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Update: *Since the writing of this briefing paper, Eli Lilly filed a notice of arbitration in September 2013, signaling its readiness to proceed with its NAFTA claim against Canada. In the notice, Eli Lilly made clear that in addition to challenging Canadian courts' invalidation of its patent for Strattera, it is also challenging the invalidation of another patent for a drug called Zyprexa. The corporation also increased the amount that it is demanding in compensation, from $100 million to nearly $500 million.*

March 2013

U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada's Patent Policy, Demand $100 Million for Invalidation of a Patent

Eli Lilly Claims Canadian Patent "Utility" Doctrine, Divergence from Other Nations' Patent Standards, and "Favoring" of Generics Violate Its NAFTA-Granted Property Rights

In November 2012, Eli Lilly and Company initiated formal proceedings under the North American Free Trade Agreement (NAFTA) to attack Canada's standards for granting drug patents, claiming that the invalidation of a patent violated three special investor privileges granted by the agreement.[1] The investor privileges provisions included in NAFTA and other U.S. "free trade" agreements (FTAs) empower private firms to directly challenge government policies before foreign tribunals comprised of three private-sector attorneys, to claim that the policies undermine investors' "expected future profits," and to demand taxpayer compensation. **Eli Lilly's NAFTA investor-state challenge marks the first attempt by a patent-holding pharmaceutical corporation to use the extraordinary investor privileges provided by U.S. "trade" agreements as a tool to push for greater monopoly patent protections, which increase the cost of medicines for consumers and governments. Eli Lilly is demanding $100 million in compensation.[2]**

Eli Lilly launched its NAFTA attack after Canadian courts invalidated Eli Lilly's monopoly patent rights for an attention deficit hyperactivity disorder (ADHD) drug called Strattera. The Canadian courts did so after determining that Eli Lilly had presented insufficient evidence (a single study involving 22 patients) when filing for the patent to show that Strattera would deliver the long-term benefits promised by the company.[3] While the $100 million NAFTA investor-state compensation demand relates to revocation of the Strattera patent, Eli Lilly makes clear in its formal "Notice of Intent" to Canada that it is not only challenging the invalidation of its particular patent, but Canada's entire legal doctrine for determining an invention's "utility" and, thus, a patent's validity.[4] While pushing for an entirely different patent standard, Eli Lilly, the fifth-largest U.S. pharmaceutical corporation,[5] is demanding $100 million from Canadian taxpayers as compensation for Canada's enforcement of its existing patent standards.

Now the Trans-Pacific Partnership (TPP) – a sweeping NAFTA-style deal under negotiation between the United States and ten Pacific Rim countries – threatens to not just replicate, but expand on the NAFTA provisions that provide the basis for such audacious challenges to countries' patent policies.

FTA Investor Privileges System Enables Backdoor Corporate Attacks on Public Interest Policies

How can a foreign corporation like Eli Lilly drag a sovereign government to a foreign tribunal comprised of private-sector attorneys to demand taxpayer compensation over a domestic court decision on patents? NAFTA and similar U.S. pacts have quietly established what is known as the "investor-state dispute resolution" regime, a system of new corporate privileges and their private extra-judicial enforcement defined by these radical features:

- The system elevates foreign corporations to the level of sovereign governments, uniquely empowering them to skirt domestic laws and courts and privately enforce the terms of a public treaty by directly challenging governments' public interest policies before foreign tribunals.
- The tribunals deciding these cases are comprised of three private sector attorneys, unaccountable to any electorate. Many of the tribunalists rotate between serving as "judges" and bringing cases for corporations against governments. Such dual roles would be deemed unethical in most legal systems. In this "club" of international investment arbitrators, there are fifteen lawyers who have been involved in 55 percent of the total international investment cases known today.[6] The tribunals operate behind closed doors, and there are no meaningful conflict of interest rules with respect to arbitrators' relationships with, or investments in, the corporations whose cases they are deciding.
- Tribunalists are paid by the hour, creating an incentive for cases to drag out endlessly. Governments are often ordered to pay for a share of tribunal costs even when cases are dismissed. Given that the average costs for such procedures total $8 million, the mere filing of a case can create a chilling effect on government policy, even if the government expects to win. (In one challenge against the Philippines, the government's tribunal and legal costs alone topped $50 million.)[7] If a tribunal rules against a challenged policy, there is no limit to the amount of money the tribunal can order the government to pay the foreign corporation. The cases cannot be appealed on the merits. Countries may file for an "annulment" for certain specific categories of tribunal "error." Annulment claims are not heard by domestic courts, but are decided by another tribunal comprised of private sector attorneys.
- Investors and corporations can demand taxpayer compensation for policies that they allege as violating special "rights" granted to foreign investors by NAFTA-style FTAs. These "rights" are phrased in vague, broad language. Tribunals have increasingly interpreted these foreign investor "rights" to be far more expansive than those afforded to domestic firms, such as the "right" to a regulatory framework that conforms to a corporation's "expectations." This "right" has been interpreted to mean that governments should make no changes to regulatory policies once a foreign investment has been established.[8]
- Claiming such expansive protections, foreign corporations have launched investor-state challenges against a wide array of consumer health and safety policies, environmental and land-use laws, government procurement decisions, regulatory permits, financial regulations and other public interest polices that they allege as undermining "expected future profits."

When the foreign investor wins a case, the government must hand the corporation an amount of taxpayer money decided by the tribunal as compensation for the offending policy. Under U.S. FTAs

and related deals, private investors have already pocketed over $3 billion in taxpayer money via investor-state cases, while more than $15 billion remains in pending claims.[9]

The investor-state regime was ostensibly established to provide foreign investors a venue to obtain compensation when their factory or land was expropriated by a government that did not have a reliable domestic court system. Instead, the regime has birthed an entire industry of lawyers, tribunalists and specialized equity funds that finance what has proved to be a very lucrative business of raiding government treasuries.

The number of investor-state cases has soared over the last decade – in 2011, the cumulative number of investor-state cases launched was nine times the cumulative investor-state caseload in 2000, even though treaties with investor-state provisions have existed since the 1950s. While only 50 such cases were filed between 1950 and 2000, today more than 450 have been filed.[10]

> *"When I wake up at night and think about arbitration, it never ceases to amaze me that sovereign states have agreed to investment arbitration at all ... Three private individuals are entrusted with the power to review, without any restriction or appeal procedure, all actions of the government, all decisions of the courts, and all laws and regulations emanating from parliament."*
>
> -**Juan Fernández-Armesto**, arbitrator from Spain
> "Arbitrator and counsel: the double-hat syndrome",
> *Global Arbitration Review*, Vol. 7 - Issue 2, 3/15/12.

The TPP Would Extend Beyond NAFTA in Providing Corporations New Rights to Attack Patent Policies

Ironically, while Canada faces an investor-state challenge from Eli Lilly, the country has joined negotiations to establish the TPP, which would expand the investor-state system further. To date, Canada alone has paid more than $155 million to foreign investors after NAFTA investor-state attacks on energy, timber, land use and toxics policies.[11] Underlying Eli Lilly's claim against Canada is the notion that government patent policies and actions are subject to the investor privileges provisions of the agreement. NAFTA's Investment Chapter does not explicitly list patents in its definition of investments that are subject to the pact's investor rights and privileges. However, some analysts have long worried that the broad, vague NAFTA definition of covered investments could be used to attack patent policies.[12] But in the TPP, the proposed Investment Chapter explicitly names "intellectual property rights" as a protected "investment."[13]

Not all TPP negotiating members have chosen to accept the deal's proposed extension of extreme investor-state provisions. Australia has already publicly refused to be party to an investor-state dispute settlement system in the TPP or any other trade deal.[14] And skepticism about the radical investor-state regime has grown with each extreme decision issued under this system. South Africa and India both recently announced that they would avoid submitting to the regime.[15] Brazil has always rejected it.[16]

As the number of investor-state attacks on popular public interest policies surge, the question is why every country does not follow Australia's lead. Sadly, the United States is adamant that the TPP include the expanded version of investor privileges and the notorious regime of private investor-state enforcement. So far, no TPP country except Australia has said no to the regime, though many countries have rejected the expanded definition of "investments" subject to private enforcement as proposed by the United States.

In the Name of "Free Trade," Eli Lilly Asserts a Right to Maintain Monopolies, but Break Promises

The trigger for Eli Lilly's NAFTA attack was the invalidation of a patent for Strattera, a drug used for treatment of ADHD. Both a Canadian federal court and a court of appeals ruled that Eli Lilly had failed to demonstrate the drug's promised utility when applying for a patent.[17]

The vast majority of Eli Lilly's formal NAFTA challenge notice to the Canadian government focuses on attacking Canada's underlying patent policies. That is to say that while Eli Lilly's demand for compensation is based on invalidation of the Strattera patent, its claim is premised on the tribunal finding that Canada's broader patent policy violates claimed investor rights.

To obtain a patent in Canada, an invention must be "useful." Different countries' patent policies define utility (usefulness) in varying ways. The right for each country to set its own substantive terms of patentability is among the "flexibilities" preserved in the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and in NAFTA's intellectual property chapter.[18] The Canadian "promise doctrine" provides that a patent will be granted so long as the promise regarding an invention's utility is *demonstrated or soundly predicted* at the time of filing. Eli Lilly lambasts this patent policy framework as "discriminatory, arbitrary, unpredictable and remarkably subjective."[19] It presumes to declare what Canada's standard of patentability policy should be – that Canada must issue a patent and allow a drug firm to charge monopoly prices if an invention simply *claims* utility *without demonstrating it*.[20] This is a critical point: Eli Lilly is asking the NAFTA investor-state tribunal to award compensation for a violation of its investor rights because Canada enforced its patentability standards, even though the underlying NAFTA provisions covering patents provide signatory countries flexibility to determine their own substantive standards for patentability.

If successful, Eli Lilly's broad-based attack could expose Canada to a slew of investor-state attacks from other drug companies that have had patents invalidated because their patent applications failed to show or predict that the medicines would provide the promised benefits. Indeed, Eli Lilly mentions in its notice another invalidated patent for an anti-schizophrenia drug named Zyprexa, a patent that Canadian courts similarly determined had failed the test of substantiating promised benefits.[21] Eli Lilly warns that if Canada's Supreme Court does not overturn the Zyprexa invalidation, the company "will have exhausted all domestic remedies regarding Zyprexa,"[22] which experts see as a thinly-veiled threat that Eli Lilly might launch another NAFTA investor-state challenge over that drug.[23] In addition, observers have noted that Pfizer may also be considering a NAFTA investor-state attack on Canada's patent policies after the Supreme Court invalidated Pfizer's patent for its famed Viagra drug late last year for failing to disclose a critical active ingredient.[24]

Eli Lilly Cites / Invents Sweeping "Rights" that Could Chill Policies that Increase Access to Affordable Medicines

Eli Lilly's specific claims are that the Canadian courts' revocation of its patent violates its NAFTA-granted special investor privileges because this government action is*:*

- A violation of the **Minimum Standard of Treatment** guaranteed to foreign investors by NAFTA's investor privileges rules. (Eli Lilly and Company is a U.S. corporation that wholly owns Eli Lilly Canada.);

- **Discriminatory** (in favor of generic firms) in violation of NAFTA's **National Treatment** rule; and
- An **Expropriation** of property rights granted to Eli Lilly by NAFTA.

Eli Lilly specifically claims that Canada's invalidation of the Strattera patent violated the "**Minimum Standard of Treatment**" that NAFTA signatories are obliged to provide to foreign investors.[25] NAFTA Article 1105 on the Minimum Standard of Treatment states: "Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security."[26] What does that mean? Ultimately the tribunal decides, and its interpretation is not subject to appeal.

Sovereign States, including the United States, have consistently argued that this standard means providing police protection and due process, such as that afforded to Eli Lilly when it defended its patent before Canada's courts. States have consistently argued that tribunals must define the Minimum Standard of Treatment using two fundamental principles of Customary International Law (CIL): State practice and *opinio juris* (a State's sense of obligation, i.e. that it is bound to the law in question).

After a string of outlandish, expansive tribunal interpretations in NAFTA cases of what the minimum standard required of States, U.S. trade negotiators inserted an Annex in the 2005 Central America Free Trade Agreement (CAFTA) and subsequent U.S. FTAs that states: "The Parties confirm their shared understanding that 'customary international law' generally and as specifically referenced in Articles 10.5 [on the Minimum Standard of Treatment], 10.6, and Annex 10-C results from a general and consistent **practice of States** that they follow from a sense of legal obligation." [emphasis added][27]

But investor-state tribunals have generated increasingly inventive interpretations of the minimum standard in NAFTA-style deals, interpretations that impose new obligations on States beyond those that they contemplated when signing the agreements. This trend includes a recent CAFTA case in which the tribunal simply ignored the CIL Annex and instead imported a definition fabricated by a previous NAFTA tribunal.[28] Not bound to the minimum standard practiced and supported by sovereign States, investor-state tribunals have repeatedly interpreted the standard to mean that governments must compensate investors if they enact policies or take actions that could violate foreign investors' expectations. The tribunals have also generated creative notions of just what such investor expectations are. As the United States argued in a previous investor-state case, "if States were prohibited from regulating in any manner that frustrated expectations – or had to compensate for any diminution in profit – they would lose the power to regulate."[29]

Yet, this extreme interpretation is precisely the one on which Eli Lilly relies in accusing Canada's courts of "contravening" its expectations by raising patent standards to include "new and additional requirements."[30] Specifically, Eli Lilly claims that the Canadian court decisions undermined its NAFTA-granted "expectations of a stable business and legal environment" and the "basic requirements of legal security."[31] Eli Lilly does not explicitly define the minimum standard, but implicitly relies on the inventive interpretation of tribunals in other NAFTA investor-state cases, while ignoring State practice – the body of thousands of domestic court cases on patentability standards and utility requirements.[32]

Unfortunately, tribunals' elastic interpretations have made the Minimum Standard of Treatment claim the single most successful investor-state allegation that corporations can mount against a State, as the

number of such cases has exploded. In 74 percent of all published U.S. FTA and Bilateral Investment Treaty (BIT) cases in which governments have been ordered to compensate investors, the tribunal has found a Minimum Standard of Treatment violation. (In 17 of 23 published cases under U.S. FTAs and BITs in which the investor has "won," it has done so by using Minimum Standard of Treatment violation claims.)[33]

Eli Lilly also claims that Canada violated NAFTA's "**National Treatment**" obligation, which requires governments to afford foreign investors treatment that is "no less favorable" than that afforded to domestic corporations "in like circumstances."[34] But after quoting this NAFTA standard, which requires countries to provide foreign investors with the same treatment provided to domestic firms under domestic law, Eli Lilly ignores it. Instead, 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 investors' home countries*. 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."[35] That is to say, *the alleged violation is the requirement to meet Canadian law.* Eli Lilly also claims that: "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."[36] Again, that is to say, *the alleged violation is that Canada is enforcing its own laws rather than those of foreign nations.* Such a speculative obligation is rather unprecedented even among the musings of inventive investor-state tribunals.

A key aspect of Eli Lilly's discrimination claim relies on the conflation of two distinct requirements: standards for *filing* an international application for a patent under the Patent Cooperation Treaty (PCT) and standards for *obtaining* a patent from a specific country. There is no such thing as an "international patent." Patents are granted by specific countries according to their domestic laws. Rather, the PCT provides for the filing of one application in one language that establishes a date of filing accepted by all PCT signatory countries and on which an "international search" is conducted to prepare a written opinion on patentability (i.e. to determine whether there are already existing patents on the same invention). According to the World Intellectual Property Organization, the main advantages of the PCT are providing the applicant with up to 18 months "to **reflect on the desirability of seeking protection in foreign countries**, to appoint local patent agents in each foreign country, to prepare the necessary translations and to pay the national fees; he is assured that, if his international application is in the **form** prescribed by the PCT, it cannot be rejected on **formal** grounds by any designated Office during the national phase of the processing of the application." [emphasis added][37]

In other words, the PCT provides for a standardized patent application, which may be granted or rejected according to applicable law in each jurisdiction in which a patent is sought. The initial international review process helps patent seekers decide if it is worth their money to try to undertake the domestic processes to seek a patent in any or many jurisdictions. And, signatory countries, including Canada, agree not to reject an *application* that meets the PCT standards on the basis that the application itself is not in the proper format. However, the decision on the merits of whether or not a patent may be issued under any specific country's patent law remains at the discretion of each country. Eli Lilly's claims of discrimination center on it being required to meet Canada's standards for patentability, as if merely *filing* an international patent application under PCT terms is the same as complying with the substantive requirements of Canadian law to *obtain* a patent.[38]

The corporation also bizarrely alleges that the Canadian courts' patent invalidation violates its NAFTA national treatment rights by advantaging Canadian generic firms that can now create and market generic versions of Strattera.[39] Here, Eli Lilly presumes to challenge Canadian courts' removal of a patent on the incredible basis that patent removals help expand the availability of less expensive generic medicines. Of course the removal of patents helps generic producers – it always does, but it does so regardless of whether the generic firms and/or the patent holders are foreign or domestic. Were Eli Lilly's skewed logic to be accepted by the tribunal, any invalidation of a foreign investor's patent, regardless of the basis, could be construed as a violation of FTA-protected national treatment rules.

Eli Lilly's final claim is that Canada violated NAFTA's obligation to not expropriate investments. The company first tries to argue that the patent invalidation constituted a "**direct expropriation**" of investments, even though that term has long been understood to mean government seizure of real property, such as land or a factory, not the invalidation of monopoly patent rights. The company then alleges in the alternative that Canada committed an "**indirect expropriation**," an extreme NAFTA provision that allows companies to obtain government compensation for "regulatory takings."[40] This is a legal theory generally rejected by most nations' courts: that governments must compensate property holders for any government policy or action that may reduce the property's value. (A classic example would be the government having to compensate for a land use law of general application if it forbids a property in a residential area from being used for more profitable industrial purposes.)

The basis of Eli Lilly's indirect expropriation claim is that: "…The judicial decisions invalidating the Strattera patent are illegal from the perspective of international law and therefore constitute an expropriation…The Government of Canada has a positive obligations to ensure Canadian law complies with Canada's international treaty obligations, as well as the reasonable investment-backed expectations of the investor."[41] Specifically, the corporation alleges that Canada's patent invalidation violates the rules of the WTO's TRIPS agreement, NAFTA's intellectual property rules, the PCT and the Paris Convention for the Protection of Industrial Property.

This argument is, in part, related to a provision of NAFTA that states that the expropriation provisions do not apply to a government's revocation or limitation of intellectual property rights to the extent that a revocation or limitation is consistent with the country's obligations under NAFTA Chapter 17, which sets forth the pact's substantive rules on intellectual property.[42] As noted above, NAFTA's intellectual property provisions, as well as the WTO's TRIPS agreement, provide countries with flexibilities to set their own standards of patentability with respect to defining standards such as utility. Eli Lilly skirts this inconvenient fact.[43]

Rather, although most of the Notice of Intent is consumed with an attack on Canada's legal basis for granting patents, with respect to its indirect expropriation claim, Eli Lilly circles back to its bizarre notions of how Canada's actions are discriminatory. The company again argues that Canada has violated the national treatment obligations for patents set forth in NAFTA, the WTO and the Paris Convention by requiring the firm to meet Canadian standards rather than U.S. or EU standards.[44] In sum, Eli Lilly is arguing that the mere fact of Canadian patentability standards being different from those in other jurisdictions is in itself an indirect expropriation of Eli Lilly's investment in violation of its NAFTA investor rights.

Eli Lilly also claims that being required to provide Canadian national patent authorities more information to determine utility than Eli Lilly was required to provide in filing its initial international patent application under the Patent Cooperation Treaty violates the PCT – and thus is "illegal" under

international law.[45] As described above, the PCT sets international standards for the *form* of a patent application, not whether the invention in question can satisfy the substantive standards to obtain a patent under any specific country's intellectual property laws.

Finally, the reference to the WTO is doubly confounding. In addition to the fact that the WTO TRIPS agreement provides flexibility for countries to determine their own standards of patentability, NAFTA predates the WTO and its TRIPS agreement, and thus does not make mention of either. NAFTA's Intellectual Property Chapter contains no general commitment to comply with other intellectual property agreements. Rather, in describing the standard that signatories are to meet – providing "adequate and effective protection and enforcement of intellectual property rights" – NAFTA names four specific international agreements, the substantive provisions of which signatories are to give effect in their domestic law: conventions concerning phonograms, literary and artistic works, industrial property and plant varieties.[46]

If the NAFTA Tribunal Allows this Claim, It Would Open the Door for Corporations to Privately Enforce Any International Intellectual Property Treaty in Investor-State Tribunals

Viewed from a broader perspective, the enormous threat posed by this NAFTA investor-state case is the prospect that in the future, investors and corporations could privately enforce the terms of any public treaty covering intellectual property matters through claims directly launched against sovereign governments in investor-state tribunals. In contrast, WTO rules can only be enforced when one government formally challenges another government before a WTO tribunal. There is no right in the WTO for a corporation to directly challenge sovereign governments. Eli Lilly is arguing that NAFTA's investor privileges and investor-state enforcement allows it or any private commercial interest to enforce international intellectual property agreements and rules not even listed in a specific trade agreement or BIT. This would vastly expand corporate rights to directly attack government policies – and would do so under terms to which governments never agreed. Worryingly, the establishment of just such a backdoor means for private corporations to directly challenge governments for alleged TRIPS violations is one serious concern raised about the TPP's draft Investment Chapter, which expands considerably on NAFTA's investor privileges.[47]

Preventing More Eli-Lilly-Like Threats to Access to Affordable Medicines Requires Changing the Investor-State Regime and Preventing its Expansion through the TPP

The outcome of Eli Lilly's investor-state attack under NAFTA is critical for those seeking to safeguard countries' ability to determine their own patent standards, a prerogative that is essential for preventing patent "evergreening" and ensuring access to affordable medicines. It is critical not just to protect Canada's right to not grant patents unlikely to deliver promised results, but to avoid instilling other governments with fear of investor-state reprisal for similar patent policies. It is critical not just so that Canadian taxpayers can ensure that the demanded $100 million goes to more worthy ends than enhancing Eli Lilly's profit margin, but to avoid emboldening other pharmaceutical firms contemplating the launch of similar investor-state demands against other governments that dare to set their own patent policies. As the Eli Lilly case gets underway, negotiations for the TPP and its proposed expansion of the investor-state system continue. Stopping the NAFTA expansion deal presents health advocates with today's biggest opportunity to halt the advance of the system that empowered Eli Lilly's audacious threat.

ENDNOTES

[1] *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*."]
[2] *Eli Lilly v. Canada*, at para. 108.
[3] *Eli Lilly v. Canada*, at paras. 76-81.
[4] *Eli Lilly v. Canada*, at paras. 42-43.
[5] "Fortune 500: Pharmaceuticals," *CNN Money*, May 21, 2012. Available at: http://money.cnn.com/magazines/fortune/fortune500/2012/industries/21/.
[6] Pia Eberhardt and Cecilia Olivet, "Profiting from Injustice," Transnational Institute and Corporate Europe Observatory report, Nov. 2012, at 8. Available at: http://www.tni.org/pressrelease/exposed-elite-club-lawyers-who-make-millions-suing-states.
[7] Pia Eberhardt and Cecilia Olivet, "Profiting from Injustice," Transnational Institute and Corporate Europe Observatory report, Nov. 2012, at 7. Available at: http://www.tni.org/pressrelease/exposed-elite-club-lawyers-who-make-millions-suing-states.
[8] For more information on this alarming trend, *see* Lori Wallach, "Fair and Equitable Treatment" and Investors' Reasonable Expectations: Rulings in U.S. FTAs & BITs Demonstrate FET Definition Must be Narrowed," Public Citizen memo, Sept. 5, 2012. Available at: http://www.citizen.org/documents/MST-Memo.pdfhttp://www.citizen.org/documents/MST-Memo.pdf.
[9] For more information, *see* "Table of Foreign Investor-State Cases and Claims under NAFTA and Other U.S. Trade Deals," Public Citizen memo, March 2013. Available at: http://www.citizen.org/documents/investor-state-chart.pdf.
[10] United Nations Conference on Trade and Development, "IIA Issues Note: Latest Developments in Investor-State Dispute Settlement," April 2012, at 3. Available at: http://unctad.org/en/PublicationsLibrary/webdiaeia2012d10_en.pdf.
[11] For more information, *see* "Table of Foreign Investor-State Cases and Claims under NAFTA and Other U.S. Trade Deals," Public Citizen memo, March 2013. Available at: http://www.citizen.org/documents/investor-state-chart.pdf.
[12] *See* NAFTA Art. 1139.
[13] *See* Article 12.2 in the leaked TPP Investment Chapter text, available at: http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf. For more information, *see* Brook Baker, "Leaked TPP Investment Chapter Presents a Grave Threat to Access to Medicines," Health GAP memo, Aug. 14, 2012. Available at: http://infojustice.org/wp-content/uploads/2012/09/Baker-Investment-in-the-TPP.pdf.
[14] *See* Adam Gartrell, "Labor Standing Firm on Pacific Trade Deal," *The Sydney Morning Herald*, March 5, 2012. Available at: http://news.smh.com.au/breaking-news-national/labor-standing-firm-on-pacific-trade-deal-20120305-1ue2b.html.
[15] Peter Leon, Jonathan Veeran and Erin Warmington, "South Africa: South Africa Declines To Renew Bilateral Investment Treaties With European Union Member States," Mondaq.com, Oct. 5, 2012. Available at: http://www.mondaq.com/x/199586/international+trade+investment/South+Africa+Declines+To+Renew+Bilateral+Investment+Treaties+With+European+Union+Member+States. Jung Eun-joo, "India plans to abolish ISD clause in FTAs," *The Hankyoreh*, April 6, 2012. Available at: http://www.hani.co.kr/arti/english_edition/e_international/527103.html.
[16] While Brazil has signed 14 Bilateral Investment Treaties (BITs), some of which include the investor-state dispute mechanism, Brazil's Congress has refused to ratify any of them to date, largely due to strong opposition to the investor-state regime. For the list of BITs, *see* ICSID, "ICSID Database of Bilateral Investment Treaties," accessed January 23, 2013. Available at: https://icsid.worldbank.org/ICSID/FrontServlet. For more information on Brazil's debate over the BITs, *see* Ricardo Barretto et al, "Bilateral Investment Treaties and International Arbitration," International Law Office, May 15, 2003. Available at: http://www.internationallawoffice.com/newsletters/detail.aspx?g=6ce64813-8cf6-4f97-b8a8-2ad950fa25ad.
[17] *Eli Lilly v. Canada*, at paras. 70-81.
[18] The ability of a State to set its own patentability standards, including its own interpretation of "utility," is a key flexibility guaranteed by the WTO's TRIPS agreement. Article 27(1) of TRIPS states that patents "shall be available for any inventions… provided that they are new, involve an inventive step and are capable of industrial application." A footnote clarifies the latter term as equivalent to "useful." TRIPS makes no attempt to further define usefulness, leaving specific interpretations up to member States. WTO, Trade-Related Aspects of Intellectual Property Rights, Art. 27(1). According to the United Nations Conference on Trade and Development (UNCTAD), "This provision sets up the criteria of patentability, without however harmonizing the way in which they have to be implemented. Members have considerable leeway in applying those three criteria (novelty, inventive step and industrial applicability)." UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, (Cambridge: Cambridge University Press, 2005), at 358. Available at: http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.1_update.pdf. NAFTA's Article 1709 on patents mimics this flexibility, stating that "a Party may deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively." NAFTA Art. 1709(1).
[19] *Eli Lilly v. Canada*, at para. 43.
[20] *See*, for example, *Eli Lilly v. Canada*, at paras. 15-16.
[21] *Eli Lilly v. Canada*, at paras. 48-52.
[22] *Eli Lilly v. Canada*, at para. 48.
[23] Luke Eric Peterson, "Newly Disclosed Document Shows that Pharma Corp Hopes to Construe Alleged Non-compliance with Patent Treaties as Breach of Investment Treaty," *Investment Arbitration Reporter*, Dec. 10, 2012. Available at: http://www.iareporter.com/articles/20121210_2.

[24] 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.
[25] *Eli Lilly v. Canada*, at paras. 98-104.
[26] NAFTA Art. 1105(1).
[27] CAFTA Annex 10-B. Parallel wording has been proposed as Annex12-B in the leaked TPP Investment Chapter text, available at http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf.
[28] *See* Lori Wallach and Ben Beachy, "CAFTA Investor-State Ruling: Annex on Minimum Standard of Treatment, Proposed for TPP, Proves Insufficient as Tribunal Ignores Customary International Law Standard, Applies MST Definition from Past NAFTA Award to Rule against Guatemala," Public Citizen memo, July 19, 2012. Available at: http://www.citizen.org/documents/RDC-vs-Guatemala-Memo.pdf.
[29] *Glamis Gold, Ltd. v. United States of America*, Award, Ad hoc – UNCITRAL Arbitration Rules (2009), at para. 576. Available at: http://italaw.com/sites/default/files/case-documents/ita0378.pdf.
[30] *Eli Lilly v. Canada*, at paras. 99-100.
[31] *Eli Lilly v. Canada*, at paras. 100, 103.
[32] While Eli Lilly does not provide an explicit basis for its claim that the minimum standard covers expectations, the company states a similar obligation in its earlier Expropriation claim (at para. 95), providing case citations on which the company also appears to rely for its minimum standard claim of "contravened[]…expectations" (at para. 100). In footnote 26, Eli Lilly cites two investor-state cases to argue that the Investment chapter protects "investment-backed expectations of the investor": *Fireman's Fund v. Mexico* and *Glamis Gold, Ltd. v. The United States of America*. In *Fireman's Fund*, the tribunal used the opinions of four attorneys to suggest that investor expectations "may be a relevant factor" in expropriation claims. *Fireman's Fund v. Mexico*, ICSID Case No. ARB(AF)/02/01, Award (July 17, 2006), at para. 176(k). In *Glamis Gold*, the tribunal actually took a relatively narrow view of what expectations may be protected by the minimum standard, stating, "Merely not living up to expectations cannot be sufficient to find a breach of Article 1105 of the NAFTA. Instead, Article 1105(1) requires the evaluation of whether the State made any specific assurance or commitment to the investor so as to induce its expectations." *Glamis Gold, Ltd. v. United States of America*, Award, Ad hoc – UNCITRAL Arbitration Rules (2009), at para. 620.
[33] For more information, *see* Lori Wallach, "Fair and Equitable Treatment" and Investors' Reasonable Expectations: Rulings in U.S. FTAs & BITs Demonstrate FET Definition Must be Narrowed," Public Citizen memo, Sept. 5, 2012. Available at: http://www.citizen.org/documents/MST-Memo.pdf.
[34] *Eli Lilly v. Canada*, at para. 105.
[35] *Eli Lilly v. Canada*, at para. 106.
[36] *Eli Lilly v. Canada*, at para. 106.
[37] World Intellectual Property Organization, "Patent Cooperation Treaty ("PCT") (1970)," accessed March 19, 2013. Available at: http://www.wipo.int/pct/en/treaty/about.html.
[38] Though Eli Lilly acknowledges in para. 21, "the PCT accords to Member countries the freedom to prescribe substantive conditions of patentability," the company asserts in para. 106 that Canada's substantive "elevated and additional standards for utility and disclosure" constitute a PCT violation. *Eli Lilly v. Canada*, at paras. 21, 106.
[39] *Eli Lilly v. Canada*, at para. 107.
[40] *Eli Lilly v. Canada*, at paras. 90-91.
[41] *Eli Lilly v. Canada*, at paras. 92, 95.
[42] "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)." NAFTA Art. 1110(7).
[43] The company reiterates its claim that the promise doctrine exceeds the definition of "useful" under NAFTA's intellectual property provisions, but again fails to acknowledge the broad and flexible nature of that definition within NAFTA. *Eli Lilly v. Canada*, at para. 93(i).
[44] *Eli Lilly v. Canada*, at para. 93(v).
[45] *Eli Lilly v. Canada*, at para. 93(iii).
[46] NAFTA Art. 1701(2).
[47] Article 12.12(5) of the proposed Investment Chapter of the TPP invokes compliance with TRIPS as a requirement for claiming a compulsory licenses exception to the chapter's expropriation provisions. Such an explicit requirement of TRIPS consistency has sparked fears among trade lawyers that an investor-state tribunal could interpret TRIPS obligations as justiciable via investor-state enforcement. A leaked version of the proposed TPP Investment Chapter is available at: http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf.