Reexamining *Eli Lilly v. Canada*: A Human Rights Approach to Investor-State Disputes?

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ABSTRACT

This Article provides valuable insight to the broader discussion of reforming investor-state disputes. Many have noted that the system is in a crisis due to a lack of democratic accountability and inconsistent decisions, which create a chilling effect on legitimate domestic law and policy. Despite substantial discussion in recent years concerning how to reform investor-state disputes, there is only limited discussion concerning the extent to which such disputes challenge domestic intellectual property (IP) limits, as well as global IP norms. Moreover, even among those who recognize the challenge to IP limits, the relevance of human rights is generally not addressed. This Article begins to fill this gap from two angles. First, it aims to promote a better understanding of how such disputes undermine the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at an important time when policymakers are recommending reliance on policy space under TRIPS. Second, it considers whether human rights might help to protect this policy space using the facts of Eli Lilly v. Canada.

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I. INTRODUCTION

Disputes that permit a company to challenge a nation's laws as violating its investments and seek compensation, so-called "investor-state disputes," pose a major threat to intellectual property (IP) norms.[1] Although there are only a few known disputes so far, such as Philip Morris' challenge to Australia's plain package tobacco laws and Eli Lilly's challenge to Canada's patent invalidations, investor-state disputes have important implications.[2] Some commentators have

1. This Article recognizes that the entire system of investor-state disputes is at a critical conjuncture as nations are considering whether to maintain the existing system, reform its mechanism in major ways, or even potentially jettison the system. *See, e.g.*, Comm'n on Int'l Trade Law, Rep. on the Work of its Fiftieth Session, ¶ 264, U.N. Doc A/72/17 (2017) (charging UNCITRAL with identifying issues with ISDS, considering whether reform is desirable, and if so, to provide solutions); Anthea Roberts, *Incremental, Systemic, and Paradigmatic Reform of Investor-State Arbitration,* 112 AM. J. INT'L L. 410, 410–11 (2018) (explaining the three possibilities). Regardless of which path results, the focus of this Article on the evaluation of TRIPS flexibilities outside of the WTO remain pertinent and can thus inform and complement any future reform.

2. There are only a few known notices to initiate investor-state disputes that limit IP rights. *See* Eli Lilly & Co. v. Gov't of Canada, ICSID Case No. UNCT/14/2, Notice of Arbitration, ¶ 85 (Sept. 12, 2013) [hereinafter *Eli Lilly*, Notice of Arbitration], https://www.italaw.com/sites/default/files/case-documents/italaw1582.pdf [https://perma.cc/43UJ-YFPX]; Philip Morris Asia Ltd. v. Austl., PCA Case No. 2012-12, Notice of Arbitration, ¶ 1.1 (Nov. 21, 2011) [hereinafter *Philip Morris Asia Ltd.*, Notice of Arbitration], https://www.italaw.com/sites/default/files/case-documents/ita0665.pdf [https://perma.cc/KNM7-7CA4]; Philip Morris Brands Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Request for Arbitration, ¶ 1.1 (Feb. 19, 2010) [hereinafter *Philip Morris*, Request for Arbitration], https://www.italaw.com/sites/default/files/case-documents/ita0343.pdf [https://perma.cc/7UXK-RRTV]. The PM v. Australia suit challenges a popular domestic regulation of tobacco that requires cigarettes to be sold in dark drab brown (i.e., "plain" packaging). *See Philip Morris Asia Ltd.*, Notice of Arbitration, *supra*, ¶ 1.5. Since this dispute was initiated, other countries have enacted similar

improperly assumed that successful initial state defenses indicate that domestic IP limits are safe from challenge.[3] To the contrary, initial investor-state disputes actually demonstrate that compliance with an international IP agreement does not immunize a nation from an investor-state dispute, which on average costs over USD $4 million simply to defend.[4] In addition, although some might assume companies would exhibit caution in bringing future disputes given that Philip Morris and Eli Lilly had to reimburse states some costs, the extent of caution is likely minimal for multinational companies.[5] First, neither of the two fully litigated disputes were considered frivolous.[6] Moreover,

laws. *See e.g.*, CAMPAIGN FOR TOBACCO-FREE KIDS, STANDARDIZED OR PLAIN TOBACCO PACKAGING: INTERNATIONAL DEVELOPMENTS 1–2 (2018), https://www.tobaccofreekids.org/assets/global/pdfs/en/standardized_packaging_developments_en.pdf [https://perma.cc/S6DD-UYC5] (noting countries that have implemented plain packaging, including both those already in force, as well as those who have politically committed to doing so).

3. *See, e.g.*, Marina Hodges, *Uruguay's Victory over Big Tobacco*, AUSTL. INST. INT'L AFF. (Aug. 24, 2016), http://www.internationalaffairs.org.au/australianoutlook/uruguays-victory-against-big-tobacco/ [https://perma.cc/HML3-CC52] (suggesting that the Uruguay award "solidifies the role of police powers" and that it will be "referenced . . . for years to come," even though there is no precedent in the field of investor-state disputes); Nathaniel Lipkus, *Canada's NAFTA Victory a Win for Judicial Sovereignty*, POL'Y OPTIONS (Apr. 7, 2017) http://policyoptions.irpp.org/magazines/april-2017/canadas-nafta-victory-a-win-for-judicial-sovereignty/ [https://perma.cc/VR2F-7XSP] ("[W]e no longer need to worry that trade tribunals will become supranational courts of appeal over domestic property law disputes.").

4. *See, e.g.*, David Gaukrodger & Kathryn Gordon, *Investor-State Dispute Settlement: A Scoping Paper for the Investment Policy Community* 19 (Org. for Econ. Cooperation & Dev., Working Paper No. 2012/3, 2012), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2207366 [https://perma.cc/7RVY-UYRV] (finding that legal and arbitration costs have averaged over USD $8 million, but the information is incomplete since of 143 publicly available awards, sixty-two awards provide no information at all about costs); Matthew Hodgson & Alastair Campbell, *Investment Treaty Arbitration: Cost, Duration, Size of Claims All Show Steady Increase*, ALLEN & OVERY (Dec. 14, 2017), http://www.allenovery.com/publications/en-gb/Pages/Investment-Treaty-Arbitration-cost-duration-and-size-of-claims-all-show-steady-increase.aspx [https://perma.cc/67X5-QTU5] (noting an average cost for respondent states of over USD $4.559 million). In addition, in some cases, arbitration costs can be significantly above average, with costs in some disputes of USD $40 to $80 million. *See, e.g.*, DIANA ROSERT, INT'L INST. FOR SUSTAINABLE DEV., THE STAKES ARE HIGH: A REVIEW OF THE FINANCIAL COSTS OF INVESTMENT TREATY ARBITRATION 8 (2014), https://www.iisd.org/sites/default/files/publications/stakes-are-high-review-financial-costs-investment-treaty-arbitration.pdf [https://perma.cc/4JH4-H6ML].

5. *See* Eli Lilly & Co. v. Gov't of Can., ICSID Case No. UNCT/14/2, Final Award, ¶ 480 (Mar. 16, 2017) [hereinafter *Eli Lilly*, Final Award], https://www.italaw.com/sites/default/files/case-documents/italaw8546.pdf [https://perma.cc/94P2-KS23] (requiring reimbursement of 75 percent of Canada's costs); Philip Morris Brands Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Award, ¶ 586 (July 8, 2016) [hereinafter *Philip Morris*, Award], https://www.italaw.com/sites/default/files/case-documents/italaw7417.pdf [https://perma.cc/ZP7Q-BLAJ] (requiring reimbursement of USD $7 million). This is consistent with the approach of some tribunals in requiring the losing party to pay costs. *See, e.g.*, *Philip Morris*, Award, *supra* ¶¶ 585–86; *see also* Micha Bühler, *Awarding Costs in International Commercial Arbitration: An Overview*, 22 ASA BULL. 249, 259 (2004); Susan D. Franck, *Rationalizing Costs in Investment Treaty Arbitration*, 88 WASH. U. L. REV. 769, 791 (2011).

6. *Eli Lilly*, Final Award, *supra* note 5, ¶¶ 455(b), 480; *Philip Morris*, Award, *supra* note 5, ¶ 586 (noting that each side raised "weighty arguments" for their respective positions).

payment of a few million dollars in fees for a single case may represent a small price for a multinational company seeking to fundamentally change global norms in its favor.[7] This is especially true because bringing a dispute may influence other countries to change their laws if such countries cannot afford to defend even a frivolous claim; accordingly, even an official loss in one dispute could be considered an overall win.[8] In addition, even a company concerned about the possible need to reimburse costs upon losing may still achieve desirable outcomes by initiating an investment dispute or merely threatening to do so; such actions may result in settlements in the company's favor.

Such investment disputes challenge previously recognized domestic safeguards under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which applies to most countries.[9] In particular, because TRIPS is a unique agreement that imposes only minimum, rather than uniform, patent requirements, it inherently permits domestic discretion in complying with TRIPS, which includes what policymakers refer to as TRIPS "flexibilities."[10] As the Author has previously argued, these initial investment disputes can be seen as a new wave of regime shifting by companies desirous of increasing IP protection and seeking a more favorable forum.[11] Unlike other domestic

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7. *See, e.g.*, Claudio Pauillo, *Part III:* Uruguay vs. Philip Morris, CENTER PUB. INTEGRITY (Nov. 15, 2010), https://www.publicintegrity.org/2010/11/15/4036/part-iii-uruguay-vs-philip-morris [https://perma.cc/AYL2-HDWU]. For example, in 2009, when Philip Morris International sued Uruguay, the company had revenues of USD $62 billion. *Id.*

8. *See, e.g.*, Krzysztof J. Pelc, Does the International Investment Regime Induce Frivolous Litigation? 2–3 (May 10, 2016) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2778056 [https://perma.cc/A5H4-MEUG].

9. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 1.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994) [hereinafter TRIPS]. All WTO members must currently be in compliance, although the least-developed countries that continue to be least-developed countries have been provided another extension from complying with obligations relating to pharmaceutical products, such as granting patent protection on such products until January 2033, with the possibility of additional extensions. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/73 (Nov. 6, 2015). Moreover, TRIPS is already an incursion on domestic policy rights since, before TRIPS, nations could elect to not provide any IP rights, or, at least have full discretion to deny patent on some issues, such as drugs. *See Access to Medicines*, 19 WHO DRUG INFO. 236, 238 (2005), http://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf [https://perma.cc/K2TB-BPLX]. Today, all WTO nations (except least-developed countries) must now provide some type of patent protection, including for drugs, which obviously impacts the right to health, including the ability to obtain affordable medicines. *See Pharmaceutical Patents and the TRIPS Agreement*, WORLD TRADE ORG. (Sept. 21, 2006), https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm [https://perma.cc/9UYZ-KYMF].

10. *See, e.g.*, TRIPS, *supra* note 9, art. 1(1); *see also infra* Section II.A (explaining TRIPS flexibilities).

11. James Gathii & Cynthia Ho, *Regime Shifting of IP Lawmaking and Enforcement form the WTO the International Investment Regime*, 18 MINN. J.L. SCI & TECH. 427, 428–30 (2017). Of

and international arenas where there are competing actors and interests to argue against increasing IP protection, there is no similar safeguard in a forum that tends to rule in favor of wealthy, multinational corporations.[12] This is particularly problematic given increasing concern about costs of patented drugs,[13] and after the 2016 United Nations (UN) High Level Panel report recommended that countries embrace TRIPS flexibilities to provide less IP protection.[14] States that follow the UN's recommendation may be in danger of inviting an investor-state dispute.

Can the consideration of human rights help in this situation? This question presents an interesting, but unexplored angle that this Article aims to address.[15] Some have repeatedly argued that human rights be more fully considered in the context of investor-state disputes

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course, this does not mean that companies have abandoned existing domestic and alternative international forums. *Id.* at 433. However, ISDS presents advantages to companies over other international forums, such as the WTO or UN, where they cannot directly participate and also where there are competing norms to promote public interest. *Id.* at 470.

12. *See* PIA EBERHARDT & CECICLIA OLIVET, PROFITING FROM INJUSTICE: HOW LAW FIRMS, ARBITRATORS AND FINANCIERS ARE FUELING AN INVESTMENT ARBITRATION BOOM 8 (2012); Gus Van Harten, *Arbitrator Behavior in Asymmetrical Adjudication: An Empirical Study of Investment Treaty Arbitration*, 50 OSGOODE HALL L. J. 211, 211 (2012). For example, in the domestic realm, companies that seek more IP rights may be countered by public interest groups advocating lower cost medicines, or freedom of expression. Similar groups may contest international lawmaking in forums such as the WTO and WIPO and also be supported by some countries that consider higher IP protection not to be in their domestic interest. *See* Sabrina Tavernise, *Tobacco Firms' Strategy Limits Poorer Nations' Smoking Laws*, N.Y. TIMES (Dec. 13, 2013) https://www.nytimes.com/2013/12/13/health/tobacco-industry-tactics-limit-poorer-nations-smoking-laws.html [https://perma.cc/J9SF-3QPN].

13. *E.g.*, EUR. COMM'N, INNOVATIVE PAYMENT MODELS FOR HIGH-COST INNOVATIVE MEDICINES: REP. OF THE EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH (EXPH) 7–8 (2018), https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_innovative_medicines_en.pdf [https://perma.cc/VT5V-T68F]; Mathias Flume et al., *Approaches to Manage Affordability of High Budget Impact Medicines in Key EU Countries,* 6 J. MKT. ACCESS & HEALTH POL'Y 1, 1 (2018); Toon van der Gronde et al., *Addressing the Challenge of High Priced Prescription Drugs in the Era of Precision Medicine: A Systematic Review of Drug Life Cycles, Therapeutic Drug Markets and Regulatory Frameworks*, 12 PUB. LIBR. SCI. 1, 2 (2017); Robert Hart, *Drugs Are Too Expensive for the NHS–People Are Paying with Their Lives*, GUARDIAN (Dec. 20, 2017), https://www.theguardian.com/science/2017/dec/20/drug-giants-hefty-prices-nhs-vital-medication-pharma-profits [https://perma.cc/2B7L-ZANK].

14. UNITED NATIONS, REPORT OF THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES 9 (2016) [hereinafter U.N. HIGH-LEVEL PANEL REPORT], https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf [https://perma.cc/C6QA-VYQA].

15. I thank the conference organizers for inviting me to speak about a human rights angle for considering IP in recent trade agreements. Although I am well aware of investor-state disputes challenging IP and have written several articles in this area, I had not previously considered the human rights angle. *See, e.g.*, Gathii & Ho, *supra* note 11; Cynthia Ho, *A Collision Course Between TRIPS flexibilities and Investor-State Proceedings*, 6 U.C. IRVINE L. REV. 395 (2018) [hereinafter Ho, *Collision Course*]; Cynthia Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERK. TECH. L. J. 213 (2015) [hereinafter Ho, *Sovereignty*].

to better promote public interest, even if not in the IP context.[16] The UN has also recommended embracing TRIPS flexibilities to promote the human right to health.[17] In addition, two recent decisions that permit human rights counterclaims may signal that tribunals are more open to considering human rights than in the past, even for agreements that have no explicit language promoting human rights.[18] Accordingly, it seems reasonable to consider whether greater reliance on human rights aspects of IP in investor-state disputes would better protect TRIPS flexibilities. Although human rights arguments have had some success in limiting patent rights on the domestic level, considering human rights issues in the context of investor-state disputes is also important given that most domestic actions may be challenged by investor-state disputes.[19]

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16. *E.g.*, Henok Gabisa, *The Fate of International Human Rights Norms in the Realm of Bilateral Investment Treaties (BITs): Has Humanity Become a Collateral Damage?*, 48 INT'L LAW. 153, 167 (2014); *see also* CANADIAN COUNCIL FOR INT'L CO-OPERATION, WHOSE RIGHTS ARE WE PROTECTING? 1 (2015); LUKE ERIC PETERSON, HUMAN RIGHTS AND BILATERAL INVESTMENT TREATIES: MAPPING THE ROLE OF HUMAN RIGHTS LAW WITHIN INVESTOR-STATE ARBITRATION 7 (2009) (explaining relationship between human rights and investment treaties and offering recommendations to better promote human rights norms); Yannik Radi, *Realizing Human Rights in Investment Treaty Arbitration: A Perspective from Within the International Investment Law Toolbox*, 37 N.C. J. INT'L L. & COM. REG. 1107, 1114 (2012) (demonstrating that human rights considerations have always been part of the investment regime and rarely breach investment treaties); Megan Wells Sheffer, *Bilateral Investment Treaties: A Friend or Foe to Human Rights?*, 39 DENV. J. INT'L L. & POL'Y 483, 502–21(2011) (providing suggestions for how to better incorporate human rights norms in the international investment regime, although primarily for future agreements).

17. U.N. HIGH-LEVEL PANEL REPORT, *supra* note 14, at 9, 27; *see also* Faisal bin Abdulla al-Henzab (Chairperson-Rapporteur of Social Forum), *Access to Medicines in the Context of the Right to Health*, ¶ 69, U/N/ Doc. A/HRC/29/44 (Feb. 18–20, 2015) (recommending TRIPS flexibilities be used "to their fullest"); Paul Hunt (Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health), *Rep. on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, U.N. Doc. A/61/338, ¶ 47 (Sept. 13, 2006) [hereinafter U.N. Rep. of Rapporteur Hunt, 2006]; Comm. on Econ., Soc., & Cultural Rights, General Comment No. 17 (2005), ¶ 35, E/C.12/GC/1712 (Jan. 2006).

18. *See* Elena Burova, *Jurisdiction of Investment Tribunals over Host States' Counterclaims: Wind of Change?*, KLUWER ARB. BLOG (Mar. 6, 2017), http://arbitrationblog.kluwerarbitration.com/2017/03/06/jurisdiction-of-investment-tribunals-over-host-states-counterclaims-wind-of-change/ [https://perma.cc/2JMZ-E4S3]; Edward Guntrip, Urbaser v. Argentina*: The Origins of a Host State Human Rights Counterclaim in ICSID Arbitration*, EJIL: TALK! (Feb. 10, 2017) https://www.ejiltalk.org/urbaser-v-argentina-the-origins-of-a-host-state-human-rights-counterclaim-in-icsid-arbitration/ [https://perma.cc/P9R7-NGSS].

19. For examples of domestic success in limiting patent rights on the basis of human rights assertions, see Laurence Helfer, *Intellectual Property and Human Rights*, *in* THE OXFORD HANDBOOK OF INTELLECTUAL PROPERTY LAW 117, 136–37 (Rochelle C. Dreyfuss & Justine Pila eds., 2018) (noting success of human rights assertions against attempts to enforce patents on HIV/AIDS medication, as well as for mandating provision of patented drugs in a number of countries); Molly Land, *Human Rights Frames in IP Contests*, *in* BALANCING WEALTH AND HEALTH 276, 278–81 (Rochelle C. Dreyfuss & Rodriguez-Garavito eds., 2014) (explaining success of human rights framing with access to medicine challenges in South Africa and Brazil); *see also* Emmanuel Kolawole Oke, *Incorporating a Right to Health Perspective into the Resolution of Patent Law*

This Article uses the facts of *Eli Lilly v. Canada* as a thought experiment to consider whether a broader embrace of human rights norms might prove helpful to protect TRIPS flexibilities. This is obviously theoretical since human rights were only briefly alluded to by amicus and not mentioned in the tribunal award.[20] Although there are other disputes involving domestic limits to trademark use on tobacco packaging, the laws at issue in those disputes are more firmly supported by a right to health generally, as well as compliance with the Framework Convention on Tobacco Control.[21] In addition, the challenged countries in those disputes enjoyed broad, popular support for their measures, which likely does not exist for other IP-related disputes.[22] The facts underlying *Eli Lilly*, on the other hand, involve a conflict between rights under an International Investment Agreement (IIA) that challenge TRIPS norms permitting nations discretion to limit the scope of patent requirements for which there is no consensus.[23] In particular, whereas most people agree that tobacco use should not be

Disputes, 15 HEALTH & HUM. RTS. 97, 98 (2013) (providing details on the impact of the right to health in Kenya regarding access to medicine).

20. *See* Eli Lilly & Co. v. Gov't of Can., ICSID Case No. UNCT/14/2, Submission of Amicus Curiae Brief of Dr. Burcu Kilic et al. (Feb. 12, 2016) [hereinafter *Eli Lilly,* Brief of Dr. Burcu Kilic et al.], https://www.italaw.com/sites/default/files/case-documents/italaw7111.pdf [https://perma.cc/X73E-MSFM] (noting that a decision in the case "has the potential to affect the operation of patent systems and thereby the public and human rights interests they serve and effect," without elaboration on what specific human rights were at issue). An unaccepted amicus brief includes some discussion. *See Eli Lilly*, ICSID Case No. UNCT/14/2, Application for Leave to File Brief by Henning Grosse Ruse-Khan et al., ¶ 15 (Feb. 12, 2016), https://www.italaw.com/sites/default/files/case-documents/italaw7112.pdf [https://perma.cc/MQ45-5AQD] (noting that the case had significant public interest because it had "human rights considerations" among other factors, but not specifically explaining what human rights considerations were relevant).

21. Indeed, the Uruguay tribunal characterized the Convention as a treaty "guaranteeing the human rights to health." *Philip Morris*, Award, *supra* note 5, ¶ 304. Of course, the focus of this Article is the extent to which ISDS intersects with TRIPS flexibilities, even though that is not the entirety of all ISDS disputes involving IP. For example, an ongoing investor-state dispute involves IP, but without any challenge to domestic IP rights that relate to TRIPS flexibilities, such that it has different issues. *See, e.g.*, Bridgestone Licensing Servs. Inc. v. Republic of Pan., ICSID Case No. ARB/16/34, Decision on Expedited Objections, ¶ 174 (Dec. 13, 2017), https://www.italaw.com/sites/default/files/case-documents/italaw9453.pdf [https://perma.cc/WK6R-V85U] (finding jurisdiction to decide dispute based on trademarks and related licenses counting as investments).

22. As one example of broad public support, the recently concluded CPTPP has a carve out from investor-state disputes for tobacco. Comprehensive and Progressive Agreement for Trans-Pacific Partnership art. 29(5), Mar. 8, 2018 [hereinafter CPTPP], https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-concluded-but-not-in-force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text/#side#CPTPP [https://perma.cc/3NX5-V6RX] (entering into force on December 30, 2018 for initial six signatories that includes Canada, Mexico and Japan); *see also* Becky Freeman, *Tobacco Carve-Out in TPP*, BMJ BLOG: TOBACCO CONTROL (Oct. 6, 2015), http://blogs.bmj.com/tc/2015/10/06/tobacco-carve-out-in-tpp/ [https://perma.cc/YH5L-ZBWF].

23. *Eli Lilly*, Final Award, *supra* note 5, ¶¶ 4–6.

encouraged, there is strident disagreement concerning whether patents should be easier or harder for companies to obtain, even though patented drugs still implicate the right to health.[24]

This Article proceeds in four parts. Part II explains the basics of investor-state disputes and how this system may limit use of TRIPS flexibilities. Part III then considers whether a broader embrace of human rights would help protect TRIPS flexibilities in such disputes. This Part first explains which human rights would be applicable before reviewing the *Eli Lilly* facts and investment claims, and then applies human rights norms. This Part reveals that embracing human rights norms is not a panacea. In particular, although some human rights norms might be consistent with promoting domestic policy space, others could lend more support to investor claims.[25] Accordingly, the final Part considers what next steps should be taken to better protect TRIPS flexibilities in the context of Investor-State Dispute Settlement (ISDS).

II. BACKGROUND

This Part provides key context to reevaluate the *Eli Lilly v. Canada* dispute. This Part first explains ISDS, as well as how it intersects with TRIPS. Then, this Part explains why current reforms to ISDS fail to protect TRIPS flexibilities.

A. The Investor-State Dispute System and Its Intersection with TRIPS Issues

This Section provides an overview of ISDS, as well as its intersection with TRIPS norms. This section begins with the genesis

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24. *See, e.g.*, Freeman, *supra* note 22; *see also infra* notes 55–56 and accompanying text (discussing opposing views in UN High Level Panel Report, as well as views of some countries and the pharmaceutical industry). This is reflected in the fact that TRIPS was a hard-won agreement and since then, despite efforts of developed countries, there has been no uniform standard of patentability. Rather, as some developed countries continue to enact higher levels of patent protection in individual agreements, others are aiming to suggest that there should be more user rights. *See* CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY 325–53 (2011).

25. Of course, human rights arguments can arguably be protective of TRIPS flexibilities in some contexts even if they do not influence an actual ruling by an international tribunal. For example, India raised human rights arguments in the WTO challenging EU actions detaining generic medicines. This challenge did not result in a WTO ruling, but the European Union settled the case, such that the human rights could have been relevant. *Intervention by India,* INTELL. PROP. WATCH (June 2009), http://www.ip-watch.org/weblog/wp-content/uploads/2009/06/intervention-by-india-seizure-of-generic-drug-consignments-at-ec-ports.pdf [https://perma.cc/4S8E-LYK9] (noting concern of UN Special Rapporteur with respect to seizures and the impact on the right to health). However, since ISDS poses unique threats to domestic flexibilities due to its chilling effect, and since investors could also embrace human rights arguments, this Article argues against relying on human rights arguments alone to protect TRIPS flexibilities.

for the unique dispute mechanism, followed by its current operation and criticisms. Then, it explains how investment disputes involving TRIPS flexibilities present additional problems.

Investor-state disputes were originally intended to provide a remedy to a unique situation that has no parallel with IP. In particular, ISDS was adopted in the early 1960s when newly democratic countries wanted to promote foreign investment and ensure foreign investors that their investments would be protected; previously, foreign investors often lacked recourse against improper state action, such as improper taking of assets.[26] Although foreign investors could theoretically bring claims against nations, those claims failed for a variety of reasons, including the fact that domestic courts had weak rule of law[27] and that there was no enforceable international mechanism to protect investors.[28] Against this backdrop, ISDS developed to permit foreign companies to bring new types of claims concerning investments before a tribunal of private arbitrators, rather than a domestic court, to ensure that companies would have recourse to protect their investments.[29] This system was based upon the pre-existing rules for private commercial arbitration, rather than judicial systems; in this setting, confidentiality was considered paramount.[30]

Although investor-state disputes were originally praised—as the number of agreements permitting the disputes, the number of claims, and the amount of awards increased—the system has provoked serious scrutiny and controversy.[31] Many countries and policymakers are

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26. *See* U.N. Conference on Trade and Development, *Investor-State Disputes: Prevention and Alternatives to Arbitration*, U.N. Doc. UNCTAD/DIAE/IA/2009/11, at 3–4 (Jan. 8, 2010); KENNETH VANDEVELDE, UNITED STATES INVESTMENT TREATIES: POLICY AND PRACTICE 7, 14, 30 (1992).

27. *See* VANDEVELDE, *supra* note 26, at 12. Other issues included sovereign immunity or courts biased against investors. *Id.* Given the lack of domestic options, home states used or threatened to use military force to help companies. *Id.*

28. *See* Susan D. Franck, *The Legitimacy Crisis in Investment Arbitration: Privatizing Public International Law Through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521, 1537 (2005). Although companies could bring an action before the International Court of Justice, even if the company obtained a favorable ruling, it was not enforceable against a nation without passage of a UN Security Council Resolution. *Id.*

29. *See* U.N. Conference on Trade and Development, *supra* note 26, at 2–3.

30. *See* Avinash Poorooye & Ronán Feehily, *Confidentiality and Transparency in International Commercial Arbitration: Finding the Right Balance*, 22 HARV. NEGOT. L. REV. 275, 277–78 (2017) (noting confidentiality as attractive to disputants); Leon Trakman, *Confidentiality in International Commercial Arbitration*, 18 ARB. INT'L 1, 1 (2002) (explaining that international commercial arbitration prizes confidentiality as a reason to choose arbitration over litigation).

31. *See, e.g.*, U.N. Conference on Trade and Development, *Special Update on Investor-State Dispute Settlement: Facts and Figures*, UNCTAD/DIAE/PCB/2017/7, at 2 fig. 1 (Nov. 7, 2017) [hereinafter UNCTAD, *Special Update*]; U.N. Conference on Trade and Development, *Recent Developments in Investor-State Dispute Settlement: Updated for the Multilateral Dialogue on Investment*, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/3/Rev., at 25 (May 28–29, 2013) [hereinafter UNCTAD, *Multilateral Dialogue*]. For example, there was only one dispute in 1982,

concerned that such disputes unduly permit foreign companies to challenge legitimate domestic policies under a nondemocratic system.[32] In particular, whereas domestic decisionmakers are democratically elected, their decisions can be effectively nullified by investor-state tribunalists who are not accountable to anyone.[33] Moreover, the tribunalists lack independence that most associate with judicial systems since they are paid by the hour and may also function as lawyers in investor-state disputes when not serving as tribunalists.[34] In addition, unlike many judicial systems, there is traditionally no right for third parties to participate.[35] There is even a lack of transparency as to the existence of some disputes.[36] To make matters worse, not only

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in contrast with over fifty new cases in 2012, and sixty-nine known cases in 2016. UNCTAD, *Special Update*, *supra*, at 1–2; UNCTAD, *Multilateral Dialogue*, *supra*, at 2–3.

32. *See* STEPHAN W. SCHILL, REFORMING INVESTOR-STATE DISPUTE SETTLEMENT: CONCEPTUAL FRAMEWORK AND OPTIONS FOR THE WAY FORWARD 1–3 (2015); Ho, *Sovereignty*, *supra* note 15, at 220–21; Gus Van Harten et al., *Public Statement on the International Investment Regime*, OSGOODE HALL L. SCH. (Aug. 31, 2010), https://www.osgoode.yorku.ca/public-statement-international-investment-regime-31-august-2010/ [https://perma.cc/7ZFL-4L53]; Jane Kelsey, *The Crisis of Legitimacy in International Investment Agreements and Investor-State Dispute Settlement,* JUD. POWER PROJECT (Jan. 9, 2018), https://judicialpowerproject.org.uk/jane-kelsey-the-crisis-of-legitimacy-in-international-investment-agreements-and-investor-state-dispute-settlement/ [https://perma.cc/SD7Z-68M8]; Anthea Roberts & Zeineb Bouraoui, *UNCITRAL and ISDS Reforms; What Are States' Concerns?,* EJIL: TALK! (June 5, 2018), https://www.ejiltalk.org/uncitral-and-isds-reforms-what-are-states-concerns/ [https://perma.cc/2W8U-MLZP]. Even the Cato Institute, which usually promotes corporate interests, has expressed concern about including ISDS in a trade agreement. Daniel J. Ikenson, *A Compromise to Advance the Trade Agenda: Purge Negotiations of Investor-State Dispute Settlement*, CATO INST. (Mar. 4, 2014), https://www.cato.org/publications/free-trade-bulletin/compromise-advance-trade-agenda-purge-negotiations-investor-state [https://perma.cc/4KT2-JHJT].

33. *See* EBERHARDT & OLIVET, *supra* note 12, at 7–9.

34. *See* NATHALIE BERNASCONI-OSTERWALDER, LISE JOHNSON & FIONA MARSHALL, ARBITRATOR INDEPENDENCE AND IMPARTIALITY: EXAMINING THE DUAL ROLE OF ARBITRATOR AND COUNSEL 26 (2010), http://www.iisd.org/pdf/2011/dci_2010_arbitrator_independence.pdf [https://perma.cc/4QBU-4UKQ]; Gaukrodger & Gordon*, supra* note 4, at 20, 44 (stating that a majority of arbitrators have served as counsel for investors in other cases, whereas only about 10 percent of arbitrators have acted as counsel for states in other cases).

35. *See, e.g.*, Jeffrey Atik, *Legitimacy, Transparency and NGO Participation in the NAFTA Chapter 11 Process*, *in* NAFTA INVESTMENT LAW AND ARBITRATION: PAST ISSUES, CURRENT PRACTICE, FUTURE PROSPECTS 135, 147 (Todd Weiler ed., 2004). However, in light of recent criticism, there is a trend towards more transparency. For example, for disputes governed by ICSID, not only may third parties make submissions, but a tribunal can accept third party amicus submissions even over the objection of parties. INT'L CTR. FOR SETTLEMENT OF INV. DISPUTES (ICSID), ICSID/15, ICSID CONVENTION, REGULATIONS AND RULES 117 rule 37(2) (2006), https://icsid.worldbank.org/en/documents/icsiddocs/icsid%20convention%20english.pdf[https://perma.cc/SZW2-C3WP] [hereinafter ICSID Rules].

36. ICSID, which handles about 60 percent of disputes, has been publishing at least legal conclusions of the tribunal since 2006, even if the parties do not consent to publication of the award. *See* ICSID Rules, *supra* note 35, at 122 rule 48(4); *see also* Julie Lee, *UNCITRAL's Unclear Transparency Instrument: Fashioning the Form and Application of a Legal Standard Ensuring Greater Disclosure in Investor-State Arbitrations*, 33 NW. J. INT'L L. & BUS. 439, 455 n.26 (2013) (explaining that new rules are an improvement in mandating publication of awards that reveals tribunal reasoning). However, that is not true for disputes done under UNCITRAL, which is also

can final awards and settlements be extraordinarily high, with some exceeding USD $1 billion,[37] but the same facts can result in different conclusions due to lack of precedential effect.[38] All of these issues contribute to a chilling effect on domestic actions—especially since the disputes are very expensive to defend.[39] Moreover, the original basis for ISDS (i.e., a lack of legal recourse for foreign investors), does not exist with respect to some countries and disputes. For example, since the United States, Canada, and member states of European Union have always had robust legal systems, there is no real need to provide an alternative forum for only foreign companies.

All of these general issues apply to investor-state disputes challenging domestic limits of IP, but investor state disputes that challenge domestic limits to IP raise additional issues, as is well illustrated by *Eli Lilly v. Canada.* In particular, although the Canadian judiciary invalidated two Eli Lilly patents pursuant to its own domestic laws and consistent with TRIPS, Eli Lilly claimed that North American

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commonly used. *See* UNITED NATIONS COMM'N ON INT'L TRADE LAW, UNCITRAL ARBITRATION RULES art. 34(5) (2014), https://www.uncitral.org/pdf/english/texts/arbitration/arb-rules-revised/arb-rules-revised-2010-e.pdf [https://perma.cc/7XUY-NNFB] (requiring consent of all parties unless legally obligated by another proceeding); LISE JOHNSON & NATHALIE BERNASCONI-OSTERWALDER, COLUMBIA CTR. ON SUSTAINABLE INV., COMMENTARY, NEW UNCITRAL ARBITRATION RULES ON TRANSPARENCY: APPLICATION, CONTENT AND NEXT STEPS 7 (2013), http://ccsi.columbia.edu/files/2014/04/UNCITRAL_Rules_on_Transparency_commentary_FINAL.pdf [https://perma.cc/TD4J-E5KJ] (noting that UNCITRAL rules are more restrictive than other arbitration rules). Although not applicable to most investment agreements, for investment disputes pursuant to treaties concluded after April 1, 2014 there is a presumption in favor of publication of the notice of Arbitration, subject to protection of confidential information. *See* UNITED NATIONS COMM'N ON INT'L TRADE LAW, UNCITRAL RULES ON TRANSPARENCY IN TREATY-BASED INVESTOR-STATE ARBITRATION arts. 2–3, 7 (2014), http://www.uncitral.org/pdf/english/texts/arbitration/rules-on-transparency/Rules-on-Transparency-E.pdf [https://perma.cc/6E3E-5A7A] (stating that notice of arbitration as well as other documents will be promptly made available to the public). However, even for the minority of treaties to which this applies, parties can avoid its application. *See id.* at 5 (noting that the rules apply unless the parties have agreed otherwise); JOHNSON & BERNASCONI-OSTERWALDER, *supra*, at 10 (explaining how states can opt out by expressly doing so in the underlying treaty or by expressly noting that the UNICTRAL 1976 rules apply).

37. *Investment Dispute Settlement Navigator: Amount of Compensation*, INV. POL'Y HUB (Dec. 31, 2017), http://investmentpolicyhub.unctad.org/ISDS/FilterByAmounts [https://perma.cc/CV2R-KRSA] (listing compensation amounts awarded and agreed in settlement, as well as compensation sought).

38. *See, e.g.*, Leon E. Trakman, *The ICSID Under Siege*, 45 CORNELL INT'L L. J. 603, 642–43 (2012). For example, several cases against Argentina used different interpretations and reached differing conclusions regarding the same basic facts even though they had the same President of the Tribunal. *Id.*; *see also* Stephanie Bijlmakers, *Effects of Foreign Direct Investment Arbitration on a State's Regulatory Autonomy Involving the Public Interest*, 23 AM. REV. INT'L. ARB. 245, 253 (2012) (noting divergent interpretation of comparable factual and legal cases in *Lauder v. Czech Republic* and *CME v. Czech Republic*).

39. *See, e.g.*, Rep. of the Indep. Expert on the Promotion of a Democratic and Equitable Int'l Order, U.N. Doc. A/HRC/30/44, at 6 (2015) (chilling effect of awards on state regulations to protect the environment, food safety, and access to generic medicine); *see also Investment Dispute Settlement Navigator*, *supra* note 37 (regarding cost of dispute).

Free Trade Agreement's (NAFTA) investment chapter entitled it to compensation of CAD $500 million for these two invalidated patents.[40] In other words, compliance with an international IP agreement (i.e., TRIPS), still left Canada vulnerable to an investor-state dispute. Moreover, any argument that Canada's laws are inconsistent with TRIPS could be addressed by the well-respected World Trade Organization (WTO) Dispute settlement mechanism; in fact, it was intended to be the sole forum for resolving TRIPS issues.[41] Although there are occasions where international agreements conflict, investment agreements do not present a direct conflict with TRIPS, yet could still disrupt TRIPS norms, such as the ability to use TRIPS flexibilities.[42] In particular, since TRIPS establishes that countries must grant patents to inventions that meet certain requirements, such as being "useful," and because TRIPS does not define this, there is technically no conflict between the stricter definition of utility Canada desired versus the lower standard that Eli Lilly asserted is proper.[43] In other words, Eli Lilly's investment claims undermine the ability to take advantage of flexibility under TRIPS to provide less protection[44] since TRIPS flexibilities inherently permit countries to retain discretion in defining key patentability terms that lack definition under TRIPS.[45] Moreover, although a single dispute only binds the parties to the dispute, investor-state disputes have been known to have a chilling effect on those who are not parties but want to avoid the expense of

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40. *See Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶ 85.

41. *See* Understanding on Rules and Procedures Governing the Settlement of Disputes art. 23, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994) (noting that states should not make their own determination of violations of WTO agreements).

42. For an example of a conflict, see Harm Schepel, *From Conflicts-Rules to Field Preemption:* Achmea *and the Relationship Between EU Law and International Investment Law and Arbitration,* EUR. L. BLOG (Mar. 23, 2018), http://europeanlawblog.eu/2018/03/23/from-conflicts-rules-to-field-preemption-achmea-and-the-relationship-between-eu-law-and-international-investment-law-and-arbitration/ [https://perma.cc/2HCV-JHY9] (noting situations of conflict between international investment law and EU law).

43. *See* TRIPS, *supra* note 9, art. 27(1) n. 5.

44. *See, e.g.*, Press Release, PhRMA, PhRMA Statement on NAFTA Tribunal Decision in the Eli Lilly Case (Mar. 21, 2017), https://www.phrma.org/press-release/phrma-statement-on-nafta-tribunal-decision-in-the-eli-lilly-case [https://perma.cc/R49E-Y3EM]. This was apparently intended by Eli Lilly. *See id.*; Adam Behsudi, *Eli Lilly Sues Canada on Drug Patents*, POLITICO (Sept. 12, 2013, 7:03 PM), http://www.politico.com/story/2013/09/eli-lilly- sues-canada-over-drug-patents-096743.html [https://perma.cc/D5XF-6M4C] (discussing the view that Lilly intended to use ISDS to force Canada to modify its patent law).

45. *See* CHAN PARK ET AL., UNITED NATIONS DEV. PROGRAMME, USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA: AN ANALYSIS OF PATENT, COMPETITION AND MEDICINES LAW 57 (2013); U.N. HIGH-LEVEL PANEL REPORT, *supra* note 14, at 22; Carlos M. Correa, *Patent Rights*, *in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189, 198–200 (Carlos M. Correa & Abulqawi Yusuf eds., 1998).

being subject to such a suit.[46] Accordingly, the dispute poses a threat to whether all countries can use TRIPS flexibilities.

B. Current Reforms Fail to Protect TRIPS Flexibilities

This Section explains why current proposals to reform ISDS fail to protect TRIPS flexibilities. To some extent, this failure is unsurprising since many IP policymakers are not aware of the tension between ISDS and TRIPS.[47] In addition, ISDS reform tends to focus on issues that impact all disputes, rather than IP-specific disputes. Although there are many different proposals for reform, this Section briefly explains the major reforms that aim to protect domestic discretion; as will be explained, these reforms are inadequate to protect TRIPS flexibilities.[48]

There are two types of reform underway.[49] One type of reform involves improving investor-state disputes in new agreements; notably, these reforms would not impact the thousands of existing agreements pursuant to which disputes may still be brought.[50] The other type of proposed reform is to essentially replace the current system with a multilateral system, including an independent investment court with an appellate mechanism.[51] Although these reforms are largely separate, each type of reform could include suggestions to limit the

46. *See* Rep. of the Indep. Expert on the Promotion of a Democratic and Equitable Int'l Order, *supra* note 39, at 6 (noting the compromised regulatory function of States due to the chilling effect of arbitration awards); *see also* Rep. of Farida Shaheed (Special Rapporteur in the Field of Cultural Rights), *Rep. in the Field of Cultural Rights*, U.N. Doc. A/70/279, ¶ 75 (Aug. 4, 2015) (noting aggravating "chilling effect" where investor state dispute awards present looming penalties) [hereinafter U.N. Rep. of Special Rapporteur Shaheed].

47. *See* Ho, *Collision Course*, *supra* note 15, at 415–20.

48. For example, there are reforms aimed at improving transparency, and also preventing corporate restructuring that while important generally, are far removed from protecting domestic discretion, including TRIPS flexibilities.

49. Of course, another type of "reform" could be to renegotiate, or even terminate, existing agreements. The UN has in fact suggested this. *See* U.N. Secretary-General, *Promotion of a Democratic and Equitable International Order*, ¶ 22, 60, U.N. Doc. A/70/285 (Aug. 5, 2015).

50. This is true for agreements such as the recently concluded Transpacific Partnership, Comprehensive Economic and Trade Agreement, and E.U.-Vietnam agreement, as well as the proposed Transatlantic Trade and Investment Partnership. *See* Ho, *Collision Course*, *supra* note 15, at 413–15; Elsa Sardinha, *Towards a New Horizon in Investor-State Dispute Settlement?*, 54 CAN. Y.B. INT'L L. 311, 311, 314 (2016) (noting that CETA provides a new investment court, with appeal possibility, as well as increased transparency); Nathalie Bernasconi-Osterwalder, *Rethinking Investment-Related Dispute Settlement*, INV. TREATY NEWS (May 21, 2015), https://www.iisd.org/itn/2015/05/21/rethinking-investment-related-dispute-settlement/ [https://perma.cc/7GFZ-AGSG] (noting options for improving the existing system).

51. *See* Press Release, Cecilia Malmström, Comm'r of Trade, Eur. Comm'n, Commission Welcomes Adoption of Negotiating Directives for a Multilateral Investment Court (Mar. 20, 2018), http://trade.ec.europa.eu/doclib/press/index.cfm?id=1819 [https://perma.cc/N7V4-8R3C] (noting that multilateral investment court initiative aims to replace existing bilateral mechanisms in the investment treaties concluded by EU member states as well as other countries).

extent to which investment claims impinge on domestic discretion. However, a closer look at the actual language in recently concluded and proposed investment agreements shows there are still problems. In particular, new language aims to limit the most typical investment claims (i.e., expropriation and fair and equitable treatment (FET)) with more explicit criteria.[52] However, as will be explained, these improvements are inadequate to protect TRIPS norms.

The language intended to limit indirect expropriation claims will fail to protect TRIPS flexibilities. The language is limited to situations when nations implement regulatory actions in a non-discriminatory way to protect legitimate public welfare objectives, including public health.[53] However, as the *Eli Lilly* dispute highlights, challenged patent laws may be created by the judiciary, rather than a regulatory agency, and thus would not seem to fall within the language for regulatory actions.[54] Moreover, there is no consensus on whether laws that limit patentability of drugs necessarily promote public health. Although some public health advocates argue this is necessarily true since fewer patented drugs result in more affordable drugs,[55] others counterargue that public health is promoted by generously providing patent protection to incentivize more research and development.[56]

52. *See, e.g.*, CPTPP, *supra* note 22, annex 9-B (limiting expropriation claims); Comprehensive Economic and Trade Agreement Between Canada of the One Part, and the European Union and its Member States, of the Other Part, Can.-E.U., art. 8.10(2), (4) , Oct. 30, 2016 [hereinafter CETA], https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:22017A0114(01) [https://perma.cc/N57Q-ZE3P] (providing examples of situations that might violate fair and equitable treatment, as well as factors to take into consideration); CETA, *supra,* annex 8-A(2)–(3) (providing details on how to assess expropriation).

53. *See* CPTPP, *supra* note 22, annex 9-B(3)(b) ("Nondiscriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations, except in rare circumstances."); CETA, *supra* note 52, annex 8-A(3) ("[E]xcept in the rare circumstance when the impact of a measure or series of measures is so severe in light of its purpose that it appears manifestly excessive, non-discriminatory measures . . . that are designed and applied to protect legitimate public welfare objectives, such as health . . . do not constitute indirect expropriations.").

54. *See Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶ 34 (referring to doctrine as created by judiciary).

55. This is, of course, a fundamental premise of the UN High Level Panel Report. *See* U.N. HIGH-LEVEL PANEL REPORT, *supra* note 14, at 8.

56. *See* Council for Trade-Related Aspects of Intellectual Property, *Minutes of the Meeting of the Council for Trade-Related Aspects of Intellectual Property Rights of Nov. 8–9, 2016*, ¶¶ 621, 623, 638–39, 649, IP/C/M/83/Add.1 (Jan. 30, 2017) (expressing view of the United States, European Union, and Switzerland that the UN report could undermine innovation and advocating instead for strong IP policy). The pharmaceutical industry often asserts that patents and other IP do not hinder access to medicine. *See* Mike Masnick, *Pharma Officials Insist That There Is 'Zero Evidence' That Patents Harm Access to Medicine*, TECHDIRT (Nov. 5, 2014, 12:45 PM), https://www.techdirt.com/articles/20141104/17103829041/merck-exec-top-pharma-lobbyist-insists-that-there-is-zero-evidence-that-patents-harm-access-to-medicine.shtml [https://perma.cc/

Language in recent agreements aiming to limit FET claims is similarly inadequate for protecting TRIPS norms. Although one recent agreement admirably attempts to restrict this typically over-expansive claim by listing criteria to consider, none of those criteria consider whether a nation is acting consistent with an international agreement.[57] There is notably reference to international laws, but in a different context. For example, the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) says that violation of another international agreement is not necessarily a breach of FET.[58] This suggests that breach of TRIPS would not automatically constitute an investment claim. However, this does nothing to protect nations in compliance with TRIPS from an expensive compensation claim based on FET. Language that aims to cabin FET claims based solely on investor expectations is also inadequate. In particular, although it is helpful to have language clarifying that denial of investor expectations alone is inadequate, new language aimed to cabin previous broad claims based on such expectations still leaves tribunals with great discretion. For example, CETA says that a tribunal *may* consider whether a specific representation was made to an investor that created a legitimate expectation that investor relied on to its detriment.[59] Eli Lilly asserted that an issued patent was a representation that it would remain valid; even though such a belief is contrary to patent norms, this FET language would not limit Eli Lilly's claim.[60] In addition, unlike expropriation claims, there is no general exception clause for any actions.[61]

WC63-4T7D]. Instead, they emphasize that patents are essential for not only providing important drugs, but also for eventual low-cost generics. *See* HO, *supra* note 24, at 164 (quoting Fred Hassan, Chairman & CEO, Schering-Plough Corp., Keynote Address at U.S. Chamber of Commerce 5th Annual Intellectual Property Summit: Fueling Innovation: To Be Our Best for a Better World) (Oct. 8, 2008) (noting that generics are the direct result of IP-fueled innovation); Martin J. Adelman, Chairman, ATRIP, Paper Presented at ATRIP Annual Meeting in Tokyo, Japan: Compulsory Licensing of Drugs: TRIPS Context 1 (Aug. 4, 2003), http://atrip.org/2003-08-04-annual-congress-tokyo-japan/ [https://perma.cc/9485-P6CR] ("[W]ithout patents there would be far fewer drugs around for people to access.").

57. *See* CETA, *supra* note 52, art 8.10(2) (noting manifest arbitrariness, denial of justice, breach of due process, as well as abusive treatment of investors, and targeted discrimination on manifestly wrongful grounds such as gender or race). In contrast, CPTPP only states that it includes denial of justice and does not specify other areas. CPTPP, *supra* note 22, art. 9.6(2)(a).

58. *Id.* art 9.6(3).

59. CETA, *supra* note 52, art. 8.10(4).

60. *See Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶ 82 (suggesting that an issued patent is a contract that is violated by a change in the law invalidating the patent).

61. *Compare* CETA, *supra* note 52, art. 8.12(5) (excluding some issues from expropriation) *with* CETA, art 8.10 (providing no exception to FET claims).

III. CAN HUMAN RIGHTS HELP?

Although this Article focuses on examining how human rights could conceivably impact an investor-state dispute challenging domestic invalidation of patents, it is first important to lay some foundation. In particular, this Part first briefly considers why it is valuable to consider human rights in the context of IIAs and then introduces pertinent human rights that would be relevant to an investment challenge to domestic laws that limit or revoke IP rights. This Part then considers how human rights would potentially be used in an investor-state dispute. After addressing these fundamental issues, this Part revisits the basic facts and investment claims of Eli Lilly. Finally, this Part considers how a broader embrace of human rights might have impacted the ultimate outcome of Eli Lilly's investment claim.

A. Why Human Rights and Which Ones?

An initial question may be why human rights should be considered in the context of interpreting IIAs. Human rights are generally meant to protect the interests of individuals.[62] In contrast, IIAs aim to protect investments of companies by permitting them to assert claims against countries.[63] However, investment claims may challenge state obligations to respect, protect, and fulfill human rights norms.[64] In addition, companies can and sometimes have relied on human rights to support investment claims.[65] In addition, since all

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62. *See* LAURENCE R. HELFER & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE 3 (2011) (referring to human rights as a system available to individuals). In the European Union, however, corporations have been found to have human rights. Anheuser-Busch Inc. v. Portugal, App. No. 73049/01, 44 Eur. H.R. Rep. 42 (finding corporate owned IP to be a property interest protected by human rights); *see also* Matthew Happold, *Who benefits from Human Rights Treaties?*, *in* LIBER AMICORUM RUSEN ERGEC 117, 117 (Isabelle Riassetto, Luc Heuschling & Georges Ravarani eds., 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3003607 [https://perma.cc/G8Q7-LV8C] (noting that although human rights are typically limited to individuals, the European Court of Human Rights and Court of Justice of the European Union have taken a different approach than the UN, as well as regional and subregional courts).

63. *See, e.g.*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2004 U.S MODEL BILATERAL INVESTMENT TREATY pmbl. (2012) (focusing solely on investments). In contrast, although TRIPS arguably protects the IP of companies, it at least recognizes competing policy interests between rights of owners and users. *See* TRIPS, *supra* note 9, art. 7 (noting protection and enforcement of IP should be "to the mutual advantage of producers and users").

64. *See* Comm. on Econ., Soc. & Political Rights (CESCR), General Cmt. No. 14: The Right to the Highest Attainable Standard of Health, U.N. Doc. E/C.12/2000/4, ¶ 33 (2000) [hereinafter CESCR General Comment No. 14] (noting right to health imposes three levels of obligations).

65. *See* LONE WANDAHL MOUYAL, INTERNATIONAL INVESTMENT LAW AND THE RIGHT TO REGULATE: A HUMAN RIGHTS PERSPECTIVE 152 (2016).

international agreements, including IIAs, are properly interpreted in accordance with customary international law, the law concerning human rights norms is relevant.

A fundamental issue is which human rights would be negatively impacted by investment disputes challenging domestic laws that limit or revoke IP rights. Relevant human rights include those of individuals protected under the International Covenant of Economic, Social and Cultural Rights (ICESCR). In particular, under ICESCR, individuals have a right to health,[66] as well as a right to benefit from scientific progress.[67] The right to benefit from scientific progress exists concurrently with a right for creators to benefit from their scientific creations, such that the actual scope of the right to benefit from scientific progress is somewhat unclear since these competing rights must be inherently balanced against one another.[68] The scope of the right to health is more certain, and the UN has repeatedly stated that the right to health includes a right to access affordable essential medicine.[69] In addition, although some aspects of the right to health are subject to progressive realization—meaning that states do not need to immediately implement certain aspects that are beyond their practical capabilities—the UN has asserted that states have a core

66. The basis for the human right to health is in the International Covenant on Economic Social and Cultural Rights, which states "the right of everyone to enjoyment of the highest attainable standard of physical and mental health." International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR]. However, some disagree with recognizing health care as a human right. *See, e.g.*, Richard D. Lamm, *The Case Against Making Healthcare a "Right,"* 25 HUM. RTS. 8, 8–9 (1998) (arguing that it is too costly to provide all healthcare that is beneficial to every citizen).

67. ICESCR, *supra* note 66, art. 15.

68. *Id.* (referring to an individual's right to the "protection of . . . interests resulting from any scientific, literary or artistic production of which he [or she] is the author," while also asserting that all individuals have a human right to "enjoy the benefits of scientific progress and its applications"); *see also* Educ., Sci., & Cultural Org. (UNESCO), *Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications*, ¶16, SHS/RSP/HRS-GED/2009/PI/H/1 (July 16–17, 2009) [hereinafter UNESCO, *Venice Statement*]; Comm. on Econ., Soc. & Political Rights (CESCR), General Cmt. No.17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She Is the Author, Comm. on Economic, Social and Cultural Rights, U.N. Doc. E/C.12/GC/1712, ¶¶ 22, 35 (2006) [hereinafter CESCR General Comment No. 17]. Moreover, it has been previously noted that IP is inherently a social product and that states have an obligation to prevent unreasonably high costs for access to essential medicines. *See* ISCER, *supra* note 66; UNESCO, *Venice Statement*, *supra*; CESCR General Comment No. 17, *supra*.

69. *See* CESCR General Comment No. 17, *supra* note 68, ¶ 35 (noting that states have a duty to prevent unreasonably high costs for essential medicines and a duty to prevent use of scientific knowledge contrary to human rights, including the right to health, which may include excluding some inventions form patentability when that would conflict with other human rights); CESCR General Comment No. 14, *supra* note 64, ¶ 43(d) (noting that the core obligation to fulfill the right to health includes providing essential drugs); *see also* U.N. Rep. of Rapporteur Hunt, 2006, *supra* note 17, ¶ 47 (recommending use of compulsory licenses to provide affordable drugs).

obligation to make "essential medicines" available and accessible, which is not subject to progressive realization.[70]

Both the right to health, as well as the right to benefit from scientific progress, could be undermined by an investor-state dispute. In particular, a dispute may challenge a nation's use of TRIPS flexibilities intended to support such rights. After all, a TRIPS flexibility, such as defining patentability narrowly to ensure some drugs are not patentable and thus affordable, could promote the right to health as well as the right for all individuals to benefit from scientific progress. Thus, if a nation cannot use its TRIPS flexibilities, it may not be in compliance with its obligation to respect, protect, and fulfill human rights norms.[71] Of course, many states arguably are currently not in compliance with the right to provide access to affordable medicine since many still lack such access.[72] An investment dispute, or even the threat of such a dispute, would likely make the situation worse.

One thorny question is the extent to which there is a human right to property, especially whether companies have such a right, since it could also impact an investment dispute. As noted earlier, human rights are generally focused on the rights of individuals. The Universal Declaration of Human Rights (UDHR) proclaims a right to property.[73] The UDHR, however, is not a treaty and has no force of law, although some may suggest that some of the rights proclaimed by the UDHR now have status of customary international law.[74] In addition, some regional agreements support a right to property.[75] Some scholars argue

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70. CESCR General Comment No. 14, *supra* note 64, ¶ 43(d) (noting that the core obligation to fulfill the right to health includes providing essential drugs); U.N. Rep. of Rapporteur Hunt, 2006, *supra* note 17, ¶¶ 56–58; Paul Hunt (Special Rapporteur), *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, ¶¶ 43–44, UN Doc. E/CN.4/2004/49/Add.1 (Mar. 1, 2004) [hereinafter U.N. Rep. of Rapporteur Hunt, 2004].

71. CESCR General Comment No. 14, *supra* note 64, ¶ 33 (noting that right to health imposes three levels of obligations). The right to health includes availability and accessibility of goods and services that impact health, as well socioeconomic conditions that impact health. *See id.* ¶¶ 4, 9.

72. *See, e.g.*, MDG GAP TASK FORCE, THE STATE OF THE GLOBAL PARTNERSHIP FOR DEVELOPMENT 53, 58–59, U.N. Sales No. E.14.I.7 (2014). Of course, lack of universal access to affordable medicine does not mean that progress has not been made. There have been some notable situations where domestic litigation has improved access. *See, e.g.*, Helfer, *supra* note 19, at 137; Land, *supra* note 19, at 278–81; Oke, *supra* note 19, at 102–03.

73. G.A. Res. 217 (III) A, Universal Declaration of Human Rights, art. 17 (Dec. 10, 1948) [hereinafter UDHR] (noting the right to own property, and not to be arbitrarily deprived of it).

74. HELFER & AUSTIN, *supra* note 62, at 8–9.

75. *See* Convention for the Protection of Human Rights and Fundamental Freedoms art. 1, Nov. 4, 1950, 213 U.N.T.S. 221 [hereinafter European Convention of Human Rights]; American Declaration on the Rights and Duties of Man art. 23, O.A.S. Res. XXX, 9th Int'l Conference of Am. States.

there should be a recognized human right to property.[76] Accordingly, corporate entities may assert a property-based human right interest to IP they own.[77]

Another important issue is who has responsibility to promote human rights. Traditionally, the state is responsible for protecting and promoting the human rights of individuals. It has also been stated that all members of society, including the private sector, have responsibilities regarding the realization of the right to health.[78] However, there is no enforceable mechanism to mandate the private sector do so; although there are current discussions aiming to impose binding human rights obligations on companies,[79] the human right to health may not be a right for which binding obligations are sought.[80] So, companies currently have no obligation to promote or respect

76. *See* José E. Alvarez, *The Human Right of Property*, 72 U. MIAMI L. REV. 580, 596 (2018); John G. Sprankling, *The Global Right to Property*, 52 COLUM. J. TRANSNAT'L L. 464, 465 (2014) (arguing that it should be considered to exist as a matter of customary law).

77. *See* Anheuser-Busch Inc. v. Portugal, App. No. 73049/01, 44 Eur. H.R. Rep. 42. There is current controversy concerning the existence of a human right to property, but this does not mean that it cannot be embraced by companies, nor that investment tribunalists will not find it persuasive. This is particularly true since the tribunal could rely on precedence from regional agreements finding a human right to IP for corporations. *See* Anheuser-Busch Inc. v. Portugal, App. No. 73049/01, 44 Eur. H.R. Rep. 42 (finding corporate-owned IP to be property interest protected by human rights).

78. CESCR Gen. Comment No. 14, *supra* note 64, ¶ 42. Although the UN has issued guidelines for pharmaceutical companies in particular, these are only suggested guidelines. *E.g.*, Paul Hunt (Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical & Mental Health), *The Right to Health*, ¶ 46, U.N. Doc. A/63/263 (Aug. 11, 2008) [hereinafter U.N. Rep. of Rapporteur Hunt, 2000] (using language of "should"); *see also* Suerie Moon, *Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry,* 15 HEALTH & HUM. RTS. 32, 36–37 (2013) (quoting Gen. Comment No. 14).

79. *See* María Fernanda Espinosa (Chair-Rapporteur), *Rep. on the Second Session of the Open-Ended Intergovernmental Working Group on Transnational Corps. & Other Bus. Enters. with Respect to Human Rights*, ¶¶ 1, 9, U.N. Doc. A/HRC/34/47 (Jan. 4, 2017) [hereinafter U.N. Rep. of Chair-Rapporteur Espinosa, 2017]; María Fernanda Espinosa (Chair-Rapporteur), *Rep. on the First Session of the Open-Ended Intergovernmental Working Group on Transnational Corps. & Other Bus. Enters. with Respect to Human Rights, with the Mandate of Elaborating an Int'l Legally Binding Instrument*, ¶¶ 1, 30, U.N. Doc. A/HRC/31/50 (Feb. 5, 2016) [hereinafter U.N. Rep. of Chair-Rapporteur Espinosa, 2016]. Since 2014, a working group established by the Human Rights Council has been focused on developing an internationally legally binding instrument to regulate multinational corporations and other business entities regarding international human rights law. *See* U.N. Report of Chair-Rapporteur Espinosa, 2017, *supra*, ¶ 1; UN Report of Chair-Rapporteur Espinosa, 2016, *supra*, ¶ 1; Human Rights Council Res. 26/9, U.N. Doc. A/HRC/RES/26/9, at 1–2 (July 14, 2014).

80. *See* Guillaume Long (Chair-Rapporteur), *Rep. on the Third Session of the Open-Ended Intergovernmental Working Group on Transnational Corps. & Other Bus. Enters. With Respect to Human Rights*, ¶¶ 54–55, U.N. Doc. A/HRC/37/67 (Jan. 24, 2018) (noting that some delegations disagreed that all human rights should be included due to the lack of universality of many human rights).

human rights unless required under domestic law, despite UN suggestions that companies do so.[81]

Although the state has responsibility to promote human rights under ICESCR, enforcing that duty can be challenging. For example, although the UN has clarified the scope of the right to health, these interpretations are not self-executing.[82] In addition, although the UN has stated that nations and companies should not pressure developing countries to enact TRIPS-plus agreements, that has had no impact, likely since there is no effective enforcement means.[83] After all, the international system focuses primarily on voluntary state action and even reporting.[84] Recognizing the difficulties with enforcement, the UN has adopted a mechanism to permit individuals to complain about enforcement of rights against nations, but only after exhausting domestic remedies.[85] However, this only applies to the minority of

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81. *See id.*; U.N. Rep. of Rapporteur Hunt, 2006, *supra* note 17, ¶ 92 (discussing the emerging consensus that corporations have human rights obligations).

82. *See* CESCR Gen. Comment No. 14, *supra* note 64, ¶ 53 (noting that a right to health can strengthen the position of health ministries at the national level, thus implying no immediate binding obligation); Benjamin Mason Meier & Larisa M. Mori, *The Highest Attainable Standard: Advancing a Collective Human Right to Public Health*, 37 COLUM. HUM. RTS. L. REV. 101, 125 (2005). *See generally* Stephen P. Marks, *Normative Expansion of the Right to Health and the Proliferation of Human Rights*, 49 GEO. WASH. INT'L L. REV. 97, 117 (2016) (noting that outside the Framework Convention on Tobacco Control, there is no legally binding human right instrument regarding the right to health, nor political will to do so).

83. *See* U.N. Rep. of Rapporteur Hunt, 2006, *supra* note 17, ¶¶ 64, 87 (stating that (1) nations should not pressure developing countries into enacting TRIPS plus agreements and (2) companies have fallen short of enforcement mechanisms anticipated by human rights).

84. *See* Judith R. Bueno de Mesquita et al., *The Future of Human Rights Accountability for Global Health Through the Universal Periodic Review*, *in* HUMAN RIGHTS IN GLOBAL HEALTH: RIGHTS-BASED GOVERNANCE FOR A GLOBALIZING WORLD 537, 549 (Benjamin Mason Meier & Lawrence O. Gostin eds., 2018). The UN subsidiary organizations do not directly enforce human rights, but rather, have committees of experts who engage in fact-finding, monitor state implementation, and interpret treaty obligations through general comments. *See* Benjamin Mason Meier & Virgínia Brás Gomes, *Human Rights Treaty Bodies: Monitoring, Interpreting, and Adjudicating Health-Related Human Rights*, *in* HUMAN RIGHTS IN GLOBAL HEALTH: RIGHTS-BASED GOVERNANCE FOR A GLOBALIZING WORLD 509, 509 (Benjamin Mason Meier & Lawrence O. Gostin eds., 2018). However, states may disregard commitments; despite the existence of the Universal Periodic Review system for reporting and recommendations of states, that system is not legally binding. *See* Mesquita et al., *supra*, at 549. Indeed, one commentator has asserted that the extent to which ICESCR is binding on state parties is "questionable" due to its vague language, especially regarding the human right to health, and that any ICESCR comments that aim to provide clarity to rights are nonbinding. James D. Fry, *International Human Rights Law in Investment Arbitration: Evidence of International Law's Unity*, 18 DUKE J. COMP. & INT'L L. 77, 95 (2007); *see also* RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 702 (AM. LAW INST. 1987) (providing a narrow list of customary human rights that does not include rights dealing with social, economic, or cultural rights, but including issues such as genocide, torture, and systematic racial discrimination).

85. G.A. Res. 63/117, Optional Protocol to the International Covenant on Economic, Social and Cultural Rights, art. 2–3(1) (Dec. 10, 2008).

countries that have adopted it.[86] In addition, this mechanism still only addresses state violations of human rights and would not address the extent to which corporate actions impact human rights.[87] Although the UN has recognized that corporations should respect human rights, its discussion tends to focus on the most heinous human rights violations that amount to international crimes, such as genocide and human trafficking, rather than the rights at issue here.[88]

B. Applying Human Rights in Investment Disputes

While a number of human rights could be relevant to investor-state disputes, a key question is how these rights might come into play. In most IIAs, there is no reference to human rights at all.[89] As such, human rights would only be relevant to the extent a tribunal considered them as part of the broader interpretive context.[90] Human rights issues have only been raised relatively recently in the context of investment

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86. *See Status of Treaties: Optional Protocol to the International Covenant on Economic, Social and Cultural Rights*, U.N.T.S (Oct. 11, 2018, 7:35 PM) https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3-a&chapter=4&clang=_en [https://perma.cc/7B8W-GVLQ] (listing current members).

87. *See* G.A. Res. 63/117, *supra* note 85, art. 2. In addition, it is unclear what impact, if any, this has had since it came into effect in 2013. A law journal search for mentions of this Convention did not find discussion of any specific uses. *See, e.g.*, Lawrence O. Gostin & Eric A. Friedman, *Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice*, 13 YALE J. HEALTH POL'Y L. & ETHICS 1, 37 (2013); Alicia Ely Yamin & Angela Duger, *Adjudicating Health-Related Rights: Proposed Considerations for the United Nations Committee on Economic, Social and Cultural Rights, and Other Supra-National Tribunals,* 17 CHI. J. INT'L L. 80, 103 (2016) (briefly mentioning Optional Protocol); *see also* THE OPTIONAL PROTOCOL TO THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS: A COMMENTARY 194 (Malcolm Langford et al. eds., 2016) (providing extensive explanation of the Convention focused on future, rather than past use).

88. *See, e.g.*, John Ruggie (Special Representative of the Secretary-General), *Interim Rep. of the Special Representative of the Sec'y-Gen. on the Issue of Human Rights & Transnational Corps. & Other Bus. Enters.*, ¶¶ 60–61, U.N. Doc. E/CN.4/2006/97 (Feb. 22, 2006).

89. *See* MOUYAL, *supra* note 65, at 4, 141 (noting that explicit references to human rights are rare, and that even references to issues consistent with human rights such as health and environment have until recently also been rare).

90. *See* Vienna Convention on the Law of Treaties arts. 31, ¶ 3(c), *opened for signature* May 23, 1969, 1155 U.N.T.S. 331 (entered into force Jan. 27, 1980) [hereinafter VCLT]. Of course, this is entirely permissible and scholars have indeed suggested that human rights should be invoked as part of the interpretive context. *See, e.g.*, Pierre-Marie Dupuy, *Unification Rather Than Fragmentation of International Law? The Case of International Investment Law and Human Rights Law*, *in* HUMAN RIGHTS IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION 45, 56–61 (Pierre-Marie Dupuy et al. eds., 2009); Susan L. Karamanian, *The Place of Human Rights in Investor-State Arbitration*, 17 LEWIS & CLARK L. REV. 423, 433, 442 (2013) (noting that tribunals can consider international human rights pursuant to ICSID and UNCITRAL rules, and also that some IIAs have language that could support a human rights interpretation); *see also supra* note 16 (noting scholars who have suggested investment tribunals embrace human rights to promote public interest).

disputes.[91] Nonetheless, scholars and some advocates have previously suggested that tribunals more broadly embrace human rights in interpreting IIAs in order to provide states more freedom to regulate.[92] However, investors can and sometimes have relied on human rights to support investment claims.[93]

How human rights would be used by tribunalists in interpreting investment claims is a tricky issue given that there are competing rights. Balancing competing human rights is generally difficult.[94] There is no hierarchy among human rights, except perhaps for a few that have *jus cogens* status, such as the right to be free from torture.[95] In addition, promotion of one right can undercut another. For example, as noted earlier, the ICESCR supports the interests of creators as well as users.[96] However, the rights of users to benefit from scientific progress is not robustly recognized as a human right.[97] Some have suggested that these competing rights should limit overly broad patents, as well as patents on minimally inventive drugs that may overly protect commercial profits.[98] In addition, the human right for

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91. *See, e.g.*, MOUYAL, *supra* note 65, at 146–51 (discussing examples of human rights in investment disputes only from 1989 and later, even though disputes have taken place for more than fifty years).

92. *See* Sheffer, *supra* note 16, at 502–21 (suggesting investment agreements should explicitly declare tribunals competent to address human rights laws so that host states can raise human rights defenses); Gabisa, *supra* note 16, at 163–64, 165–66 (noting that international investment practice should not be divorced form general international law, such that human rights obligations should be considered, and also suggesting that human rights issues can be raised, even though decisions to date have given "little or no attention" to such issues).

93. *E.g.*, Karamanian, *supra* note 90, at 422, 433 (noting investors relying on human rights principles such as due process and discrimination).

94. *See, e.g.*, Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1122–23 (2007).

95. *See* World Conference on Human Rights, *Vienna Declaration and Programme of Action*, ¶ 5, U.N. Doc. A/CONF.157/23 (June 25, 1993) (asserting that the international community must place human rights on the same footing); Erika de Wet, *The Prohibition of Torture as an International Norm of Jus Cogens and Its Implications for National and Customary Law*, 15 EUR. J. INT'L L. 97, 114 (2004) (stating that *jus cogens* norms, such as the prohibition against torture, are superior to customary international law). All human rights are considered to stand on the same footing, except for those with *jus cogens* status. *See, e.g.*, World Conference on Human Rights, *supra*; de Wet, *supra*. For the few human rights with jus cogens status, they have higher status than other human rights. *See* MOUYAL, *supra* note 65, at 97. States may not deviate from rights that have *jus cogens* status and any attempt to enter agreements that limit these rights would be invalid. *See Jus Cogens*, MERRIAM-WEBSTER.COM DICTIONARY, https://www.merriam-webster.com/legal/jus%20cogens [https://perma.cc/RVR4-YW8L] (last visited Oct. 9, 2018).

96. *See supra* notes 67–68 and accompanying text

97. *See, e.g.*, Peter K. Yu, *The Anatomy of the Human Rights Framework for Intellectual Property*, 69 SMU L. REV. 37, 39, 41 (2016) (noting that the right to science and culture is a relatively underexplored area and the only provision in article 15 of the ICESCR for which there is currently no interpretive comment) [hereinafter Yu, *Anatomy of Human Rights*].

98. *See* CESCR General Comment No. 17, *supra* note 6, ¶ 35 (noting that IP is inherently a social product and that states have an obligation to prevent unreasonably high costs for access to essential medicines); Rep. of High Comm'r of Hum. Rts., *The Impact of the Agreement on Trade-*

innovators and creators is not identical to the scope of IP, since IP is merely an incentive.[99] Innovators have no human right to any particular form of patent protection.[100] However, these suggestions only address dealing with human rights in isolation and not solely as interpretive context to core obligations under IIA. In addition, the human right to health, including the right to affordable essential medicines, may compete with an arguable human right to property.

It is especially unclear how an investment tribunal might consider competing human rights to interpret explicit investment provisions—especially to the extent that IIAs generally do not even reference human rights. Traditional rules of interpretation would suggest that IIA language be given primacy. There might be more leeway to consider human rights if there was an actual conflict between explicitly conflicting obligations. However, such an express conflict seems unlikely in the context of challenges to domestic actions limiting IP norms. The situation parallels the TRIPS context where there is no consensus on whether TRIPS expressly conflicts with the human right to health or how to address such a conflict.[101] Although the UN has suggested that human rights under the ICESR have primacy over international agreements, such as TRIPS,[102] none of these

Related Aspects of Intellectual Property Rights on Human Rights, ¶ 68, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001) [hereinafter Rep. of High Comm'r Hum. Rts., *TRIPS Impact*]. One scholar goes further in suggesting that the human right to benefit from scientific progress should focus on the most vulnerable and disadvantaged, rather than profits for creators or improvements to the affluent. *See* Audrey R. Chapman, *Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications*, 8 J. HUM. RTS. 1, 14 (2009).

99. *See* CESCR General Comment No. 17, *supra* note 68, ¶ 35 (noting that states have a duty to prevent unreasonably high costs for essential medicines and a duty to prevent use of scientific knowledge contrary to human rights, including the right to health, which may involve excluding some inventions form patentability when that would conflict with other human rights); U.N. Rep. of Special Rapporteur Shaheed, *supra* note 46, ¶ 32 (noting that contrary to IP, human rights are inalienable).

100. U.N. Rep. of Special Rapporteur Shaheed, *supra* note 46, ¶ 90 (noting no such right under ICESCR).

101. *See, e.g.*, Sub-Commission on Human Rights Res. 2000/07, ¶ 2 (Aug. 17, 2017) (noting actual or potential conflicts between TRIPS and human rights and that human rights should have primacy); Lawrence R. Helfer, *Human Rights and Intellectual Property: Conflict or Co-existence*, 5 MINN. J. L. SCI. & TECH. 47, 47 (2003); Gabrielle Marceau, *WTO Dispute Settlement and Human Rights*, 13 EUR. J. INT'L L. 753, 792 (2002) (noting no conflict between WTO provisions and human rights treaty unless WTO mandates or prohibits an action that human rights treaty prohibits or mandates, which would be rare); Yu, *supra* note 94, at 1042 (arguing that focus should be on how to resolve tension and providing some suggestions without necessarily adopting UN recommendation that human rights should always trump). These different views of conflicts reflect different interpretations of what constitutes a conflict. *See* HELFER & AUSTIN, *supra* note 62, at 66 (noting that narrowly defining a conflict to only exist if an IP treaty mandates activity barred by a human rights agreement would likely result in no conflicts, but a broader interpretation of conflict to consider incompatible behavior might hold otherwise).

102. *See* Sub-Commission on Human Rights Res. 2000/07, *supra* note 101, pmbl., ¶ 3 (noting human rights have primacy); G.A. Res. 65/216, Globalization and Its Impact on Full

interpretations are legally binding.[103] Indeed, prior investor-state tribunals have held that human rights obligations do not present a conflict with investment norms.[104] This is perhaps not surprising since the field of human rights is not an area that tribunalists are typically familiar with; they are typically chosen for knowledge in the field of investment, rather than human rights.[105] Nonetheless, investment claims may still impact human rights.[106]

C. Eli Lilly *Facts and Claims*

Before reexamining the *Eli Lilly* case using a human rights lens, it is important to first review the basic facts and claims at issue. Accordingly, this section first revisits the essential facts underlying Eli Lilly's dispute, followed by an explanation of the investment claims.

1. Facts Underlying Eli Lilly's Dispute

The investment dispute against Canada was initiated after Eli Lilly exhausted domestic options to obtain patents on profitable drugs sold as Strattera and Zyprexa.[107] In both situations, patents were denied because Eli Lilly's patents failed to meet Canada's "promise doctrine," a judicial interpretation of the core patent requirement of

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Enjoyment of Human Rights, ¶¶ 19–34, U.N. Doc. E/CN.4/Sub.2/2001/10 (Aug. 2, 2001) (noting IP undermines human rights); Rep. of High Comm'r of Hum. Rts., *TRIPS Impact, supra* note 98, ¶ 22 (noting that IP laws must promote access and opposing TRIPS plus treaties); Yu, *supra* note 94, at 1041 (human rights to have primacy).

103. *See* HELFER & AUSTIN, *supra* note 62, at 54–56.

104. For example, countries have not prevailed in asserting that investment claims interfere with human rights obligations, such as the right to provide water. *See, e.g.*, Suez v. Arg. Republic, ICSID Case No. ARB/03/19, Decision on Liability, ¶¶ 260–64 (July 30, 2010) [hereinafter *Suez*, Decision on Liability], https://www.italaw.com/sites/default/files/case-documents/ita0826.pdf [https://perma.cc/RCC5-BN3K] (rejecting assertion by Argentina and amici that the right to water trumps BIT obligations in the context of rejecting defense of necessity in privatizing water and sewage systems that impacted the foreign investor because defense of necessity was not met based on tribunal's assessment that Argentina could have adopted other methods to avoid violating investor rights and that Argentina was at least in part responsible for the situation); Azurix Corp. v. Arg. Republic, ICSID Case No. ARB/01/12, Award, ¶ 3 (July 14, 2006) [hereinafter *Azurix*, Award], https://www.italaw.com/sites/default/files/case-documents/ita0061.pdf [https://perma.cc/6CFR-GA8L] (rejecting Argentina's proposition that a conflict between a BIT and human rights should be resolved in favor of human rights and asserting that "it fail[ed] to understand the incompatibility").

105. *See, e.g.*, Iona Knoll-Tudor, *The Fair and Equitable Treatment Standard and Human Rights Norms, in* HUMAN RIGHTS IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION 311, 337 (Pierre-Marie Dupuy et al. eds., 2009).

106. *See* Rep. of the Indep. Expert on the Promotion of a Democratic and Equitable Int'l Order, *supra* note 39, ¶ 12 (asserting investment agreements adversely impact human rights).

107. *See Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶ 21 (noting that trial court decisions were unsuccessfully appealed and the Supreme Court of Canada denied leave to hear further appeals).

utility that exists under both NAFTA and TRIPS that was overturned in a separate case after the *Lilly* dispute.[108] This doctrine only applied to certain situations where a patent must establish utility. In particular, it only applied when a patent applicant, such as Eli Lilly, "promised" that an invention will have a particular purpose.[109] Typically, an applicant would only make such a promise if it had previously obtained a more fundamental patent, such as the chemical composition of a drug, and later wanted to obtain an additional patent on a new use of that drug. An application satisfied the promise doctrine if it disclosed data to support such a promise.[110] Eli Lilly had to make such promises because it had already received at least one full term of patent protection for the basic chemical compound underlying each drug, and was seeking additional protection after earlier patents expired.[111] The invalidated patent on Strattera failed to satisfy its promise of treating Attention Deficit Hyperactivity Disorder (ADHD) as a chronic condition; the court found the patent failed to include any data to establish that it would be efficacious for long-term use.[112] The invalidated patent on Zyprexa was similarly found to promise a superior treatment for long-term treatment of psychosis without supporting data.[113]

A major issue in the dispute was whether it was significant that Canada's promise doctrine was unique, as Eli Lilly and others sympathetic to pharmaceutical companies highlighted.[114] Admittedly, Canada's promise doctrine diverged from the utility doctrines of most countries.[115] However, as some patent scholars have noted, different jurisdictions use different patentability standards to achieve the same goal as the promise doctrine; for example, the United States polices a

108. *E.g.*, *id.*, ¶¶ 51–53, ¶¶ 62–64. After this investment dispute, the Supreme Court of Canada abolished the doctrine in a case involving an invention that satisfied one, but not all, promises made, although it left the door open to a different patent law doctrine to govern similar behavior. AstraZeneca Can. Inc. v. Apotex Inc., [2017] 1 S.C.R. 943 (Can.); *see also Canada's Supreme Court Abolishes Controversial Promise Doctrine,* PCK (June 30, 2017), https://www.pckip.com/patent/promise-doctrine-abolished-one-use-mere-scintilla-utility-will-satisfy-utility-requirement [https://perma.cc/5TAT-25WU].

109. *See, e.g.*, Eli Lilly Can. Inc. v. Novopharm Ltd., [2012] 1 F.C.R. 349, para. 76 (Can.).

110. *Id.*

111. *See, e.g.*, Eli Lilly v. Canada, Case No. UNCT/14/2, Government of Canada Statement of Defence, ¶ 53 (June 30, 2014), https://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf [https://perma.cc/7M8H-ZQZZ] [hereinafter *Eli Lilly*, Government of Canada Statement of Defence].

112. *See* Novopharm Ltd. v. Eli Lilly & Co. [2010] F.C. 915, para. 60 (Can. Ont.)

113. *See* Eli Lilly Can. Inc. v. Novopharm Ltd.*,* [2011] F.C. 1288, para. 218 (Can. Ont.).

114. *See Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶¶ 34–39.

115. *See id.* ¶¶ 34–39 (explaining unique nature of Canada laws).

similar problem through the patent doctrine of "written description."[116] These different patent doctrines have the same essential goal of limiting the social cost of patents in terms of higher prices to the most worthwhile inventions. These doctrines all share the same goal of helping to ensure that an inventor has disclosed something of adequate value before a patent is granted.[117]

Although not explicitly addressed by Canada, the *Eli Lilly* dispute implicitly challenged TRIPS flexibilities.[118] In particular, TRIPS contains identical language to NAFTA's IP chapter concerning domestic obligations to provide patents to "inventions" that meet key requirements that are undefined.[119] In other words, both TRIPS and NAFTA provide member states flexibilities with respect to undefined key requirements, which include the definition of utility.[120] Although most countries embracing TRIPS flexibilities have chosen to interpret other aspects of patentability, like what constitutes a patentable "invention" or what is "new,"[121] the notion of TRIPS flexibilities applies to all undefined patent requirements. A PhRMA press release after the award suggests a goal of Eli Lilly's dispute was to directly challenge such flexibilities.[122]

116. *See id.*; *Eli Lilly*, ICSID Case No. UNCT/14/2, Second Expert Report of Timothy R. Holbrook, ¶ 5 (Dec. 5, 2015), https://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207020.pdf [https://perma.cc/23MD-8RDF]; *Eli Lilly*, ICSID Case No. UNCT/14/2, Expert Report of Timothy R. Holbrook, ¶ 7 (Jan. 26, 2015), https://www.italaw.com/sites/default/files/case-documents/italaw4137.pdf [https://perma.cc/HL7S-8FE4]; E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CAN. INTELL. PROP. REV. 35, 53–57, 61–77 (2014); Dmitry Karshtedt, *The Completeness Requirement in Patent Law*, 56 B.C. L. REV. 949, 974–76 (2015). *But see*, Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Application for Leave to File a Non-Disputing Party Amicus Curiae Submission by Intellectual Property Law Professors (Feb. 12, 2016), https://www.italaw.com/sites/default/files/case-documents/italaw7150.pdf [https://perma.cc/YQ37-WSWS] (opposing view by seven law professors). However, as explained by Canada, the opposing view of these law professors is not supported. Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Government of Canada Observations on Issues Raised in Amicus Submissions, ¶ 18 (Apr. 22, 2016), https://www.italaw.com/sites/default/files/case-documents/italaw7264.pdf [https://perma.cc/E6GU-BNAX].

117. *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 535–36 (1966) ("[A] patent is not a hunting license."); Eli Lilly Can. Inc. v. Novopharm Ltd., [2012] 1 F.C.R. 349, paras. 70, 76 (Can.).

118. *See supra* 44–46 (explaining how the *Eli Lilly* dispute challenges TRIPS flexibilities); Ho, *Collision Course*, *supra* note 15, 440–53 (discussing how the *Eli Lilly* dispute threatens TRIPS flexibilities). *See generally Eli Lilly*, Notice of Arbitration, *supra* note 2.

119. *Compare* TRIPS, *supra* note 9, art. 27(2), *with* North American Free Trade Agreement, Can.-Mex.-U.S., art. 1709(2), Dec. 17, 1992, 32 I.L.M. 289 [hereinafter NAFTA].

120. *See* TRIPS, *supra* note 9, art. 27; NAFTA, *supra* note 119, art. 1709(2).

121. *See, e.g.*, The Patents Act, No. 39 of 1970, INDIA CODE (2005), § 3(d) (limiting the definition of what is an invention within the meaning of the Act).

122. *See* Press Release, PhRMA, *supra* note 44 (noting that because Canada is the "only country" with its interpretation of utility law, it breaks "the letter and spirit" of international rules on IP).

In addition, a different type of TRIPS flexibility was implicitly challenged by Eli Lilly's claim that the promise doctrine improperly discriminates against pharmaceuticals as a field of technology in violation of NAFTA and TRIPS.[123] WTO jurisprudence makes an important distinction between legitimate differentiation and improper discrimination, which is also supported by the Declaration on Regulatory Sovereignty.[124] A WTO panel noted that there is no prohibition against dealing with problems that may exist only in certain product areas.[125] Notably, the panel stated that even when a country intended to regulate a particular area, it did not constitute implicit discrimination since "preoccupation" with the impact of a law to one area is not discriminatory unless there is evidence that the broader purpose is a "sham."[126] Nothing indicates that the promise doctrine was a "sham." A court applied this doctrine to a mechanical invention.[127] The fact that more pharmaceutical patents were invalidated could simply reflect that the industry was violating the doctrine, rather than indicating that the doctrine discriminates against the industry.[128] Nonetheless, if the tribunal had been sympathetic to Eli Lilly's position, this would have immediately contradicted current WTO norms that are well recognized.[129]

Canada's promise doctrine addressed a key issue in the pharmaceutical industry that is of particular concern to those who advocate using TRIPS flexibilities. In an attempt to maximize revenue, the pharmaceutical industry has a practice of sequentially patenting

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123. *Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶¶ 66, 79.

124. *See* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. TECH. L. REV. 445, 450–53 (2007) (agreeing with differentiation goal and further arguing that there should be no discrimination so long as a legitimate purpose is demonstrated); Matthias Lamping et al., *Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS* 4 (Max Planck Inst. for Innovation & Competition, Research Paper No. 14–19, 2014), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2500784 [https://perma.cc/67E4-GNDQ].

125. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 7.92, WT/DS114/R (adopted March 17, 2000).

126. *Id.* ¶ 7.104.

127. Bell Helicopter Textron Canada Limitée v. Eurocopter, [2013] FCA 219 (Can). In addition, before changes to Canadian patent law eliminated the promise doctrine after the conclusion of the Eli Lilly investment dispute, the Canadian Manual on patent examining procedure used a mechanical example. *See* CAN. INTELLECTUAL PROP. OFFICE, K1A 0C9, MANUAL OF PATENT OFFICE PRACTICE, ¶ 12.08 (2016), http://publications.gc.ca/collections/collection_2016/opic-cipo/Iu71-4-9-2016-2-eng.pdf [https://perma.cc/5LX8-Q362]; *see also* Ho, *supra* note 15, *Collison Course*, at 447 (discussing this provision).

128. Indeed, it has long been recognized that uniform patent standards may result in different applications to different technologies. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003).

129. *See generally* Lamping et al., *supra* note 124 (discussing the importance of state discretion—within the confines of international law—in making patent system decisions).

minor modifications or different uses of a drug after first obtaining a patent on the basic chemical compound.[130] The industry considers this appropriate "life cycle management."[131] However, public health advocates and some governments, including both India and member states of the European Union, consider this to be an inappropriate way of "evergreening" patent profits.[132] In other words, profits will continue (be "ever green") if companies can patent different aspects of a drug such that they can continue to charge high prices on the same drug even after the initial patent expires.

Eli Lilly's patents illustrate how Canada's promise doctrine addressed this problem. Both of the invalidated patents were attempts to obtain additional patent protection after the original patent on the underlying chemical compound had expired.[133] Moreover, Eli Lilly did not even make any modifications to the compound, but instead simply attempted to claim—without any basis—that it had a new use.[134]

2. Eli Lilly's Investment Claims

Eli Lilly asserted two separate investment claims pursuant to the investment chapter of NAFTA against Canada based on the invalidation of two patents.[135] Eli Lilly claimed (1) that the invalidated patents constituted expropriation because the value of its patents were destroyed and (2) that it was denied fair and equitable treatment.[136] These represent prototypical investment claims, but Eli Lilly's basis for these claims are notable.

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130. *See, e.g.*, JOHN R. THOMAS, CONG. RES. SERV., R40917, PATENT "EVERGREENING": ISSUES IN INNOVATION AND COMPETITION 3 (2009); Roger Collier, *Drug Patents: The Evergreening Problem,* 185 CAN. MED. ASSOC. J. E385 (2013); Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 HOUS. J. HEALTH L. & POL'Y 379, 380 (2007).

131. *See, e.g.*, TONY ELLERY & NEAL HANSEN, PHARMACEUTICAL LIFECYCLE MANAGEMENT: MAKING THE MOST OF EACH AND EVERY BRAND, at xx (2012); Vandana Prajapati et al., *Product Lifecycle Management Through Patents and Regulatory Strategies,* 13 J. MED. MARKETING 171, 171 (2013).

132. *E.g.*, Novartis A.G. v. Union of India, (2013) 6 SCC 1 (India); European Comm'n, *Pharmaceutical Sector Inquiry Preliminary Report*, at 103 (Nov. 28, 2008), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [https://perma.cc/GJM6-CW8Y]; TONY HARRIS ET AL., PHARMACEUTICAL PATENTS REVIEW REPORT 106–07 (2013), https://www.ipaustralia.gov.au/sites/g/files/net856/f/2013-05-27_ppr_final_report.pdf [https://perma.cc/8RR6-SN6N]; Nathalie Vernaz et al., *Patented Drug Extension Strategies on Health Care Spending: A Cost-Evaluation Analysis*, 10 PLOS MED. e1001460 (2013).

133. *See Eli Lilly*, Government of Canada Statement of Defence, *supra* note 111, ¶¶ 3–4.

134. *See, e.g.*, *id.* ¶ 4.

135. *Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶¶ 3–4, 74–84.

136. *Id.* ¶¶ 74–84.

Eli Lilly asserted that its patents were indirectly expropriated based on a variety of reasons. Indirect expropriation claims are often made when investments lose value,[137] which would seem to apply here. However, one could alternatively argue that canceled patents should not be considered an investment at all.[138] Eli Lilly asserted that indirect expropriation was supported by alleged violations of international IP standards, including the patent requirements under NAFTA that mirror TRIPS patentability requirements.[139] In particular, it asserted that the promise doctrine was a change in the law that Eli Lilly could not have anticipated.[140] Eli Lilly also claimed that invalidations of its patents were "contrary to the public purpose" of patents to provide an exclusive right—even though patents are routinely invalidated when they are found to fail patentability requirements.[141] Lastly, it asserted that the promise doctrine discriminates against pharmaceutical patents in violation of NAFTA's patent requirements, which again mirror TRIPS.[142]

Eli Lilly also alleged that Canada violated FET because the judicial invalidations were allegedly arbitrary and inconsistent with its legitimate expectation of a stable business and legal environment.[143] In particular, Eli Lilly alleged that it could not have anticipated that the Canadian law on utility would be "so drastically altered" and also "retroactively applied" to invalidate its patents.[144] There was a factual dispute concerning whether Canada's laws had changed at all, let alone whether they were drastically changed.[145] Nonetheless, the FET claim threatened TRIPS flexibilities. In particular, Eli Lilly's investment claim is fundamentally premised on the assumption that nations cannot modify laws, completely contrary to domestic and international norms.[146] It is in fact routine for common law countries like Canada and the United States to change standards of patentability.[147] The United States has, for example, changed the standards of

137. *See, e.g.*, NAFTA, *supra* note 119, art. 1110; *see also* SUZY H. NIKIEMA, INT'L INST. FOR SUSTAINABLE DEV, BEST PRACTICES: INDIRECT EXPROPRIATION 5 (2012).

138. *See, e.g.*, Ho, *Sovereignty*, *supra* note 15, at 246.

139. *Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶ 75.

140. *Id.* ¶ 77.

141. *Id.* ¶ 78. However, patent law has never been static, such that companies should expect modifications, including ones that result in invalidation of patents. *See, e.g.*, Ho, *Sovereignty*, *supra* note 15, at 271–72.

142. *Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶ 79.

143. *See id.* ¶¶ 81–82.

144. *Id.* ¶¶ 82–83.

145. *See* Ho, *Sovereignty*, *supra* note 15, at 236 n.88 (noting controversy).

146. *See Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶ 34 (noting change in law); *see also id.* ¶ 29 (asserting that Canada's utility law was different at the time NAFTA was signed).

147. *See* Ho, *Sovereignty*, *supra* note 15, at 271–72, 281.

nonobviousness, as well as the scope of patentable subject matter, such that previously issued patents were subsequently invalidated.[148]

D. Eli Lilly *Revisited*

This Section considers two possible extremes of how a broader embrace of human rights norms might have impacted a tribunal's consideration of Eli Lilly's investment claims. This Section also contemplates hypothetical best and worst case scenarios of incorporating human rights, even though it is likely that neither would be a realistic outcome. Rather, the goal of this Section is to highlight that although embracing human rights might initially seem to promote domestic norms, it could alternatively simply reinforce existing investment rights.

1. Human Rights to Promote Health and Scientific Progress Benefits

The best argument based on human rights would likely be that the human right to benefit from scientific progress and the human right to health should trump, or at least modify, interpretation of investment claims. These arguments both prove difficult, as explained below.

Although some might consider it ideal for human rights to trump investment claims in order to promote the human right to health as well as state sovereignty,[149] this seems unrealistic for a number of reasons. First, tribunals have thus far rejected state attempts to rely on human rights, such as the human right to water, as a complete defense from investment claims.[150] The rights at issue here, similar to the right to water, lack a robust mechanism of enforcement at the international level.[151] In addition, most agreements, including NAFTA's investment chapter, lack any explicit provision to promote human rights, or alternatively, any exception to investor claims premised on human

148. *See* Steven Seidenberg, *After* Alice*: Business-Method and Software Patents May Go Through the Looking Glass*, 101 A.B.A. J. 19 (2015); Donald Vinson, *Key Cases Shaping the Future for Patent Litigation Funders*, LAW360 (Apr. 27, 2015, 10:13 AM), http://www.law360.com/articles/646193/print?section=ip [https://perma.cc/2KHB-VXJS] (noting that patent owners may reconsider pursuing infringement in light of the potential for validity challenges).

149. In particular, those concerned about the extent to which IIAs tend to elevate corporate interests about those of society may consider it preferable for human rights norms to be valued over investment claims.

150. *See supra* note 104.

151. *See supra* notes 79–89 and accompanying text (discussing difficulty enforcing human right to health).

rights.[152] Most investment agreements, including NAFTA's investment chapter, actually have no exceptions at all to FET claims.[153] Moreover, the argument that human rights should trump IP rights in the TRIPS context has had limited impact.[154]

The WTO experience is particularly instructive. Notably, although the UN has repeatedly suggested that human rights should have primacy over trade norms and noted actual or potential conflicts with TRIPS, WTO jurisprudence thus far has not embraced human rights in modifying explicit TRIPS requirements.[155] Rather, the WTO has arguably taken a very technical approach to treaty terms and assumed that the final text should not be further interpreted in light of other international agreements, even though that would be consistent with general rules of interpretation under the Vienna Convention.[156]

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152. *See, e.g.*, Kathryn Gordon et al., *Investment Treaty Law, Sustainable Development and Responsible Business Conduct: A Fact Finding Survey* (Org. for Economic Cooperation & Dev., Working Paper No. 2014/01, 2014) (finding that only 0.5 percent of investment agreements contain human rights considerations).

153. *See, e.g.*, NAFTA, *supra* note 119, art. 1103; *see also* CPTPP, *supra* note 22, art. 9.6 (FET provision without exceptions).

154. Although the Doha Public Health Declaration is arguably consistent with the human right to health, patents on essential medicines seem fundamentally inconsistent with UN suggestions for human rights to trump IP. After all, if nations must provide patents, including on essential medicines, human rights do not prevail. Although there are some who have advocated this situation, there was no consensus in the UN 2016 High Level Panel Report; rather, this was only the view of a minority. *See* U.N. HIGH-LEVEL PANEL REPORT, *supra* note 14, at 54 (comments of Jorge Bermudez, Winnie Byanyima, and Shiba Phurailatpam suggesting drugs on the WHO List of Essential Medicines be exempt from IP to promote the right to health). Moreover, a different minority believed that the Panel Report already goes too far in even suggesting that nations use TRIPS flexibilities. *Id.* at 57–58 (comments of Andrew Witty and Maria C. Freire noting that the report "overstates" TRIPS flexibilities, disputing that nations have the right to self-define patentability criteria, and suggesting TRIPS flexibilities will have negative long-term impacts on promoting innovation for countries).

155. *See* U.N. Econ. & Soc. Council [ECOSOC], Sub-Comm. on the Promotion and Protection of Human Rights, *The Realization of Economic, Social and Cultural Rights: Globalization and Its Impact on the Full Enjoyment of Human Rights, Preliminary Rep. on Its Fifty-Second Session*, U.N. Doc. E/CN.4/Sub.2/2000/13, at 26 (2000) (prepared by J. Oloka-Onyango & Deepika Udagama) (noting primacy of human rights law over all other regimes of international law); Subcomm. on Human Rights Res. 2000/7, U.N. Doc. E/CN.4/SUB.2/RES/2000/7, ¶¶ 3, 11 (August 17, 2000) (noting actual or potential conflicts and urging states to recognize primacy of human rights over TRIPS).

156. S*ee, e.g.*, Henrik Horn & Petros C. Mavroidis, *International Trade: Dispute Settlement*, *in* RESEARCH HANDBOOK IN INTERNATIONAL ECONOMIC LAW 177, 208 (Andrew T. Guzman & Alan O. Sykes eds., 2007) (noting that panels tend to read treaty terms in "clinical isolation"); Dispute Settlement Body, *Proposal by the LDC Group: Negotiations on the Dispute Settlement Understanding*, ¶ 5, WTO Doc. TN/DS/2/17 (Oct. 9, 2002) (noting concern that panels as well as the Appellate Body show "an excessively sanitized concern with legalisms"); *see also* Sayed M. Zonaid, *Trading in Human Rights: Questioning the Advance of Human Rights into the World Trade Organization*, 27 FLA. J. INT'L L. 261, 282–91 (2015) (noting that despite an increased global focus on human rights, they are still not broadly embraced at the WTO and arguing human rights could be more broadly embraced, although also recognizing some possible issues). *See generally* VCLT, *supra* note 90, arts. 31, 32.

The WTO panel and Appellate Body decisions concerning IP are actually generally criticized by academics for not fully promoting human rights or public policy.[157] Although the 2001 Doha Public Health Declaration on the TRIPS Agreement and Public Health is considered consistent with the human right to health,[158] scholars have criticized WTO panels for narrowly interpreting TRIPS.[159] The 2018 panel decision upholding Australia's right to limit use of trademarks to minimize tobacco use was a unique situation where the Declaration was cited.[160] However, this situation is unique in that it involves challenge to a nation that is implementing an international agreement fundamentally premised on the human right to health.

Given the minimal role human rights norms have played in mediating TRIPS jurisprudence, the possibility of human rights norms influencing investor-state disputes seems unlikely. After all, TRIPS has some explicit language permitting consideration of domestic policy that is consistent with human rights,[161] whereas most IIAs do not.[162]

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157. *See, e.g.*, Denis Borges Barbosa et al., *Slouching Toward Development*, 2007 MICH. ST. L. REV. 71; Susy Frankel, *WTO Application of "The Customary Rules of Interpretation of Public International Law" to Intellectual Property*, 46 VA. J. INT'L L. 365, 397 (criticizing panel for assuming TRIPS needs not further balancing); Molly Land, *Rebalancing TRIPS,* 33 MICH. J. INT'L L. 433, 450–59 (2012) (criticizing WTO panel for failing to interpret the copyright exception appropriately due to improperly assuming that similar language in GATT jurisprudence was relevant, such that policy concerns were not considered); Peter K. Yu, *TRIPS Enforcement and Developing Countries,* 26 AM. U. INT'L L. REV. 727, 768 (2011) (criticizing panels for mentioning, but not fully embracing, articles 7 and 8 of TRIPS). Some scholars have suggested that the WTO take a more proactive approach. *See, e.g.*, Christophe Geiger, *Implementing an International Instrument for Interpreting Copyright Limitations and Exceptions*, 40 INT'L REV. INTELL. PROP. & COMPETITION L. 627, 629–31 (2009); Ruth L. Okediji, *The Limits of Development Strategies at the Intersection of Intellectual Property and Human Rights*, *in* INTELLECTUAL PROPERTY, TRADE, AND DEVELOPMENT 355, 365 (Daniel Gervais ed., 2007).

158. *See* CARLOS CORREA & DUNCAN MATTHEWS, THE DOHA DECLARATION TEN YEARS ON AND ITS IMPACT ON ACCESS TO MEDICINES AND THE RIGHT TO HEALTH 12–17 (2011) (noting that the Doha Declaration is critical for realizing the right to health, including using TRIPS flexibilities to promote access to affordable drugs).

159. *See, e.g.*, Land, *supra* note 157, at 450–59. Of course, there has not been a WTO panel decision since Doha for which access to medicine is an issue.

160. Moreover, it was to reinforce article 8 of TRIPS, which was already part of the interpretive context. Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Docs. WT/DS435, WT/DS441/R, WT/DS458/R, WT/DS467/R, paras 7.2.3.9.5–7.2.4.1.1 (adopted June 28, 2018) (considering TRIPS article 8's mention of societal interest to include public health as backdrop to interpreting what is a "justifiable" encumbrance of trademarks pursuant to TRIPS article 20). Moreover, this decision focused on implementation of the Framework Convention on Tobacco Control, which has a strong public health focus.*See supra* note 21 and accompanying text (concerning health focus of this Convention).

161. *See, e.g.*, TRIPS, *supra* note 9, pmbl., arts. 7–8; *see also* World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

162. Only recently have IIAs expressly mentioned concerns about health issues. *See, e.g.*, CANADIAN MODEL FIPA: AGREEMENT BETWEEN CANADA AND ———— FOR THE PROMOTION AND PROTECTION OF INVESTMENTS art. 11 (2004), https://www.italaw.com/documents/Canadian2004-

Moreover, WTO jurists—who tend to have a background in public service—are considered far more sensitive to domestic concerns than most who serve as tribunalists for investor-state disputes.[163] In contrast, investment tribunals are typically comprised of lawyers who are likely familiar with commercial law, rather than human rights.[164] The WTO experience shows that although there may be an academic or moral argument for prioritizing human rights norms, this argument can be hard to reconcile with explicit rights under an agreement, whether it be TRIPS or an IIA.

Even using human rights to simply interpret but not overrule investment claims may be tricky. As noted above, the WTO has been reluctant to embrace human rights in its interpretation of TRIPS provisions that expressly permit consideration of public policy.[165] In addition, although the human right to health is well defined and includes a right to access affordable medicine, the drugs at issue in *Eli Lilly* were not essential medicines.[166] An argument could be made that although Eli Lilly's drugs were not essential medicines, interpreting investment claims in favor of Eli Lilly could negatively impact access to essential medicines by creating a chilling effect on domestic laws regarding essential medicines. However, this is obviously an attenuated argument.

If a tribunal were inclined to embrace the human right to health, as well as the right to benefit from scientific progress, it could conceivably do so in a few ways. First, it could arguably read the scope

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FIPA-model-en.pdf [https://perma.cc/4BXY-CE3W] (noting that it is inappropriate to encourage investment by relaxing domestic health, safety, or environmental measures). In addition, recently concluded agreements and proposed agreements that expressly mention domestic policy were trumpeted as "state of the art" protections of traditionally domestic areas of discretion such as health, safety, and the environment. *See, e.g.*, OFFICE OF U.S. TRADE REP., FACT SHEET: INVESTOR-STATE DISPUTE SETTLEMENT (ISDS) (2015), https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2015/march/investor-state-dispute-settlement-isds [https://perma.cc/BQ4T-3WPR].

163. Joost Pauwelyn, *The Rule of Law Without the Rule of Lawyers? Why Investment Arbitrators Are from Mars, Trade Adjudicators are from Venus*, 109 AM. J. INT'L L. 761, 781–82 (2015). That said, since WTO panels are not to create new law and human rights only inform interpretation of ambiguous phrases, it is perhaps not surprising the WTO has not broadly embraced human rights in general or with respect to TRIPS. *See generally id.*

164. *See* EBERHARDT & OLIVET, *supra* note 12, at 38–41 (providing details of commonly used arbitrators, including a number who work in the private sector); Pauwelyn, *supra* note 163, at 773 (noting that most common background for ISDS arbitrators is private sector); Sergio Puig, *Blinding International Justice*, 56 VA. J. INT'L L. 647, 655 (2016) (noting that a small group of primarily commercial arbitrators serve as tribunalists and other times as counsel or party experts); Sergio Puig, *Social Capital in the Arbitration Market*, 25 EUR. J. ITN'L L. 387, 388, 402 (2014).

165. *See, e.g.*, Frankel, *supra* note 157, at 397.

166. *See* WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES (20th ed. 2017), http://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1 [https://perma.cc/43XD-D34K] (not listing either of the drugs in the case).

of investments narrowly to entirely exclude canceled patents from the scope of investments. In particular, an argument could be made that inventors only have human rights to benefit materially from their inventions when their inventions are considered adequately valuable, such as by complying with domestic patent requirements.[167]

The cancellation of a patent for failing to comply with patentability requirements should indicate that the invention as disclosed does not provide value to society. If that were the case, no further analysis of the investment claims would be needed, since there would be no investment to protect. In addition, even when inventors have a human right related to scientific progress, that right notably exists only for actual individuals and not companies that might own the invention.

Alternatively, even if canceled patents were considered investments, a claim for expropriation could be avoided by interpreting NAFTA's existing exception from expropriation in light of human rights. In particular, NAFTA, as well as many other investment agreements, states that there is no expropriation of IP if a nation cancels or revokes IP consistent with relevant IP norms.[168]

Eli Lilly improperly asserted that Canada's laws were not consistent because they were different than other countries and also because its laws arguably changed after the patents at issue were granted.[169] However, perhaps an embrace of human rights norms—including the right to health, as well as the right of all to benefit from scientific discoveries—would suggest that the facts relied upon by Eli Lilly are irrelevant. After all, the UN has suggested that the human right to health should be promoted by TRIPS flexibilities (i.e., by reading undefined patent requirements in TRIPS (and NAFTA) in a way that limits patents).[170]

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167. This seems especially true since the right of inventors to material benefits from their discoveries is more debated than whether authors enjoy protection of moral and material interests. *See* U.N. Rep. of Special Rapporteur Shaheed, *supra* note 46, ¶ 28 (noting that this is strongly debated); Yu, *Anatomy of the Human Rights*, *supra* note 97, at 89. In addition, the UN has cautioned that even if creators of scientific inventions are to enjoy material benefits, this does not give such individuals the ability to challenge domestic laws as providing inadequate financial remuneration and that this human right does not extend to corporations that own patents. U.N. Rep. of Special Rapporteur Shaheed, *supra* note 46, ¶¶ 32–34.

168. NAFTA, *supra* note 119, art. 1110(7) (limiting expropriation claims if consistent with NAFTA's own IP chapter which is similar to TRIPS); OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2004 U.S. MODEL BILATERAL INVESTMENT TREATY art. 6(5) (2012) (exempting compulsory licenses issued in accordance with TRIPS from expropriation claims); United States-Chile Free Trade Agreement, Chile-U.S., art. 10.9(5), June 6, 2003, https://ustr.gov/trade-agreements/free-trade-agreements/chile-fta/final-text [https://perma.cc/3EWN-SP4Y] (exempting limitation of IP consistent with the IP chapter of this agreement).

169. *See, e.g.*, *Eli Lilly*, Notice of Arbitration, *supra* note 2, ¶¶ 34–39.

170. *See, e.g.*, U.N. HIGH-LEVEL PANEL REPORT, *supra* note 14, at 22–23.

Although not strictly required, there is some textual support for embracing human rights norms in interpreting investment claims under NAFTA. Obviously, tribunals are to interpret treaties in light of the object and purpose of the agreement, including preambles.[171] Under NAFTA, the preamble not only mentions the need to promote investment, but also the need to preserve "flexibility to safeguard the public welfare."[172] In addition, NAFTA states that it is "inappropriate to encourage investment by relaxing domestic health . . . measures."[173] This statement is made in the context of environmental measures, but nonetheless could be relied upon to indicate that public welfare issues are recognized by the parties.[174] In addition, the FET claims under NAFTA are expressly tied to international law.[175] Granted, the FET reference to international laws is made with respect to protecting investor rights.[176] However, there is at least an argument that since international law is mentioned, NAFTA's text has some express language to support interpreting investor rights in light of the broader international context, including human rights norms.

2. Human Rights to Reinforce Investor Rights

There is a distinct possibility that an investment tribunal could and would use human rights to reinforce investor rights and claims. There are several reasons for this. First, human rights are, at best, part of the broader interpretive context. In the past, tribunals have not necessarily embraced, or even fully acknowledged, human rights arguments in their final awards.[177] In addition, even when human

171. VCLT, *supra* note 90, art. 31.

172. NAFTA, *supra* note 119, pmbl.

173. *Id.* art. 1114(2).

174. *Id.* (article is titled "Environmental Measures").

175. *Id.* art. 1105(1) ("Each party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment.").

176. *Id.*

177. *See, e.g.*, Biloune v. Ghana Invs. Ctr., 95 INT'L L. REP. 197, 203 (1989) (noting Tribunal "competence is limited to commercial disputes . . . other matters—however compelling the claim or wrongful the alleged act—are outside this Tribunal's jurisdiction."); Moshe Hirsch, *Investment Tribunals and Human Rights: Divergent Paths*, *in* HUMAN RIGHTS IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION 97, 99 (Pierre-Marie Dupuy et al. eds., 2009) (noting consistent trend of tribunals to decline to consider specific international human rights instruments, although for different reasons); Silvia Steininger, *What's Human Rights Got to Do With It? An Empirical Analysis of Human Rights References in Investment Arbitration*, 31 LEIDEN J. INT'L L. 33, 44 (2018). However, in a number of cases, the tribunal decision was consistent with the amicus position promoting human rights, which might suggest that it was influential, even if not cited. Sarah Schadendorf, *Human Rights Arguments in Amicus Curiae Submissions: Analysis of ICSID and NAFTA Investor-State Arbitrations*, 10 TRANSNAT'L DISP. MGMT. 1, 11, 23 (2013). Indeed, it has been suggested that too robust an embrace of human rights norms would actually be improper and grounds for annulment. *See* Knoll-Tudor, *supra* note 105, at 336.

rights are mentioned in awards, regional—rather than international—norms tend to be the focus.[178] Moreover, tribunals may cite rights under regional agreements, even if they are not directly binding on the parties.[179]

A tribunal could rely on human rights, including those from only regional agreements, in favor of investors and their rights. In particular, although there is not a right to property under the ICESCR, there is a right to property in the European Court of Human Rights, to which tribunals often refer even if not binding on disputes.[180] Notably, this court is the source of the most rulings of any international forum except for the European Court of Justice.[181] In fact, it has been suggested that arbitrators sensitive to criticism cite to European human rights law as a way to respond to criticism about lack of legitimacy or incursion of domestic sovereignty, even if such law is cited in a way that may still tend to promote investor rights.[182] In addition, other sources suggest a right to property for corporations that could reinforce existing investment claims. For example, the UDHR supports a right to property and also supports the idea that entities, in addition to individuals, have such a right.[183] In addition, some scholars have argued that such a right exists.[184] Although this is controversial, it would be easy for a tribunal to rely on this, as well as the European Court of Human Rights jurisprudence, as interpretive context to reinforce investment claims.

Although NAFTA's preamble is not as limited as some agreements that focus solely on promoting investment, it is unclear how a tribunal would read the preamble.[185] After all, unlike a pure investment agreement, NAFTA addresses multiple topics beyond

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178. *See e.g.*, Steininger, *supra* note 177, at 35.

179. *See id.* at 49. A number of tribunals cite to the European Convention of Human Rights, including in cases that do not involve countries bound to this agreement, which could be a function of the well-developed case law of the European Court of Human Rights, especially regarding right to property. *Id.* at 40.

180. *Id.*; *see also* ICESCR, *supra* note 66.

181. José E. Alvarez, *The Use (and Misuse) of European Human Rights Law in Investor-State Dispute Settlement*, *in* THE IMPACT OF EU LAW ON INTERNATIONAL COMMERCIAL ARBITRATION (Franco Ferrari ed. 2017).

182. *Id.* at 55–56.

183. UDHR, *supra* note 73, art. 17.

184. *See, e.g.*, Sprankling, *supra* note 76, at 479. *But see* Yu, *Anatomy of Human Rights*, *supra* note 97, at 92–95 (questioning a human right to property).

185. *See, e.g.*, ORG. FOR ECON. CO-OPERATION & DEV., INTERNATIONAL INVESTMENT LAW: UNDERSTANDING CONCEPTS AND TRACKING INNOVATIONS 135 (2008) (noting that survey of OECD-country IIAs found that many include a short preamble that does not focus on social issues, although that is changing in recent years); SUSTAINABLE DEVELOPMENT IN WORLD INVESTMENT LAW 126 (Marie-Claire Cordonier Segger et al. eds., 2010) (noting that most IIA preambles focus on investment conditions, and that tribunals rely on these to interpret investment claims).

investment.[186] Therefore, the non-investment language could be considered not to apply when interpreting investment claims. Alternatively, the language about safeguarding the "public welfare" is so broad that the outcome of relying on this is unclear.[187] In particular, a tribunal could consider that the public welfare is safeguarded by protecting investor rights, rather than narrowly interpreting investor rights in favor of promoting more domestic discretion. After all, some argue that protecting investor rights is better for the public at large, since foreign investment allegedly can improve the economic welfare of a nation.[188] It is difficult to determine in the abstract whether a tribunal would go so far, especially in a current climate where decisions are scrutinized. Nonetheless, it is worth considering that such broad language is capable of more than one interpretation.

IV. BACK TO THE FUTURE

Since a broader embrace of human rights presents challenges and perhaps even serious pitfalls, it is important to consider what steps should be taken in the future.[189] This Part offers two major suggestions. The first suggestion is to raise more awareness that investor-state disputes create a problem for IP norms, especially the existing sliver of domestic policy space under TRIPS. The second is to encourage tribunals to continue with principles that promote policy space short of a full embrace of all human rights norms, including mechanisms that promote more deference.

A. Raising Awareness of the Problem

An important initial step to fixing the problem is to raise awareness of the tension posed by investor-state disputes for domestic IP rights, including the need to preserve policy space under TRIPS. Without recognition of the problem, it is difficult to build necessary

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186. *See generally* NAFTA, *supra* note 119. For example, NAFTA covers trade in goods, trade in services, financial services, technical barriers to trade, government procurement, and intellectual property. *See* NAFTA, *supra* note 119, pt. two (trade in goods); *id.* pt. three (technical barriers to trade); *id*. pt. four (government procurement); *id.* pt. six (intellectual property).

187. *Id.* pmbl. (noting that governments have agreed to "preserve their flexibility to safeguard the public welfare").

188. *See, e.g.*, *Investment*, OFF. U.S. TRADE REPRESENTATIVE, https://ustr.gov/issue-areas/services-investment/investment [https://perma.cc/5BWE-MH74] (last visited Oct. 24, 2018) (noting the importance of investment and that IIAs promote investment).

189. This step can be taken along with raising human rights considerations in investment disputes. However, as just discussed, raising human rights issues does not guarantee desired results with respect to protecting TRIPS flexibilities, and in fact may reinforce investor rights. *See supra* Section III.D.2.

consensus to address it. As mentioned earlier, the initial disputes could portend an important and serious threat to TRIPS flexibilities.[190] In addition, the extent of the problem may be even worse than currently known since disputes under some arbitration rules permit parties to keep the existence of a dispute, including documents regarding the initiation of the dispute, completely confidential.[191] Although scholars are increasingly focusing on how investment disputes challenge TRIPS flexibilities, the issue remains inadequately understood.[192] This is well illustrated by the fact that the highly publicized 2016 UN High Level Panel Report as a way to reconcile IP, health, and trade interests recommends TRIPS flexibilities without acknowledging that they may not be realistic if states fear investor-state disputes.[193] This is especially true for developing countries that are encouraged to adopt these flexibilities, but would lack financial resources to defend an investment dispute. After all, even developed countries have either abandoned sound domestic policy regulations or deferred implementation to avoid investor-state disputes.[194]

Of course, how to raise awareness can be more challenging, but can be done, nonetheless. Only in recent years has consensus developed concerning a need to seriously evaluate and potentially reform the ISDS system.[195] Although tribunalists and some states may be opposed to any suggestion that would change the status quo, there is widespread discussion of the need for reform by both developed and developing countries.[196] One such actor is the European Union; while it once robustly supported ISDS, it now advocates serious reform of the system

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190. *See supra* Section II.B.

191. *See* Ho, *Collision Course*, *supra* note 15, at 406–07.

192. *See, e.g.*, *id.* at 435. Of course, Vanderbilt's symposium is a refreshing change. In addition, along similar lines, scholars from around the world devoted two days to discussing the intersection of IP and investment disputes. *See Enforcing IP in Trade and Investment: What Safeguards for Its Social Function?*, CTR. FOR INT'L INTELLECTUAL PROP. STUD., http://www.ceipi.edu/en/library-and-publications/proceedings-of-conferences/enforcing-intellectual-property-in-trade-and-investment-agreements-what-safeguards-for-its-social-function/ [https://perma.cc/5L4D-RA75] (last visited Oct. 10, 2018) (providing videos of talks from two-day conference).

193. *See* U.N. HIGH-LEVEL PANEL REPORT, *supra* note 14, at 9. Moreover, only one of the six supplemental commentaries to the report mentioned ISDS as an issue. *Id.* at 54 (suggesting that FTAs should be revised to exclude TRIPS-plus measures and ISDS).

194. *See, e.g.*, Gathii & Ho, *supra* note 11, at 451–52 (explaining that Canada ceased efforts to enact plain packaging after a threat of an investment dispute). Similarly, New Zealand took a "wait and see" attitude after Australia was challenged with an investment dispute. *See* Eric Crosbie & Forge Thomson, *Why Did It Take 53 Months for NZ to Introduce Plain Cigarette Packs?*, NOTED (June 14, 2018), https://www.noted.co.nz/health/health/plain-cigarette-packs-introduction-delayed-in-nz/ [https://perma.cc/27YR-QJPS].

195. *See* Roberts & Bouraoui, *supra* note 32.

196. *See id.*

that would include a multilateral investment court.[197] Notably, the Eurpoean Union's change in approach occurred largely due to concerns raised by member states, as well as the broader public.[198]

Accordingly, awareness of investor-state disputes is quite important. Broader discussion of this problem by all those concerned about TRIPS flexibilities—including the UN, WHO, WTO/TRIPS Council, as well as NGOs and relevant policymakers—would be valuable. Broader discussion of the tension between TRIPS and human rights was previously helpful in shining a spotlight on the tension that led to the human-rights-informed 2001 Doha Public Health Declaration, as well as subsequent efforts to promote use of TRIPS flexibilities.[199]

B. Near-Term Stopgap Measures

The promotion of domestic policy space regarding IP rights without a full embrace of human rights norms presents a tricky issue. This is especially difficult under the existing structure of investment disputes that are decided by a small group of arbitrators under a financial structure that incentivizes them to rule in favor of investors, or at least craft opinions that leave the door open for future claims. Increasing arbitrator independence via reform of the qualifications to be an arbitrator would be desirable but challenging to implement,

197. *Compare* European Comm'n, *Incorrect Claims About Investor-State Dispute Settlement*, at 1–4 (2013), http://trade.ec.europa.eu/doclib/docs/2013/october/tradoc_151790.pdf [https://perma.cc/PQ26-QQ7V] (defending investor-state disputes), *with* European Comm'n, *Investment in TTIP and Beyond—the Path for Reform: Enhancing the Right to Regulate and Moving from Current Ad Hoc Arbitrations Towards an Investment Court*, at 1 (2015), http://trade.ec.europa.eu/doclib/docs/2015/may/tradoc_153408.PDF [https://perma.cc/2EPZ-MWRF] (outlining new suggestions for ISDS reform).

198. *See* Cécile Barbière, *France and Germany United Front Against ISDS*, EURACTIV (Jan. 15, 2015, 1:04 AM), https://www.euractiv.com/section/trade-society/news/france-and-germany-to-form-united-front-against-isds/ [https://perma.cc/3GBA-YTRA]; Andrew Grice, *TTIP: Activists Triumph As Contentious US Free Trade Deal Clause Suspended*, INDEPENDENT (Jan. 13, 2015, 7:02 PM), https://www.independent.co.uk/news/uk/politics/ttip-activists-triumph-as-contentious-us-free-trade-deal-clause-suspended-9976090.html [https://perma.cc/548F-K6RF].

199. *See, e.g.*, Human Rights Council Res. 2001/21, U.N. Doc. E/CN.4/SUB.2/RES/2001/21, at 2 (Aug. 16, 2001) (noting "actual or potential conflicts" between human rights obligations and TRIPS); Comm. on Econ., Soc. & Cultural Rights (CESCR), Statement on the Work of Its Twenty-Seventh Session: *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, ¶ 4, U.N. Doc. E/C12/2001/15 (Dec 14, 2001) (noting that IP rights "must be balanced with the right . . . to enjoy the benefits of scientific rights"); U.N. Econ. & Soc. Council [ECOSOC], Sub-Comm. on the Promotion and Protection of Human Rights, Globalization and Its Impact on the Full Enjoyment of Human Rights, Progress Rep. on Its Fifty-Third Session, ¶¶ 20–24, U.N. Doc. E/CN.4/Sub.2/2001/10 (Aug. 2, 2001) (submitted by J. Oloka-Onyango & Deepika Udagama) (noting that IP undermines human rights objectives); Rep. of High Comm'r of Hum. Rts., *TRIPS Impact, supra* note 98, ¶ 28.

unless proposals for a multilateral investment court come to fruition.[200] However, setting arbitrator independence aside, increased public awareness and criticism of ISDS generally may itself be helpful in producing desirable results. In particular, tribunalists may be more likely to adopt procedures to address criticisms of a lack of democratic accountability. Similarly, perhaps tribunalists conscious of public criticism may even embrace doctrines that provide more domestic flexibility.

The initial ISDS cases involving IP suggest that tribunalists are aware of criticism of ISDS generally, and perhaps take such criticism into account with respect to procedural issues.[201] For example, in *Philip Morris Asia Ltd. v. Australia*, the tribunal properly dismissed the dispute after Philip Morris attempted to reincorporate to become a "foreign" company under the Australia-Hong Kong Bilateral Investment Agreement.[202] Although that may seem clearly inappropriate, other tribunals have previously blessed such action.[203] However, this maneuver attracted a great deal of attention that contributed to discussions of how then-pending agreements would bar such action.[204] Accordingly, the tribunal may have been sensitive to

200. If a multilateral investment court is a viable option, this could result in an overhaul of rules concerning arbitrators in all disputes. Otherwise, it would be difficult to change the current rules since existing arbitrators would likely strongly lobby against changing the status quo.

201. *See, e.g.*, Philip Morris Asia Ltd. v. Austl., PCA Case No. 2012-12, Award on Jurisdiction and Admissibility, ¶¶ 587–88 (Dec. 17, 2015) [hereinafter *Philip Morris Asia Ltd.*, Award on Jurisdiction and Admissibility], https://www.italaw.com/sites/default/files/case-documents/italaw7303_0.pdf [https://perma.cc/9AQC-TFG2]. Accepting amicus briefs can be seen as part of a trend of tribunals reacting to criticism of lack of transparency or democratic accountability. *See* Sophie Lamb, *Recent Developments in the Law and Practice of Amicus Briefs in Investor-State Arbitration*, 5 INDIAN J. ARB. L. 72, 87 (2017).

202. *Philip Morris Asia Ltd.*, Award on Jurisdiction and Admissibility, *supra* note 201, ¶ 588.

203. *See* JANE KELSEY & LORI WALLACH, "INVESTOR STATE" DISPUTES IN TRADE PACT THREATEN FUNDAMENTAL PRINCIPLES OF NATIONAL JUDICIAL SYSTEMS 3 (2012); Rachel Thorn & Jennifer Doucleff, *Disregarding the Corporate Veil and Denial of Benefits Clauses: Testing Treaty Language and the Concept of "Investor," in* THE BACKLASH AGAINST INVESTMENT ARBITRATION 3, 5 (Michael Waibel et al. eds., 2010); Anne van Aaken, *Perils of Success? The Case of International Investment Protection,* 9 EUR. BUS. ORG. L. REV. 1, 20 (2008) (noting extreme case in *Tokios Tokeles v. Ukraine* in which Ukrainian investors incorporated in Lithuania and then used that to invest back in Ukraine).

204. *See, e.g.*, John Brinkley, *What Doesn't Kill Philip Morris Seems to Make It Stronger*, FORBES (July 17, 2017, 1:07 PM), https://www.forbes.com/sites/johnbrinkley/2017/07/17/what-doesnt-kill-philip-morris-seems-to-make-it-stronger/#107e25ddbd57 [https://perma.cc/V4R4-ZWPF]; Matthew Webb, *Treaty Shopping: How Philip Morris Cherry-Picked Worst Case BITs*, INFOJUSTICE.ORG (Dec. 2, 2012), http://infojustice.org/archives/28044 [https://perma.cc/XYC3-5VF9] (suggesting that countries amend treaties to bar actions such as PMI). However, the strong publicity associated with Philip Morris' bold move has led to new language in recent agreements that aim to limit such action. *See, e.g.*, CETA, *supra* note 52, art. 8.1; *see also* EUR. PARLIAMENT, DIRECTORATE-GENERAL FOR EXTERNAL POLICIES, THE INVESTMENT CHAPTERS OF THE EU'S

public sentiment. Also, the tribunals in *Philip Morris v. Uruguay* as well as in *Eli Lilly v. Canada* both accepted third-party amici even though there is no absolute right for parties to participate;[205] this is consistent with a recent trend of tribunals accepting more amicus briefs as one way to address criticism of lack of transparency and lack of democratic accountability.[206] Notably, there were a large number of amicus briefs filed in *Eli Lilly v. Canada*,[207] and the tribunal accepted all of them unless the briefs were barred by the narrow NAFTA guidelines limiting participation to only citizens of NAFTA.[208]

The *Philip Morris v. Uruguay* tribunal's analysis and rejection of an expropriation claim suggests that heightened public attention may result in a highly deferential approach to states. All of the tribunalists in *Philip Morris v. Uruguay* embraced a deferential approach to states in evaluating indirect expropriation; in particular, they excluded from the scope of indirect expropriation any state actions that were based on police power to protect public health so long as done in a nondiscriminatory manner.[209] The tribunalists included Gary Born, who was chosen by Philip Morris[210] and is a supporter of traditional ISDS, which tends to favor companies.[211] Based on a broad reading of the Vienna Convention rules concerning customary international law, all tribunalists concurred that bona fide exercise of police powers on issues such as public health precludes compensation

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INTERNATIONAL TRADE AND INVESTMENT AGREEMENTS IN A COMPARATIVE PERSPECTIVE 17 (2015), http://www.europarl.europa.eu/RegData/etudes/STUD/2015/534998/EXPO_STU(2015)534998_EN.pdf [https://perma.cc/K7HE-N3JA] (explaining how CETA and other agreements aim to limit forum shopping).

205. Eli Lilly & Co. v. Gov't of Canada, ICSID Case No. UNCT/14/2, Procedural Order No. 4, at 3–4 (Feb. 23, 2016) [hereinafter *Eli Lilly*, Procedural Order No. 4], https://www.italaw.com/sites/default/files/case-documents/italaw7145.pdf [https://perma.cc/9YNE-Z368]; Philip Morris Brand Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Procedural Order No. 3, ¶¶ 1–3 (Feb. 17, 2015) [hereinafter *Philip Morris*, Procedural Order], https://www.italaw.com/sites/default/files/case-documents/italaw4161.pdf [https://perma.cc/3SGK-F5QR].

206. *See* Lamb, *supra* note 201, at 87.

207. *See* LUKE ERIC PETERSON, AS UNPRECEDENTED NUMBER OF WOULD-BE AMICUS CURIAE INTERVENE IN ELI LILLY V. CANADA NAFTA CASE ARBITRATORS FACE SEVERAL DILEMMAS, INV. ARB. REPORTER (2016).

208. *See Eli Lilly*, Procedural Order No. 4, *supra* note 205, ¶¶ 2–4. The tribunal dismissed Canada's claim that some of the amicus briefs should be rejected because they were from organizations that Eli Lilly was a member of. *See id.* ¶¶ 2–3.

209. *See Philip Morris*, Award, *supra* note 5, ¶ 188.

210. *See id.* ¶ 18 (noting that Philip Morris chose Gary Born).

211. *See* CECILIA OLIVET ET AL., WINNING THE DEBATE AGAINST PRO-ISDS VOICES: AN ACTIVIST'S ARGUMENTATION GUIDE 7 (2017) (highlighting Born as a prominent defender of ISDS who has dismissed criticisms as "surprisingly ill-informed"); Simon Lester, *Gary Born Defending Investment Arbitration*, INT'L ECON. L. & POL'Y BLOG (Aug. 8, 2016, 6:29 AM), http://worldtradelaw.typepad.com/ielpblog/2016/08/gary-born-defending-isds.html [https://perma.cc/JT8J-JMKV].

even if it directly harms an investor, so long as it is nondiscriminatory and proportionate.[212] This is remarkable not only because there are earlier decisions that state otherwise, which this tribunal could have followed, but also because this tribunal provided a robust discussion for a broad police power.[213] In particular, the tribunal provided a thorough recitation of other investment disputes supporting an exception from expropriation when state actions were designed to promote human health, and even cited recent agreements with supportive language, even though such language is not binding nor part of current customary international law.[214] The tribunal nonetheless asserted that these agreements "reflect the position under general international law."[215]

Similarly, the tribunal's 2–1 rejection of Philip Morris's FET claim could have been strongly influenced by heightened public attention and scrutiny of this case.[216] Although such claims are often interpreted quite broadly,[217] the majority held that "[t]he responsibility for public health measures rests with the government and investment tribunals should pay great deference to governmental judgments of national needs in matters such as the protection of public health."[218]

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212. *Philip Morris*, Award, *supra* note 5, ¶¶ 287, 305.

213. *See id.* ¶¶ 305–07.

214. *See id.* ¶ 300 (citing 2004 and 2012 US Model BIT sections that contain exception clauses against expropriation except in "rare circumstances" for nondiscriminatory regulatory actions, as well as the 2004 and 2012 Canada Model BITs, and even the EU-Canada CETA agreement).

215. *Id.* ¶ 301 (noting that even though the provisions could have been introduced out of abundance of caution, they nonetheless "reflect the position under general international law").

216. *See id.* ¶ 391 (noting WHO and PAHO amicus briefs supporting Uruguay action); *Philip Morris vs. Uruguay: Intellectual Property Debate in International Investment Arbitration*, BERKELY TECH L.J. BLOG (Nov. 7, 2014), http://btlj.org/2014/11/philip-morris-vs-uruguay-intellectual-property-debate-in-international-investment-arbitration/ [https://perma.cc/XCQ9-GE68] (noting the case was closely watched by the international investment community, as well as by policymakers); *see also* Matthew C. Porterfield & Christopher R. Byrnes, *Philip Morris v. Uruguay: Will Investor-State Arbitration Send Restrictions on Tobacco Marketing Up in Smoke?*, INV. TREATY NEWS (July 12, 2011), http://www.iisd.org/itn/2011/07/12/philip-morris-v-uruguay-will-investor-state-arbitration-send-restrictions-on-tobacco-marketing-up-in-smoke/ [https://perma.cc/8ZQH-XKZ4].

217. Bryan Mercurio *Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements*, 15 J. INT'L ECON. L. 871, 894 (2012); *see also* LISE JOHNSON & LISA SACHS, COLUM. CTR. ON SUSTAINABLE INV., THE TPP'S INVESTMENT CHAPTER: ENTRENCHING, RATHER THAN REFORMING, A FLAWED SYSTEM 5 (2015), http://ccsi.columbia.edu/files/2015/11/TPP-entrenching-flaws-21-Nov-FINAL.pdf [https://perma.cc/GD5V-Y4FW]; Barnali Choudhury, *Evolution or Devolution? Defining Fair and Equitable Treatment in International Investment Law*, 6 J. WORLD INV. & TRADE 297, 298 (2005).

218. *Philip Morris*, Award, *supra* note 5, ¶ 399. Notably, the tribunal further held that:

> [T]he present case concerns a legislative policy decision taken against the background of a strong scientific consensus as to the lethal effects of tobacco. Substantial deference is due in that regard to national authorities' decisions as to the measures which should be taken to address an acknowledged and major public health problem. The fair and

The majority also embraced the "margin of appreciation," a concept from the European Convention on Human Rights that generally favors domestic actions, even though its original context is not pursuant to IIAs.[219] Although one tribunalist disagreed,[220] perhaps public attention at least helped garner a majority on this issue—even though the concept has not been consistently adopted by prior tribunals.[221]

The *Eli Lilly* award shows some acknowledgment of domestic discretion, but it is not necessarily protective of TRIPS flexibilities. Although some commentators have selectively focused on a few parts of the Award that contain some recognition that investor-state tribunals should not serve as an appellate tier, the opinion overall still clearly permits companies to challenge domestic decisions, including ones by domestic courts.[222] After all, in the same sentence in which the tribunal stated that it should not serve as an appellate tier, it also said that in exceptional circumstances, in which there is clear evidence of egregious and shocking conduct, a FET claim could exist.[223] This is actually consistent with recent investment chapter language that purportedly limits indirect expropriation claims that target domestic action taken

> equitable treatment standard is not a justiciable standard of good government, and the tribunal is not a court of appeal.

Id. ¶ 418.

219. *Id.* ¶ 398. Although Uruguay is not a party to this Convention, the tribunal nonetheless referred to it over the objection of Philip Morris, to support granting discretion to domestic regulatory agencies to address policy determinations, at least in the context of public health. *Id.* ¶¶ 398–99.

220. *See* Philip Morris Brands Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Concurrence and Dissent, ¶¶ 82–88 (July 8, 2016), https://www.italaw.com/sites/default/files/case-documents/italaw7428.pdf [https://perma.cc/9L9L-JUFC] [hereinafter *Philip Morris*, Concurrence and Dissent] (concurrence and dissent by Born, Arb.) (rejecting the relevance of margin of appreciation).

221. *See* Pezold v. Republic of Zimb., ICSID Case No. ARB/10/15, Award, July 28, 2015, ¶ 465, https://www.italaw.com/sites/default/files/case-documents/italaw7095_0.pdf [https://perma.cc/PQ9R-2Z49] (rejecting margin of appreciation); MOUYAL, supra note 65, at 153–54 (noting mixed reception to host claim reliance on the human rights concept of margin of appreciation). *See generally Philip Morris*, Award, *supra* note 5.

222. *See* Richard Gold, Opinion, *NAFTA Patent Ruling a Big Victory for Canadian Innovation*, GLOBE & MAIL (Apr. 6, 2017), https://www.theglobeandmail.com/report-on-business/rob-commentary/nafta-patent-ruling-a-big-victory-for-canadian-innovation/article34617647/ [https://perma.cc/8SF5-EB6P] (asserting that Canada's successful defense "is only the beginning" of an ability to shape its own innovation policy); Lipkus, *supra* note 3 (asserting that Canada "no longer need[s] to worry that trade tribunals will become supranational courts of appeal over domestic property law disputes").

223. *Eli Lilly*, Final Award, *supra* note 5, ¶ 224 ("[T]he Tribunal emphasizes that a NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of the national judiciary.").

on account of public health, yet leaves open the door to undefined "rare" situations when this could still be an expropriation.[224]

It is unclear why the *Eli Lilly* tribunal was less deferential than the tribunal that ruled in favor of Uruguay, but it could be that there was no state action clearly consistent with an international agreement promoting the right to health.[225] Another contributing factor could be that restrictive NAFTA rules on third-party amici barred any submissions from the WHO, which was permitted to submit an amicus in *Philip Morris v. Uruguay*.[226] However, there were amici who explicitly raised concerns about TRIPS flexibilities, which are nonetheless not at all mentioned in the award.[227] This is not entirely surprising, since TRIPS flexibilities do not provide a direct defense to any of the investment claims and Canada itself did not embrace discussion of TRIPS flexibilities in its defense.[228]

The *Eli Lilly* award may reflect some acknowledgement of the importance of the dispute to domestic policy space on patents, yet in a way that clearly permits future disputes. The tribunal could have entirely rejected the challenge as improper based on actions by the judiciary unless there was a denial of justice, as Canada argued, but it declined to do so.[229] However, it was also not the worst-case scenario for Canada. After all, the tribunal could have relied on some older decisions to find for Eli Lilly based on the fact that the value of the patents was now nullified.[230] Of course, if the tribunal relied on such older decisions it would have been contrary to recent decisions

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224. CPTPP, *supra* note 22, annex 9-B(3)(b); CETA, *supra* note 52, Annex 8-A(3); EUR. COMM'N, COMMISSION DRAFT OF TEXT TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP), annex I, ¶ 3 (2015), http://trade.ec.europa.eu/doclib/docs/2015/september/tradoc_153807.pdf [https://perma.cc/V52M-HSLY].

225. In contrast, Uruguay was trying to implement the UN Framework Convention on Tobacco Control, which is expressly intended to promote public health. *See Philip Morris*, Award, *supra* note 5, ¶¶ 79, 85, 95. Moreover, given the importance of such domestic laws to promote public health, the investment disputes challenging tobacco limitations garnered substantial publicity in comparison to Eli Lilly's dispute against Canada.

226. FREE TRADE COMM'N, STATEMENT OF THE FREE TRADE COMMISSION ON NON-DISPUTING PARTY PARTICIPATION § B(1) (Oct. 7, 2003), https://www.state.gov/documents/organization/38791.pdf [https://perma.cc/CFY2-ED4W] (limiting tribunal discretion to accept submissions from a "person of a Party"); *see also Eli Lilly*, Procedural Order No. 4, *supra* note 205, at 2 (interpreting this to exclude those who are not present in the United States, Mexico, or Canada).

227. *Eli Lilly*, Brief of Dr. Burcu Kilic et al., *supra* note 20, at 2–3.

228. *See generally Eli Lilly*, Government of Canada Statement of Defence, *supra* note 111 (providing no mention of TRIPS flexibilities).

229. *See Eli Lilly*, Final Award, *supra* note 5, ¶¶ 186–90 (stating Canada's assertion that there was no denial of justice due to Eli Lilly's admission, expropriation was impossible); *id.* ¶¶ 218–25 (tribunal stating that expropriation need not be limited to denial of justice, although suggesting that only exceptional circumstances would result in expropriation).

230. *See* Ho, *Sovereignty*, *supra* note 15, at 265–66 (discussing the "sole effect doctrine").

concerning expropriation that suggest the need to balance loss of investment value against state interests.[231] The tribunal did not embrace this approach, which could be viewed as finding no significant state interest in Canada's patent law. Rather, perhaps in an attempt to avoid addressing whether significant state interests existed in a case involving patents for drugs that were not essential, it framed the entire decision on an evidentiary failure by Eli Lilly to establish that there was a dramatic change in the law.[232]

There still remains a question of what to do in the near future for subsequent companies that bring investor-state disputes challenging IP norms. Advocates, including amici, can of course suggest that tribunals consider and utilize balancing principles such as proportionality, or even the margin of appreciation mentioned in *Philip Morris v. Uruguay*.[233] However, as the *Eli Lilly* award indicates, tribunals may not feel any need to follow existing doctrine. What both disputes show, nonetheless, is some sensitivity to public concern, without entirely foreclosing future options for claimants.[234] For example, even the majority's opinion in *Philip Morris v. Uruguay* couched the ruling on the FET claim in terms of Uruguay's limited financial abilities to do its own rigorous studies; this leaves open the

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231. *See* SEBASTIÁN LÓPEZ ESCARCENA, INDIRECT EXPROPRIATION IN INTERNATIONAL LAW 10 (2014); RUDOLF DOLZER & CHRISTOPH SCHREUER, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 148–49 (2d ed. 2012) (explaining that tribunals are also increasingly considering whether legitimate expectations as an additional factor in evaluating expropriation); Ursula investors have Kriebaum, *Expropriation*, *in* INTERNATIONAL INVESTMENT LAW: A HANDBOOK 38–41 (Marc Bungenberg et al. eds., 2015) (noting that since the early 2000s, tribunals have shifted away from the primary effect doctrine).

232. *See Eli Lilly*, Final Award, *supra* note 5, ¶ 307 (noting that a fundamental question is whether there was a dramatic change in Canada's utility requirement for Eli Lilly to prevail).

233. *See Philip Morris*, Award, *supra* note 5, ¶ 399. Proportionality analysis should ensure a more thoughtful balance of competing interests through its multiprong analysis of considering (a) whether the state action serves a legitimate government purpose and is generally suited to achieve this purpose (through some causal relationship); (b) whether the state action is "necessary" in that there is no less restrictive measure that is equally effective; and (c) a balance between the effects of the measure and the importance of the government purpose. *See* Benedict Kingsbury & Stephen Schill, *Public Law Concepts to Balance Investors' Rights with State Regulatory Actions in the Public Interest—The Concept of Proportionality*, *in* INTERNATIONAL INVESTMENT LAW & COMPARATIVE PUBLIC LAW 75, 86–87 (Stephan W. Schill ed., 2010). Some tribunals have previously applied such analysis, albeit not in disputes involving IP. *See, e.g.*, Eureko B.V. v. Republic of Pol., R.G. 2005/14005/A, Partial Award, ¶ 77, (Aug. 19, 2005) (reasonableness incorporated into fair and equitable treatment standard); Saluka Investments B.V. v. Czech Rep., UNCITRAL, Partial Award, ¶ 297 (Perm. Ct. Arb. 2006), https://www.italaw.com/sites/default/files/case-documents/ita0740.pdf [https://perma.cc/T8L6-HCU7]; MTD Equity Sdn. Bhd. v. Republic of Chile, ICSID Case No. ARB/01/7, Award, ¶113 (May 25, 2004); Pope v. Gov't of Canada, Interim Award, ¶ 99 (June 26, 2000), https://www.italaw.com/sites/default/files/case-documents/ita0674.pdf [https://perma.cc/ZFH6-9L9C] (reasonableness of administrative agency considered for FET claim).

234. *See supra* notes 204–11 and accompanying text (noting that public concern may have influenced Uruguay award).

possibility that tobacco companies could be successful in a challenge against a developed country.[235] In addition, although Canada successfully defended against Eli Lilly's investment claims, the tribunal's evidentiary framework did not provide any template for other countries to easily defend against future investment claims.[236] To the contrary, it may simply signal to companies the type of proof necessary to win.

V. CONCLUSION

Although embracing human rights is not a complete panacea to protecting domestic sovereignty—and especially limits on IP—from investor-state disputes, it still reveals some useful insight at an important time when such disputes are being revisited. In particular, it helps reinforce the need to protect domestic discretion to limit IP at a time when expansive IP rights—especially in the context of patents—pose major budgetary problems for even developed countries.[237] In addition, although the initial investor-state disputes challenging IP are concerning, this Article hopefully helps shed further light on the problem as an important step towards better balancing investor rights against domestic sovereignty and the general public, including protecting their human rights.

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235. *Philip Morris*, Award, *supra* note 5, ¶¶ 393–96 (noting Uruguay's "limited technical and economic resources" as pertinent to finding Uruguay need not conduct additional studies).

236. That award notably did not actually analyze the individual investment claims and instead focused on whether Eli Lilly had presented adequate evidence to prove its factual assertion of a dramatic change in Canadian patent law, which was essential to prevailing on the investment claims. *See Eli Lilly*, Final Award, supra note 5, ¶¶ 307–08. Accordingly, unless the identical arises in other disputes, the tribunal decision provides no guidance. For a pro-state interpretation to investment claims, see Ho, *Sovereignty*, *supra* note 16, at 283.

237. *See, e.g.*, OXFAM, HIGH PRICED MEDICINES AND LACK OF NEEDS-DRIVEN INNOVATION: A GLOBAL CRISIS THAT FUELS INEQUALITY 4 (2017), https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/ib-high-priced-medicines-innovation-220917-en.pdf [https://perma.cc/6ZZG-X6EA].