expropriation" under international law. In that situation, "compensation . . . shall be equivalent to the value of the expropriated . . . investment immediately before the date on which such expropriation . . . became publicly known." A nominal 6 percent royalty—which Bayer received as compensation for the Nexavar compulsory license—may arguably fall below this threshold and give rise to an actionable claim for indirect expropriation.[132]

Jones Day goes further and explains that the issuance of the Bayer compulsory license might also have denied Bayer effective means to protect its rights within the domestic legal system since it was not granted interlocutory injunctions against the production of generic medicines during the pendency of its appeals.[133]

B. FOREIGN INVESTORS' RIGHTS TO NATIONAL TREATMENT AND TO THE BENEFIT OF MOST FAVORED NATION TREATMENT FACILITATE IMAGINATIVE DISCRIMINATION CLAIMS

Article 9.4 contains the relevant definitions of National Treatment:

> 1. Each Party shall accord to investors of another Party *treatment no less favorable than that it accords, in like circumstances, to its own investors* with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments in its territory.
> 2. Each Party shall accord to covered investments *treatment no less favorable than that it accords, in like circumstances, to investments in its territory of its own investors* with respect to

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[132] Jones Day Commentary, *supra* note 119, at 3 (citations omitted). This claim by Jones Day is also far-fetched since compulsory licenses have been expressly authorized by international treaties, including the Paris Convention, since the late nineteenth century and compulsory licensing rules were enshrined in Indian law well before Bayer applied for its patent on Nexavar. Paris Convention, *supra* note 12, art. 5(a)(2).

[133] Jones Day Commentary, *supra* note 119.

> the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments. (Emphases added)[134]

In sum, national treatment prevents favoritism toward domestic investors compared to foreign investors. On this ground, as Jones Day argues, compulsory licenses granted to domestic companies,[135] especially pursuant to local manufacturing requirements, would violate national treatment as domestic generic firms would obtain investment advantages that the foreign originator firm lacks without a local manufacturing facility.[136] Similarly, the denial or invalidation of a patent owned by a foreign inventor might result in a national treatment discrimination claim if domestic inventors were allegedly being treated more favorably in similar circumstances.

Most-favored nation (MFN) treatment is defined in Article 9.5:

> 1. Each Party shall accord to investors of another Party treatment no less favorable than that it accords, in like circumstances, to investors of any other Party or of any non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments in its territory.
> 2. Each Party shall accord to covered investments treatment no less favorable than that it accords, in like circumstances, to investments in its territory of investors of any other Party or of any non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.
> 3. For greater certainty, the treatment referred to in this Article does not encompass international dispute resolution procedures or mechanisms such as those

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[134] Investment Chapter, *supra* note 10 (emphasis added).

[135] Granting compulsory licenses to local firms is completely lawful under Article 31 of the TRIPS Agreement, though it is also lawful to issue a compulsory license to a foreign company and to import the medicine. This importation strategy is easily pursued if there is no patent in the foreign country where the foreign licensee is located. If there is a patent, a compulsory license would have to be issued to the same manufacturer by the exporting country. *See* Brook K. Baker, *Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilize TRIPS Flexibilities in Non-Producing Countries*, U.K. DEPARTMENT FOR INTERNATIONAL DEVELOPMENT, HEALTH SYSTEMS RESOURCE CENTRE (Aug. 2004), *available at* http://www.iprsonline.org/resources/docs/Baker_TRIPS_Flex.pdf.

[136] Jones Day Commentary, *supra* note 119, at 3.

> included in Section B [referencing customary international law which arises from "a general and consistent practice of States that they follow from a sense of legal obligation"].[137]

MFN allows investors to expand their rights beyond those negotiated in a particular treaty by shopping for better investment rights in other international investment agreements or in other kinds of agreements incorporated by reference into the Investment Chapter or related provisions. Investors in the past have used MFN to seek better procedural treatment, expanded scope of protection, and stronger substantive rights. For example, one type of right that might be available are the so-called pre-establishment rights. These rights provide foreign investors with enforceable minimum guarantees of access to the market via removal of barriers to entry and a certain level of predictability, security, and transparency as to entry conditions. In other words, pre-establishment protections ensure that an investor can get its foot in the door.[138] This right is particularly important for foreign IP right holders who have a firm sense of entitlement once they have received a patent in a patent-friendly country like the U.S. For example, to support its claim for patent protection in India on Glivec, Novartis made much of the fact that Glivec had been patented by "40 other countries."[139]

C. THE IMPLICIT AND EXPLICIT INCLUSION OF IP RIGHTS AS PROTECTED INVESTMENTS IS DEEPLY PROBLEMATIC WITH RESPECT TO MEDICINES

The Article 9.1 definition of "investment" is broad enough to cover medicines-related intellectual property rights in that it only requires "*commitment of capital or other resources*, *the expectation of gain or profit*, or the assumption of risk."[140] Pharmaceutical inventions typically involve investment of capital or other resources during the research and development process. Similarly, by granting rights to exclude others, IPRs certainly create an expectation of gain or profit—indeed an expectation of monopoly rents. Accordingly, unless IP rights are expressly excluded from the investment chapter and from the definition of "investment," there is a risk that IPRs, which routinely require both commitments of capital and an expectation of profit, would be implicitly

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[137] Investment Chapter, *supra* note 10 (emphasis added).

[138] *See* ANDREW PAUL NEWCOMBE, LLUIS PARADELL, LAW AND PRACTICE OF INVESTMENT TREATIES: STANDARDS OF TREATMENT 137–39 (Kluwer Law Int'l, the Netherlands, 2009).

[139] FAQ on the Indian Glivec Patent Case, *available at* http://www.novartis.com/files/faq-on-the-indian-glivec-patent-case.pdf.

[140] Investment Chapter, *supra* note 10 (emphasis added).

covered. In this regard, it is also important to point out that the definition of covered "investors" covers pre-establishment rights that arise even before the foreign investment has been made.[141]

However, the Investment Chapter's definition of investment goes further to explicitly reference: "intellectual property rights."[142] Protecting any and all intellectual property rights is problematic in at least five ways, given uncertainty about the intended breadth of its coverage:

First, "intellectual property rights" will certainly be interpreted broadly to include all of the IPRs codified in the TRIPS Agreement, but the interpretation of certain flexibilities is contested. For example, Article 6 prohibits resort to interstate dispute settlement with respect to IP exhaustion rules, but it does not directly permit or authorize international exhaustion, otherwise known as parallel importation.[143] Accordingly, a disgruntled pharmaceutical company could very easily object to the importation and sale of a medicine it had sold more cheaply elsewhere claiming that parallel importation had violated its expectation of patent-based market segmentation and higher profits in certain markets. It would not make sense for a private arbitral panel to decide such a complex issue.

Secondly, not only might the vague and sometimes ambiguous language of TRIPS be interpreted expansively to justify an investor-state arbitral proceeding, but that same foreign IP investor might over-strenuously interpret the expanded IP rights conferred by the TPP itself.[144] For example, a Party might decide that it has a public-health flexibility—and a human rights need—to enact an exception to TPP-based data exclusivity rights in the event of the issuance of a TRIPS- or TPP-compliant compulsory license. The adversely affected "investor" might conclude that the express language of the TPPA IP chapter does not directly authorize such an exception and that the failure to pay total compensation as opposed to a mere royalty is an indirect expropriation.

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[141] *Id.* The definitions of investor of a party and investor of a non-Party in Article 9.1 both reference "an investor that attempts to make" an investment in a country. Footnote 12 clarifies:

> For greater certainty, the Parties understand that . . . an investor 'attempts to make' an investment when that investor has taken concrete action or actions to make an investment, such as channeling resources or capital in order to set up a business, or applying for a permit or license.

[142] *Id.*

[143] TRIPS Agreement, *supra* note 7, art. 6, "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

[144] This possibility has strong support in another section of the Investment Chapter, which creates an exception with respect to remedies for direct or indirect expropriation pertaining to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the IP Chapter. Investment Chapter, *supra* note 10, art. 9.7.5.

Alternatively, if the decision were adjudicatory, a failure to pay total compensation may be viewed as a violation of its reasonable expectations of absolute market exclusivity under Articles 18.50 or 18.52. This latter, minimum-standard-of-treatment claim would be strengthened since there is currently little international state practice enacting exceptions to data exclusivity. Once again, a U.S.-based foreign investor would not need to convince the USTR to file a WTO or TPPA state-to-state dispute—it could do so unilaterally. Moreover, it could bypass the Party's judicial procedures and jump straight into pro-industry arbitral proceedings. The company could safely assume that the revolving door justice of non-democratically selected arbitrators, who move seamlessly from representing IP rightholders, advising and representing governments, and donning the false cloak of arbitral neutrality, would prevail. Worse yet, the mere threat of such a lawsuit could deter Parties from adopting lawful public health measures permitted by TRIPS because of the prohibitive costs of arbitral hearings and the risk of excessive judgment awards should they lose.

Thirdly, a foreign pharmaceutical investor might simply rely on the TPPA-compliant law of the TPPA Party and claim that its investor rights had been infringed by an adverse decision on a pending IP claim. For example, despite the fact that the IP chapter requires countries to allow patents on new uses of existing medicines, a patent office might still conclude that a particular extension of an existing use lacks an inventive step. The pharmaceutical company could argue that the TPPA-compliant national law actually creates a presumption in favor of the patentability of all new uses, including expansions of existing uses, providing an expectation of profit from exclusive rights on an evergreening patent. Instead of challenging the denial of its secondary patent application in court, the company could bypass that step and immediately claim dilution of its putative—but not yet granted—IP rights and expectations of profit in investor-state arbitration.

Fourthly, there is a risk that a foreign IP rightholder might bring claims based on what it considers to be inadequate enforcement, e.g., the failure to criminally prosecute a trademark counterfeiter because of scarce prosecutorial and judicial resources or a failure to impose the level of damages that the IP rightholder proposes. Although the TRIPS Agreement mainly relies upon private enforcement—e.g., the creation of a procedurally fair judicial system for the private prosecution of IP infringement claims—the TPPA IP Chapter creates multiple new enforcement rights with respect to civil remedies, criminal sanctions, and border measures. Failure to provide fair and equitable treatment in "criminal, civil, or administrative adjudicatory proceedings in accordance with the principle of due process" constitutes an actionable minimum standard of

treatment violation.[145] Paradoxically, a government could face foreign investor claims for failure to unilaterally enforce what are fundamentally private rights—no longer could Parties use their TRIPS-compliant right not to prioritize publicly funded IP enforcement.[146] Note as well, the cumulative nature of IP-investors' rights: (1) rightholders can bring private claims based on longer, broader, and more readily attainable patent rights and on new data exclusivity rights and they can obtain enhanced damages, injunctions, and seizure orders; (2) they can pursue stronger party-initiated border measures that could include seizures of goods in transit and rely on *ex parte*, *sua sponte* border measures by customs officials and seek criminal enforcement of trademarks and copyrights; (3) when frustrated, they can lobby for state-to-state dispute resolution under the TPPA; and (4) they can now challenge the state directly with investor-state dispute resolution. Although IP right-holders already have unique and special enforcement rights under the TPP IP Chapter, they now receive even greater enforcement rights with investor-state arbitration.

Fifthly, there is a risk that an IP rightholder might bring a claim because of a governmental failure to intercept alleged infringing products in-transit[147] via stringent border measures. This too might be interpreted to violate the right to fair and equitable treatment in administrative border procedures. In the pharmaceutical context, drug companies have initiated seizures of medicines-in-transit on multiple occasions in Europe, not because they violated IP rights in the countries of origin or destination, but because they interfered with fictional patent and trademark rights in the transit country.[148] Contrary to what is required by TRIPS, TPPA border measures do not explicitly require that questions of infringement be considered from the perspective of the destination country.[149]

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[145] Investment Chapter, *supra* note 10, art. 9.6.2(a).

[146] *Id.* art. 41.5.

[147] The IP Chapter expressly covers goods in transit, Art. 18.76. Although the border measures rules do not directly cover patent or data rights, medicines can get caught up in border measures based on claims that they their names or markings are confusingly similar to a registered trademark. One such case involved the seizure of medicines bearing the international non-proprietary name amoxicillin, which German border agents considered to be confusingly similar to the brand name drug, Amoxil. *European Generic Drug Seizures Take Centre Stage at TRIPS Council Meeting*, 13 BRIDGES WKLY. TRADE NEWS DIG. 6, 6–7 (June 10, 2009), http://www.ictsd.org/bridg es-news/bridges/news/european-generic-drug-seizures-take-centre-stage-at-trips-council-meeting.

[148] *See* Request for Consultations by India, European Union – Seizure of Generic Drugs in Transit, WT/DS408 (May 11, 2011), http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm; Request for Consultations by Brazil, European Union – Seizure of Generic Drugs in Transit, WT/DS409, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm.

[149] Investment Chapters, *supra* note 10, art. 18.76.1.

D. THE COMPULSORY LICENSING AND BRACKETED PATENTING EXCEPTIONS IN THE INVESTMENT CHAPTER ARE INSUFFICIENT TO PROTECT PARTIES' LEGITIMATE INTERESTS TO ACCESS AFFORDABLE MEDICINES

Subparagraph 1(f) of Art. 9.10 prohibits a TPPA Party from imposing or enforcing any investment-related requirement or enforcing any investment-related commitment or undertaking "to transfer a particular technology, a production process, or other proprietary knowledge to a person in its territory."[150] This provision could arguably doom the right to issue compulsory or government use licenses. To partially remedy this problem, subparagraph 9.10.3(b)(i) eliminates this requirement where "a Party authorizes use of an intellectual property right in accordance with Articles 31 of the TRIPS Agreement, or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement."[151] Similarly, with respect to Article 9.8, which prohibits the expropriation or nationalization of a covered investment either directly or indirectly, subparagraph 5 excludes Investment Chapter remedies for the issuance of compulsory licenses granted pursuant to the TRIPS Agreement or with respect "to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter 18 (Intellectual Property) and the TRIPS Agreement."[152]

These provisions individually and collectively create a partial but incomplete safe haven for only some of the government action that is entirely lawful under TRIPS. For example, TRIPS Article 31, referenced in TPP Art. 9.10.3(b)(i) and Art. 9.8.5, covers only a portion of legally issued compulsory licenses under TRIPS. Specifically, the referenced TRIPS-compulsory licensing language does not directly reference the TRIPS/health solution.[153] Likewise, the Investment Chapter language on compulsory licensing does not permit the possibility of judicially authorized compulsory licenses such as those granted in the U.S. in *eBay Inc. v. MercExchange, L.L.C.*[154] and its progeny and in India in *F. Hoffman La-Roche v. Cipla Ltd.*[155] Such judicial licenses are directly authorized by Article 44.2 of the TRIPS Agreement.[156] Moreover, as discussed previously, Art. 9.8.5 does

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[150] *Id.* art. 9.10.

[151] LUKES VANHONNAKER, INTELLECTUAL PROPERTY RIGHTS AS FOREIGN DIRECT INVESTMENT RIGHTS: FROM COLLISION TO COLLABORATIONS 150 (Edward Elgar Publ'g 2015).

[152] *Id.* Note, there are additional exceptions for non-conforming performance requirement measures detailed in Article 9.10.

[153] *See supra* note 127.

[154] 547 U.S. 388, 393–97 (2006).

[155] 148 (2008) DLT 598 (N. Del. H.C.).

[156] TRIPS Agreement, *supra* note 7, art. 44.2:

not completely preclude challenges to other adverse IP-related decisions or policy changes.

E. THE LIMITATIONS ON PERFORMANCE REQUIREMENTS MIGHT INTERFERE WITH ENSURING REDUNDANT SOURCES OF MEDICINES AND LEGITIMATE TECHNOLOGY TRANSFER AND INDUSTRIAL DEVELOPMENT

Article 9.10.1(b), subject to certain exceptions, prohibits a Party from imposing requirements in order to achieve a given level or percentage of domestic content with respect to foreign investment rights.[157] Many countries have used such "performance" provisions in the past as a development strategy to expand their economies via local content rules and related technology transfer and local working rules. To similar effect, Article 9.10.1(h)(i) prohibits Parties from purchasing, using, or according preference to their own domestic technologies.[158] Most developed countries, including the U.S., achieved industrial development in part by fostering rules requiring local content, by favoring local industries, and by procuring and purchasing domestically. Now the U.S. is intent on kicking away the technology ladder and preventing countries from also developing industrial policy to grow their technological base and industrial capacity.[159]

The TRIPS Agreement has vague and largely unenforced obligations to ensure technology transfer to developing countries,[160] but some countries have taken matters into their own hands to try to preserve sovereign rights to promote technological advancement, particularly in important areas like pharmaceuticals. For example, both India and Brazil have local production/local working rules in their compulsory licensing schemes that

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> Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. *In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available* (emphasis added).

157 Investment Chapter, *supra* note 10.

158 *Id.*

159 *See* HA JOON CHANG, KICKING AWAY THE LADDER: DEVELOPMENT STRATEGY IN HISTORICAL PERSPECTIVE (London, Anthem Press 2003); Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space Not IP Shackles*, *in* INTERNATIONAL ECONOMIC LAW AND AFRICAN DEVELOPMENT (Laurence Boulle, Emmanuel T. Laryea & Franziska Sucker eds., 2014). *See* Suerie Moon, *Meaningful Technology Transfer to LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2*, ICTSD POLICY BRIEF NO. 9 (2011), http://ictsd.org/downloads/2011/05/technology-transfer-to-the-ldcs.pdf.

160 *See* TRIPS Agreement, *supra* note 7, arts. 7, 66.2.

authorize the grant of compulsory licenses when local working, other than by importation, is not achieved. The U.S. filed a WTO complaint against Brazil on this issue in 2001, but the complaint was voluntarily dismissed in accordance with a consultation compromise.[161] Although Brazil has never used the impugned local-working provision, India has recently granted its first statutory compulsory license based in part on Bayer's failure to produce any content locally.[162]

Preserving sovereign rights to maintain or develop local pharmaceutical capacity is critical to assured access to medicines, not only to industrialization. When a rightholder has exclusive rights to a single source of supply, there are frequently monopoly-based affordability problems, but there are also high risks of interrupted supply if manufacturing, capacity, or quality assurance problems occur.[163] Many countries choose to develop local pharmaceutical capacity precisely to ensure that they have locally managed sources of supply of essential life-saving medicines to supplement potentially fragile supplies available from limited number of producers on the global market.

V. THE *ELI LILLY* CASE:[164] A PHARMACEUTICAL INVESTOR-STATE CLAIM GONE WILD[165]

The hypothetical risks of investor-state claims in the pharmaceutical context have now materialized. On November 7, 2012, Eli Lilly filed a Notice of Intent to Submit a Claim to Arbitration for CND$100 million[166] against Canada due to

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[161] *See* Brazil-Measures Affecting Patent Protection, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (last visited Oct. 19, 2015).

[162] *Natco Pharma Ltd. v. Bayer Corp.*—Compulsory License Application No. 1 of 2011 (Controller of Patents, Mumbai), Mar. 9, 2012, http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf. Although on review the Intellectual Property Appellate Board slightly modified the local working standard adopted by the Comptroller of Patents, the local working rule still has vitality in India. *See* IPAB decision ¶¶ 50–53, http://www.ipabindia.in/Pdfs/Order-45-2013.pdf.

[163] The development of drug resistance due to poor antiretroviral adherence is a significant problem in areas where drug supply is often interrupted. *See* Nina Veenstra, Alan Whiteside, David Lalloo & Andrew Gibbs, *Unplanned antiretroviral treatment interruptions in southern Africa: how should we be managing these?*, 6 GLOBALIZATION & HEALTH 1–5 (2010), *available at* http://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-6-4.

[164] *See supra* note 6.

[165] *See* Public Citizen, *U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada's Patent Policy, Demand $100 Million for Invalidation of a Patent* (2013), https://www.citizen.org/eli-lilly-investor-state-factsheet.

[166] Notice of Intent, *supra* note 64, ¶ 108. Although *Eli Lilly v. Canada* is the first investor-state claim to be filed, there may be others in the works. For example, Eli Lilly, in its complaint, indicated its probable intention to sue make and investor-state claim if its patent on Zyprexa, an anti-schizophrenia drug, is invalidated. *Id.* ¶ 48. There are also rumors that Pfizer might be preparing an investor-state claim based on the invalidation of its patent on Viagra, a well-known erectile

the invalidation of its patent on pharmaceutical drug Strattera used to treat attention-deficit hyperactivity disorder (ADHD) ("the Strattera patent"). The patent was invalidated by the Canadian Federal Court on September 14, 2010, and Eli Lilly's appeal to the Federal Court of Appeal was unsuccessful. In reaching its invalidation decision, the Federal Court of Appeal addressed three issues—did the trial judge err (1) by invalidating the patent for lack of demonstrated utility by misconstruing its promise, (2) by requiring too high a standard of utility, and (3) by deciding that Eli Lilly could not rely on the sound prediction of utility of the invention because the limited and short term study that it relied on was not disclosed in the patent application and because it did not provide an adequate factual foundation of the sound prediction/promise of the patent?[167] The principle evidence weighed by the Federal Court of Appeal was the patent application itself and a twenty-one-person, three-week, double-blind placebo cross-over study that showed a 30% greater reduction of ADHD in eleven of twenty-one patients.[168] The Federal Court of Appeal ruled that this short-term study was erroneously not disclosed in the patent application.[169] Even if it had been disclosed, the study would have been insufficient to predict, as promised, that Strattera would be an effective long-term treatment of chronic attention deficit hyperactivity disorder.[170] In terms of the governing legal standard, the Federal Court of Appeal held that the utility of a patent is determined by the inventive promise made by the applicant either directly or by "sound prediction" and that such a promise or sound prediction must rest on disclosure made in the patent application itself.[171]

Eli Lilly submitted a second Notice of Intent to Submit a Claim to Arbitration to Canada on June 13, 2013,[172] adding a claim relating to its patent

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dysfunction medicine, for a failure to disclose the critical active pharmaceutical ingredient. *See* Luke Eric Peterson, *U.S. Pharma Corp Puts Canada on Notice of NAFTA Claim following Patent Invalidation at Hands of Canadian Court; More Such Claims in Wings?*, INVESTMENT ARBITRATION REPORTER (Dec. 3, 2012), http://www.iareporter.com/articles/20121203_2. There has previously been NAFTA claims against the U.S. by Apotex, Inc. with respect to its inability to have a 180-day exclusivity period as a first generic entrant, where another generic company had been the first to challenge the underlying patent but had settled with the patent holder. This case relates to intellectual property rights because it involves challenges thereto, but the technical rule on marketing exclusivity rights is contained in Food and Drug Administration statutes and regulations. *See* Apotex, Inc. v. United States of America, Case No. ARB(AF)/12/1 (ICSID 2012), http://italaw.com/cases/1687.

167 Eli Lilly Co. v. Teva Canada Ltd., 2011 FAC 220.

168 *Id.* ¶¶ 10–14.

169 *Id.* ¶¶ 46–47.

170 *Id.* ¶ 40.

171 *Id.* ¶¶ 49, 51.

172 Eli Lilly and Co. v. Gov't of Canada, Case No. UNCT/14/2, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven (Strattera and Zyprexa) (ICSID 2013), http://www.italaw.com/sites/default/files/case-documents/italaw1530.pdf.

on the antipsychotic drug Zyprexa, which is used to treat schizophrenia and related psychotic disorders ("the Zyprexa patent"). The Zyprexa patent was invalidated by the Canadian Federal Court on November 10, 2011 for its failure of sound prediction, and Eli Lilly's appeal to the Federal Court of Appeal was again unsuccessful. Eli Lilly's investor-state claim against Canada now concerns the invalidation of both the Strattera and the Zyprexa patents.

On September 12, 2013, Eli Lilly submitted its Notice of Arbitration,[173] setting out in detail its grievances against Canada, all of which fundamentally relate to Canada's application of its "promise" doctrine to invalidate Eli Lilly's previously granted patents. Eli Lilly pursues claims with respect to violations of minimum standards of treatment and expropriation making the following allegations against Canada:

> (a) Failure to meet its obligation under NAFTA Article 1709(1) to grant patents for inventions in all fields of technology that "are new, result from an inventive step and are capable of industrial application";[174]
> (b) Failure to meet its obligation under NAFTA Article 1709(7) to ensure that patent rights are enjoyable "without discrimination as to field of technology";[175]
> (c) Failure to meet its obligation under NAFTA Article 1701(1) to provide "adequate and effective protection and enforcement of intellectual property rights";[176]
> (d) Direct and indirect expropriation of Eli Lilly's intellectual property in the form of the patent rights conferred by the Strattera and Zyprexa patents, in violation of NAFTA Article 1110;[177] and
> (e) Violation of the minimum standard of treatment accorded to investors under NAFTA Article 1105.[178]

On September 29, 2014 Eli Lilly submitted a Claimant's Memorial containing further details of its grievances against the Canadian government. Several paragraphs of the Memorial are devoted to an explanation of the "low threshold" set by the traditional utility requirement, from which Canada's

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[173] Eli Lilly and Co. v. Gov't of Canada, Case No. UNCT/14/2, Notice of Arbitration (ICSID 2013), http://www.italaw.com/sites/default/files/case-documents/italaw1582.pdf.
[174] *Id.* ¶ 5.
[175] *Id.*
[176] *Id.*
[177] *Id.* ¶¶ 74–79.
[178] *Id.* ¶¶ 80–84.

"promise" doctrine represents a 'dramatic,' 'arbitrary,' and 'unpredictable' departure.[179] Utility, Eli Lilly claims, is "binary" and does not require an assessment of the degree of comparative utility.[180] It simply requires that an invention be "capable or susceptible of being put to a specific industrial use."[181] Furthermore, Lilly claims that Canada's utility requirement "bears no resemblance to the longstanding patent utility standards of its NAFTA partners, the United States and Mexico."[182]

The 'wrongful' nature of Canada's judicial decisions can be demonstrated, Lilly claims, by the fact that Zyprexa and Strattera have been successfully patented in eighty-one and thirty-six jurisdictions, respectively.[183] Canada is the "only jurisdiction in the world" that has invalidated these patents on the basis of inutility.[184] What Lilly fails to mention is that its Strattera patent was invalidated by the U.S. District Court of New Jersey one month prior to its invalidation by the Canadian Federal Court on the same grounds of inutility.[185]

Contrary to Eli Lilly' claim, the so-called "promise" doctrine is "a legal concept with deep historical roots and global reach."[186] The notion that patents contain promises of specific utility is found in many jurisdictions around the world (albeit under different labels and guises) and is essentially a method of purposive construction of patent claims.[187] The 'promise' made by a patent is the representation that the patented invention will achieve or avoid specific outcomes, for example, the treatment of a specific disease in a certain manner. The Canadian doctrine essentially requires the court to construe the patent's explicit or implicit promise(s) within the context of the patent as a whole through the eyes of a skilled reader, in relation to the science and information available at the time of filing.[188] Utility must be demonstrable at the date of filing; since it can only be predicted at this time, there must be a factual basis and line of reasoning that supports the soundness of this prediction.[189]

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[179] Eli Lilly and Co. v. Gov't of Canada, Case No. UNCT/14/2, Claimant's Memorial [hereinafter Claimant's Memorial] (ICSID 2014), ¶ 8, http://www.italaw.com/sites/default/files/case-documents/italaw4046.pdf.

[180] *Id.* ¶ 42.

[181] *Id.* ¶ 45.

[182] *Id.* ¶ 145.

[183] *Id.* ¶¶ 114–142.

[184] *Id.* ¶ 115.

[185] Eli Lilly and Co. v. Gov't of Canada, Case No. UNCT/14/2, Government of Canada Counter Memorial [hereinafter Counter Memorial] (ICSID 2015), ¶ 37, http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf. This District Court decision was, however, overturned on appeal.

[186] Gold & Shortt, *supra* note 99, at 37.

[187] *Id.*

[188] *Id.* at 42.

[189] Counter Memorial, *supra* note 185, ¶ 126.

In its Claimant's Memorial, Eli Lilly alleges that Canada has violated the following three obligations under NAFTA:

1. Chapter 17, which requires Canada to provide patents to inventions in all fields of technology without discrimination on the following grounds[190]:
   a. Both patents were invalidated despite meeting the criterion of "capable of industrial application" in Article 1709(1);
   b. The promise doctrine discriminates against pharmaceutical inventions, contrary to Article 1709(7);
   c. The patents were invalidated on a legal ground that did not exist at the time the patents were initially granted, contrary to Article 1709(8);
   d. The invalidation of the patents represents a failure by Canada to provide adequate and effective protection and enforcement of intellectual property rights, contrary to Article 1701(1).
2. Article 1105, which requires Canada to afford 'fair and equitable treatment' to Lilly's investments by failing to provide[191]:
   a. Protection against arbitrary treatment;
   b. Protection of legitimate, investment-backed expectations;
   c. Protection against discriminatory treatment.
3. Article 1110, which prohibits the direct or indirect expropriation of foreign investments except under certain conditions, none of which apply here[192]:
   a. The patents were not invalidated for a "public purpose";
   b. The promise doctrine was not applied on a "non-discriminatory basis";
   c. The expropriation did not occur in accordance with the minimum standard of treatment required by Article 1105(1).

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[190] Claimant's Memorial, *supra* note 179, ¶ 17.
[191] *Id.* ¶ 18.
[192] *Id.* ¶ 14.

These arguments (and Canada's response) will be explored further below.

A. ALLEGED VIOLATIONS OF CHAPTER 17

First, Eli Lilly claims that the phrase "capable of industrial application" within Article 1709(1) is "well understood in the patent context" and merely requires that "an invention have the *capacity* to be put to a specific use in industry."[193] Accordingly, Eli Lilly argues, "a good faith interpretation of 'capable of industrial application' and 'useful' in accordance with the ordinary meaning of those terms leads to a straightforward conclusion: an invention with the capacity to be put to specific use in industry meets the standard articulated in NAFTA Article 1709(1)."[194] Eli Lilly claims that this interpretation is supported by the subsequent practice of the NAFTA parties,[195] the Patent Cooperation Treaty (PCT),[196] and the TRIPS negotiations.[197]

In its Counter Memorial, Canada assembles eight experts and witnesses to support its defense against Eli Lilly. Each expert or witness statement invariably chastises Eli Lilly for its misstatements of U.S. and Mexican law, its misleading narrative of the 'harmonization' of international patent law and its history of speculative patent filing.[198] Canada describes Eli Lilly's summary of the U.S. utility standard as "simplistic, inaccurate, and [ignorant of] the complexities of the standard,"[199] particularly given that "U.S. law reaches many of the same results as do Canada's utility rules."[200] Moreover, "like Canadian law, United States law has evolved since NAFTA came into force, undermining any suggestion by [Lilly] that the Parties enshrined a particular standard in NAFTA."[201] Canada equally criticizes Eli Lilly's description of Mexican patent law as "flawed, self-serving and inaccurate,"[202] failing to acknowledge its distinct interpretation of "industrial applicability" and its substantial patent reform post-NAFTA.[203] Canada then provides a comprehensive history of WIPO, WTO and TRIPS negotiations to demonstrate that the "utility requirement continues to evade international consensus."[204] Finally, Canada argues that the PCT "is

193 *Id.* ¶ 189.
194 *Id.* ¶ 192.
195 *Id.* ¶ 196.
196 *Id.* ¶ 203.
197 *Id.* ¶¶ 205–206.
198 Counter Memorial, *supra* note 185, ¶ 20.
199 *Id.* ¶ 171.
200 *Id.* ¶ 11.
201 *Id.* ¶ 173.
202 *Id.* ¶ 176.
203 *Id.* ¶ 12.
204 *Id.* ¶ 196.

irrelevant, as it does not deal with substantive patent law issues at all."[205] It merely covers the basic requirements of "form and content" that must be met in order for PCT applications to be accepted and processed by national authorities.[206] Moreover, filing in accordance with the PCT is no guarantee that a patent application will produce a successful patent that will survive judicial review.[207]

Eli Lilly argues that NAFTA Chapter 17 "explicitly contemplates that a Party 'may implement in its domestic law *more* extensive protection of intellectual property rights than is required' under Chapter 17,"[208] but that Canada has "acted inconsistently with its obligations under Chapter 17" by providing less protection by means of creating an additional hurdle to patentability.[209] By invalidating patents despite "ample evidence" that the patented drugs had the capacity to be put to a specific industrial use,[210] Canada has "substantially redefined utility as contemplated by NAFTA," setting a dangerous precedent for the unilateral reinterpretation of 'internationally-accepted' meanings.[211]

Eli Lilly's second argument under Chapter 17 is that the promise doctrine represents *de facto* discrimination against the pharmaceutical sector, contrary to Article 1709(7). Although Canada's promise doctrine applies *prima facie* to all technical fields, Eli Lilly argues that, in practice, it has exclusively affected the pharmaceutical sector.[212] Eli Lilly claims that since 2005, inutility findings jumped from 0% to 40% for pharmaceutical patents, while inutility findings for non-pharmaceutical patents declined within the same period.[213] Eli Lilly even goes so far as to assert discrimination based on nationality, claiming that the impugned patents in all twenty-three inutility decisions were initially granted to pharmaceutical companies headquartered outside of Canada.[214] Canada rejects these allegations as "based upon a selective and misleading analysis of patent litigation outcomes."[215] Canada asserts that "[o]ut of hundreds of patent challenges in the 2005–2014 period, only three pharmaceutical patents have

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[205] *Id.* ¶¶ 13, 208.

[206] Eli Lilly and Co. v. The Gov't of Canada, Government of Canada Statement of Defence, Case No. UNCT/14/2 (ICSID 2014), June 30, 2014, ¶ 94, http://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf.

[207] *Id.*

[208] Claimant's Memorial, *supra* note 179, ¶ 185.

[209] *Id.*

[210] *Id.* ¶ 212.

[211] *Id.* ¶ 17.

[212] *Id.* ¶¶ 214–215.

[213] *Id.* ¶ 222.

[214] *Id.* ¶ 226.

[215] Counter Memorial, *supra* note 185, ¶ 135.

been invalidated on the sole basis of lack of 'utility,' two of which are [Lilly's patents] which are the subject of this arbitration."[216]

Thirdly, Eli Lilly claims that Article 1709(8) protects its patents from invalidation based on legal grounds (i.e., the promise doctrine) that did not exist at the time the patents were initially granted.[217] Canada rejects this argument, asserting that the promise doctrine is based on longstanding principles of Canadian patent law that existed prior to the initial grant of Eli Lilly's patents.[218] Furthermore, it has been a requirement of Canadian law since the 1970s that patent applications disclose a sound prediction of utility where utility cannot be demonstrated at the filing date.[219] Where a patentee relies upon a sound prediction of utility, the patentee must disclose the factual basis and line of reasoning that supports that prediction in order to distinguish a useful promise from a mere idea.[220]

Finally, Eli Lilly argues that Canada's invalidation of its patents constitutes a failure to provide adequate and effective protection of its intellectual property rights in violation of Article 1701(1).[221] In this regard, Eli Lilly mistakenly equates the protection of IPRs guaranteed by NAFTA with the imposition of specific, self-serving interpretations of substantive patent law on NAFTA parties. Contrary to this view, Canada claims that it provides full protection of IPRs through its domestic legal system, supported by full and fair judicial enforcement.[222]

B. ALLEGED VIOLATIONS OF ARTICLE 1105

Eli Lilly also claims that the invalidation of its patents violates "at least three well-established aspects of the Minimum Standard of Treatment," including protection against arbitrary treatment, protection of legitimate, investment-backed expectations, and protection against discriminatory treatment.[223] Eli Lilly alleges that the promise doctrine is arbitrary because it is "completely unpredictable and unreasonably difficult to satisfy."[224] It claims that inventors "have no way of knowing what 'promises' a Canadian court might subjectively find in the patent application" and patentees "have no way of knowing how

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216 *Id.* ¶ 8.
217 Claimant's Memorial, *supra* note 179, ¶ 228.
218 Counter Memorial, *supra* note 185, ¶ 394.
219 *Id.* ¶ 128.
220 *Id.* ¶ 126.
221 Claimant's Memorial, *supra* note 179, ¶ 234.
222 Counter Memorial, *supra* note 185, ¶ 401.
223 Claimant's Memorial, *supra* note 179, ¶¶ 257–260.
224 *Id.* ¶ 19.

much evidence the court will require to satisfy those promises."[225] According to Eli Lilly, "even successful, published, and statistically significant clinical trial results fail to satisfy the judges' standards of design, size, or duration."[226] Moreover, Eli Lilly claims that "Federal Courts often seek to construe the promise of the patent not from the patent claims that legally define the scope of invention, but from statements in the disclosure never intended to relate to utility."[227] This construction of promised utility, combined with the imposition of "heightened evidentiary burdens" and an additional disclosure rule for sound prediction of utility, combine to render the promise doctrine, in Eli Lilly's eyes, entirely arbitrary.[228] Eli Lilly adds, as a final insult, that the promise doctrine "leads to illogical and absurd results."[229]

In its defense, Canada argues that the construction of a patent's promise is neither "subjective" nor "arbitrary" but rather "a fair interpretation of the patent in accordance with the long established "purposive" and "informed" approach to patent construction.[230] This requires, first, construing the patent as a whole, "having regard to both the claims and the description in the patent specification; secondly, reading the patent from the perspective of a skilled reader . . . equipped with common general knowledge in the relevant field"; and finally, reading expert evidence on how a skilled reader would have understood the patent."[231] After applying these settled rules of interpretation, "if the court determines that a skilled reader would have understood the patent to contain a [specific] promise, then that is the promise to which the patent will be held."[232] Accordingly, patents are interpreted, not "subjectively," but rather according to the application of "ordinary and settled rules of construction."[233]

Furthermore, patents are not subject to a "heightened evidentiary" burden; rather, they "benefit from a presumption of validity," and if that validity is subsequently challenged, "the ordinary balance of probabilities test applies."[234] Judges do not arbitrarily concoct how much scientific evidence is required to show that a prediction of utility is sound; they assess, based on the evidence put forward by the parties, whether the skilled reader would have viewed the

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225 *Id.*
226 *Id.* ¶ 265.
227 *Id.* ¶ 65.
228 *Id.* ¶ 79.
229 *Id.* ¶ 258.
230 Counter Memorial, *supra* note 185, ¶ 101.
231 *Id.* ¶ 102.
232 *Id.* ¶ 103.
233 *Id.* ¶ 255.
234 *Id.* ¶ 257.

prediction as sound.[235] This is not 'arbitrariness'—this is, Canada claims, the essence of the adjudicative process.[236]

Eli Lilly's expectations that Canadian law would remain frozen in time from the date its patents were first granted were allegedly "reasonable" because it "could not reasonably have expected that Canada would promulgate such a unique and arbitrary doctrine—particularly one that violates Canada's international obligations."[237] When Eli Lilly initially patented Zyprexa and Strattera, it "legitimately expected that Canada's patent utility requirement would not be changed in an arbitrary and unreasonable manner."[238] There is no way it could have foreseen the erection of "new and unanticipated hurdles to patentability,"[239] which had "no basis in Canada's statutory patent law."[240]

Canada rejects these arguments, asserting that "evolution in the law is an inevitable feature of any legal system" and nothing in NAFTA prohibits the domestic law of Parties from evolving over time.[241] Moreover, Eli Lilly's patents were invalidated on the basis of "longstanding, rational, and fair rules of Canadian patent law that have not changed since [Lilly] filed its patents."[242] To support its argument, Canada refers to the leading Canadian case on the law of utility—*Consolboard v MacMillan Bloedel (Sask.) Ltd.* (1981)—and Justice Dickson's remarks that a patent is "not useful" if it "will not do what the specification promises that it will do."[243] Canada argues that the promise doctrine was recognized as "an integral part of Canadian law by the Supreme Court of Canada long before [Lilly] filed its patent applications."[244]

Eli Lilly further claims that its legitimate expectations were rooted in Canada's international commitments under NAFTA and the PCT.[245] The promise doctrine's "dramatic and internationally wrongful departure" from such international commitments was "outside the 'acceptable margin of change' that investors must reasonably anticipate."[246] Eli Lilly also claims that its legitimate expectations stemmed from the initial grant of the Zyprexa and Strattera patents.[247] These patents, Eli Lilly explains, were "*more* than a mere

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235 *Id.* ¶ 258.
236 *Id.*
237 Claimant's Memorial, *supra* note 179, ¶ 20.
238 *Id.* ¶ 259.
239 *Id.* ¶ 36.
240 *Id.* ¶ 279.
241 Counter Memorial, *supra* note 185, ¶ 81.
242 *Id.* ¶ 83.
243 *Id.* ¶ 92.
244 *Id.* ¶ 93.
245 Claimant's Memorial, *supra* note 179, ¶ 272.
246 *Id.* ¶ 279.
247 *Id.* ¶ 286.

representation to Lilly from the government of Canada; they were a bundle of legally enforceable rights."[248] In response, Canada reminds Eli Lilly that

> every inventor seeking a patent in Canada is well aware (because the *Patent Act* makes this clear) that the decision of the Patent Office to grant a patent is always subject to review by the Federal Court for actual compliance with the *Patent Act*. No reasonable patentee expects the grant of a patent . . . to be unassailable.[249]

Furthermore, Eli Lilly could not "reasonably expect Canadian courts to ignore longstanding principles and rules of Canadian law, whether or not [Lilly] itself was properly advised in this regard."[250] Eli Lilly could not have legitimately expected that "latently defective patents would be enforced when challenged."[251]

Canada highlights three fatal flaws in Eli Lilly's argument that its legitimate expectations require protection under Article 1105. First, Eli Lilly failed to show that the theory of legitimate expectations is a rule of customary international law protected by Article 1105(1).[252] Secondly, the doctrine of legitimate expectations cannot be applied to judgments of domestic courts interpreting domestic law.[253] Thirdly, Eli Lilly could not have reasonably held the expectations it claims; Canada's rules on utility are long-standing and the grant of a patent is always subject to reassessment by the courts for compliance with Canadian law.[254] To accept Eli Lilly's arguments here would be to offer every disappointed litigant an international remedy for any domestic ruling it had expected to win.[255]

Furthermore, notwithstanding Eli Lilly's earnest claims to the contrary, "nothing in the record even remotely resembles the type of egregious behaviour which past NAFTA tribunals have said must be evident in order to breach Article 1105(1)."[256] NAFTA jurisprudence clearly shows that "a violation of Article 1105(1) will not be found unless there is evidence of serious malfeasance, manifestly arbitrary behaviour or denial of justice by the respondent NAFTA Party."[257] Eli Lilly did not suffer from "lack of due

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248 *Id.*
249 Counter Memorial, *supra* note 185, ¶ 6.
250 *Id.* ¶ 16.
251 *Id.* ¶ 219.
252 *Id.* ¶ 266.
253 *Id.*
254 *Id.*
255 *Id.*
256 *Id.* ¶ 15.
257 *Id.* ¶ 227.

process, procedural irregularities, political interference, lack of impartiality, pretence of form or bad faith or anything else which could offend judicial propriety."[258]

The only basis upon which an international tribunal could impugn the judgment of a domestic court interpreting domestic law as a violation of international law would be a denial of justice—which is not the case here.[259] Eli Lilly was afforded "full opportunity to plead its case" and the Court reached rational decisions based on extensive factual and expert evidence and "issued reasoned judgments relying on long-standing precedent and principles of Canadian patent law."[260] In total, nine different Canadian judges were involved in the Strattera and Zyprexa patent cases before the final invalidation decisions were reached.[261] The cases were decided "reasonably and in good faith on the basis of evidence adduced by the Parties in an **open** adversarial proceeding," in stark contrast to the private, unappealable tribunal decision which Lilly now seeks.[262]

Canada claims that the doctrine of "legitimate expectations" is "fundamentally [inapplicable to] judgments of the domestic judiciary acting in an adjudicative function of domestic statutory interpretation."[263] Eli Lilly "has not identified a single instance of an international tribunal finding a violation of an investor's 'legitimate expectations' based solely on the outcome of a domestic court's interpretation or application of domestic law."[264]

Henning Gross Ruse-Khan agrees that Eli Lilly's purported expansion of the theory of legitimate expectations is unreasonable and unsustainable in this context. Ruse-Khan argues that intellectual property rights such as patents cannot provide the right holder with "a legitimate expectation that measures interfering with the use of these rights in the host state will not occur."[265] A

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[258] *Id.* ¶ 246.
[259] *Id.* ¶ 230.
[260] *Id.* ¶ 214.
[261] *Id.* ¶ 21.
[262] *Id.* ¶ 100 (emphasis added).
[263] *Id.* ¶ 266.
[264] *Id.* ¶ 218.
[265] Henning Grosse Ruse-Kahn, *Litigating Intellectual Property Rights in Investor State Arbitration: From Plain Packaging to Patent Revocation* 27 (Univ. of Cambridge Faculty of Legal Studies Research Paper Series, Paper No. 52/2014, 27, 2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711##. Several scholars have already offered critiques of Eli Lilly's IP-related ISDS claims. *See*, *e.g.*, Ruth L. Okediji, *Is Intellectual Property "Investment"?* Eli Lilly v. Canada *and the International Intellectual Property System*, 35 U. PA. J. INT'L L. 1121 (2014) (arguing that IPRs should not automatically be considered investments for ISDS purposes and that when they are ISDS claims can be highly disruptive of the desired policy space needed for rational IP systems); Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH. L.J. 213 (2015) (arguing that IPR invalidations should not be and are not

patent is a domestic statutory creation, granted upon the fulfillment of certain conditions. If one of those conditions is not met, the grant can be revoked as easily as it was given. Ruse-Khan summarizes his position as follows:

> In all cases, the grant of the patent certainly does not and cannot create any legitimate expectation that the exclusivity it confers is absolute and will remain without interference from accepted checks and balances inherent in the IP system. Instead, the expectations of the patent holding investor are *a priori* limited by the regulatory tools the domestic IP law of the host state foresees. Even in case a host state newly introduces such tools, or changes its policy of using existing ones after the investor has obtained his patent, the general acceptance and widespread state practice vis-a-vis these measures would strongly side against findings of interference with legitimate expectations. In *Eli Lilly vs. Canada*, the investor hence cannot legitimately expect from the grant of patents by the Canadian Patent Office (CPO) that those remain free from any validity challenges in the courts. Also a change in how the Canadian courts apply patentability standards such as utility or the disclosure obligation as such does not affect legitimate investor expectations: No expectation for a stable and predictable business environment can go so far that the circumstances prevailing at the time the investment is made must remain unchanged. Any resort to familiar and commonly used mechanisms to limit IP exclusivity . . . should never be considered as a breach of [fair and equitable treatment standards].[266]

Furthermore, Ruse-Khan argues that the negative, rather than positive, character of IP rights—which allow the right holder to prevent others from utilizing the protected subject matter but do not confer a positive right to exploit that matter—naturally permits national governments to impose further

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covered by investment chapter rules and that Eli Lilly had no legitimate expectation that common law interpretation of Canada's patent law might not change). *See generally* Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property* (NYU School of Law Pub. Law & Legal Theory Research Paper Series, Working Paper No. 14-53, 2014) (arguing that assetization of IPRs is highly disruptive of the multiple public policy considerations animating well-tailored and well-balanced IP regimes and that investor-state dispute settlement of unfettered IP-related investment claims could further undermine the IP public policy balance).

[266] Ruse-Kahn, *supra* note 265, at 27.

limitations on the use of the protected subject matter, in the form of regulatory controls.[267] As Ruse-Khan concludes:

> [T]he negative right to exclude others from exploiting IP-protected subject matter does not entail a guarantee against state intervention which imposes conditions upon the production or limits the use and sale of the patented product. For example, the introduction of price controls for a certain patented medication does not interfere with the patent for that medicine. Since such a measure is outside the protection IP rights confer, these rights cannot create legitimate expectations as to the (continued) absence of such measures.[268]

In relation to Eli Lilly's allegation of discriminatory treatment, Canada dusts off this argument with three swift strokes. First, Article 1105 "protects against unjustifiable discriminatory treatment in court proceedings founded on the investor's foreign nationality, not mere differential treatment. In order to challenge the judgment of a domestic court, [Lilly] would have to demonstrate that 'it was the victim of discrimination on account of its nationality.' "[269] Secondly, all patent applicants, Canadian and foreign alike, across all industries, are held to the same standard of promised utility. Even if it were true that more pharmaceutical patents have been invalidated than in other industries, this is "symptomatic of the litigiousness of the pharmaceutical industry, not the discriminatory effect of Canadian law."[270] Finally, contrary to the misleading statistics peddled by Eli Lilly, there have only been three patent invalidations based solely on inutility, two of which were the Strattera and Zyprexa patents disputed here.[271]

C. ALLEGED EXPROPRIATION OF ELI LILLY'S INVESTMENTS

To argue that the invalidation of its patents constitutes both direct and indirect expropriation under Article 1110, Eli Lilly relies upon what it calls the classic definition of direct expropriation as the "open, deliberate, and acknowledged takings of property."[272] It argues that regardless of whether the expropriation is deemed to be direct or indirect, it must be compensable, as it

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[267] *Id.* at 27–29.
[268] *Id.* at 28.
[269] Counter Memorial, *supra* note 185, ¶ 262.
[270] *Id.* ¶ 263.
[271] *Id.* ¶ 264.
[272] Claimant's Memorial, *supra* note 179, ¶ 239.

does not fall within the exception provided by Article 1110(7).[273] Consequently, the expropriation violates NAFTA Chapter 17,[274] and arbitrarily conflicts with Eli Lilly's reasonable investment-backed expectations.[275]

Eli Lilly then outlines why Canada's expropriation of its investments does not fall within any permissible exceptions: (a) the expropriation was discriminatory as it treated pharmaceutical patents less favorably than patents in other fields of technology;[276] (b) the expropriation lacked a public purpose because it "serves no rational policy";[277] and (c) the expropriation was not carried out in accordance with Article 1105(1) because it did not accord fair and equitable treatment and full protection and security to Eli Lilly's investments.[278]

Far from serving no rational policy, Canada's promise doctrine is designed "to ensure that patentees provide the consideration they promised in exchange for the grant of a 20-year monopoly . . . to ensure that patents are filed on the basis of true invention, rather than of speculation."[279] Moreover, Eli Lilly's tendency to file numerous patent applications with little or no basis for the alleged new uses suggests a desire to monopolize areas of research and innovation, thereby demonstrating the importance of rigorous Canadian patent laws.[280] Between 1992 and 2004, Lilly filed patent applications claiming twelve alleged new uses of atomoxetine (Strattera) in the treatment of psoriasis, stuttering, incontinence, hot flashes, anxiety, learning disabilities, cognitive failure, conduct disorder, tic disorders, oppositional defiant disorder, pervasive development disorder and ADHD, with only half of these applications actually referring to experimental data.[281] Similarly excessive patent applications were filed (and later abandoned) for olanzapine (Zyprexa).[282] Eli Lilly's history of speculative patenting effectively created a "thicket" of low-quality patent applications, which were later abandoned—precisely the kind of behavior which Canadian patent law is designed to prevent.[283]

Eli Lilly claims that the invalidation of its patents has "deprived [its] investments of substantially all value."[284] The loss of patent protection for Zyprexa and Strattera allegedly allowed Lilly's competitors to enter the market

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[273] *Id.* ¶ 241.
[274] *Id.* ¶ 242.
[275] *Id.* ¶ 243.
[276] *Id.* ¶ 248.
[277] *Id.* ¶ 249.
[278] *Id.* ¶ 251.
[279] Counter Memorial, *supra* note 185, ¶ 7.
[280] *Id.* ¶ 9.
[281] *Id.* ¶¶ 153–154.
[282] *Id.* ¶ 155.
[283] *Id.* ¶ 164.
[284] Claimant's Memorial, *supra* note 179, ¶ 14.

and sell copies of the drugs, and Eli Lilly could no longer enforce its patent rights against infringers.[285] On the contrary, Canada claims, the assessment of whether a substantial deprivation has occurred requires a consideration of the investor's enterprise as a whole.[286] Strattera and Zyprexa form

> just one part of [Lilly's] overall enterprise in Canada, which continues to grow and enjoys substantial profits in numerous lines of business. Nor did the measures prevent [Lilly] from continuing to produce and sell its atomoxetine and olanzapine based products. It still holds a valid [Notice of Compliance] permitting it to sell these products . . . at considerable profit.[287]

One might reasonably note that Eli Lilly in fact collected years of unwarranted supra-competitive prices on the basis of patent claims later found to be invalid. One might also reasonably note that both patents were nearing the end of their patent terms when invalidated.

Eli Lilly claims that its argument is supported by past precedent, where "tribunals have concluded that judicial measures qualify as indirect expropriations when they result in a substantial deprivation and violate a rule of international law."[288] In this case, Eli Lilly claims that the revocation of its patents violated international law by failing to provide the adequate and effective protection of IPRs demanded by NAFTA Chapter 17.[289]

Canada sweeps away Eli Lilly's claims with three clean brushstrokes. First, there cannot be an 'expropriation' of property when no property rights exist at all. There is no inherent right to a patent at common law; it is an entirely statutory creation and as it lives by the pen, so it dies. "When a domestic court has determined through the good faith application of domestic law that a property right is invalid . . . there is no 'taking' of a property right which did not properly exist in the first place."[290] The judicial invalidation of a patent cannot constitute expropriation as there is no transfer of property but simply a recognition that no property exists.[291] Accordingly, Eli Lilly's patents were not property interests capable of expropriation under Article 1110(1) because they were not valid property interests at all.[292]

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[285] *Id.* ¶ 21.
[286] Counter Memorial, *supra* note 185, ¶ 410.
[287] *Id.* ¶ 411.
[288] Claimant's Memorial, *supra* note 179, ¶ 180.
[289] *Id.* ¶ 185.
[290] Counter Memorial, *supra* note 185, ¶ 17.
[291] *Id.* ¶ 19.
[292] *Id.* ¶ 303.

Secondly, Canada is protected by Article 1110(7) which provides that a revocation of an IPR cannot engage Article 1110(1) if it is consistent with NAFTA Chapter 17.[293] Canada argues that it is plainly compliant with Chapter 17.[294] Canada's *Patent Act* provides that a patent may be available for any invention that is "useful,"[295] and the criterion of utility is applied without distinction as to field of technology.[296] Moreover, the absence of any fixed international meaning of the term "utility" or the phrase "capable of industrial application" is evident from the text of NAFTA itself and "confirmed by the divergent practice of the Parties post NAFTA."[297] Thirdly, Eli Lilly's expropriation claim fails to meet the three-step test for expropriation under customary international law because an invalid patent is not a property interest capable of expropriation.[298] In light of these arguments, Canada refutes Eli Lilly's allegations that its *bona fide* judicial determination of rights at domestic law constituted direct or indirect expropriation.[299]

Eli Lilly makes an expropriation claim despite a provision in NAFTA that is essentially identical to the TPPA Investment Chapter clause supposedly creating a safe haven for compulsory licenses and for patenting decisions. The relevant NAFTA provision, Article 1110(7), reads as follows: "This Article [Expropriation and Compensation] does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property)."[300] The arguments raised by Eli Lilly in this dispute demonstrate the potential ineffectiveness of such clauses that ostensibly shelter FTA-compliant patent revocations from expropriation claims.

From a policy perspective, allowing Eli Lilly to succeed on such far-fetched arguments would turn investor-state arbitration tribunals into supranational courts of appeal. As Canada adeptly warns,

> If a domestic court's adjudication of property rights can be transformed into an expropriation by alleged inconsistency with any of these other international law obligations, then NAFTA

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293 *Id.* ¶ 305.
294 *Id.*
295 *Id.* ¶ 350.
296 *Id.* ¶ 384.
297 *Id.* ¶¶ 305, 364.
298 *Id.* ¶ 310.
299 *Id.* ¶ 306.
300 North Atlantic Free Trade Agreement, U.S.-Can.-Mex., art. 110(7), Dec. 17, 1992, 32 I.L.M. 289 (1993); *cf.* Investment Chapter, *supra* note 10, art. 9.8.5.

> Chapter Eleven tribunals will be transformed both into tribunals with plenary jurisdiction over all international treaties and supranational courts of appeal in domestic property law issues.[301]

Canada concludes by criticizing Lilly's attempts

> to substitute Canadian patent policy and requirements for an alternative, detailed set of rules of its own making. [Lilly's] rules would promote the granting of patent monopolies on the basis of speculation, in a manner dissuading innovation, and with the public receiving only misleading and incomplete disclosure in return. These are not the rules set out by Canada's legislature in the *Patent Act*.[302]

Eli Lilly v. Canada sets a dangerous precedent for pharmaceutical corporations to attack foreign governments for differences between foreign standards of patentability and the standards enjoyed by pharmaceutical corporations in their home countries. As Eli Lilly was seeking additional patents on already-patented compounds, it needed to prove the superiority of its own drugs over other members of the patented class. In this regard, Canadian law is designed to prevent experimental over-patenting that would pre-emptively fence off areas of research on the basis of speculation.[303] Canada is entitled to design domestic patentability standards to prevent abuses of the patent system. However Eli Lilly is seeking to elevate its own competing views of how Canadian patent law ought to apply, into legally-enforceable expectations.[304] Such an unprecedented incursion on national sovereignty will continue to occur as long as investor-state dispute settlement provisions are included within international treaties. While Canada possesses the financial capacity to defend itself against such attacks, developing countries may not.

VI. CONCLUSION: STRIKE THE INVESTMENT CHAPTER OR OTHERWISE LIMIT ITS APPLICATION TO IPRS

Under the logic of Eli Lilly's investor-state claim, foreign investors' IP-based expectations have now become unbound. Even the doctrine of legitimate expectations, which is itself a huge stretch of operative minimum standards of treatment principles, is no longer tethered to operative due process (minimum

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[301] Counter Memorial, *supra* note 185, ¶ 334.
[302] *Id.* ¶ 419.
[303] *Id.* ¶ 7.
[304] *Id.* ¶ 2.

standards of treatment) or to promises of regulatory coherence (indirect expropriation) or to equal treatment compared to domestic firms (national treatment). Instead Eli Lilly hitches its investment expectations to the best deal on IP achieved anywhere else in a cross-referenced investment agreement. Moreover, it suggests that its expectations can go in only one direction—upward. Any reversal, modification, or rebalancing[305] of existing IP protections would dilute the gleam in its eye—unlimited profits on the horizon—and justify a full compensatory damage assessment in its favor.

The practical implications of this radical assertion of investor privilege is two-fold. First, foreign IP investors, mainly from rich countries, could now directly sue virtually any government, rich or poor, to enforce any and all directly or indirectly incorporated IP-related treaties or the highest standard of comparable national IP law found anywhere in the world. These investor prerogatives sit on top of state-to-state dispute resolution mechanisms under TRIPS and other trade agreements. They sit on top of more stringent border and criminal enforcement measures that consume state resources. They sit on top of state-state investment clause dispute resolution. Finally they sit on top of new deterrent civil remedies, mandatory injunction rights and draconian damages. In other words, IP rightholders' enforcement options are now unbound.

Secondly, a tribunal of three private international trade lawyers will now sit as an ad hoc subcommittee with power to review and veto every sovereign decision affecting the intellectual property rights of Big Pharma. Rejecting an IP-related trade pact, such as, the U.S.-SACU FTA,[306] refusing to join an IP enforcement treaty such as the Anti-Counterfeiting Trade Agreement,[307] tightening up patentability standards through legislative, administrative, or

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[305] Dreyfuss & Frankel, *supra* note 265, at 3 ("[I]nvestment rationales are largely impervious to flexibility and balancing."); Okediji, *supra* note 265, at 1122–23.

> Lilly's arguments amount to a claim that, in agreeing to an in- vestment treaty, a government takes on an affirmative obligation to constrain the evolution of national legal standards, or to limit the public policy that fuels such evolution to the equilibrium that existed at the time the treaty was signed. Such a backwards-looking approach suggests a rigidity not contemplated in the international intellectual property framework and that, uncurbed, would undermine the capacity of intellectual property law and policy to respond to dynamic shifts in the national or global technological frontier.

[306] *See* Drusilla K. Brown, Kozo Kiyota & Robert M. Stern, *An Analysis of the U.S.-SACU FTA Negotiations* (IPC Working Paper Series No. 17, 2006), *available at* http://deepblue.lib.umich.edu/handle/2007.42/41235.

[307] The Anti-Counterfeiting Trade Agreement (ACTA) was rejected by the European Parliament on 4 July 2012. *See* European Parliament rejects ACTA, EUROPEAN PARLIAMENT (Apr. 7, 2012), *available at* http://www.europarl.europa.eu/news/en/news-room/content/20120703IPR48247/html/European-Parliament-rejects-ACTA.

judicial action,[308] instituting new opposition procedures,[309] rejecting patent term extensions,[310] granting compulsory licenses,[311] denying data exclusivity or patent-registration linkage[312] or shortening data and marketing exclusivity on biologics,[313] creating a new bio-similars pathway,[314] requiring disclosure of clinical trial data,[315] or allowing parallel importation of medicines as the U.S. Supreme Court did with textbooks[316]—all of the aforementioned could potentially result in an investor suit and an unappealable arbitral decision. In other words, foreign IP rightholders' ability to oversee and set national IP policy is also now unbound. Although this Article focuses on IP-related investment claims, it is worth noting that pharmaceutical-related investor-state dispute settlement claims could also be brought with respect to drug regulatory decisions affecting marketing approvals,[317] required warnings, inspections, and with respect to adverse decisions or due process defects affecting the listing of a medicine for reimbursement.[318]

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[308] Moeller IP Advisors, *Non-patentable subject matter according to the New Guidelines of the Argentine PTO*, http://www.moellerip.com/non-patentable-subjectmatter-according-to-the-new-guidelines-of-the-argentine-PTO. Ho argues that investment claims might be brought against patent standards designed to prevent evergreening as in India.

[309] The 2011 America Invents Act radically revises the U.S. system of post-grant patent review by providing four new post-grant opposition proceedings in addition to existing ex parte reexamination. *See* 35 U.S.C. §§ 312–313 (2015).

[310] India is reported to have rejected patent term extensions in its free trade agreement negotiations with the European Union. *See* James Love, *Negotiating Text, EU/India FTA*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 28, 2013), http://keionline.org/node/1691.

[311] India, Brazil, Thailand, Indonesia, Ecuador, and many others countries have granted compulsory licenses on medicines, including several European countries. *See* Reed Beall & Randall Kyhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MEDICINE e1001154 (2012), *available at* http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154. For a statement of concern about the possible invalidation of compulsory licenses in India through use of investment challenges, *see* Prabhas Ranjan, *Medical Patents and Expropriation in International Investment Law – with Special Reference to India*, 5 MANCHESTER J. INT'L ECON. L. 72 (2008); for a critical view of investment claims relating to compulsory licenses, *see* Gibson, *supra* note 128; Ho, *supra* note 265, at 64–67; for a favorable view, see Rutledge, *supra* note 128.

[312] Ho, *supra* note 265, at 67–71.

[313] *See* Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 262(k)(7).

[314] At the end of March 2010, the United States enacted the Biologics Price Competition and Innovation Act (BPCI), the long-awaited U.S. pathway to biosimilars, though operation of this pathway is still dependent on regulatory action by the FDA. 42 U.S.C. § 262(k). Europe has had an established pathway for biosimilars since 2005. European Medicines Authority Committee for Medicinal Products for Human Use, CHMP/437/04 London, 30 October 2005.

[315] Ho, *supra* note 265, at 289–91.

[316] *See* Kirtsaeng v. John Wiley & Sons, Inc., 133 S. Ct. 1351 (2013).

[317] Ho, *supra* note 265, at 222.

[318] Such claims might specifically be grounded on the TPPA Transparency Chapter.

Unbounded intellectual property rights are oxymoronic given that they are purely and completely based on allowance and recognition by governments. Although IP right holders like to elevate their exclusive rights into the realm of natural law, IPRs are most commonly recognized as instrumental rights that balance incentives for innovation, investment in quality, and creativity against access and in some instances disclosure, as is the case for patent rights.[319] As creatures of legislative and judicial balancing, IPRs are granted and modified according to changing social circumstances and emergent technologies. Subject only to superseding international, bilateral, or regional trade agreements or relevant constitutional protections, they can be strengthened or weakened, lengthened or shortened, and broadened or narrowed by policy changes, limitations, and exceptions. To argue that they set forth a stable, durable set of entitlements that can only be strengthened is naïve at best and duplicitous at worst. "Since innovators should know that the legal rules may change while they are engaged in research, during the registration process, or even later, it is difficult to see how a law that meets the standards required by international IP obligations can amount to an expropriation."[320] It would be equally disinformational for drug companies to claim that compulsory licenses are confiscatory, since government rights to issue compulsory licenses have been codified in the Paris Convention for nearly 130 years[321] and the governments that have issued compulsory licenses or government use orders on medicines have had rights to do so enshrined in their national legislation for decades. Similarly, it would be disingenuous to claim a violation of a minimum standard of treatment or of national treatment simply due to dissatisfaction with a particular country's standard of patentability.

There are many reasons to renegotiate or even strike the TPPA Investment Chapter, as it would dramatically increase corporate power at the same time that it restricts government sovereignty to regulate foreign and domestic business activities and enforce IP-related claims on an even-handed basis in domestic forums. However, too little attention has been given to the grave risks that the Investment Chapter poses to access to medicines.[322] Big Pharma has had a big

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[319] Dreyfuss & Frankel, *supra* note 265.

[320] *Id.* at 35. The concept of legitimate expectations has not generally been interpreted to allow arbitral compensation based on the unfreezing of relevant legal frameworks. Michele Potesta, *Legitimate Expectation in Investment Treaty Law: Understanding the Roots and Limits of a Controversial Concept*, 28 ICSID REV. 88, 98–121 (2013).

[321] Paris Convention, *supra* note 12, art. 5(A)(2).

[322] Of course, the dangers are not limited to access to medicines. There have already been multiple foreign investor challenges to public health measures such as tobacco control and environmental toxins and degradation. But, conceivably there are foreign investor risks with respect to tightening labor standards, to adopting minimum wages, to enacting climate control regulations, to seeking access to green technologies, to sourcing educational materials and

hand in the U.S.'s IP Chapter and Investment Chapter proposals. Negotiating parties should refuse to ratify both TRIPS-plus IP standards and enforcement measures and substantive investment clause provisions and investor-state dispute resolution that will needlessly tie their hands in safeguarding the health of their people. Accordingly, the best solution with respect to IP-specific investment claims, and the broader risks of investor-state claims altogether, is to delete the Investment Chapter entirely. There is no compelling reason why foreign investors should have rights that are not available to domestic investors or why investments should receive special substantive and enforcement protections that are not available to other forms of trade in goods and services.[323]

The second-best solution to the risk of dangerous investor-state arbitral proceedings is to rewrite the Investment Chapter to explicitly exclude IPRs and to clarify that IPRs are not even indirectly protected by the definition of "investment."[324] This solution could best be accomplished by an addition to Art. 18.3: "4. This Chapter does not apply with respect to the enforcement of any rights conferred pursuant to Chapter 18 (Intellectual Property) or any other intellectual property rights contained in any other trade agreement, international treaty, or national legislation of any other country."

Either of these solutions would force foreign IP rightholders to assert their domestically derived IP-related claims in domestic courts, just as domestic IP companies must do. By excluding investor-state IPR claims, Parties could maintain sovereign control over the determination of IP standards and the adjudication of IP rights, retain freedom to develop their own IP jurisprudence, and relegate rightholders to pursue their claims in national courts alleging adjudicative and administrative improprieties, confiscatory measures, or other government wrongdoing. There would also be supplemental protection pursuant to state-to-state dispute resolution with respect to alleged violations of intellectual property norms established in the TPPA.

The third-best solution is to adopt language that would allow investor claims only with respect to IP rights actually granted and judicially affirmed by the Party under its existing IP laws and hope that the far-fetched investor claims that Eli Lilly has asserted against Canada will be summarily dismissed and discredited. Limiting foreign IP investors to IP rights and expectations grounded purely in changeable domestic law, rather than their wish-list of

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scientific journals, and many other matters of public interest, social justice, and human rights concern.

323 Dreyfus and Frankel reach a more moderate position that recognizes that there might be a value of protecting IP-related investment rights in some circumstances. *See* Dreyfus & Frankel, *supra* note 265, at 45.

324 *See* Ho, *supra* note 265, at 275–77.

externally established maximalist rights, might avoid abusive investor-state claims seeking to enforce ephemeral claims and yet unrealized rights under TRIPS, the TPP, or even the national law of other Parties.

Although solutions to the risk of unbounded corporate power to enforce IP rights in investor-state dispute resolution exist, those solutions will not be adopted if countries remain injudicious and if activists do not continue to highlight the risks of such claims. The risks concerning access to medicines are clear and dramatic—as long as medicines remain inaccessible and unaffordable, people will pay with their lives. However, the risks are equally severe with respect to tobacco control, environmental hazards, and many other matters implicating human rights and social justice. It is time for legal academics and diverse social movements to shine an illuminating light on the danger of ever-expanding corporate power and of private arbitration of public interests. The most immediate concern may well be the intersection of the TPPA IP Chapter, Transparency Annex, and Investment Chapter, but there are similar dangers in the soon-to-be concluded EU-India FTA and in the pending U.S./E.U. Trans-Atlantic Trade and Partnership. If investor power remains unchecked, the weapon of investor-state claims will be used against poor countries and rich countries alike and monopoly power will become even further entrenched to the detriment of us all.