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

Eli Lilly Claims that Canadian “Utility” Doctrine, Divergence from Other Nations’ Patent Standards Expropriates its Extraordinary NAFTA-Granted Property Rights

Eli Lilly and Company has initiated formal proceedings under the North American Free Trade Agreement (NAFTA) to attack Canada’s standards for granting drug patents, claiming that the denial of a medicine patent is an expropriation of its property rights 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, claiming that the policies undermine their “expected future profits.” Eli Lilly’s move marks the first attempt by a patent-holding pharmaceutical corporation to use U.S. “trade” agreement investor privileges as a tool to push for greater monopoly patent protections, which increase the cost of medicines for consumers and governments.

Eli Lilly launched its NAFTA attack after Canadian courts invalidated Eli Lilly’s monopoly patent rights for an attention deficit hyperactivity disorder (ADHD) drug, having determined that the drug had failed to deliver the benefits the firm promised when obtaining the patent. However, in its formal notice of intent to take Canada to a NAFTA investor tribunal, Eli Lilly makes clear that it is not only challenging the invalidation of its particular patent, but Canada’s entire legal doctrine for determining a medicine’s “utility” and, thus, a patent’s validity. While pushing for a patent standard that would raise medicine prices, Eli Lilly, the fifth-largest U.S. pharmaceutical corporation,² is demanding \$100 million from Canadian taxpayers as compensation for Canada’s enforcement of its existing medicine patent standards.³

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’ medicine patent policies.

Stealth 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 democratically-

determined policy? NAFTA and similar U.S. pacts have quietly established what is known as the “investor-state” regime, a system of new corporate privileges 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 are comprised of three private sector attorneys, unaccountable to any electorate, who rotate between serving as “judges” and bringing cases for corporations against governments.⁴ The tribunals operate behind closed doors, and there are no conflict of interest rules. The tribunalists are paid by the hour and governments are often ordered to pay for a share of tribunal costs even when cases are dismissed. There is no limit to the amount of money tribunals can order governments to pay corporations. There are very limited appeal rights.
- The corporations can demand taxpayer compensation for policies that they allege as violating special “rights” granted to foreign investors by NAFTA-style FTAs. 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.⁵
- 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.⁶

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 – last year the cumulative number of launched investor-state cases was nine times the cumulative investor-state caseload in 2000, even though treaties with investor-state provisions have existed since the 1950s.⁷

The TPP Would Extend Beyond NAFTA in Providing Corporations New Rights to Attack Medicine 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 has paid more than \$140 million to foreign investors after NAFTA investor-state attacks on energy, timber and toxics policies. Part of Eli Lilly’s claim against Canada is that the invalidation of

its patent constituted an expropriation of its “investment.”⁸ NAFTA does not list patents in its definition of a protected “investment,” although some analysts have long worried that the broad, vague NAFTA definition could be used to attack medicine patent policies. But in the TPP, the proposed Investment Chapter explicitly names “intellectual property rights” as a protected “investment.”⁹

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.¹⁰ South Africa recently announced that it would also avoid agreeing to the regime. Brazil has always rejected it.¹¹ 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 several 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 its patent for Strattera, a drug used to treat ADHD. Both a Canadian federal court and a court of appeals ruled that the patented drug failed to demonstrate the utility that Eli Lilly had promised when applying for the monopoly protection rights provided by the patent. The Canadian court decisions paved the way for Canadian drug producers to produce a less expensive, generic version of the ADHD drug.¹² (The domestic court case challenging Eli Lilly’s patent for Strattera was initiated by Novopharm, a generic drug company.)

Eli Lilly’s formal NAFTA challenge notice to the Canadian government directly targets Canada’s basis for the patent invalidation, known as the “promise doctrine.” To obtain a patent in Canada, as in most countries, a drug must be shown to be “useful.” Countries’ policies define usefulness in varying ways.¹³ The Canadian “promise doctrine” provides that a drug patent will be honored so long as promises regarding the drug’s efficacy are also honored. The corporation lambasts this patent policy framework as “discriminatory, arbitrary, unpredictable and remarkably subjective.”¹⁴ It presumes to declare what Canada’s policy should be – that Canada must issue a patent and allow a drug firm to charge monopoly prices if a medicine has a “mere scintilla” of utility.¹⁵

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 medicines have not met the promises they made to initially obtain patents. Indeed, Eli Lilly mentions in its notice another invalidated patent for an anti-schizophrenia drug named Zyprexa, which Canadian courts similarly determined to fall short of promised benefits.¹⁶ 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,” which experts see as a thinly-veiled threat that Eli Lilly might launch another NAFTA investor-state challenge over that drug.¹⁷ In addition, observers have noted that Pfizer may also be considering a NAFTA investor-state attack on Canada’s medicine 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.¹⁸

Eli Lilly Cites / Invents Sweeping “Rights” that Could Chill Access-to-Medicines Policies

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.¹⁹ 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. But investor-state tribunals have generated increasingly inventive interpretations of the minimum standard,²⁰ arguing that it also requires governments not to enact policies that could plausibly violate foreign investors' expectations. 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.”²¹ 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.”²² Such 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 explodes.²³

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.”²⁴ But after quoting this NAFTA definition, Eli Lilly ignores it, inventing instead a standard that would require Canada to afford foreign investors treatment no less favorable than what Canadian companies could hypothetically *receive in other countries*.²⁵ Such a speculative obligation is rather unprecedented even among the musings of inventive investor-state tribunals, seemingly concocted by Eli Lilly itself.

The corporation also alleges that the courts' patent invalidation violates national treatment by advantaging Canadian generic firms that can now create and market generic versions of Strattera.²⁶ 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 patent invalidation, regardless of the basis, could be construed as a violation of FTA-protected national treatment obligations. Such an interpretation would jeopardize generic medicines in nearly any country that finds cause to terminate a patent but also finds itself subject to a NAFTA-style treaty.

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 that Canada committed an “indirect expropriation,” an extreme NAFTA provision that allows companies to obtain government compensation for “regulatory takings.”²⁷ This is a legal theory generally rejected by most nations' courts, including the U.S. Supreme Court, 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.) Interestingly, Eli Lilly does not argue that Canada's policy violates NAFTA's Intellectual Property Chapter. This highlights how it would expand corporate privileges under NAFTA immensely if a tribunal would accept Eli Lilly's claim and allow a patent revocation to be considered an indirect expropriation. NAFTA's Investment Chapter explicitly states that the expropriation provision "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)."²⁸ Rather than try to show that Canadian policy violates the Intellectual Property Chapter, and thus that the patent revocation is subject to an expropriation claim, Eli Lilly is trying to expand the scope of what the expropriation provision covers altogether. Unfortunately, the investor-state system empowers three private attorneys meeting behind closed doors in a foreign tribunal to now determine the validity of Eli Lilly's inventive interpretation and the legitimacy of Canada's patent policy.

Another argument in Eli Lilly's claim that Canada has expropriated its investment is that Canada's policy does not comply with international agreements that fall outside of both Canadian domestic law and NAFTA itself. The corporation alleges that Canada's patent invalidation violates the rules of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), and that NAFTA obliges adherence to those rules.²⁹ However, NAFTA predates the WTO and its TRIPS agreement, and thus does not even 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.³⁰

Moreover, 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. Arguing that NAFTA requires countries to enforce international agreements and rules not even listed in NAFTA 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 rules.³¹

Preventing More Eli-Lilly-Like Threats to Access to 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 the patent standards they believe serve the public interest in access to affordable medicines. It is critical not just to protect Canada's prerogative to end patents found to not deliver promised results, but to avoid instilling other governments with fear of investor-state reprisal for similar policies to rein in medicine costs. 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 seeking to balance the rights of consumers and pharmaceutical firms. As the Eli Lilly case gets under way, 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 "Fortune 500: Pharmaceuticals," *CNN Money*, May 21, 2012. Available at: <http://money.cnn.com/magazines/fortune/fortune500/2012/industries/21/>.

³ *Eli Lilly v. Canada*, at para. 108.

⁴ For more information on such conflicts of interest in the investor-state system, see "Profiting from Injustice," Transnational Institute and Corporate Europe Observatory report, Nov. 2012. Available at: <http://www.tni.org/pressrelease/exposed-elite-club-lawyers-who-make-millions-suing-states>.

⁵ 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.pdf>.

⁶ For more information, see "Table of Foreign Investor-State Cases and Claims under NAFTA and Other U.S. Trade Deals," Public Citizen memo, June 2012. Available at: <http://www.citizen.org/documents/investor-state-chart.pdf>.

⁷ 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.

⁸ *Eli Lilly v. Canada*, at paras. 89-97.

⁹ 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>.

¹⁰ 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>.

¹¹ 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>.

¹² *Eli Lilly v. Canada*, at paras. 70-86.

¹³ 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 17(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. 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. The World Health Organization has expressed concern that NAFTA-style FTAs curtail this critical flexibility: "Some of the recent FTAs seek to define the patentability criteria such as utility to conform to the US standard...No public health-related justification seems to support this emerging trend." Sisule Musungu and Cecilia Oh, "The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?" Commission on Intellectual Property Rights, Innovation and

Public Health, World Health Organization, August 2005, at 65-66. Available at:

<http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>.

¹⁴ *Eli Lilly v. Canada*, at para. 43.

¹⁵ *Eli Lilly v. Canada*, at para. 101.

¹⁶ *Eli Lilly v. Canada*, at paras. 48-52.

¹⁷ 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.

¹⁸ 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.

¹⁹ *Eli Lilly v. Canada*, at paras. 98-104.

²⁰ For an example of such expansive interpretations, 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>.

²¹ *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>.

²² *Eli Lilly v. Canada*, at paras. 99-100.

²³ 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>.

²⁴ *Eli Lilly v. Canada*, at para. 105.

²⁵ *Eli Lilly v. Canada*, at para. 106.

²⁶ *Eli Lilly v. Canada*, at para. 107.

²⁷ *Eli Lilly v. Canada*, at paras. 90-91.

²⁸ North American Free Trade Agreement, U.S.-Can.-Mex. Ch. 11, Art. 1110(7), Dec. 17, 1992, 32 I.L.M. 639.

²⁹ *Eli Lilly v. Canada*, at paras. 92-93.

³⁰ North American Free Trade Agreement, U.S.-Can.-Mex. Ch. 17, Art. 1701(2), Dec. 17, 1992, 32 I.L.M. 639.

³¹ See the proposed Investment Chapter of the TPP, Article 12.12(5), available at: <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf>.