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Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines – Eli Lilly and the TPP

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I. Brief Historical Background and Framework of International Investment Agreements and Investor-State Dispute Resolution

Free trade agreements (FTAs) and bilateral investment treaties (BITs) typically contain investment clauses designed to attract direct foreign investment and protect the interests of foreign investors.[1] In addition to defining the types of foreign investment that are entitled to protection, investment clauses typically allow for both state-state and investor-state dispute resolution, meaning that if a foreign investor believes that its investment has been unlawfully devalued by government action it can directly launch arbitral proceeding against the offending government before a private panel of trade lawyers. Typical claims under investment clauses address: (1) alleged violations of a ***minimum standard of treatment*** for foreign investors, i.e., fair and equitable treatment and full protection and security – which, most States have agreed, requires police protection and adjudicative due process; (2) direct or ***indirect expropriation***, including what we call in the U.S. regulatory takings; and (3) ***national treatment or most favored nation*** which requires host governments to afford foreign investors treatment that is no less favorable than that afforded to domestic corporations in similar circumstances or no less favorable treatment 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, now recognized as having contributed to asset bubbles and global financial insecurity, and place restrictions on prudent capital controls, now officially endorsed by the International Monetary Fund as legitimate tools for preventing and mitigating financial crises.. Finally, the treaties greatly restrict performance requirements designed to promote domestic inputs as a condition of foreign investment activity. [2]

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[1] 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. 67-130 (2005); Zachary Elkins, Andrew T. Guzman & Beth A. Simmons, *Competing for Capital: The Diffusion of Bilateral Investment Treaties, 1960-2000*, 60 INT'L ORG. 811-846 (2006).

[2]

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 BIT generally affords 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

The vast majority of investor-state dispute resolution claims are handled by the International Centre for the Settlement of Investment Disputes (ICSID) and the United Nations Commission on International Trade Law (UNCITRAL), although there are alternative arbitral forums, regional and otherwise.[3] Most investment treaties allow recourse to ICSID or UNCITRAL arbitration without first exhausting local judicial or administrative remedies, a right frequently not allowed to domestic investors either with respect to exhaustion or post-exhaustion review. Typically, a panel of three arbitrators is chosen to establish an investor-state dispute resolution tribunal, often from a surprisingly small pool of international trade lawyers.[4] Decisions are non-reviewable except through annulment proceedings that address a narrow range of tribunal "errors" and are not heard by judges but by another arbitral tribunal.[5] Although arbitral decisions are not precedential, panels frequently cite other tribunal decisions even as they ignore the opinions of sovereign States to ratchet up investor protections.

Investor-state dispute resolution is facing a crisis of credibility given its perceived bias towards investor prerogatives, but the analysis here focuses not on legitimacy debates as such,[6] but rather on a particular threat to access to medicines if pharmaceutical companies

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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.

United State Trade Representative, Bilateral Investment Treaties, *available* at http://www.ustr.gov/trade-agreements/bilateral-investment-treaties.

[3] 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 27 September 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 5 April 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.

[4] Pia Eberhardt & Cecilia Olivet, *Profiting from Injustice*, Transnational Institute and Corporate Europe Observatory Report, 8 (Nov. 2012), *available* at http://www.tni.org/pressrelease/exposed-elite-club-lawyers-who-make-millions-suing-states.

[5] 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 concern over the absence of appellate review in the investor-state arbitration context).

[6] *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

pursue investor-state claims. More specifically, the analysis focuses on pro-investor draft investment chapter in an ongoing regional trade negotiation – the Trans-Pacific Partnership Agreement (TPP)[7] - and on the first investor-state arbitral claim ever by a patent-holding pharmaceutical company under a U.S. free trade agreement, demonstrating the danger of investment claims in the pharmaceutical context.[8]

The investor-state 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 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 speeding the financing and development of comparative advantage and lubricating participation in the expanding global economy.[9] The number of BITs and other international investment agreements has proliferated reaching 2833 at the end of 2011.[10] 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

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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. 223-255 (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").

[7] According to the United State Trade Representative website, "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 will enhance trade and investment among the TPP partner countries, promote innovation, economic growth and development, and support the creation and retention of jobs." *See* http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/united-states-trans-pacific-partnership. Since that time, Mexico and Canada, the U.S.'s NAFTA trade partners have also joined the negotiations. Japan has also recently asked to participate in the negotiations, see "Statement by Acting U.S. Trade Representative Demetrios Marantis on Japan's Announcement Regarding the Trans-Pacific Partnership" (March 15, 2013), *available at* http://www.ustr.gov/about-us/press-office/press-releases/2013/march/amb-marantis-statement-japan-tpp. Other countries, including Thailand, are said to be interested. The U.S. is reportedly urging South Korea to join the talks as well. Park Hyun & Seong Yeon-cheon, "To counter China, US is seeking to expand its presence in the Asia-Pacific region, and wants SK as a partner," THE HANDKYOREH (March 21, 2013) *available at* http://www.hani.co.kr/arti/english_edition/e_international/579052.html. The 15th round of negotiations was held in Singapore, March 4-13, 2013, with the 16th round scheduled in in Lima, Peru in May 15-24, 2013. For an outline of the broad parameters of the TPP, *see* http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/outlines-trans-pacific-partnership-agreement. For a detailed analysis by the Congressional Research Service, see Ian F. Feargusson et al., THE TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS AND ISSUES FOR CONGRESS (March 19, 2013), *available at* http://www.fas.org/sgp/crs/row/R42694.pdf.

[8] The investor-state claim is *Eli Lilly and Company v. The Government of Canada,* Notice of Intent to Submit a Claim to Arbitration under NAFTA (Nov. 7, 2012), *available* at http://italaw.com/sites/default/files/case-documents/italaw1172.pdf. [Hereinafter *Eli Lilly v. Canada*.]

[9] Eric Neumayer & Laura Spess, *Do bilateral investment treaties increase foreign direct investment to developing countries?*, 33 WORLD DEVEL. 1567-85 (2005).

[10] United National Conference on Trade and Development, *World Investment Report 2012 Overview: Toward a New Generation of Investment Policies*, 18 (2012), *available* at http://www.unctad-docs.org/files/UNCTAD-WIR2012-Overview-en.pdf.

entitled to the benefit of the "best" investment clause protections that the host country has granted to investors from any other state.[11]

Although modern investment clauses and investor-state dispute resolution have been with us since the 1950s, resort to them was limited during their first 50 years when only fifty investor-state claims were filed.[12] Investors reserved their claims for those exceptional cases where hard investments were nationalized or transferred to others without compensation by regimes either committed to state ownership or captured by crony capitalism. In contrast, since 2001, four hundred investor-state disputes have been filed. Investors have won nearly $3 billion from taxpayers in arbitral awards and another $15 billion in claims is pending under U.S. FTAs and BITs alone.[13] Moreover, the average cost of arbitral proceedings is nearly $8 million, although the Philippines' tribunal costs and legal costs in a single case exceeded $50 million.[14]

This sea change in investor-state claims occurred because investors belatedly realized that not only could they bring claims against banana-republic confiscations but against emerging economies and even advanced democracies whenever their unrequited expectations of profits were thwarted by government regulations, adverse adjudicative decisions, and other state practices. 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, financial regulations, consumer protection,

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[11] Robert Stumberg, *MFN in the TPP Investment Chapter* (2012) draft available from the author, citing *Most-Favoured Nation Treatment*, UNCTAD Series on Investment Issues in International Investment Law II (2010); Pia Acconci, *Most-Favoured-Nation Treatment*, in THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW (Peter Muchlinski, Federico Ortino and Christoph Schreuer, eds., 2008).

[12] United Nations Conference on Trade and Development, *IIA Issues Note: Latest Developments in Investor-State Dispute Settlement*, 3 (April 2012), *available* at 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, Ch. 2 (Oxford University Press, New York, 2010).

[13] *See* Public Citizen, *Table of Foreign Investor-State Cases and Claims under NAFTA and Other U.S. Trade Deals* (March 2013), *available* at http://www.citizen.org/documents/investor-state-chart.pdf. The fact that an investor-state 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 US FTAs and these are only a subset of investor-state awards. *See* Public Citizen, *Table of Foreign Investor-State Cases and Claims under NAFTA and other U.S. Trade Deals* (March 2013), *available* at http://www.citizen.org/documents/investor-state-chart.pdf. 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 AN. SURVEY INT'L & COMP. L. 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* (2008), *available* at http://www.academia.edu/262767/PricewaterhouseCoopers_International_Arbitration_Corporate_Attitudes_and_Practices.

A recent study from UNCTAD shows a sharp uptick in new investor-state arbitration cases in 2012, 62 new cases initiated, with a total of 518 known cases having been filed. UNCTAD, RECENT DEVELOPMENTS IN INVESTOR-STATE DISPUTE SETTLEMENT NO. 1 (March 2013), *available* at http://unctad.org/en/PublicationsLibrary/webdiaepcb2013d3_en.pdf. Most of the cases were against developing or transition economies. Forty-two arbitral decisions were issued in 2012. Of those decided on the merits, 70% were decided in favor of investors, including a $1.77 billion award in *Occidental v. Ecuador* (ICSID Case No. ARB/06/01), Award, 5 October 2012. To date the total number of concluded cases has reached 244, of which approximately 42% were decided in favor of the State, approximately 31% in favor of the investor, and approximately 27% settled.

[14] Eberhardt & Olivet, *supra* note 4 at 7.

public health, and public safety laws, and a range of other public interest policies.[15] Claims in extractive industries are common. For example, Churchill Mining has filed a $2 billion claim against Indonesia relating to its mining regulations.[16] ICSID recently ordered Ecuador to pay Occidental Petroleum $1.77 billion in a disagreement over an oil concession contract in the largest investor-state award to date. Claims relating to environmental and public health hazards are also common. One prominent public health example is the pending arbitral claim against Australia under a 1993 Australia-Hong Kong bilateral investment treaty brought by an affiliate of Phillips Morris challenging plain packaging restrictions on tobacco products.[17] Phillips Morris is pursuing its 2011 arbitral claim despite the Australian High Court having confirmed the constitutionality of the Tobacco Plain Packaging Act of 2011.[18] 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 that it knew about when it purchased the property from a previous polluter. In an earlier instance, Canada reversed an environmental ban on a gasoline additive MMT, a probable carcinogen, after U.S. Ethyl Corporation filed a NAFTA investor-state claim against it.

Although many investor-state cases implicate public health and safety, prior to 2012 no patent-holding pharmaceutical company had filed an investor-state challenge under any U.S. FTA based on alleged intellectual property rights. That moratorium ended in November 2012, when Eli Lilly and Company announced its intent to initiate arbitration proceedings under the North American Free Trade Agreement (NAFTA) investment clause to attack Canada's invalidation of a patent on an attention deficit hyperactivity disorder medicine called Strattera.[19] In doing so, Eli Lilly is challenging a well-established patent rule in Canada, the so-called promise doctrine, whereby a medicine or any other product's "utility," and thus patentability, must be demonstrated or soundly predicted at the time of filing a patent.[20] Eli Lilly makes a number of specific investment chapter claims, discussed further below, including that the Canadian ruling involved a violation of a minimum standard of treatment, indirect expropriation, and discrimination in violation of national treatment norms. The analysis below will first address the provisions in the Draft TPP Investment

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[15] *Id.*

[16] *Churchill Mining PLC v. Republic of Indonesia*, ICSID Case No. ARB/12/14 (2012), *available at* http://www.italaw.com/cases/1479.

[17] *See* Tania Voon, *Acquisition of Intellectual Property Rights: Australia's Plain Tobacco Packaging Dispute*, 2 Eur. Intel. Prop. J. * (forthcoming 2013); Patricia Randall, *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 (September 9, 2012), *available* at http://aftinet.org.au/cms/sites/default/files/Leesburg%20Ranald%20forum%20paper%20090912.pdf.

[18] *J. T. International S. A. v. Commonwealth of Australia; British American Tobacco Australasia Limited v. Commonwealth of Australia,* HCA 43 (2012). Phillips Morris has a second, tobacco-related investor-state case that it filed earlier against Uruguay under a different BIT (Swiss-Uruguay), which is shows the willingness of foreign corporations headquartered in one country to treaty shop for corporate affiliates that are domiciled in another state with favorable investment treaty provisions. *Request for Arbitration, FTR Holdings S.A. (Switzerland) v. Oriental Republic of Uruguay*, ICSID case no. ARB/10/7 (February 19, 2010). FTR Holding S.A. is a subsidiary of Philip Morris International Inc. (PMI) and PMI has its Operation's Center in Switzerland.

[19] The challenged court decision is *Eli Lilly Co. v. Teva Canada Ltd*., 2011 FAC 220, *available* at http://decisions.fca-caf.gc.ca/en/2011/2011fca220/2011fca220.pdf. The Supreme Court of Canada denied review. *Eli Lilly Co. v. Teva Canada Ltd*., *available* at http://www.scc-csc.gc.ca/case-dossier/cms-sgd/dock-regi-eng.aspx?cas=34396. The investor-state claim is *Eli Lilly v. Canada*, *supra* note 8. Chapter 11 of NAFTA adopted investor-state arbitration. North American Free Trade Agreement Between the Government of Canada, the Government of Mexico, and the Government of the United States, 17 December 1992, Can. T.S. 1194 No.2, 32 I.L.M. 289 (entered into force January 1, 1994).

[20] *Id.*

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.

II. The Leaked Draft Trans-Pacific Partnership Investment Chapter is a Booby-Trap for Access to Medicines

The leaked TPP Intellectual Property Chapter proposed by the U.S. has been analyzed extensively with respect the dangers it poses in terms of access to medicines[21] and with respect to its IP enforcement provisions.[22] Similarly, the leaked Draft TPP Investment Chapter[23] has also been closely analyzed primarily with respect to the generic dangers of its extra-judicial investor-state dispute settlement provisions.[24] This analysis expands on earlier 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 undertaking by governments (state-state dispute resolution, border measures, and criminal enforcement). In essence, the inclusion of intellectual property rights granted in the US TPP IP Chapter gives IP-"investors" new substantive "investment rights" that they could now directly, selectively, and cumulatively enforce against sovereign governments' regulations, policies, and adjudicatory decisions using Draft TPP Investment Chapter investor-state dispute resolution.

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

- First, the minimum standard of treatment provision, 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 nations provisions can be interpreted to prevent unanticipated forms of alleged discrimination against foreign investors.

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[21] Trans-Pacific Partnership, Intellectual Property Rights Chapter February Draft, *available at* http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf; Trans-Pacific Partnership, Intellectual Property Rights Chapter September 2011 Draft (Selected Provisions), *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf [hereinafter US TPP IP Chapter]. With respect to substantive IP issues affecting access to medicines, there are proposals to relax standards of patentability, to eliminate certain patent exclusions, to extend patent terms to compensate for regulatory delays, to limit required disclosures, to forbid pre-grant opposition procedures, and to require data exclusivity and patent-registration linkage, all TRIPS-plus measures. *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.R. 105, 149-183 (2013).

[22] With respect to enforcement issues affecting access to medicines, there are proposals to mandate injunctions, to authorize seizures and other measures at the border, and to require enhanced civil remedies and expanded criminal enforcement. Flynn et al. *supra* note 21, at 183-200.

[23] Draft TPP Investment Chapter, *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf.

[24] *See e.g*. Public Citizen, *Public Interest Analysis of Leaked Trans-Pacific Partnership (TPP) Investment Text* (June 13, 2012), *available at* 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* (June 14, 2012), *available at* http://www.scoop.co.nz/stories/PO1206/S00186/national-says-yes-to-investor-rights-to-sue.htm.

- 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 have and given drug companies' proclivities to bring lawsuits against governments.[25]
- 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 TPP Parties might need in order to truly safeguard lawful measures that promote access to affordable medicines for all set forth in the TRIPS Agreement and further clarified in the Doha Declaration on the TRIPS Agreement and Public Health.[26]
- 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 12.6.1 of the Draft TPP Investment Chapter requires that, as a "minimum standard of treatment," "Each Party shall accord to covered investments treatment in accordance with customary international law, including fair and equitable treatment and full protection and

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[25] Using just India as an example, Bayer unsuccessfully sued India to achieve judicially mandated patent-registration linkage, a suit that was dismissed in the Delhi High Court with special leave to appeal dismissed by the Supreme Court of India. *Bayer Corp. v. Union of India*, 41 P.T.C. 634 (Del. 2009); *Bayer Corp. v. Union of India*, 9 February 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. LAW & MED. 577-88 (2011); Anshul Mittal, *Patent Linkage in India: Current Scenario and Need for Deliberation*, 15 J. INTEL. PROP. RGTS. 187-96 (2010). Bayer has also initiated an appeal to the Indian Patents Appeal Board seeking reversal of a compulsory license granted to Natco on its cancer medicine, Nexavar (sorfenib tosylate). IPAB Judgment *available* at http://www.ipab.tn.nic.in/045-2013.htm. Bayer has indicated its intention to appeal to the High Court. "Patent board rules against Bayer in cancer drug case," REUTERS (March 4, 2013), *available* at http://in.reuters.com/article/2013/03/04/india-patent-appeal-bayer-nexavar-idINDEE92309H20130304. Novartis 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 of the TRIPS Agreement. That suit was dismissed by the Madras High Court in 2007. *Novartis AG v. Union of India, 4 Madras L.J. 1153 (2007); see Shamnad Basheer & Prashant Reddy, "Ducking" TRIPS In India: A Saga Involving Novartis and the Legality of Section 3(d)*, 20 NAT'L LAW SCHOOL OF INDIA REV. 131-155 (2008). Although Novartis declined to appeal the High Court decision, it did continue to appeal the denial of a patent on its cancer medicine, Glivec. That appeal has had a tortured history culminating in an appeal to the Supreme Court of India, which dismissed Novartis's effort both to obtain a patent on Glivec and to motivate a change in the interpretation of section 3(d) of the India Patents Act that would make it easier to evergreen patents on medicines thereby extending periods of exclusive rights. *Novartis v. Government of India*, Civil Appeal Nos. 2706-2716 OF 2013 (April 1, 2013), *available* at http://supremecourtofindia.nic.in/outtoday/patent.pdf. This decision was received jubilantly by access to medicines activists, but received harsh criticism from Novartis and its supporters. *See* Patralekha Chatterjee, *Novartis Loses Patent Bid: Lessons from India's 3(d) Experience*, IP-WATCH (April 1, 2013), *available* at http://www.ip-watch.org/2013/04/01/novartis-loses-patent-bid-lessons-from-indias-3d-experience/.

[26] WTO Agreement on the Trade Related Aspects of Intellectual Property Rights, Art. 8(1), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS]; 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), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm [hereinafter Doha Declaration].

security."[27] Although subparagraph 1 does not require treatment in addition to or beyond that required by customary international law, subparagraph 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."[28] Investor-state tribunals have used increasingly expansive interpretations of this "minimum standard of treatment" that depart further and further from the "customary international law" actually practiced by States, despite a U.S.-sponsored annex, first inserted in the Central America Free Trade Agreement (CAFTA), defining customary international law as resulting from the "general and consistent practice of States" (compare Annex 12-B in the Draft TPP Investment Chapter).[29] Indeed, in the recent ruling on the *Railroad Development Corporation v. Republic of Guatemala* case brought under CAFTA, an investor-state tribunal simply ignored the CAFTA annex and arguments from four governments 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.[30]

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.*[31] 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."[32] 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 or candor in an administrative process."[33] More problematically, the tribunal decided that if a state breaches "representations" that were "reasonably relied upon" by investors at the time of investment, that breach constitutes evidence of unfair or inequitable conduct that violates the minimum standard of treatment.[34] 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 even in the absence of direct representations, let alone binding commitments allowing unfettered and immutable market participation or profit-making opportunities.[35] Such expansive interpretations of the "minimum standard of treatment" have made these claims an investor favorite. In nearly 75% of the investor-state cases that a foreign investor has "won" under U.S. FTAs and BITs, the tribunal cited a "minimum standard" violation to rule against the respondent Party.[36]

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[27] Draft TPP Investment Chapter *supra* note 23.
[28] *Id.*
[29] *Id.* 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" (September 2012), *available* at http://www.citizen.org/documents/MST-Memo.pdf?iframe=true&width=100%&height=100%.
[30] For more information on the case and its expansive interpretation of the minimum standard, *see* Public Citizen, *Railroad Development Corporation (RDC) v. Guatemala*, *available* at http://www.citizen.org/RDC-vs-Guatemala#!prettyPhoto[iframe]/0/.
[31] Decision *available at* http://www.state.gov/documents/organization/34643.pdf.
[32] *Id.* ¶ 89.
[33] *Id.*
[34] *Id.*
[35] *See* Fiona Campbell, *Fair and Equitable Treatment in International Investment Agreements*, Institute for Sustainable Development (2007), *available at* http://www.iisd.org/pdf/2007/inv_fair_treatment.pdf.
[36] *See* Public Citizen's memo: http://www.citizen.org/documents/MST-Memo.pdf?iframe=true&width=100%&height=100%.

In the pharmaceutical context, foreign investors might claim that the "minimum standard of treatment" 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 violating a minimum standard of treatment. In sum, whenever foreign IP rightholders disagree with judicial or administrative decisions or think that those decisions are insufficiently transparent or candid, the foreign rightholder could potentially bring investment chapter claims directly against the government without ever being required to even exhaust domestic 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 just two reasons to suggest that India has run afoul of Article 31 of TRIPs.[37]

Article 12.12 of the Draft TPP Investment Chapter also prohibits direct and "indirect expropriation" of a covered investment, which includes failure to pay full market value upon expropriation. [38] 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 broader bracketed portion of subparagraph 5, which includes an exception to the expropriation rule for "the revocation, limitation, or creation of intellectual property rights,

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[37] Jones Day Commentary, "Treaty Protection for Global Patents: A Response to a Growing Problem for Multinational Pharmaceutical Companies," 3 (October 2012), *available* at http://www.jonesday.com/files/Publication/96b88f45-3c81-4e6e-b640-9ca243920ad5/Presentation/PublicationAttachment/523d7608-c58a-4bab-bd96-9e1d121287ea/Treaty%20Protection.pdf. The *Novartis v. India* case, discussed *supra* note 25, involved the denial of an evergreening patent on Glivec, an important cancer medicine. The Bayer case referred to involves india first grant of a compulsory license, also on a cancer medicine. *Id.* What's striking about the Jones Day advice is that it's so inaccurate on the law. Although TRIPS Article 31, *supra* note 26, does allow patent holders to seek termination of a compulsory licenses when the conditions giving rise to 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 can only be granted for "emergencies" or that they are limited to lifesaving medicines. (Note: it is frankly bizarre that Jones Day would suggest that Bayer's cancer drug is not a life-saving drug since extended life is something that Bayer has consistently claimed since it brought its medicine to the market.) 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, *supra* note 26, at ¶ 5.

[38] Draft TPP Investment Chapter *supra* note 23.

to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter __ (Intellectual Property Rights),"[39] as important as it may be if adopted, does not give rights to create novel exceptions to intellectual property rights in the absence of full remuneration. Pursuant to the indirect expropriation rule, it would become 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 medicines-related patents. Likewise, payment of partial liability payments 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 we will see further below with respect to the *Eli Lilly v. Canada* investor complaint.

Possible meanings of indirect expropriation are addressed further in proposed Annexes 12-B, C, and D and clarify the imperative to protect investor expectations. Annex 12-C is the most far reaching clarification and requires a case-by-case, fact-based inquiry that considers subparagraph 4(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* (emphasis added); and (iii) the character of the government action.[40]

Subparagraph (b) sets some loose boundaries on those expectations:

> Except in rare circumstances, non-discriminatory regulatory actions by a Party that are designed and applied to protect the legitimate public welfare objectives [23 For greater certainty, the list of legitimate public welfare objective in this subparagraph is not exhaustive] such as public health, safety, and the environment, do not constitute indirect expropriations.[41]

Although this public welfare exception helpful, it is not an absolute privilege. Investors can claim: (1) that their cases are the rare ones where even non-discriminatory regulation is not permitted, (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.

To give concrete examples, if a compulsory license were granted on a medicine pursuant to the Paragraph 6 System,[42] would that be deemed confiscatory? Some commentators have

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[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] 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. WTO Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. [Hereinafter Paragraph 6 System.] *See* 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. 613-715 (2004). Although an amendment based on the Paragraph 6 System 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 if the compulsory license exception is adopted in the Draft TPP Investment Chapter it is not clear that Paragraph 6 System licenses would be judged to have been issued "in accordance with the TRIPS Agreement."

suggested that compulsory licenses in general should be considered a taking, others not,[43] 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, a foreign pharmaceutical investor might claim this objective was a rare, challengeable circumstance, or that is evidenced discriminatory bias in favor of domestic firms, or that local working requirements violate TRIPS Article 27.1 by discriminating against imports. Likewise, if facially neutral compulsory licensing rights were used more routinely to grant pharmaceutical-related licenses, as has occurred in Indonesia, which recently issued compulsory licenses on seven different hepatitis and antiretroviral medicines,[44] 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 royalty rate might be deemed confiscatory.[45]

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.[46]

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.[47]

B. Foreign investor's rights to national treatment and to most favored nation treatment authorizes imaginative discrimination claims

Article 12.4 contains the relevant definitions of National Treatment:

> 1. Each Party shall accord to investor of another Party *treatment no less favourable than that it accords, in like circumstances, to its own investors* with respect to the

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[43] *Cf.* Peter B. Rutledge, *TRIPS and BITS: An Essay on Compulsory Licenses, Expropriation, and International Arbitration*, 13 N.C. J. LAW & 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.R. 357-422 (2010).

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

[45] 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), *available* at http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf.

[46] Jones Day Commentary, *supra* note 37, 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 19th century and compulsory licensing rules were enshrined in Indian law well before Bayer applied for its patent on Nexavar. Paris Convention for the Protection of Industrial Property, Art. 5(a)(2).

[47] *Id.*

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 favourable than that it accords, in like circumstances, to investments in its territory of its own investors* with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments in its territory. (Emphases added.)[48]

In sum national treatment prevents favoritism toward domestic investors compared to foreign investors. On this grounds, as argued by Jones Day, compulsory licenses granted to domestic companies,[49] especially pursuant to local manufacturing requirements, would violate national treatment – domestic generic firms would obtain investment advantages that the foreign originator firm does not have unless it sets up a local manufacturing facility.[50] Similarly, the denial of a patent or invalidation of a patent owned by a foreign inventor by a national patent office or court might result in a national treatment discrimination claim if domestic inventors were allegedly being treated more favorably in similar circumstances.

Most-favored nation treatment is defined in Article 12.5:

1. Each Party shall accord to *investor of another Party treatment no less favourable than that it accords, in like circumstances, to its own 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 favourable 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 in its territory.
3. For greater certainty, the treatment referred to in this Article does not encompass international dispute resolution procedures or mechanisms such as those include 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"]. (Emphases added.)[51]

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 and/or in other kinds of agreement 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 expanded right that might be available are so-called pre-establishment rights, which 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

[48] Draft TPP Investment Chapter *supra* note 23.

[49] 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. Dept. for Int'l Development, Health Systems Resource Centre (2004)

[50] Jones Day Commentary, *supra* note 37, at 3.

[51] Draft TPP Investment Chapter *supra* note 23.

as to entry conditions. In other words, pre-establishment protections ensure that an investor can get its foot in the door.[52] 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."

C. The implicit and explicit inclusion of IP rights as protected investments is deeply problematic with respect to medicines

The Article 12.2 definition of "investment" is broad enough to cover medicines-related intellectual property rights (patents, data and other trade secrets) in that it only requires "*commitment of capital or other resources*, *the expectation of gain or profit*, or the assumption of risk (emphasis added)."[53] 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 covered. In this regard, it is also important to point out that the definitions of covered "investors" covers pre-establishment rights, rights that arise even before the foreign investment has been made.[54]

However, the proposed definition of investment goes further to directly reference: (g) "intellectual property rights [which are conferred pursuant to domestic laws of each Party]."[55] The unbracketed text 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" could be interpreted over broadly to include all of the IPRs codified in the loose language of the TRIPS Agreement. For example, TRIPS Agreement Art. 39.3 currently provides data protection against "unfair commercial use" for undisclosed data compiled at consideration expense and submitted to regulatory authorities. Major transnational pharmaceutical companies and EU and US trade negotiators have consistently interpreted this language as requiring data exclusivity – monopoly control over the data so as to prevent regulatory reliance on or reference to the data when considering a generic company's attempt to register an equivalent product. Many other countries and leading expert commentators believe that Art. 39.3 does not require data exclusivity, a protection explicitly rejected during the negotiation of the TRIPS Agreement.[56] At present, the only

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[52] *See* Andrew Paul Newcombe, Lluís Paradell, LAW AND PRACTICE OF INVESTMENT TREATIES: STANDARDS OF TREATMENT, 137-139 (Kluwer Law Int'l, the Netherlands, 2009).

[53] Draft TPP Investment Chapter *supra* note 23.

[54] The definition of investor of a Party and investor of a non-Party both reference "an investor that attempts to make" an investment in a country. Footnotes 7 and 8 both clarify: "For greater certainty, the Parties understand that an investor 'attempt 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 permits or licenses." *Id.*

[55] *Id.*

[56] *See e.g.*, Carlos Correa, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT (2002); Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303-344 (2008).

way that this interpretive battle can be decided multilaterally is for an aggrieved WTO Member to bring a WTO complaint against another Member, such as India, which refuses to provide data exclusivity. However, despite intense industry lobbying on this issue, the Office of the United States Trade Representative (USTR) has initiated only one such complaint against Argentina and subsequently abandoned it[57] because of concerns that it would lose and because of other complex political calculations that structure a Member's decision to fully prosecute a WTO complaint or not.

However, if the Draft TPP Investment Chapter is adopted, even if the US proposal for data exclusivity in its IP Chapter were to be rejected, a foreign pharmaceutical company could bring an extra-judicial arbitral claim (e.g. violation of reasonable expectations covered by the minimum standard of treatment) against a TPP Party based on an interpretive dispute whether TRIPS requires data exclusivity. In fact, Bayer sought a related, judicially imposed rule on patent-registration linkage in India and lost.[58] The company would hope that the revolving-door trade lawyers selected to lead the investor-state dispute resolution tribunal would adopt the company's position despite convincing expert opinion and widespread state practice to the contrary. In essence, the foreign investor will have gained an alternative forum for seeking to enforce novel interpretations of TRIPS and thereby gain new data monopolies. The foreign pharmaceutical IP-investor, in all probability from the US or Europe, would have rights that no domestic pharmaceutical company would have. The foreign IP-investor could choose to appeal an adjudicatory loss and thereafter still seek separate investor-state arbitration or it could avoid the appeal process entirely and go straight to arbitration.

Second, not only might the loose 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.[59] 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 TPP IP chapter does not authorize such an exception and that the failure to pay total compensation (not a mere royalty) is an indirect expropriation or alternatively, if the decision were adjudicatory, that its reasonable expectations of data-based market exclusivity has been violated. This latter, minimum-standard-of-treatment claim would be strengthened since there is little international state practice at present of 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 TPP

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[57] The United States brought a WTO complaint against Argentina on the grounds that Argentinian law had no exclusivity for test data. (30) After almost 2 years, the dispute was settled at the consultation stage and without a hearing. On May 2002, the Governments of the U.S and Argentina agreed "should Argentinean law be inconsistent with Article 39.3 ... Argentina agrees to submit to the National Congress within one year an amendment to Argentinean law, as necessary, to put its legislation in conformity with its obligations under Article 39.3." *See* Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, 20 June 2002, (IP/D/18/Add. 1, IP/D/22/Add. 1), *available at* www.wtocenter.org.tw/SmartKMS/fileviewer?id=18205. As expected, Argentina did not accept the U.S. claim that exclusive rights should be granted for test data and left its law unchanged.

[58] Tsui, *supra* note 25, at 577-88.

[59] This possibility has strong support in another section of the Draft TPP Investment Chapter *supra* note 23, Art. 12.12.5, which, in bracketed text, 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.

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 would bet that the revolving door justice of non-democratically selected arbitrators, who move seamlessly from representing IP rightholders, advising and representing governments, and putting on 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 flexibilities that they might otherwise believe exist in the TPP because of the prohibitive costs of arbitral hearings and the risk of excessive judgments should they lose.

Third, a foreign pharmaceutical investor might simply rely on the TPP-compliant law of the TPP Party and claim that its investor rights had been infringed by an adverse decision on a pending IP claim. For example, if the TPP IP chapter requires countries to allow patents on new forms of existing medicines, a patent office might still conclude that a particular new polymorph form lacks an inventive step. The pharmaceutical company could argue that the TPP-compliant national law actually creates a presumption in favor of patentability of new forms and thus that it has 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 jump over that step and immediately charge dilution of its putative – but not yet granted – IP rights and expectations of profit in investor-state arbitration.

Fourth, there is a risk that a foreign IP rightholder might bring claims because of 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 US TPP 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 principles of due process" constitutes an actionable minimum standard of treatment violation under Draft TPP Investment Chapter Article 12.6.2(a). 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.[60] Note as well, how cumulative IP-investors rights now are: (1) they can bring private claims based on longer, broader, easier-to-obtain, and longer patents rights and on new data exclusivity rights and they can get 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 IP rights; (3) when frustrated, they can lobby for state-to-state dispute resolution under the TPP; and (4) they can now challenge the state directly with investor-state dispute resolution and/or seek state-state investment arbitration. Although IP right-holders already have unique and special enforcement rights under the US TPP IP Chapter, now they get super-sized enforcement with investor-state arbitration.

[60] *Id*., Article 41.5: "It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. *Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general*." (Emphasis added.)

Fifth, there is a risk that an IP rightholder might bring a claim because of a governmental failure to intercept alleged IP-infringing, in transit[61] medicines via stringent border measures. This too might 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 rights in the transit country.[62] Admittedly, the US TPP IP Chapter Proposal on border measures, Art. 14.1, instructs customs official to apply the law of the importing country, as required by TRIPS. However, trademark-related IP rights, including those involving confusingly similar drug names or trade dress, might be enforced through investor-state proceedings based on misunderstanding of the governing law and of trademark status in the importing country.

D. The compulsory licensing and bracketed patenting exception in the Draft TPP Investment Chapter are insufficient to protect Parties' legitimate interests to access affordable medicines

Bracketed subparagraph 1(f) of Art. 12.7 prohibits a TPP 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."[63] If left in this form, such a provision could doom the right to issue compulsory or government use licenses. To partially remedy this problem, subparagraph 12.7.3(b)(i) eliminates this requirement where a TRIPS Art. 31, unauthorized-use license (or alternatively a TPP-compliant unauthorized-use license[64]) has been issued.[65] Similarly, with respect to Art. 12.12, which prohibits the expropriation or nationalization of a covered investment either directly or indirectly, subparagraph 5 creates an exception for the issuance of compulsory licenses granted pursuant to the TRIPS Agreement. In addition, there is a bracketed addition to subparagraph 5 that extends the exception against prohibited expropriation or nationalization to other IP-related acts: "or to the revocation, limitation, or creation of IP rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter __ (IP rights)."[66]

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[61] The US TPP IP Chapter expressly covers goods in transit, Art. 14.4. Note, although Article 14 does 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. Christian Wagner-Ahlfs, *Seizure of Indian generic amoxicillin in Frankfurt*, ESSENTIALDRUGS.ORG, *available at* http://www.essentialdrugs.org/edrug/archive/200906/msg00014.php.

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

[63] Draft TPP Investment Chapter *supra* note 23.

[64] The proponent of this bracketed alternative, presumably, the US, would seem to hope that TPP-compliant unauthorized uses might be narrower than TRIPS Article31-compliant unauthorized uses. By using the "unauthorized use" language, the bracketed text would exclude limited exceptions under Article 30 of TRIPS and would further exclude judicially granted licenses under Article 44.2.

[65] Draft TPP Investment Chapter *supra* note 23. Subparagraph 3(b)(ii) creates an exception to permit remedies for anti-competitive practices. There are additional limited exceptions for environmental measures, subparagraph 3(c), government procurement, subparagraph 3(e), and other matters.

[66] *Id*. Note, there are additional exceptions for non-conforming performance requirement measures detailed in Article 12.9. Pursuant to Article 12.9.2, performance requirements for specific sectors, subsectors, or activities are permissible via a negotiated negative list.

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.[67] For example, TRIPS Article 31, referenced in the bracketed language of TPP Art. 12.7.3(b)(i) and Art. 12.12.5, covers only a portion of legally issued licenses under TRIPS. Specifically, the referenced TRIPS-CL language does not directly reference proposed TRIPS Article 31bis or the current waiver of Article 31(f) found in the Paragraph 6 System.[68] Likewise, the bracketed Draft TPP Investment Chapter language on compulsory licensing in subparagraph 3(b)(i) and the unbracketed TRIPS-compulsory licensing language in Art. 12.12.5 do not allow the possibility of judicially authorized compulsory licenses such as those granted in the U.S. in *eBay Inc. v. MercExchange, L.L.C.*[69] and its progeny and in India in *Roche v. Cipla*.[70] Such judicial licenses are directly authorized by Article 44.2 of the TRIPS Agreement.[71] Moreover, as discussed previously, the bracketed subparagraph (5) does not completely preclude challenges to adverse IP-related decisions or policy changes.

E. The limitations on performance requirements will interfere with ensuring redundant sources of medicines and legitimate technology transfer and industrial development

Article 12.7.1(b), subject to certain exceptions, prohibits a Party, with respect to foreign investor rights, from imposing requirements in order to achieve a given level or percentage of domestic content.[72] Many countries have used such "performance" provisions in the past as a development strategy to grow their economies via local content rules and related technology transfer/local working rules. To similar effect, Article 12.7.1(h) prohibits Parties from purchasing, using, or according preferences to their own domestic technologies.[73] Most developed countries, including the US, achieved industrial development in part by fostering rules requiring local content, by favoring local industries, and by procuring and purchasing domestically. Now the US is intent on kicking away the technology ladder and preventing countries from also developing industrial policy to grow their technological base and industrial capacity.[74]

The TRIPS Agreement has vague and largely unenforced obligations to ensure technology transfer to least developed countries,[75] but some countries have taken matters into their

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[67] TRIPS currently allows many other flexibilities including limitations and exceptions, exemptions, opposition procedures, exhaustion rules, definitions of patentability, etc. *Supra* note 26.
[68] *Supra* note 42.
[69] 547 U.S. 388, 126 S. Ct. 1837 (2006).
[70] CS (OS) No.89/2008.
[71] TRIPS, *supra* note 26: "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.)
[72] Draft TPP Investment Chapter *supra* note 23.
[73] *Id*.
[74] *See* Ha Joon Chang, KICKING AWAY THE LADDER: DEVELOPMENT STRATEGY IN HISTORICAL PERSPECTIVE (London, Anthem Press 2002); Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space Not IP Shackles* (2013 submitted for publication Law & Development Review).; *cf.* Suerie Moon, *Meaningful Technology Transfer to LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2*, ICTSD Policy Brief No. 9 (2011), *available* at http://ictsd.org/downloads/2011/05/technology-transfer-to-the-ldcs.pdf.
[75] *See* TRIPS, *supra* note 26, Articles 7 and 66.2.

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 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.[76] Although Brazil has never used the challenged local-working provision, India has just granted its first statutory compulsory license based in part on Bayer's failure to produce any content locally.[77]

Preserving sovereign rights to try to maintain or to develop local pharmaceutical capacity is critical to 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. Many countries choose to develop local pharmaceutical capacity precisely in order to ensure that they have locally managed sources of supply of essential life-saving medicines to supplement potentially fragile supplies available from only one or a small number of producers on the global market.

III. The Eli Lilly v. Canada Case: A Pharmaceutical Investor-State Claim Gone Wild[78]

The hypothetical risks of investor-state claims in the investor-state dispute resolution context have now become real. On November 2, 2012, Eli Lilly filed a claim for $100 million (Canadian)[79] against Canada because the Canadian Federal Court of Appeal had invalidated Eli Lilly's patent on Strattera in a declaratory judgment brought by Teva Canada.[80] In reaching its invalidation decision, the Federal Court of Appeals addressed three issues – did the trial judge err by invalidating the patent for lack of demonstrated utility by misconstruing its promise, by requiring too high a standard of utility, and deciding that Eli Lilly could not rely on the sound prediction of utility of the invention because the limited

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[76] *See* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

[77] *Natco Pharma Ltd v Bayer Corporation*—Compulsory Licence Application No 1 of 2011 (Controller of Patents, Mumbai), 9 March 2012, *available at* 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, *supra* note 25.

[78] This analysis relies substantially on a Public Citizen report, *U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada's Patent Policy, Demand $100 Million for Invalidation of a Patent* (March 2013), *available* at https://www.citizen.org/eli-lilly-investor-state-factsheet.

[79] *Eli Lilly v. Canada*, *supra* note 8, at ¶ 108. Although the Eli Lilly case 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*. at ¶ 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 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), *available* at 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*, ICSID Case No. ARB(AF)/12/1, *available* at http://italaw.com/cases/1687.

[80] *Eli Lilly v. Canada, supra* note 8, at ¶¶ 76-81.

and short term study that it relied on was not disclosed in the patent application and because it did not an adequate factual foundation of the sound prediction/promise of the patent?[81] The principle evidence weighed by the Federal Court of Appeals was the patent application itself and a 21-person three-week, double-blind placebo cross-over study that showed a 30% greater reduction of ADHD in 11 of 21 patients.[82] In a nutshell, the Federal Court of Appeals ruled that this short-term study was not revealed in the patent even though it should have been and that even if it had been the study would have been insufficient to predict, as claimed and promised, that Strattera would be an effective long-term treatment of chronic attention deficit hyperactivity disorder.[83] In terms of the governing legal standard, the Federal Court of Appeals held that the utility of a patent is determined by inventive promise that the applicant has made either directly or by "sound prediction" and that such a promise or sound prediction must rest on disclosure made in the patent application.[84]

In its investor-state arbitration claim, Lilly asserts that both the promise doctrine and the disclosure requirement go well beyond normal practice and that these additional requirements are not found in the Patent Cooperation Treaty.[85] In essence, Eli Lilly seeks to challenge both the invalidation of its patent and the Canadian promise/disclosure utility doctrine in its entirety.[86] Eli Lilly is pursuing claim with respect to a minimum standard of treatment, indirect expropriation, and national treatment discrimination. Although the first two claims are far fetched, they are at least within the arbitral ballpark. On the other hand, the third claim, national treatment discrimination, is hallucinatory, but even so is expensive to defend and dangerous in the face of the relatively unbridled discretion of arbitral tribunals.

With respect to minimum standard of treatment, Eli Lilly is drawing on the arbitral investment doctrine that investors are entitled to compensation for violation of a minimum standard of treatment whenever their expectations of profit are unjustly unsettled by a foreign government's policies or actions, in this case judicial reinterpretation and development of patent law requirements. Eli Lilly claims that the judge-made law and Canada's imposition of higher patent standards than those used elsewhere, including "new and addition requirements [promise/disclosure]"[87] contravened its "most basic and legitimate expectations of a stable business and legal environment."[88] It argues that at the time of filing its patent application it "could not have anticipated that the requirement for utility at the time of its investment (a "mere scintilla") would be so drastically altered by the adoption into Canadian law and practice of the doctrine of 'promise of the patent' … ."[89] As

[81] *Eli Lilly v. Teva*, *supra* note 19, at ¶ 3.
[82] *Id*. at ¶¶ 10-14.
[83] *Id*. at ¶¶ 46-51.
[84] *Id.*
[85] *Eli Lilly v. Canada*, *supra* note 8, at ¶¶ 70-81. The Patent Cooperation Treaty establishes the World Intellectual Property Organization as a clearinghouse for patent application in treaty member states. Patent Cooperation Treaty, *available* at http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf. The PTC specifies a procedural standard and common format for PCT applications and it conducts a preliminary international search and report on prior art. However, patent applications must be perfected and prosecuted in each member country that the applicant has designated, and the patent application must satisfy the substantive law of each nation state. WIPO, PCT Applicant's Guide – National Phase, ¶¶ 6.001, 6.013-.17, *available* at http://www.wipo.int/pct/guide/en/gdvol2/pdf/gdvol2.pdf.
[86] *Eli Lilly v. Canada*, *supra* note 8, at ¶¶ 42-43.
[87] *Id*. at ¶ 99.
[88] *Id*. at ¶ 100.
[89] *Id*. at ¶ 101.

of the time of its investment, Lilly argues that it "reasonably relied on disclosure obligations that were enshrined in domestic law through incorporation by reference of PCT requirements and could not have anticipated that non-statutory, new and additional disclosure obligations adopted years later would be retroactively applied to invalidate the Strattera Patent."[90] In sum, "The measures ... violated the 'full protection and security' requirement of Article 1105(12), which likewise includes basic requirements of legal security."[91]

With respect to expropriation, Eli Lilly claims both direct and indirect expropriation.[92] The direct expropriation claim is preposterous given unanimous jurisprudence limiting that concept to governmental seizure of real property.[93] The indirect expropriation claim, on the other hand, is more subtle. Here Eli Lilly claims that:

> The judicial decisions invalidating the Strattera patent are illegal *from the perspective of international law* and therefore constitute an expropriation (emphasis added). … The Government of Canada has a positive obligation to ensure Canadian law complies with Canada's international treaty obligations, as well as the reasonable investment-backed expectations of the investor.[94]

In support of its non-reliance on Canadian national law and norms, nor even on NAFTA undertakings, as the basis for its "legitimate expectations" but rather external sources, Eli Lilly alleges that Canada's promise/disclosure rules on violate: (1) the TRIPS Agreement, which was not even operative when NAFTA was negotiated,[95] (2) the PCT, which expressly covers procedural elements of patent applications, not substantive patenting standards,[96] and (3) the Paris Convention for the Protection of Industrial Property,[97] which literally has no relevant provision on standards for deciding utility.[98] In drawing on each of these treaties, Eli Lilly is advancing the novel proposition that its reasonable expectation of profits are not merely drawn from "representations" instantiated in Canada's preexisting legal framework for defining and protecting intellectual property nor from undertaking in the operative investment clause treaty, in this case NAFTA. Instead, Eli Lilly is saying that its reasonable expectations of profits derive from phantom representations made in international treaties, including those not directly applicable in terms of timeliness or defining utility-doctrine and disclosure-requirement norms. Eli Lilly has probably chosen to try to rely on extra-NAFTA texts because NAFTA's IP chapter explicitly grants NAFTA Members flexibility how to define "usefulness," meaning that Canada's promise doctrine, though unique is NAFTA compliant.

In relation to this claim it is important to note that Eli Lilly is making an indirect expropriation claim despite a provision in NAFTA that is essentially identical to the proposed clause in the Draft TPP Investment Chapter supposedly creating a safe haven for

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[90] *Id*. at ¶ 102
[91] *Id*. at ¶ 103.
[92] *Id*. at ¶¶ 90-91.
[93] Public Citizen, *supra* note 61, at 7.
[94] *Eli Lilly v. Canada*, *supra* note 8, at ¶¶ 92, 95.
[95] The TRIPS Agreement, concluded in 1994 and with an effective date of 1995, is mentioned twelve times in the Notice of Intent. *Id*. at ¶¶ 6, 9-11, 17, 32, 42, 52, 55, 63, 93, and 96.
[96] The PCT, which Canada had signed before NAFTA, is mentioned fourteen times in the Notice of Intent. *Id*. at 19-21, 23-26, 59-60, 63, 66, 68, 82, and 93.
[97] The Paris Convention is only mention in paragraph 34 and 93(v), and the only reference is to the national treatment obligations of the treaty – nothing about utility.
[98] *Id*. at ¶ 93.

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)." [99] Despite this clause sheltering NAFTA-compliant patent revocations from expropriation disciplines, Eli Lilly has made claims not just based on NAFTA's IP chapter and the Paris Convention incorporated by reference but on IP rules misrepresented and imported from non-NAFTA treaties.[100]

The last investment claims made by Eli Lilly against Canada charge national treatment discrimination. It is here that Eli Lilly efforts to incorporate foreign IP norms reaches its apex. Remember, national treatment requires countries to allow foreign investors treatment that is no less favorable than that granted to domestic corporations in like circumstances.[101] However, instead of comparing equal treatment under domestic law, "Eli Lilly invents a standard that would require Canada to afford foreign investors treatment no less favorable than that afforded *under the laws of the foreign investor's home countries* (emphasis in the original)."[102] Thus, in paragraph 106 of its investor-state complaint, Eli Lilly states:

> The measures in issue disadvantage foreign nationals and render their patents especially vulnerable to attack by insisting on proof of utility and disclosure of evidence that is not required by the foreign applicants' *own national jurisdictions* or international rules. The measures in issue *de facto* discriminate against Lilly, a U.S. investor, when compared to domestic investors, by requiring the Strattera patent (which was filed on the basis of an international application) to meet elevated and additional standards for utility and disclosure that are not required by the laws of *the United States of America, the European Union, or the harmonized PCT* [Patent Cooperation Treaty] rules. The measures in issue disadvantage foreign nationals and render their patents especially vulnerable to attack by insisting on proof of utility and disclosure of evidence that is not required by the foreign applicants' own *national jurisdictions* or international rules. (Emphases added.)[103]

Notice, what has become a recurring, indeed dominant feature of Eli Lilly's investor claim – that its reasonable expectations may be drawn not just from preexisting Canadian laws and practices, but rather from higher external standards such as utility rules and disclosure norms in other countries. Moreover, it argues that the procedural and formalistic requirement that WIPO administers under the Patent Cooperation Treaty supersede substantive disclosure requirement contained in national law.

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[99] *Cf*. Draft TPP Investment Chapter *supra* note 23, Articles 12.7.3(b)(i) and 12.12.5.

[100] NAFTA, *supra* note 19, Article 1701(2) names only four specific international agreements to which signatories are obligated domesticate into their national law: conventions on phonograms, literary and artistic works, industrial property, and plant varieties. Accordingly, it is only the Paris Convention for the Protection of Industrial Property is properly referenced in the Eli Lilly complaint – TRIPS and the PCT should be considered completely irrelevant.

[101] Draft TPP Investment Chapter *supra* note 23, Article 12.4.

[102] Public Citizen, *supra* note 76, at 6.

[103] *Eli Lilly v. Canada*, *supra* note 8, at ¶ 106. This is the first time that Eli Lilly expressly clarified its claim that it was entitled to the benefit of U.S. and E.U. law, but it had referenced U.S. law seven times previously, ¶¶ 12, 14, 15, 29, and 84-86. It had referenced E.U. law four previous times, ¶¶ 13, 16, 22, 30.

As a final feature of this topsy-turvy analysis – that "my treatment in your country must be equal not just to treatment you provide to domestic firms but also to the better treatment I get in my country or anywhere else in the world" – Eli Lilly argues that Canada's patent invalidations somehow advantage Canadian generic companies that can now freely produce and market generic versions of Strattera thereby being able to reap the economic benefits associated with Lilly's investments, thus destroying Lilly's [exclusive] market share and associated profits.[104] Naturally, every patent invalidation or denial "opens the door" to competition because it precludes the exercise of exclusive rights. However, such invalidations or denials can result in competition not just by domestic producers but also by producers from any other country where a patent bar does not exist.

IV. Conclusion: Strike the Investment Chapter or Otherwise Limits its Application to IPRs

Under the logic of Eli Lilly's investor-state claim, foreign investors' expectations have now become unbound. Even the doctrine of legitimate expectations, which is itself a huge stretch of operative minimum standard of treatment principles, is no longer tethered to operative due process (minimum standard 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 expectation to the best deal on IP achieved anywhere else. Moreover, it suggests that its expectations tolerate movement on IP policy in only one direction – upward. Any reversal of IP maximalization would dilute the gleam in its eye – unlimited profits on the horizon.

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 IP-related treaties and/or the highest standard of comparable national 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. And they sit on top of new deterrent civil remedies, mandatory injunction rights and draconian damages. In other word, IP rightholders enforcement options are now unbound.

Second, 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, i.e. the U.S.-SACU FTA,[105] refusing to join an IP enforcement treaty such as the Anti-Counterfeiting Trade Agreement,[106] tightening up standards of patentability legislatively, administratively, or judicially, [107] instituting new opposition procedures, [108] rejecting patent term

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[104] *Id.* at ¶ 107.

[105] *See* Drusilla K. Brow, Kozo Kiyota, & Robert M. Stern, *An Analysis of the U.S.-SACU FTA Negotiations*, IPC Working Paper Series Number 17, (2006), *available* at http://deepblue.lib.umich.edu/bitstream/handle/2027.42/41235/IPC-working-paper-017-BrownKiyotaStern.pdf?sequence=1.

[106] The Anti-Counterfeiting Trade Agreement (ACTA) was rejected by the European Parliament on 4 July 2012, *see* http://www.europarl.europa.eu/news/en/pressroom/content/20120217BKG38488/html/ACTA-before-the-European-Parliament.

[107] *See* Adoption of Guidelines for Patentability Examination of Patent Applications Directed to Chemical and

extensions,[109] granting compulsory licenses,[110] shortening data and marketing exclusivity on biologics,[111] creating a new bio-similars pathway,[112] allowing parallel importation of medicines as the US Supreme Court did with textbooks[113] – all of these could potentially result in an investor suit and unappealable arbitral review. In other words, foreign IP rightholders opportunities to oversee and set national IP policy and to ratchet it upwards is also now unbound.

Unbounded intellectual property rights are oxymoronic given that they are purely and completely based on allowance and recognition by governments.[114] 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 innovations, investment in quality, and creativity against access and ins some instances disclosure, as is the case for patent rights. As creatures of legislative and judicial balancing, IPRs are granted and modified according to changing social circumstances and technologies. They can be strengthened or weakened, lengthened or shortened, and broadened or narrowed by 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. It is disinformational for drug companies to claim that compulsory licenses are confiscatory, since governments rights to issue compulsory license has been codified in the Paris Convention for nearly 130 years[115] and since 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 is disingenuous to claim a violation of a minimum standard of treatment or of national treatment simply because you dislike a particular country's standard of patentability and because you obtain patents in other countries according to less stringent standards of patentability.

There are many reasons to strike the Draft TPP Investment Chapter, a chapter that dramatically increases corporate power at the same time that it restricts government sovereignty to regulate foreign and domestic business activities and to afford the enforcement of 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

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Pharmaceutical Inventions (2012), *available* at http://www.moellerip.com/index.php?PN=news_detail&FX=0&DX=139&EX=1.

[108] 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* amended 35 U.S.C. §§ 312 and 313.

[109] India is reported to have rejected patent term extensions in its free trade agreement negotiations with the European Union. *See* leak draft of latest Negotiating Text, EU/India FTA , *available* at http://keionline.org/node/1691.

[110] 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://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154.

[111] *See* Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 351(k)(7). Information concerning compulsory licenses in Indonesia and India can be found *supra* in notes 25 and 44.

[112] At the end of March 2010, the United States enacted the Biologics Price Competition and Innovation Act (BPCI), the long awaited US 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.

[113] *See Kirtsaeng v. John Wiley & Sons, Inc*., No. 11-697 (U.S. Mar. 19, 2013).

[114] Naturally, all property rights, intellectual or real, are granted and enforced by government.

[115] Paris Convention, *supra* note 46, Art. 5(A)(2).

access to medicines.[116] Big Pharma has had a big hand in the US's proposed TPP IP Chapter and now in the Investment Chapter as well. Negotiating parties should reject 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 helping to safeguard the health of their people. Accordingly, the best solution with respect to IP-specific investment claims, and to 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 nor are investments so different in kind from trade in goods and services that they are entitled to special substantive and enforcement protections.

The second-best solution to the risk of dangerous investor-state arbitral proceedings is to explicitly exclude IPRs from the Draft TPP Investment Chapter and to clarify that IPRs are not even indirectly protected by the definition of "investment." This solution could best be accomplished by an addition to Art. 12.3: "4. This Chapter does not apply with respect to the enforcement of any rights conferred pursuant to Chapter __ (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 IP-related claims in domestic courts, just as domestic IP companies must do. By excluding investor-state IPR claims, Parties could obtain 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 country courts alleging adjudicative and administrative improprieties, confiscatory measures, or other government wrongdoing. There would as well be supplemental protection pursuant to state-to-state dispute resolution with respect to alleged violation of intellectual property norms established in the TPP.

The third-best solution is to adopt the bracketed language that allows investor claims only with respect to IP rights actually granted 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 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 Parties.[117]

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 unvigilant and if activists do not continue to highlight the risks of such claims. The

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

[117] The author appreciates the comments and suggestions of Ben Beachy on this paper and of Peter Maybarduk and Sanya Smith on an previous related paper. I also appreciate the contributions of faculty colleagues at Northeastern U. School of Law at a faculty scholarship luncheon where I presented this paper on April 10, 2013..

risks concerning access to medicine are relatively clear and dramatic – lives are at stake. 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 US TPP IP Chapter and the Draft TPP Investment Chapters, but there are similar dangers in the soon-to-be concluded EU-India FTA as well. 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.