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INTELLECTUAL PROPERTY: A BEACON FOR REFORM OF INVESTOR- STATE DISPUTE SETTLEMENT

*Daniel Gervais**

I. INTRODUCTION

This Article attempts to resolve clashes between intellectual property and investor-state dispute settlement (“ISDS”). ISDS clauses contained in bilateral, plurilateral, or multilateral trade and investment agreements give multinational investors (corporations) a right to sue a state in a binding proceeding before an independent arbitral tribunal.¹ This jurisgenerative right to file a claim against a state in an international tribunal with mandatory jurisdiction is exceptional; it is generally reserved to other states.² Only multinational corporations can use ISDS to file claims against states in which they invest, provided the state is party to a bilateral investment treaty (“BIT”) or a trade agreement containing an investment chapter (“International Investment Agreement” or “IIA”).³ The ISDS case filed by the global pharmaceutical company Eli Lilly against Canada based

* Milton R. Underwood Chair in Law, Vanderbilt University Law School and Director of the Vanderbilt Intellectual Property Program. President, International Association for the Advancement of Teaching and Research in Intellectual Property (“ATRIP”). The Author thanks Dan Burk, Susy Frankel, Christophe Geiger, Molly Land, Tim Meyer, Svetlana Yakovleva and Peter Yu, for their useful comments on the initial draft or for agreeing to discuss the ideas developed in this Article. The Author also wishes to thank the editorial team at the Journal for their excellent work on the manuscript. All errors and opinions expressed should be attributed to the Author and not to any other person or organization.

1. See *Fact Sheet: Investor State Dispute Settlement (ISDS)*, OFFICE U.S. TRADE REP., <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2015/march/investor-state-dispute-settlement-isds> (last visited Jul. 25, 2018) [hereinafter *USTR Fact Sheet*]. The main remedy available to investors is the payment of compensation, as investor-state dispute settlement (“ISDS”) tribunals cannot order a government to change a measure even if it found to have affected the rights of an investor. See *id.* The possibility of paying additional compensation in the future to the complainant (assuming the impact on the investment continues) or to other investors similarly affected, however, may lead a country to change the impugned measure. See Adam H. Bradlow, *Human Rights Impact Litigation in ISDS: A Proposal for Enabling Private Parties to Bring Human Rights Claims Through Investor-State Dispute Settlement Mechanisms*, 43 YALE J. INTL. L. 355, 388 (2018) (explaining how the threat of ISDS can be sued to change human rights norms).

2. See José E. Alvarez, *Are Corporations “Subjects” of International Law?*, 9 SANTA CLARA J. INT’L L. 1, 11–12 (2011).

3. See *id.* at 31; see also Glen Kelley, *Multilateral Investment Treaties: A Balanced Approach to Multinational Corporations*, 39 COLUM. J. TRANSNAT’L L. 483, 489–90 (2001); David R. Sedlak, *ICSID’s Resurgence in International Investment Arbitration: Can the Momentum Hold?*, 23 PENN ST. INT’L L. REV. 147, 147–49 (2004).

on the invalidation by a Canadian court of two patents was the first direct major clash between IP and ISDS.⁴

The case added a layer to the already highly controversial nature of ISDS. Joseph Stiglitz, Nobel Prize-winning economist and major critic of ISDS, noted in a letter to Congress that ISDS protected foreign property more than domestic property and that prior experience with ISDS suggested that ISDS locked in “regulatory boundaries, by subjecting any changes to laws or rules by Federal, state or local government to challenge by foreign investors.”⁵ Moreover, ISDS proceedings cost millions of dollars. In the *Philip Morris* case (discussed later), Uruguay might have had to settle had it not been for the reported financial support it received from Michael Bloomberg.⁶ Along similar lines, a group of more than 200 law professors asked that no trade deal containing ISDS provisions be signed by the United States, noting that ISDS gives foreign corporations the ability to bypass the “robust, nuanced, and democratically responsive” U.S. legal framework; circumvent local, state, or federal domestic administrative bodies and courts; and “re-litigate cases they have already lost in domestic courts.”⁷ This is no small issue: according to the United Nations, as of 2016, there are 3,304 IIAs in existence around the world (2,946 BITs and 358 other treaties with investment provisions), and they cover almost all countries.⁸

The traditional justification for ISDS is that it provides a remedy for uncompensated or improperly compensated expropriations of private assets owned by, or for the unfair or inequitable treatment of, foreign investors.⁹ In recent years, however, ISDS has moved well past traditional, or direct, expropriation—that is, transfer of property rights to the state. Two core

4. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Final Award, (March 16, 2017), <https://icsid.worldbank.org/en/Pages/cases/casedetail.aspx?CaseNo=UNCT/14/2> [hereinafter *The Canada Award*].

5. Letter from Joseph E. Stiglitz to U.S. Cong. (May 18, 2015), <http://www.scribd.com/doc/265770405/Letter-to-Congress-Stiglitz-on-Trade-Deal>.

6. See James Gathii & Cynthia Ho, *Regime Shifting of IP Lawmaking and Enforcement from the WTO to the International Investment Regime*, 18 MINN. J.L. SCI. & TECH. 427, 436 (2017) (noting “Uruguay would have had to settle the case with Philip Morris had billionaire philanthropist Michael Bloomberg not volunteered to fund the costs of ICSID litigation.”). The average cost, according to the Organization for Economic Co-operation and Development (OECD), is \$8 million but can reach \$30 million. David Gaukrodger & Kathryn Gordon, *Investor-State Dispute Settlement: A Scoping Paper for the Investment Policy Community*, 19 (OECD, Working Papers on Int’l Inv. No. 2012/03), <http://dx.doi.org/10.1787/5k46b1r85j6f-en>.

7. Laurence H. Tribe et al., 220+ Law and Economics Professors Urge Congress to Reject the TPP and Other Prospective Deals that Include Investor-State Dispute Settlement (ISDS), PUB. CITIZEN (Sept. 7, 2016), www.citizen.org/documents/isds-law-economics-professors-letter-Sept-2016.pdf.

8. U.N. Conference on Trade and Development, *World Investment Report 2016: Investor Nationality: Policy Challenges*, U.N. Doc. UNCTAD/WIR/2016, at 101 (June 22, 2016) [hereinafter *UNCTAD Report*].

9. See *USTR Fact Sheet*, *supra* note 1.

norms of ISDS—*indirect* expropriation and fair and equitable treatment (“FET”)—have been pushed by investors in ISDS proceedings in new areas of law and policy. Investors routinely use claims of indirect expropriation to challenge regulatory measures that do not effectuate a direct expropriation but rather “effectively neutralize” the enjoyment of the property.¹⁰ Investors have also made abundant use of the FET standard, a most controversial issue in ISDS scholarship.¹¹ In the context of the North American Free Trade Agreement (the “NAFTA”), an interpretive note issued by the NAFTA Free Trade Commission tried to stem this tide by stating that the FET standard does not require “treatment in addition to or beyond that which is required by the customary international law minimum standard treatment of aliens.”¹²

Eli Lilly v. Canada is a case about two pharmaceutical patents that were invalidated by Canadian courts for lack of utility. The tribunal in this case used both indirect expropriation and the FET standard.¹³ The case is a prime example of ISDS’s notable recent incursion in the field of intellectual property (“IP”), an incursion that is said to have caused a “regulatory chill”—namely, the risk that a regulatory change might trigger liability if it increases the costs or decreases the profits of a foreign investor, as the invalidation of a patent might by preventing capture of the patent rent.¹⁴ No

10. *Lauder v. Czech Republic*, Final Award, ¶ 200 (Sept. 3, 2001), 9 ICSID Rep. 66 (2006).

11. *See* GEBHARD BÜCHELER, PROPORTIONALITY IN INVESTOR-STATE ARBITRATION 182–83 (2015).

12. NAFTA Free Trade Commission, *Note of Interpretation of Certain Chapter 11 Provisions* (July 31, 2001), http://www.sice.oas.org/tpd/nafta/commission/ch11understanding_e.asp; *see also* North American Free Trade Agreement art. 1105, Can.-Mex.-U.S., Dec. 17, 1992, 32 ILM 289 (1993). On the FTC, *see* Gabrielle Kaufmann-Kohler, *Interpretive Powers of the Free Trade Commission and the Rule of Law*, in FIFTEEN YEARS OF NAFTA CHAPTER 11 ARBITRATION 175 (Frédéric Bachand & Emmanuel Gaillard eds., 2011).

13. *The Canada Award*, *supra* note 4, ¶ 181; *see also* Kaufmann-Kohler, *supra* note 12, at 181.

14. *See* Brook K. Baker & Katrina Geddes, *The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS*, 49 LOY. U. CHI. L.J. 479, 505 (2017) (“The risks of regulatory chill are of course exacerbated by general IP-maximalist pressures from the United States, the European Union, Japan, Switzerland, and other pro-pharma countries, and by extra-arbitral pressures relating to specific ISDS claims, such as those described previously concerning the *Eli Lilly v. Canada* arbitration.”); Plamen Dinev, *Regulatory Chill and the TTIP: An Intellectual Property Perspective*, 39 EUR. INT. PROP. REV. 344, 345 (2017) (noting that “[p]erhaps the most fiercely criticised aspect of the inclusion of ISDS in the TTIP is the possibility of regulatory chill.”); Peter K. Yu, *The Investment-Related Aspects of Intellectual Property Rights*, 66 AM. U. L. REV. 829, 859 (2017) (“Regulatory chill, while difficult to prove, is particularly problematic in the intellectual property field . . .”). Patent rents are the difference between marginal costs and the sales price made possible by the patent right. Patent rents are typically used to cover new research and development, but in the case of pharmaceutical companies go mostly toward profits and advertising. Frederick M. Abbott, *The WTO Medicines Decision*:

industry is more dependent on patent protection than pharmaceuticals: products are enormously costly to develop and test, but once a new drug is on the market, it can be copied at a very low cost, meaning that the (usually only) way to recoup investments and turn a profit is the market exclusivity provided by a patent.¹⁵ Yet pharmaceuticals differ from other consumer-oriented goods, in part because consumers often rely on doctors—who may be influenced by pharmaceutical marketing—and in part because the product is often paid for by public authorities. This causes a tension between a policy of fostering pharmaceutical innovation, on the one hand, and using the public purse responsibly, on the other.¹⁶ Baker and Geddes argue that, in this context, the enormous profits that patents can help generate “give perverse incentives to right-holders to advance spurious and marginal claims . . . The growing number of ISDS cases based on IP claims is troubling indeed, as is their *in terrorem* effect.”¹⁷

A second ISDS complaint, filed by Philip Morris against Uruguay under the Swiss-Uruguay Bilateral Investment Treaty (“BIT”), directly challenged IP (trademark) measures taken by Uruguay. The complainant described these measures as indirect expropriation and a FET violation.¹⁸ Because tobacco control is seen by many as a crucial public health measure, the case was seen as a frontal challenge to Uruguay’s regulatory sovereignty.¹⁹

IP is a particularly interesting field of study in the ISDS context for at least three reasons. First, IP sits at the intersection of private property rights and public policy objectives of innovation and economic and human

World Pharmaceutical Trade and the Protection of Public Health, 99 AM. J. INT’L L. 317, 325 (2005).

15. See JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 88–89 (2008).

16. See Michelle C. Perez, *Trading Goods for Bad: Is Public Policy Undermined by Investor State Dispute Mechanisms?*, 49 U. MIAMI INTER-AM. L. REV. 132, 166 (2018) (“The general consensus was that not only was this a great victory for Uruguay and the concept of national sovereignty”); Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH. L.J. 213, 218–19 (2015). Canada has a publicly-funded healthcare system that covers most of the cost of many pharmaceutical products. See, e.g., *Ontario Public Drug Program –Public Information*, ONT. MINISTRY HEALTH AND LONG-TERM CARE, <http://www.health.gov.on.ca/en/public/programs/drugs/> (“[I]f you qualify, Ontario’s drug programs will pay most of the cost of some of your prescription drugs.”).

17. Baker & Geddes, *supra* note 14, at 513.

18. Philip Morris Brands Sàrl v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Award, ¶¶ 193, 313 (July 8, 2016), <https://icsid.worldbank.org/en/Pages/cases/casedetail.aspx?CaseNo=ARB/10/7> [hereinafter *The Uruguay Award*].

19. See Julian Arato, *The Private Law Critique of International Investment Law*, 113 AM. J. INTL. L. 1, 15 (2019) (“The objection is that ISDS has tended to strike a balance weighted too heavily in favor of investor property, at the expense of host state regulatory autonomy. . .”).

development.²⁰ This Article examines whether and how ISDS tribunals adjudicating claims by investors that their (private) IP rights were unduly affected by state action can and should reach beyond the text of the applicable IIA and into the public policy realm. Putting the spotlight on the ISDS/IP interface illuminates similar impacts of ISDS on the state's ability to intervene in key policy areas.

Second, IP law by nature crosses lines that separate legal disciplines. In the field of ISDS, in which investors are pushing for protection of private rights, IP also reflects public policy choices, on the one hand, and now also human rights.²¹ In the context of both *Eli Lilly v. Canada* (concerning pharmaceutical patents) and *Philip Morris v. Uruguay* (concerning tobacco control), the right to health in particular comes to mind.²² The following Venn diagram shows that there will be cases in which all three domains (IP, human rights, and investor protection) intersect. The award in the Uruguay case discussed below provides a good example of a triple intersection.

20. See *id.* at 3. Domestically, public law is the law of relations between the state and the citizen, which IP does to a point (as with applications to register rights or criminal enforcement of IP rights), and private law is the law of relations between citizens (such as property—of which IP has at least some of the contours—torts and contracts). See Hanoch Dagan & Avihay Dorfman, *Just Relationships*, 116 COLUM. L. REV. 1395, 1401–06 (2016) (discussing Nozick's, Rawls', Dworkin's and Kant's views on the public law/private law distinction). Public law reflects public policy choices, such as for the provision of public health services. The distinction is useful though it may not always be clear and coherent. See *id.* at 1406–09.

21. Laurence R. Helfer, *The New Innovation Frontier? Intellectual Property and the European Court of Human Rights*, 49 HARV. J. INT'L L.J. 1, 1 (2008) (“[H]uman rights law is intellectual property's new frontier.”).

22. This article uses the term “human rights,” but the same reasoning could apply to internationally-recognized social rights. For a discussion of the overlaps and distinctions between the two notions, see Robert Wai, *Countering, Branding, Dealing: Using Economic and Social Rights In and Around the International Trade Regime*, 14 EUR. J. INT'L L. 35, 70–71 (2003).

Third, and finally, newer IIAs provide sector-specific public interest carve-outs that aim to put certain regulatory matters beyond the reach of ISDS tribunals. For example, recent IIAs signed by the European Union (the “EU”) exclude environmental protection measures from ISDS review.²³ Then, as the *Eli Lilly v. Canada* case was proceeding, Canadian and EU negotiators made a last minute change to the text of the Comprehensive Economic and Trade Agreement (the “CETA”) by adding a declaration that effectively excludes most IP measures from the jurisdiction of ISDS tribunals.²⁴ Such exclusions pose an interpretative challenge: should policy areas not so named *a contrario* remain subject to closer scrutiny (for

23. See Comprehensive Economic and Trade Agreement, Can.-E.U., arts. 22.1, 23.2, 24.3, Oct. 30, 2016, 2017 O.J. (L 11) 23 [hereinafter CETA]; Free Trade Agreement Between the European Union and the Republic of Singapore, E.U.-Sing., art. 13.1(a), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=961/> (not yet signed) (last updated Apr. 18, 2018); Agreement Establishing an Association Between the European Union and Its Member States, on the One Hand, and Central America on the Other arts. 286, ¶¶ 1–2, 287, June 29, 2012, 2012 O.J. (L 346) 1; Trade Agreement Between the European Union and Its Member States, of the One Part, and Colombia and Peru, of the Other Part, Colom.-E.U.-Peru, arts. 269, ¶ 3, 270, ¶ 2, June 26, 2012, 2012 O.J. (L 354) 1; Free Trade Agreement Between the European Union and Its Member States, of the One Part, and the Republic of Korea, of the Other Part, E.U.-S. Kor., arts. 13.4, 13.5, Oct. 6, 2010, 2011 O.J. (L 127) 1.

24. The tribunal in *Eli Lilly and Company v. Canada* (ICSID Case No. UNCT/14/2) was constituted in April 2014. *Case Details: Eli Lilly and Company v. Canada* (ICSID Case No. UNCT/14/2), INT’L CTR. FOR INV’R-STATE DISPUTES, WORLD BANK GRP., <https://icsid.worldbank.org/en/Pages/cases/casedetail.aspx?CaseNo=UNCT/14/2> (last visited Jan. 7, 2019). The CETA declaration was agreed upon in August 2014. See Michael Geist, *Did Canada Cave on the Pharmaceutical Patent ISDS Issue in CETA?: Still No Text, But Official Comments Suggests It Did*, MICHAEL GEIST (Aug. 6, 2014), <http://www.michaelgeist.ca/2014/08/canada-cave-pharmaceutical-patent-isds-issue-ceta-still-text-report-suggests/>; Gus Van Harten, *A Report On The Flawed Proposals For Investor-State Dispute Settlement (ISDS) In TTIP And CETA* 7 (Osgoode Hall Law Sch. Legal Studies Research Paper Series, Research Paper No. 16, 2015).

example, the vast majority of IIAs that, unlike CETA, do not carve out IP) and, if so, according to which test or standard?²⁵

The topic is also timely. ISDS, which emerged in earnest in 1993 in the NAFTA, is also contained in the more recent Dominican Republic-Central America FTA (the “CAFTA-DR”).²⁶ In fact, ISDS clauses now apply to almost all bilateral trade relations, though they are being negotiated as part of major trade deals where they may undergo significant changes.²⁷ ISDS will likely form part of the possible new trade deal between the world’s two largest trading partners (the European Union and the United States), known as the Transatlantic Trade and Investment Partnership (the “TTIP”)—should it come into being—as the United States insists on having the clause, and the EU’s current position in international trade talks is to reform, not exclude, ISDS.²⁸ The EU has proposed creating a permanent ISDS court “in order to develop a coherent, unified and effective policy on investment dispute resolution.”²⁹ The Transpacific Partnership (the “TPP”) Agreement also contains ISDS provisions, and such provisions are likely to be included

25. See *infra* notes 144 and 183 and accompanying text.

26. Dominican Republic-Central America-United States Free Trade Agreement, Aug. 5, 2004, 119 Stat. 462, 43 I.L.M. 514 [hereinafter CAFTA-DR]. The ISDS provisions are in Chapter 10. See Vivian H.W. Wang, *Investor Protection or Environmental Protection? “Green” Development Under CAFTA*, 32 COLUM. J. ENVTL. L. 251, 260–61 (2007).

27. Under the “new NAFTA,” the U.S.-Mexico-Canada Agreement (USMCA), ISDS provisions were removed between Canada and the United States, though U.S. investors still have three years to use NAFTA’s ISDS system. See Jack Caporal & William Alan Reinsch, *From NAFTA to USMCA: What’s New and What’s Next?*, CTR. FOR STRATEGIC INT’L STUD. (Oct. 3, 2018), <https://www.csis.org/analysis/nafta-usmca-whats-new-and-whats-next>.

28. ISDS has been one of the stumbling blocks in the more recent TTIP negotiations due to EU demands to improve the mechanism by creating a permanent investment court, an option discussed further in Part V, *infra*. See Luis Miguel Velarde Saffer & Amir Ardelan Farhadi, *Lessons from the Deathbed of the Trans-Pacific Partnership (TPP): Are Recent Critiques of the Investor-State Dispute Settlement (ISDS) System Warranted?*, 11 DISP. RESOL. INT’L 3, 5 (2017) (“Criticisms of the [ISDS] system are not new, and have been stumbling blocks in the negotiation of other investment treaties, such as the Transatlantic Trade and Investment Partnership (TTIP). Nevertheless, the solution should not be to abandon the system, but rather to improve it. This has been the case in the context of the TTIP negotiations, where the European Commission proposed the creation of the so-called investment court to address, among others, concerns regarding arbitrators’ impartiality and the system’s transparency.”). Saffer and Farhadi discussion emphasizes the contrast between private rights in goods the use of which in almost all cases is decided by private actors, and goods in which public policy choices are embedded (often but not necessarily a public good). A number of IP rights have both aspects. The owner of a patent can decide how to exploit (or not) that patent. But the usage of patents related to materials significantly affected by public policy (pharmaceuticals, certain classes of weapons etc.) will be directly regulated or, as is the case with the patents and trademarks at play in the two cases discussed in the Article, will at least intersect with public policy concerns. See generally *id*.

29. *Questionnaire on Options for a Multilateral Reform of Investment Dispute Resolution*, EUROPEAN COMMISSION, http://trade.ec.europa.eu/consultations/index.cfm?consul_id=233 (last updated Jan. 7, 2018).

in most future BITs.³⁰ This Article suggests ways in which both future trade agreements and any permanent forum established to hear ISDS cases can better integrate vital public policy concerns by using intellectual property as a beacon for reform.

Against this backdrop of expansion and critiques of overreach, many countries are sticking with ISDS but simultaneously trying to reform it to limit its reach in policy areas where they wish to preserve regulatory autonomy.³¹ For example, India carved out an exception for intellectual property compulsory licensing in its most recent model BIT, precluding such disputes from ISDS.³² Stated differently, with over 3,000 IIAs in existence and more to follow, ISDS is here to stay, but a reform of its scope and mode of application is afoot.³³

As more and more carve-out clauses emerge, what is the situation for IIAs that contain *no* such carve-outs? Can states avoid paying compensation ordered by an ISDS tribunal for public policy measures that affect private IP rights without such exclusions? As will be apparent from the Article's accounts of two major recent ISDS cases, the respondent states justified in different ways the compatibility of the IIAs containing the applicable ISDS clauses (NAFTA and the Swiss-Uruguay BIT) with the IP measures

30. For information on the TPP, see *Summary of the Trans-Pacific Partnership Agreement*, OFFICE U.S. TRADE REP. (Oct. 4, 2015), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/summary-trans-pacific-partnership>; *Trans Pacific Partnership Agreement (TPP): Comprehensive and Progressive Agreement for Trans Pacific Partnership Agreement (CPTPP) - Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam: Background and Negotiations*, ORG. AM. STATES FOREIGN TRADE INFO. SYS., http://www.sice.oas.org/TPD/TPP/TPP_e.ASP (last visited Jan. 7, 2018). For a discussion about the inclusion of ISDS provisions in BITs, see Nikesh Patel, Note, *An Emerging Trend in International Trade: A Shift to Safeguard Against ISDS Abuses and Protect Host-State Sovereignty*, 26 MINN. J. INT'L L. 273 (2017) (reviewing bilateral and plurilateral agreements and model BITs containing ISDS provisions in several parts of the world, in both developing and merging economies).

31. See Patel, *supra* note 30, at 302 ("As recent global trade policies and agreements suggest, changes to ISDS signal an emerging shift towards further safeguards against ISDS abuses and greater protections for host state sovereignty."); Sergio Puig & Gregory Shaffer, *Imperfect Alternatives: Institutional Choice and the Reform of Investment Law*, 112 AM. J. INT'L L. 361, 408 (2018) (arguing that States need flexibility in their approach to ISDS and noting that "[c]ontexts differ across states, and choices should depend on those contexts.").

32. See Sonia E. Rolland & David M. Trubek, *Legal Innovation in Investment Law: Rhetoric and Practice in Emerging Countries*, 39 U. PA. J. INT'L L. 355, 397 (2017) ("Article 2.4 [of the 2016 model BIT] carves out from the treaty local government measures, which is a vast exclusion for a federal state like India, any measure related to taxation and a number of other issues such as compulsory licenses of intellectual property rights . . .").

33. See Anthea Roberts, *Incremental, Systemic, And Paradigmatic Reform of Investor-State Arbitration*, 112 AM. J. INT'L L. 410, 410 (2018) ("[M]any states view investor-state arbitration as akin to a horse that has bolted from the barn. Wishing to close the stable door, a wide range of states are considering the merits of various reform proposals.").

challenged by Eli Lilly and Philip Morris, respectively.³⁴ Canada argued that the invalidation by a court of two pharmaceutical patents could not be reviewed in an ISDS proceeding and that such invalidation amounted neither to indirect exportation nor to unfair or inequitable treatment. Canada, in other words, played the game within strict ISDS boundaries.³⁵ Uruguay took a different approach to defend itself against Philip Morris' claim that its plain packaging legislation was expropriatory and constituted a violation of FET. Beyond traditional ISDS arguments, it invoked human rights to justify limits on the use of trademarks on cigarette packs.³⁶

The Article proceeds as follows. First, it presents the *Eli Lilly v. Canada* dispute in Part II. The Article then turns to *Philip Morris v. Uruguay* in Part III. In Part IV, the Article compares and contrasts the two awards. Using lessons from this comparative analysis in Part V, the Article examines a number of existing and possible new doctrinal mechanisms that could be used to resolve IP/ISDS clashes and considers the role that human rights might play in this context.

II. ELI LILLY V. CANADA

A. Overview of the Dispute

Eli Lilly v. Canada drew considerable attention, both in Canada and around the world.³⁷ This Part provides a brief overview of the case and considers the Tribunal's findings that are most relevant to the IP/ISDS interface.³⁸

Eli Lilly, the claimant, is a pharmaceutical company headquartered in the United States and distributing throughout the globe. The dispute stemmed from the invalidation of two patents on Lilly's drugs Zyprexa and Strattera (atomoxetine and olanzapine, respectively) by Canadian courts for

34. See NAFTA, *supra* note 12; Agreement on the Reciprocal Promotion and Protection of Investments, Switz.-Uru., art. 10, Oct. 7, 1988, 1976 U.N.T.S. 389.

35. See *infra* Part II.A.

36. See *infra* Part III.A.

37. See, e.g., Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines – Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement*, 23 J. INTEL. PROP. L. 1 (2015); Sean Flynn, *Section III: Issues Concerning Enforcement and Dispute Resolution*, 40 COLUM. J.L. & ARTS 353 (2017); Gathii & Ho, *supra* note 6; Ho, *supra* note 16; Valentina S. Vadi, *Towards A New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investments*, 5 N.Y.U. J. INTEL. PROP. & ENT. L. 113 (2015).

38. For a comprehensive picture of the case, see case documents (including party briefs) available at *Eli Lilly and Company v. Canada* (ICSID Case No. UNCT/14/2), International Centre for Settlement of Investment Disputes, <https://icsid.worldbank.org/en/pages/cases/casedetail.aspx?caseno=unct/14/2> (last visited Jan. 7, 2019).

failure to meet one of the core patentability criteria: utility.³⁹ The case was heard at the International Centre for Settlement of Investment Disputes (the “ICSID”) in Washington, D.C.—a forum of choice for investor-state disputes—under the United Nations Commission on International Trade Law (the “UNCITRAL”) Arbitration Rules.⁴⁰

ICSID is known for the discreetness and effectiveness of its services.⁴¹ Under the UNCITRAL Rules, an *ad hoc* tribunal, usually composed of three experts, is established to hear each case.⁴² Although ICSID hearings typically are not public—and calls for more transparency have been made—the “memorials” (briefs) filed by the parties and expert reports, as well as tribunal orders, are generally made available to the public on the ICSID website.⁴³

Eli Lilly used the notion of *indirect* expropriation to challenge the judicial application of patent law to specific inventions. In a nutshell, Lilly argued that it “relied on Canada’s patent law when it sought patent protection for Zyprexa and Strattera and launched those drugs in Canada” and that the patents were issued “after a careful review by Canada’s patent examiners in light of Canada’s utility” doctrine.⁴⁴ Because new interpretations by courts of patentability criteria normally apply to existing patents as well as future ones,⁴⁵ any significant change tightening the interpretation of a patentability criterion could, in Lilly’s view, amount to expropriation of its intellectual property. This argument amounted to a challenge by a private, non-state actor to Canada’s sovereign ability to regulate and evolve its patent law through court interpretations. It is important to bear in mind in this context that patent invalidity is a common defense to a patent infringement lawsuit, and a significant number of patents

39. Utility is one of the basic patentability criteria in US and Canadian patent law. The Canada Award, *supra* note 4, Claimant’s Memorial, ¶ 4 (Sept. 29, 2014). In countries other than the United States and Canada, a standard known as industrial applicability is an approximate equivalent of the utility criterion. See Convention on the Grant of European Patents art. 52, ¶ 1, Nov. 29, 2000, 2001 O.J. EUR. PAT. OFF. SPEC. ED. NO. 4, at 54, 77.

40. NAFTA, *supra* note 12, art. 1120 (parties may submit claims under ICSID Convention or UNCITRAL Arbitration rules). For the text of UNCITRAL, see U.N. Comm’n on Int’l Trade Law, *Rep. of Its Forty-Sixth Session*, annexes I, II, U.N. Doc. A/69/17 (2014). For a discussion of how UNCITRAL has struggled to update its rules due to divergences of views among States, see Roberts, *supra* note 33.

41. See Ibrahim F.I. Shihata, *The Settlement of Disputes Regarding Foreign Investment: The Role of the World Bank, with Particular Reference to ICSID and MIGA*, 1 AM. U. J. INT’L L. & POL’Y 97, 103 (1986).

42. See U.N. Comm’n on Int’l Trade Law, *supra* note 21, art. 7.

43. See J. Anthony VanDuzer, *Enhancing the Procedural Legitimacy of Investor-State Arbitration Through Transparency and Amicus Curiae Participation*, 52 MCGILL L.J. 681, 706 (2007).

44. The Canada Award, *supra* note 4, Claimant’s Memorial, ¶ 20.

45. *E.g.*, *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016) (examining the validity of two software patents issued in 2001 and 2003 based on the new interpretation of patent eligibility in *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208 (2014)).

challenged in courts are invalidated in whole or in part when EU, Japanese, and United States cases are aggregated.⁴⁶

Eli Lilly also argued that the interpretation of patentability criteria by Canadian courts violated Canada's obligations to afford "fair and equitable treatment" to Lilly's investments under NAFTA.⁴⁷ Specifically, Eli Lilly alleged that the court decisions violated: (i) protection against arbitrary treatment because Canada's patent law is completely unpredictable and unreasonably difficult to satisfy; (ii) protection of legitimate, investment-backed expectations; and (iii) protection against discriminatory treatment.⁴⁸

B. *The Award*

The Tribunal released the Award in March 2017.⁴⁹ Though the Tribunal rejected all of Eli Lilly's substantive claims on the merits, the case remains relevant for IP policy in part because the Tribunal had no difficulty accepting that patents were protected investments as opposed to the *research* necessary to generate the invention protected by the patent, which may have been invested in another country.⁵⁰ Stated differently, a protected investment can be limited, it seems, to prosecution of the patent application in a country where no research has taken place.⁵¹

The applicable rules of interpretation in this case included the text of the IIA at issue—NAFTA⁵²—and "*applicable rules of international law*["], which NAFTA specifically mentions.⁵³ According to the Award, those applicable rules are articles 31 and 32 of the Vienna Convention on the Law of Treaties (the "VCLT"), as well as "other applicable rules of international law that may be relevant to the case before it."⁵⁴ This comes as no surprise;

46. For 2015 data, see Douglas R. Nemec & Scott M. Flanz, *After Period of High Invalidation Rates, New US Patent Challenge Procedures May Slow Down to Moderate Pace* (April 26, 2016), SKADDEN, <https://www.skadden.com/insights/publications/2016/04/after-period-of-high-invalidation-rates-new-us-pat>. In a 2015 case before the Supreme Court, the debate was whether the defendant's *belief* that a patent is invalid is a defense. The court found that it was not. *See Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015).

47. The Canada Award, *supra* note 4, Claimant's Memorial ¶ 18.

48. *Id.* ¶¶ 19–20.

49. *See* The Canada Award, *supra* note 4.

50. *See id.* ¶¶ 167, 469 (referring to the Zyprexa and Strattera Patents as "the investments at issue in this arbitration") The TRIPS Agreement prohibits discrimination as to the place of invention. *Cf.* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

51. A second, separate investment might be the subsequent commercialization of the product protected by the patent.

52. The Canada Award, *supra* note 4, ¶ 4.

53. NAFTA, *supra* note 12, art. 102, ¶ 2 (emphasis added).

54. The Canada Award, *supra* note 4, ¶ 106. *See generally* Vienna Convention on the Law of Treaties art. 31 ¶ 3(a), May 23, 1969, 1155 U.N.T.S. 331 (requiring a treaty to be interpreted in light of the parties' subsequent agreements) [hereinafter VCLT].

it is generally well-accepted that the VCLT articles on treaty interpretation reflect customary international law.⁵⁵ ISDS tribunals often apply them even where the applicable IIA is silent on applicable rules.⁵⁶ Indeed, a detailed review of 229 ISDS awards revealed that 132—approximately sixty percent—of those cited the VCLT.⁵⁷

On the merits, the tribunal concluded that only *egregious errors* by a domestic court could be subject to an ISDS claim absent a due process or equivalent procedural fault.⁵⁸ “Egregiousness” is a known standard in determining the existence of a breach of customary international law.⁵⁹ In adopting that standard, the Tribunal refused to categorically exclude review by ISDS tribunals of patent invalidations by domestic courts, but it set the bar for complainants very high, noting that this review could only happen “in very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct.”⁶⁰ The Tribunal accepted “the analysis and conclusions of the NAFTA Chapter Eleven tribunal in *Glamis Gold v. United States* on the content of the customary international law minimum standard of treatment.”⁶¹ In *Glamis Gold*, the tribunal defined the standard as “an act that is sufficiently egregious and shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons—so as to fall below accepted international standard.”⁶² Bad faith, though not a formal requirement, is often present in such cases, which adds a crucial dimension: it seems self-evident that neither Eli Lilly nor Phillip Morris could establish bad faith as the motivation for the measures they were attacking.⁶³

55. See *LaGrand* (Ger. v. U.S.), Judgment, 2001 I.C.J. Rep. 466, ¶ 99 (June 27); *Arbitral Award of 31 July 1989* (Guinea-Bissau v. Sen.), 1991 I.C.J. Rep. 53, ¶ 48 (Nov. 12).

56. See, e.g., *Malaysian Historical Salvors SDN BHD v. Malaysia*, ICSID Case No. ARB/05/10, Decision on Application for Annulment, ¶¶ 56–57 (Apr. 16, 2009), http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C247/DC1030_En.pdf.

57. TRINH HAI YEN, *THE INTERPRETATION OF INVESTMENT TREATIES* 38 (2014).

58. See *The Canada Award*, *supra* note 4, ¶ 224.

59. See, e.g., *id.*; *Glamis Gold, Ltd. v. United States*, Award, ¶¶ 620, 627 (June 8, 2009), <https://www.state.gov/documents/organization/125798.pdf>; *International Thunderbird Gaming Corporation v. United Mexican States*, Award, ¶ 194 (Jan. 26, 2006), https://www.iisd.org/pdf/2006/itn_award.pdf.

60. See *The Canada Award*, *supra* note 4, ¶ 224. The Tribunal also quotes from *Glamis Gold, Ltd. v. United States* that violating the customary international law minimum standard of treatment requires “a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons.” *Id.* ¶ 222.

61. *The Canada Award*, *supra* note 4, ¶ 222.

62. *Glamis Gold*, ¶ 627; see also *The Canada Award*, *supra* note 4, ¶ 224.

63. *Glamis Gold*, ¶ 22 (“[A]lthough bad faith may often be present in such a determination and its presence will certainly be determinative of a violation, a finding of bad faith is not a requirement for a breach”)

Though courts are organs of the state, the Tribunal also agreed with Canada that ISDS tribunals are not courts of appeal for domestic courts.⁶⁴ Thus, the Tribunal accepted Canada's claim that its courts' interpretation of patentability criteria effectuated a valid exercise of discretion in the application of public policy objectives. As the Tribunal explained, the appropriate test was the existence of a "rational connection" between the policy objective and the measure.⁶⁵

The Award referenced several earlier arbitral awards to justify its conclusions, as could be expected since a broad quantitative survey of ISDS awards shows that ISDS tribunals "tend to follow an approach based in a common law, rather than a civil law, tradition when addressing interpretive issues."⁶⁶

Before turning to *Philip Morris*, it is important to note that neither human rights nor broader principles of international law beyond the ones sparingly used to interpret the treaty—such as the VCLT—played a significant role in the Award. This absence may be due to the fact that Canada did not invoke human rights or fundamental rights in its counter-memorial, nor in its Rejoinder on the Merits.⁶⁷ As we shall now see, matters took on a very different hue in the second case.

III. PHILIP MORRIS V. URUGUAY

A. Overview of the Dispute

Philip Morris v. Uruguay, also heard at ICSID, was based on a 1988 Switzerland-Uruguay BIT.⁶⁸ Philip Morris, the global company known mostly for its sale of tobacco products, and its local affiliate in Uruguay challenged two public health measures adopted by Uruguay to reduce smoking, especially among young smokers. The challenged measures included a "single presentation" requirement that prohibited different packaging or "variants" for cigarettes sold under a given brand.⁶⁹ For

64. The Canada Award, *supra* note 4, ¶ 221.

65. *Id.* ¶ 423.

66. Ole Kristian Fauchald, *The Legal Reasoning of ICSID Tribunals—An Empirical Analysis*, 19 EUR. J. INT'L L. 301, 357 (2008).

67. See The Canada Award, *supra* note 4, Counter –Memorial (Jan. 27, 2015), <https://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf>; The Canada Award, *supra* note 4, Rejoinder Memorial (Dec. 8, 2015), <https://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207014.pdf>.

68. Agreement on the Reciprocal Promotion and Protection of Investments, *supra* note 34.

69. The "Single Presentation Requirement was implemented through Ordinance 514 dated 18 August 2008 ('Ordinance 514') of the Uruguayan Ministry of Public Health (the 'MPH'). Article 3 of Ordinance 514 requires each cigarette brand to have a "single presentation" and prohibits different packaging or 'variants' for cigarettes sold under a given brand." The Uruguay Award, *supra* note 18, ¶ 10.

example, Philip Morris could no longer sell Marlboro Red, Marlboro Gold, Marlboro Blue, and Marlboro Green (Fresh Mint); it had to pick one and only one, and it picked Marlboro Red and its licensee in Uruguay ceased selling all other product variants.⁷⁰ A second measure, known as the “80/80 Regulation” imposed an increase in the size of prescribed health warnings on the front and back of the cigarette packages from 50% to 80%, leaving only 20% of the cigarette pack for trademarks, logos, and other information.⁷¹ Claimants argued that these measures impacted sales, affected their trademark value, and reduced the value of their investments in Uruguay, thus impairing the use and enjoyment of their investments.⁷² They also argued that the measures constituted a lack of FET, a denial of justice, and an indirect expropriation.⁷³ Uruguay responded, *inter alia*, that it adopted the measures as a matter of public health (presented as a human right) and to implement the WHO (the “World Health Organization”) Framework Convention on Tobacco Control (the “FCTC”).⁷⁴

B. *The Award*

A majority of the ISDS tribunal (2-1) agreed with Uruguay that the two challenged measures—though imperfect or even defective policy implementations when their outcomes are measured against their stated objective(s)—constituted a valid exercise of the country’s “police powers” and “[a]s such” they could not constitute an expropriation.⁷⁵

The Tribunal’s main finding in this respect was that the challenged measures were not “arbitrary and unnecessary” but rather were *potentially effective* means to protect public health.⁷⁶ The measures were introduced as part of a larger scheme of tobacco control, and it was difficult to disentangle the exact impact of their different components. Overall, however, smoking

70. *Id.*

71. *Id.* ¶ 11.

72. *Id.*

73. *Id.* ¶¶ 10–12.

74. *Id.* ¶ 13; WHO Framework Convention on Tobacco Control, May 21, 2003, 2302 U.N.T.S. 166. See generally *The WHO Framework Convention on Tobacco Control: An Overview*, WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL 1, 1 (Jan. 2005), http://www.who.int/fctc/about/WHO_FCTC_summary_January2015.pdf?ua=1.

75. The notion of police powers in international law “refers to the state’s right to promote a recognized ‘social purpose’ or the ‘general welfare’ by regulation.” The Uruguay Award, *supra* note 18, ¶¶ 305–07 (emphasis added). In the Award, Arbitrator Gary Born noted, in his separate opinion, that it was even “[m]indful of Uruguay’s extensive legislative authority and broad regulatory discretion, it [was] impossible to see how a hastily-adopted measure that is so ill-suited to its articulated purpose, and that treads so far onto protected rights and interests, can satisfy even the Tribunal’s stated standard.” *Id.* Annex B ¶¶ 176–77. See also Jon A. Stanley, *Keeping Big Brother Out of Our Backyard: Regulatory Takings as Defined in International Law and Compared to American Fifth Amendment Jurisprudence*, 15 EMORY INT’L L. REV. 349, 373 (2001).

76. The Uruguay Award, *supra* note 18, ¶ 306.

in Uruguay did decline, notably among young smokers, thus giving Uruguay the benefit of the doubt with respect to policy.⁷⁷ The two-prong test applied by the Tribunal gave Uruguay generous regulatory leeway: the Tribunal considered the measure valid if (a) the objective was legitimate and (b) it was “capable of contributing to the achievement” of said policy objective.⁷⁸ The Tribunal deemed public health a legitimate objective and the measures capable of contributing to this end. As in *Eli Lilly v. Canada*, the Uruguay Award aimed to follow in the footsteps of previous ISDS awards.⁷⁹

Human rights references appear twice in the Uruguay Award. First, European Court of Human Rights (the “ECtHR”) jurisprudence is used both to reinforce the normative underpinning of the police powers doctrine and to extend its scope.⁸⁰ The Award makes capacious use of the police powers doctrine, citing a number of previous ISDS awards—though not IP-focused—in support of its use of ECtHR precedents.⁸¹ Among them was *Tecmed Técnicas Medioambientales Tecmed S.A. v. United Mexican States*,

77. See *id.*

78. See *id.*

79. See Fauchald *supra* note 66, at 357.; and E. Gaillard, *Use of*

General Principles of International Law in International Long-term contracts, INTL BUS. LAWYER, 217 (May 1999), (“[A]rbitral tribunals have a strong tendency to use precedents established by arbitral awards rendered in similar circumstances.”) The Uruguay Award cited, *inter alia*, *Methanex v. United States*, a case in which the tribunal stated:

[A]s a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, *inter alios*, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.

Methanex Corp. v. United States, Final Award of the Tribunal on Jurisdiction and Merits, Part IV ¶ 7 (Aug. 3, 2005), <https://www.italaw.com/sites/default/files/case-documents/ita0529.pdf>. Another well-known ISDS case cited in the Award is *Saluka v. Czech Republic*, in which the tribunal had noted that it was well established in international law that “states are not liable to pay compensation to a foreign investor when, in the normal exercise of their regulatory powers, they adopt in a non-discriminatory manner bona fide regulations that are aimed at the general welfare.” *Saluka Investments BV v Czech Republic*, Partial Award, ¶¶ 255–56 (Mar. 17, 2006), <https://www.italaw.com/sites/default/files/case-documents/ita0740.pdf>.

80. See The Uruguay Award, *supra* note 18, ¶ 295 (“[A] range of investment decisions have contributed to develop the scope, content and conditions of the State’s police powers doctrine, anchoring it in international law. According to a principle recognized by these decisions, whether a measure may be characterized as expropriatory depends on the nature and purpose of the State’s action. Some decisions have relied on the jurisprudence of the European Court of Human Rights, based on Article 1 of Protocol 1 of the Convention.”) Interestingly, the Award also notes, “Among international conventions to which Uruguay is a party is the European Convention for the Protection of Human Rights, whose Article 1, Protocol 1, is another source of decisions regarding the police powers doctrine.” *Id.* at n.403.

81. *Id.* at n.390.

a case in which the arbitral tribunal examined “the actions of the State . . . to determine whether such measures are reasonable with respect to their goals.”⁸² The reference to the ECtHR decisions was *not* used to justify the application of a specific right in the ECHR but rather to assess the *proportionality* of the impugned measures and the state’s “margin of appreciation” in implementing a measure when faced with competing norms—intellectual property and investment protection on the one hand, and public health on the other.⁸³ The second human rights reference in the Award appears in the description of the FCTC as *guaranteeing* “human rights to health.”⁸⁴ Unfortunately, the Award does not discuss the basis for that finding nor its exact consequences.

It is worth noting that there was a significant divergence of views in the Uruguay Award between the majority opinion and arbitrator Gary Born’s partial dissent. Mr. Born took the view that there is no general principle of proportionality in international treaty interpretation and that the terms of the BIT between Switzerland and Uruguay should govern.⁸⁵ The dissent also discusses whether the “margin of appreciation” states a general principle of international law—and therefore is applicable to all IIAs—or whether it is instead regime-specific and thus must be found in the terms of the IIA at issue.⁸⁶ The next Part turns to that exact question.

IV. COMPARATIVE ANALYSIS OF THE AWARDS

This Part compares the most directly relevant elements of the Canada and Uruguay Awards—namely, the application of the margin of appreciation doctrine and the role of human rights. It then draws lessons on the standard of review that should apply in the ISDS context when a tribunal is called upon to review a regulatory measure or change in the law effected by legislation, regulation, or a court or administrative agency when such measure or change is presented under an indirect expropriation theory or a FET violation.

A. *The Margin of Appreciation Issue*

ISDS scholarship describes the state’s margin of appreciation in this context as granting states “some latitude to make initial determinations as to whether their actions” fall within the scope of measures not precluded by the IIA containing the ISDS clause, so that the function of the ISDS tribunal

82. Tecmed Técnicas Medioambientales Tecmed S.A. v. United Mexican States, ICSID Case No. ARB(AF)/00/2, Award, ¶ 122 (May 29, 2003), http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3785/DC4872_En.pdf.

83. The Uruguay Award, *supra* note 18, at n.404.

84. *Id.* ¶ 304.

85. *Id.* Annex B ¶ 191 (Born, dissenting).

86. See Alvarez, *supra* note 2, ¶¶ 138, 182–85.

is to determine “the permissible and legitimate boundaries of the margin of appreciation that arises from the terms of the [IIA].”⁸⁷ The Uruguay Award illustrates that, even in an ISDS proceeding, the notion can be defined more broadly as reflecting regulatory leeway in implementing any commitment in an international instrument.

The Uruguay Award uses ECtHR decisions revolving around a broad margin of appreciation notion that applies to states party to the European Convention on Human Rights (the “ECHR”) to implement their international law obligations.⁸⁸ This notion of margin of appreciation is situated at the “core of the European human rights culture.”⁸⁹ It is common to ECtHR jurisprudence and the EU legal order, though it is not always interpreted the same way in both.⁹⁰ At the ECtHR, it “stands for the notion that the authorities of each party state to the [ECHR] ought to be allowed a certain measure of discretion in implementing the standards enshrined in the Convention.”⁹¹ By contrast, in the jurisprudence of the Court of Justice of the European Union (the “CJEU”), it is used more or less interchangeably with the notion of margin (or scope) of discretion.⁹² A number of commentators note that it also fits squarely within the CJEU’s jurisprudence on proportionality.⁹³

To make sense of what looks like a doctrinal salad bowl intermixing different tests, one can turn to scholarship on the notion of margin of appreciation, the relationship between the ECtHR and the CJEU, and, more generally, the relationship between the ECtHR and international law.⁹⁴

87. William W. Burke-White & Andreas von Staden, *Investment Protection in Extraordinary Times: The Interpretation and Application of Non-Precluded Measures Provisions in Bilateral Investment Treaties*, 48 VA. J. INT’L L. 307, 370 (2008).

88. The Uruguay Award, *supra* note 18, ¶¶ 531–32. Philip Morris’ denial of justice claim is discussed by and received some support from Gary Born, who filed a concurring/dissenting opinion. *See id.* Annex B ¶¶ 44–72.

89. NINA-LOUISA AROLD LORENZ ET AL., THE EUROPEAN HUMAN RIGHTS CULTURE - A PARADOX OF HUMAN RIGHTS PROTECTION IN EUROPE? 69 (2013).

90. *Id.* at 69–70.

91. *Id.* at 73.

92. *See id.* at 90.

93. *Id.* at 91–92.

94. *See, e.g.*, Christina Binder, *The European Court of Human Rights and the Law of Treaties*, in THE EUROPEAN COURT OF HUMAN RIGHTS AND PUBLIC INTERNATIONAL LAW: FRAGMENTATION OR UNITY? 41, 46, 56 (Christina Binder & Konrad Lachmayer eds., 2014) (discussing the European Court of Human Rights’ (“ECtHR”) limited reception of international law, including the VCLT); MAGDALENA FOROWICZ, THE RECEPTION OF INTERNATIONAL LAW IN THE EUROPEAN COURT OF HUMAN RIGHTS 352 (2010) (“Although exclusively aimed at applying and enforcing the ECHR, the jurisdiction of the Strasbourg bodies has become porous to international sources and influences.”); HANNEKE CECIEL KATRIJN SENDEN, INTERPRETATION OF FUNDAMENTAL RIGHTS IN A MULTILEVEL LEGAL SYSTEM : AN ANALYSIS OF THE EUROPEAN COURT OF HUMAN RIGHTS AND THE COURT OF JUSTICE OF THE EUROPEAN UNION 141 (2011) (comparing the approach of both courts in cases involving human and fundamental rights and noting that “it would be difficult, it would

Although this Article obviously cannot and should not try to summarize this vast body of work, for our purposes, the narrower question we need to answer is whether the margin of appreciation doctrine as applied by the ECtHR and the related notion of proportionality are the optimal ways to judge a state's leeway in assessing a national intellectual property regime's compatibility with an IIA.⁹⁵

The answer depends on three elements. First, there are several notable differences between ISDS and the ECHR. For example, the ECHR contains a reference to what is "necessary in a democratic society," a phrase that is not common in IIAs.⁹⁶ The term "democratic" arguably implies divergences in the polity of views of many matters and the ability to express those views, including on specific policy choices to implement treaty-based obligations and exact implementations of such choices.⁹⁷ This, in turn, implies that states must have considerable leeway to implement obligations in a variety of ways.⁹⁸ States with vastly different values and political systems enter into IIAs. To be clear, if states need policy leeway, it may not be for democratic reasons.

Second, a number of ISDS tribunals have tried to gauge the *appropriateness* or *reasonableness* of a measure, or the *rational connection* between it and its stated objective. The margin of appreciation doctrine is not meant to perform this function. To the contrary, as Ronald Macdonald noted, the margin of appreciation approach may actually obscure the question of appropriateness.⁹⁹

Third, the application of the margin of appreciation by the ECtHR "has become increasingly intertwined with the consideration of proportionality" in a way that makes the relationship between the two notions insufficiently clear.¹⁰⁰ In this sense, as noted above, the ECtHR intermixes the test just as the CJEU tends to do.¹⁰¹ Proportionality at the ECtHR merely echoes the

also be highly impractical and counterproductive if two different standards of fundamental rights protection were in force at the same time."'). See generally FUNDAMENTAL RIGHTS IN THE EU: A MATTER FOR TWO COURTS (Sonia Morano-Foadi and Lucy Vickers eds., 2015).

95. See Helfer *supra* note 21, at 9–11. Of course, neither ISDS chapters in IIAs nor the ECHR are primarily intellectual property instruments, even though a number of ECtHR decisions have affected IP rights. See *id.* at 2.

96. European Convention on Human Rights art. 10, Nov. 4, 1950, E.T.S. No. 5.

97. See DAVID HARRIS ET AL., LAW OF THE EUROPEAN CONVENTION ON HUMAN RIGHTS 510–20 (3d ed. 2014).

98. See Ronald St. J. Macdonald, *The Margin of Appreciation*, in THE EUROPEAN SYSTEM FOR THE PROTECTION OF HUMAN RIGHTS 111 (Ronald St. J. Macdonald ed., 1993).

99. *Id.* at 124.

100. William W. Burke-White & Andreas van Staden, *Private Litigation in a Public Sphere: The Standard of Review in Investor-State Arbitrations*, 35 YALE J. INT'L L. 283, 306–07 (2010); see also Stephan W. Schill, *General Principles of Law and International Investment Law*, in INTERNATIONAL INVESTMENT LAW: THE SOURCES OF RIGHTS AND OBLIGATIONS 154 (Tarcisio Gazzini & Eric De Brabandere eds., 2012).

101. See Helfer, *supra* note 21, at 10.

“fair balance” standard as required by article 1 of protocol 1 of the ECHR, which “provides governments considerable leeway to regulate private property in the public interest.”¹⁰² The article considers the two tests, therefore, as functionally similar as applied. The harder question is whether that test is useful in an ISDS context.

A state may justify a contested measure using a variety of tests. A *negative* test is probably the easiest: proving that a measure is *not* egregious is not hard, especially if the burden of proving egregiousness falls on the complainant.¹⁰³ Then there are *positive* tests.

“Rational connection” is the lowest “positive” bar that a state must pass to justify a measure. Absent bad faith, very few measures would have no demonstrable rational connection with their underlying policy objective. The rational connection test is almost the reverse side of the egregiousness coin: if a measure has a rational connection to its stated objective, it is not egregious. The rational connection is not a complete bar, however.¹⁰⁴ Indeed, this is a point of disagreement between the majority and the dissent in the Uruguay Award. Arbitrator Born did not argue that Uruguay adopted its tobacco control measures in bad faith but wrote that “the single presentation requirement does not bear even a minimal relationship to the legislative objective cited by Uruguay for the requirement” and that the measure was “arbitrary and irrational.”¹⁰⁵

At a higher level, one would require evidence that a measure was effective in achieving its stated purpose.¹⁰⁶ Under one approach—not

102. Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms art. 1, Mar. 20, 1952, 213 U.N.T.S. 262. For a discussion, see *id.*

103. See Vera Korzun, *The Right to Regulate in Investor-State Arbitration: Slicing and Dicing Regulatory Carve-Outs*, 50 VAND. J. TRANSNAT'L L. 355, 376 (2017) (“Arbitral tribunals rely on several factors in distinguishing legitimate regulation from regulatory expropriation. . . . Some tribunals have attempted to distinguish between the two types of regulation by looking at their goals, nature, and the manner in which they were applied. In doing so, they have relieved the state of the obligation to provide compensation where regulation had a legitimate public purpose and was applied in a nondiscriminatory manner.”) For example, in *Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Award ¶ 132 (June 26, 2003), the panel noted that the complainant had to establish “[m]anifest injustice in the sense of a lack of due process leading to an outcome which offends a sense of judicial propriety.”

104. See, e.g., *Belokon v. Kyrgyz Republic*, Award, ¶¶ 231–34 (Oct. 24, 2014), <https://www.italaw.com/cases/documents/3804> (finding that the administration of a bank during a period of violent regime had no rational connection with the state’s objectives); Charles H. Brower II, *Politics, Reason, and the Trajectory of Investor-State Dispute Settlement*, 49 LOY. U. CHI. L.J. 271, 298 n.117 (2017).

105. The Uruguay Award, *supra* note 18, Annex 2 ¶¶ 86, 88 (Born, dissenting).

106. Arguably the dissent in *Phillip Morris v. Uruguay* is situated somewhere between absence of a rational connection and lack of demonstrable effectiveness. See *id.* annex 2 ¶ 119. (“[T]here were no documents or other materials accompanying any of the drafts of the proposed ordinances (in either 2008 or 2009) that explained the purpose or background of the single presentation requirement or how the requirement was contemplated to work in practice,

applied in ISDS but common in international trade law—the state must prove that the measure was the least restrictive among available alternatives under the so-called “necessity tests.”¹⁰⁷ The egregiousness standard adopted in the Canada Award may seem easier to apply than the broad but fuzzy police powers doctrine used in the Uruguay Award. Yet, in this Article’s view, they do not differ much in practice, for it is suggested that a measure would run afoul of the margin of appreciation in most cases if it was egregious, or worse, adopted in bad faith. Then, as already mentioned, egregiousness is arguably the flip side of rational connection, though its application might differ if burdens of proof are reversed.¹⁰⁸

Naturally, a tribunal might be tempted to overlay its application of these tests with a normative pro-investor veneer given that a main object and purpose of ISDS instruments is to protect investors.¹⁰⁹ The trade law standard from the World Trade Organization (the “WTO”), that requires a WTO member to show that it adopted the *least trade-restrictive regulatory measure* would transform ISDS radically and severely restrict regulatory leeway, but it is, as noted, not applied in ISDS.¹¹⁰ Put differently, though most ISDS tribunals will not second-guess the *choice of policy objective* of a respondent state, tribunals have two options: either limit themselves to gauging the appropriateness of the measure or insist on getting evidence from the respondent state that the measure was the least investment-restrictive measure. The choice between those two options can lead to vastly different outcomes. Applying the margin of appreciation/proportionality doctrine or its doctrinal cousin—the egregiousness test—limits a tribunal’s

nor that addressed any empirical evidence that would bear upon the requirement’s goals or efficacy.”)

107. Various variants (and thus exact levels) of this test exist. See WTO Secretariat, “Necessity Tests” in the WTO, WTO doc. S/DPDR/W/27 (Dec. 2, 2003).

108. The burden of proving a violation under the egregiousness standard would seem to fall naturally on the complainant. The rational connection test could be used either as an integral part of the complainant’s case, in which case that party would bear the burden of proving an absence of rational connection (something similar to the approach chosen by the WTO Panel in *Australia Plain Packaging*—Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications And Other Plain Packaging Requirements Applicable To Tobacco Products And Packaging*, ¶¶ 7.2418–7.2420, WTO Docs. WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (adopted June 28, 2018) [hereinafter WTO Plain Packaging Report]), or as a defense resting on the respondent’s shoulders.

109. The VCLT, *supra* note 54, provides the rules of treaty interpretation used by ISDS tribunals. Article 31(1) of the VCLT states that “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.” (emphasis added). See, e.g., *Busta v. Czech Republic*, Case No. V 2015/014, Final Award, ¶ 115 (Arb. Inst. Stockholm Chamber Com. Mar. 10, 2017), <https://www.italaw.com/sites/default/files/case-documents/italaw8558.pdf>, (“The object and purpose of the BIT is the “promotion and protection of investments”).

110. In an ISDS context, this might be called the *least investor-impacting measure*. See Peter Van den Bossche, *Looking for Proportionality in WTO Law*, 35 LEGAL ISSUES ECON. INTEGRATION 283, 288 (2008).

ability to restrict states to the least investment-impacting measure and is likely to provide more regulatory autonomy.

Perhaps because of this, a number of ICSID tribunals have chosen to follow the ECtHR's path, at least formally. Those awards then tend to mention "proportionality" explicitly, as in *Total v. Argentina*, a case in which the tribunal stated that the "reasonableness of the normative changes challenged and their appropriateness in light of a criterion of proportionality also have to be taken into account."¹¹¹ There, the tribunal used proportionality to balance "the investor's interest in regulatory stability and the host State's interest in adaptation of the regularity framework"¹¹²

How does margin of appreciation or proportionality apply in the context of intellectual property and its link with policy targets such as public health, access to health innovations, and innovation policy? Choosing to follow the ECtHR's approach affords considerable leeway to a state's regulatory interventions. All arbitrators in the Uruguay Award recognized the importance of the public health objective that supported the restriction of Philip Morris's use of its trademarks, though one arbitrator dissented on the appropriateness analysis and the very role of the tribunal in assessing it.¹¹³ This demonstrates that the ISDS/IP interface is quite unlikely to clash on the *purpose* of an IP measure (e.g., innovation or public health). The dispute is much more likely to center on how *appropriate* the measure is when viewed from an investment protection perspective. Hence, imperfect as it may be, applying the ECtHR's margin of appreciation standard—and the related notion of proportionality to which it is increasingly assimilated—to answer this question leads to more favorable outcomes for respondent states than the application of the stricter standard of whether the challenged measure is the least investor-impacting.

The fact that the reasoning used by the ECtHR in assessing proportionality has been called upon in a number of ISDS awards to *cross legal systems* from human rights to international investment law shows the range of available standards that an ISDS tribunal might apply when reviewing state actions, "particularly[] the application of defenses . . . that raise quasi-constitutional issues."¹¹⁴ That being said, some, but far from all, ISDS tribunals have agreed to cross the definitional waters that separate the ECHR and IIAs. In *von Pezold v. Zimbabwe*, for example, the tribunal stated:

[D]ue caution should be exercised in importing concepts from other legal regimes (in this case European human rights law) without a

111. *Total S.A. v. Argentine Republic*, ICSID Case No. ARB/04/1, Decision on Liability, ¶ 134 (Dec. 27, 2010), http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C30/DC7833_En.pdf.

112. Schill, *supra* note 98, at 156.

113. *See supra* notes 75 and 88.

114. Burke-White & von Staden, *supra* note 100, at 302.

solid basis for doing so. Balancing competing (and non-absolute) human rights and the need to grant States a margin of appreciation when making those balancing decisions is well established in human rights law, but the Tribunal is not aware that the concept has found much support in international investment law.¹¹⁵

Still, the increasingly frequent use of ECtHR cases in ISDS awards might make it *jurisprudence constante*, which would be a significant development given the common law approach used by most ISDS tribunals.¹¹⁶ Part V explains how this can be accomplished in structured fashion.

B. *A Role for Human Rights in ISDS Disputes Involving IP*

As noted in the previous Part, unlike the Canada Award, the Uruguay Award expressly mentions human rights, specifically the right to health as enshrined in the FCTC. This was not a surprise, as references to human rights are common in ISDS awards.¹¹⁷ However, a survey of ISDS awards showed that “references to European human rights law are, in fact, *as likely to come from investor claimants as respondent states*. They are, in short, as likely to be used as a sword in *favor of investor rights* than as a shield to defend against them.”¹¹⁸ Indeed, “the ECHR and international investment regimes share at least two common general substantive goals: to protect access to justice and to protect some forms of property.”¹¹⁹

To take a regional example, the right to the protection of property is also one of the fundamental rights protected by the EU Charter, as is the freedom to conduct business.¹²⁰ Some ISDS awards used those rights to adopt a narrow approach to other fundamental rights arguments. For example, an ISDS award noted that the term “basic rights” in an IIA should be interpreted to refer to “basic property rights,” not the broader legal and

115. von Pezold v. Republic of Zim., ICSID Case No. ARB/10/15, Award, ¶¶ 465–66 (July 28, 2015), https://www.italaw.com/sites/default/files/case-documents/italaw7095_0.pdf.

116. See Cont’l Cas. Co. v. Argentine Republic, ICSID Case No. ARB/03/9, Award, ¶ 108 (Sept. 5, 2008), <https://www.italaw.com/sites/default/files/case-documents/ita0228.pdf>. On the common law approach, see Agreement on the Reciprocal Promotion and Protection of Investments, *supra* note 34. *Jurisprudence constante* may be defined as “a body of case law that meets a sufficient threshold of uniformity and consistency[. It] is, at a maximum, persuasive, but with ‘considerable authoritative force.’” Paul Cho, *What if the International Criminal Court Could Prosecute President al-Assad for the Chemical Weapon Attacks in Ghouta?*, 49 ST. MARY’S L.J. 165, 189 (2017).

117. See José E. Alvarez, *The Use (and Misuse) of European Fundamental Rights Law in Investor-State Dispute Settlement*, in THE IMPACT OF EU LAW ON INTERNATIONAL COMMERCIAL ARBITRATION 519, 524 (Franco Ferrari ed., 2017).

118. *Id.* (emphasis added).

119. *Id.* at 525.

120. *Id.* Examples of ISDS awards where the “fundamental right of property” in the ECHR was mentioned include Total S.A. v. Argentine Republic, ICSID Case No. ARB/04/01, Decision on Liability, ¶ 129 (Dec. 27, 2010), http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C30/DC7833_En.pdf.

political rights that one might expect to be referenced by the term under the ECHR or other human rights instruments.¹²¹ This is not always the case, however. What can be described as broader human rights—in this context, rights beyond private property protection—played a role in a number of other ISDS awards. In *Tulip Real Estate and Development v. Republic of Turkey*, for example, the tribunal referenced, first, article 31(3)(c) of the VCLT and noted in this context that the VCLT’s reference to “relevant rules of international law” covered all sources of international law, including human rights law.¹²² It then concluded that “[p]rovisions in human rights instruments dealing with the right to a fair trial” were relevant to the interpretation of the ICSID Convention and that using them did not add obligations extraneous to the ICSID Convention.¹²³

The door is thus open to *both parties* to ISDS disputes to bring human rights arguments, whether for the investor to support the “property” component of intellectual property or for the state to justify measures to limit the scope of an intellectual property right. *No explicit rule prevents* an ISDS tribunal from considering such arguments, including as a way to “balance” outcomes.¹²⁴ Let us now see what can be done to push the argument one or more steps further.

C. Lessons Drawn from Comparing the Awards

The Canada and Uruguay cases have both been described as efforts by multinational investors to limit the state’s ability to regulate its intellectual property regime by threatening to impose financial “penalties” for making decisions unfavorable to the complainants.¹²⁵ The two cases were ultimately decided on very different bases. In *Eli Lilly v. Canada*, the right of domestic courts to make and change IP law was affirmed by the tribunal but

121. *Al-Warraq v. Republic of Indon.*, Final Award, ¶ 521 (Dec. 15, 2014), <https://www.italaw.com/sites/default/files/case-documents/italaw4164.pdf>.

122. *Tulip Real Estate & Dev. Neth. B.V. v. Republic of Turk.*, ICSID Case No. ARB/11/28, Decision on Annulment, ¶ 87 (Dec. 30, 2015), <https://www.italaw.com/sites/default/files/case-documents/italaw7037.pdf>.

123. *Id.* ¶ 92.

124. The desire of a number of arbitration tribunals to achieve balance in their decisions has been studied by a number of scholars. Puig and Strezhnev have identified frequent attempts to take account of the parties’ unequal access to legal resources, for example. *See, e.g.*, Sergio Puig & Anton Strezhnev, *The David Effect and ISDS*, 28 EUR. J. INT’L L. 731, 733 (2017) (“[E]ven in the absence of formal guidance, investment arbitrators pay attention to the capabilities and potential resource constraints of the parties and behave in a way that is consistent with a preference for rectifying inequalities in litigation resources.”).

125. *Cf. Vadi*, *supra* note 37, at 186 (describing a trend of investors using international arbitration to challenge state regulatory regimes); Ruth L. Okediji, *Is Intellectual Property “Investment”?* *Eli Lilly v. Canada and the International Intellectual Property System*, 35 U. PA. J. INT’L L. 1121, 1123–24 (2014) (arguing that, if *Eli Lilly* succeeds in requiring Canada to change its utility standard, the implications could be “stunning” for intellectual property policy “in all countries”).

considered reviewable—subject in an ISDS context to an egregiousness standard—absent a failure of due process.¹²⁶ As a standard to measure domestic judicial decisions, egregiousness leaves scant room for human rights to enter the debate; it is not easy to see how a human or fundamental rights argument would make an otherwise egregious court decision acceptable. In contrast, the Uruguay Award expressly used the ECtHR’s margin of appreciation notion to recognize the state’s police powers to regulate health, a key public policy area.¹²⁷ It also referred to the right to health enshrined in the WHO’s FCTC. Hence, though both the Canada and Uruguay ISDS awards give a good measure of deference to public policy measures, they do so on very different grounds.¹²⁸

The police powers doctrine used in the Uruguay Award undoubtedly provides states with a fair degree of flexibility for acts by all branches of government.¹²⁹ Put differently, the Award anchors in both the ECtHR’s margin of appreciation doctrine and the FCTC’s guarantee of the right to health, thus giving Uruguay almost invincible regulatory autonomy.¹³⁰ The Tribunal’s normative triangle—with public policy goals in one corner, the possible influence of human rights in another, and the impact on the investor in a third corner—mirrors the Venn diagram in the introduction.¹³¹ It effectuates a “balancing” that offers significant analytical latitude to future ISDS tribunals willing to follow in those footsteps. By the same token, however, because the Tribunal’s framework widens the analytical spotlight, it may also give claimants more weapons, as the frequent use of fundamental rights to property by investors demonstrates.

In contrast, the tribunal in *Eli Lilly v. Canada* required a more focused discussion of the egregiousness of a measure—in this case, a court decision—which limited the scope of the analytical exercise. Though the egregiousness standard may not be crystalline, it provides a high bar for claimants and thus a good degree of predictability for the future—recalling that, beyond the substantive elements of the standard, the evidentiary burden rests with the claimant. For most states, the Canada Award provides a broad shield against ISDS challenges to judicial acts.

Based on this analysis of the tools available to ISDS tribunals, the Article now turns to a discussion of whether the doctrinal bridges built in these two IP-focused awards are sufficiently robust, especially in an EU context in which the need to comply with fundamental EU Charter rights might be invoked.¹³²

126. Common law courts *do* make and change the law; they do not merely interpret it. See *supra* Part II.A.

127. See *supra* Part III.A.

128. See *supra* Parts II and III.

129. See *supra* note 80.

130. See *supra* Part IV.A.

131. See *supra* note **Error! Bookmark not defined.** and accompanying illustration.

132. Charter of Fundamental Rights of the European Union, 2012 O.J. C 326/391.

V. A PATH TOWARD INCLUSIVE ISDS

The prominent cases at the IP/ISDS interface, *Philip Morris v. Uruguay* and *Eli Lilly v. Canada*, reveal different paths that ISDS tribunals can follow in factoring in public interest considerations. *Philip Morris* keeps public interest at bay by imposing the egregiousness test, a very difficult test for investors to meet, while *Eli Lilly* expressly balances investor protection against the public interest reflected in human rights.¹³³ These different outcomes may be due in part to IP's peculiar nature. IP stands, both normatively and doctrinally, with a foot in both private and public law.¹³⁴ It thus differs from the more traditional property, or private law, interests that ISDS aims to protect. IP incorporates public policy objectives such as innovation, access to information, and public health, which are reflected in the mix of rights, limitations and exceptions to the IP rights of authors and inventors.¹³⁵ As a relatively new phenomenon in the ISDS field (few ISDS tribunals have heard IP-related cases), *Eli Lilly v. Canada* and *Philip Morris v. Uruguay* serve as exemplars to probe how ISDS tribunals can deal with investment protection while factoring in broader public interest issues. The stark divergence of approach by the two tribunals illuminates the difficulty faced by ISDS tribunals in this context. Outcomes are difficult, if not impossible, to predict.

In this Part, the Article suggests a structured approach to build a robust interface between ISDS and IP against the backdrop of lessons learned from *Eli Lilly* and *Philip Morris*. Then, we answer the question of whether IP can serve, as the title of the Article suggests, as a beacon in other areas of law where public policy impacts the use of private property rights. The proposed approach could thus serve as a model doctrinal path for ISDS tribunals that wish to factor the public interest into their deliberations. The Article suggests that ISDS interpretive approaches that take account of the public interest can be termed *inclusive* ISDS, as opposed to ISDS focusing strictly on investor protection, which can be termed *exclusive* ISDS.

A. Applicable Parameters

International law does not recognize a supremacy or hierarchy of human or fundamental rights over trade and investment rules—at least not beyond *jus cogens*.¹³⁶ As the International Law Commission noted, there is

133. See *supra* Part IV.C.

134. See *supra* note 20 and accompanying text.

135. See Christophe Geiger, *The Social Function of Intellectual Property Rights, or How Ethics Can Influence the Shape and Use of IP Law* (Max Planck Inst. for Intellectual Prop. & Competition Law, Research Paper No. 13-06, 2013).

136. *Jus cogens*, or “compelling law,” refers to a body of “norms of general international law from which no derogation is possible.” Valentina Vadi, *Jus Cogens in International Investment Law and Arbitration*, 46 NETH. Y.B. INT’L L. 357, 357 (2015). *Jus cogens* can and has been applied by ISDS tribunals. See *id.* at 382 (“[*Jus cogens* . . . can play a legitimising

thus a possibility of “fragmentation” in this context.¹³⁷ Therefore, building an interface between IP and ISDS or a triangular one between IP, ISDS, and human rights requires the application of norms from each sector “horizontally” to another area. As the previous Part demonstrated, beyond the text of IIAs, several key principles of international law permeate ISDS awards in a way that allows norms to cross legal disciplinary borders, particularly (a) the fundamental or human right to property and human rights invoked by respondent states to justify measures designed to implement such rights; (b) the notion of a state’s margin of appreciation “borrowed” from ECtHR jurisprudence; and (c) other basic principles such as the right to a fair trial.

Articles 31 and 32 of the VCLT, also regularly invoked by ISDS tribunals, provide useful interpretive pathways for the texts of IIAs that may supplement or replace the use of the ECtHR jurisprudence and the notions of margin of appreciation and proportionality.¹³⁸ VCLT “general balancing principles (such as transparency, non-discrimination, necessity, and proportionality) [are] used in deciding on whether national restrictions of freedom of trade are necessary for the protection of public interests.”¹³⁹ Not unlike a number of ISDS cases discussed above, WTO dispute settlement reports often limit the scope of their review of WTO Members’ regulatory autonomy on the basis of general balancing principles, not ECtHR decisions. Moreover, such reports arguably have tended to apply a greater degree of deference when the policy area is of great importance, such as public health.¹⁴⁰

One could end the analysis here and suggest that ISDS tribunals already have at their disposal a sufficient doctrinal toolbox composed of (a) the margin of appreciation and proportionality doctrines, which they can anchor in ECtHR jurisprudence, (b) the related police powers doctrine, and (c) the VCLT, which can support balancing efforts based on those doctrines. Is there another, possibly better option?

B. *Express Interfaces*

Including *express interfaces* in the text of IIAs is a common practice in trade law but thus far has not been used much in investment law. This

role in investor-state arbitration, making sure that the most fundamental values of the international community are not violated by either foreign investors or host states . . .”).

137. Int’l Law Comm’n, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, U.N. Doc. A/CN.4/L.682 (Apr. 13, 2006).

138. See *supra* note 56 and accompanying text.

139. Ernst-Ulrich Petersmann, *Human Rights and International Trade Law: Defining and Connecting the Two Fields*, in *Human Rights And International Trade* (Th. Cottier, J. Pauwelyn, and E. Bürgi, eds) 29, 34 (2005).

140. See *id.* and the discussion on TRIPS and public health mentioned *supra* note 50.

Section thus considers how such interfaces function in trade law to determine whether there are obstacles to their use in the ISDS context.

Express interfaces can be seen as filters that limit claims that can pass through the jurisdictional sieve.¹⁴¹ The necessity test is an example of a filter: the tribunal can review a measure and must decide whether it passes the test.¹⁴² An exclusion, in contrast, means that, if the measure is found to be covered by the text of the exclusion clause, the tribunal must decline to review its adequacy.¹⁴³

1. Express Interfaces in Trade Law

IAs often contain express interfaces between trade law and fundamental rights that can take the form of either *specific* or *general* exceptions.

Specific exceptions are those linked to the exercise by the state of a specific policy objective. Such interfaces provide leeway for identified regulatory measures to be taken without a violation of the state's commitments and other trade obligations. Specific interfaces thus usually apply to named policy areas such as labor, environment, and sustainable development. Exceptions of this type are contained, for example, in the majority of post-WTO (1995) trade agreements negotiated by the EU.¹⁴⁴ They often take the form of a list of international conventions setting out applicable standards that a member state (or the EU itself) has the right to implement.¹⁴⁵ Another option is to provide safeguards for labor, environment, and sustainable development that put these interests expressly above that of trade liberalization. For example, under article 23.2 of the CETA, the parties "seek to ensure those laws and policies provide for and encourage high levels of labour protection and shall strive to continue to

141. See Lise Johnson et al., *International Investments Agreements, 2014: A Review of Trends and New Approaches*, 2016 Y.B. INT'L INV. L. & POL'Y 15, 47.

142. See *id.* ("Filter mechanisms limit the issues that tribunals may review, at least in the first instance; however, if the designated body or committee is unable to resolve the issue, it often reverts back to the tribunal for determination.").

143. See *id.* (Exclusions go "a step further by excluding certain types of measures from review by arbitral tribunals altogether. These ISDS exclusions differ from filter mechanisms in that they preclude certain types of measures or actions from ever being reviewed by the tribunal.").

144. CETA, *supra* note 23; Free Trade Agreement Between the European Union and the Republic of Singapore, *supra* note 23; Agreement Establishing an Association Between the European Union and Its Member States, on the One Hand, and Central America on the Other, *supra* note 23; Trade Agreement Between the European Union and Its Member States, of the One Part, and Colombia and Peru, of the Other Part, *supra* note 23; Free Trade Agreement Between the European Union and Its Member States, of the One Part, and the Republic of Korea, of the Other Part, *supra* note 23.

145. See, e.g., Trade Agreement Between the European Union and Its Member States, of the One Part, and Colombia and Peru, of the Other Part, *supra* note 23.

improve such laws and policies with the goal of providing high levels of labour protection.”¹⁴⁶

General exceptions, in contrast, aim to preserve a state’s “right to regulate.”¹⁴⁷ This “right to regulate” permits a departure from specific investment commitments assumed by a state. In a functioning democracy, it could also be defined as “an affirmation of states’ authority to act as sovereigns on behalf of the will of the people.”¹⁴⁸ Whichever definition is accepted, one can legitimately posit that the right to regulate cannot be merely “what’s left” after a chunk of sovereignty is given up by a state in an IIA, as this would place trade liberalization commitments above other international legal obligations. Hence, the right to regulate is best seen as a principle ensuring that restrictions on state sovereignty are not interpreted as interfering with key areas of public policy.¹⁴⁹

The most important *general* exceptions are those contained in article XX of the General Agreement on Tariffs and Trade (the “GATT”) and article XIV of the General Agreement on Trade in Services (the “GATS”). The latter targets, *inter alia*, measures “*necessary* to protect public morals or to maintain public order” and “*necessary* to protect human . . . life or health.”¹⁵⁰ They are thus subject to what is usually referred to as a necessity test.¹⁵¹ This test posits that trade liberalization commitments should trump other policy areas *but for* a demonstrable necessity (however that term is then defined in context) to adopt certain regulatory measures.¹⁵²

There are in fact several versions of this necessity test in WTO Agreements.¹⁵³ A classic exposition of one of the principal necessity tests is

146. CETA, *supra* note 23, art. 23.2; *see also* Free Trade Agreement Between the European Union and the Republic of Singapore, *supra* note 23, art. 13.2, ¶ 2; Trade Agreement Between the European Union and Its Member States, of the One Part, and Colombia and Peru, of the Other Part, *supra* note 23, art. 268.

147. AIKATERINI TITI, THE RIGHT TO REGULATE IN INTERNATIONAL INVESTMENT LAW 52 (2014) (summarizing the “right to regulate”); *id.* at 169 (“Another way of incorporating an express right to regulate in an IIA is to draft a general regulatory clause applicable to the entire treaty.”).

148. LONE WANDHAL MOUYAL, INTERNATIONAL INVESTMENT LAW AND THE RIGHT TO REGULATE: A HUMAN RIGHTS PERSPECTIVE 8 (2016).

149. *See* Nicholas DiMascio & Joost Pauwelyn, *Nondiscrimination in Trade and Investment Treaties: Worlds Apart or Two Sides of the Same Coin?*, 102 AM. J. INT’L L. 48, 58–79 (2008) (comparing deference in trade and investment law toward the right to regulate).

150. General Agreement on Tariffs and Trade art. XX, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194; General Agreement on Trade in Services, art. XIV, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, annex 1B, 1869 U.N.T.S. 183 (emphasis added).

151. *See* “Necessity Tests” in the WTO, *supra* note 111.

152. *See* Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46 VAND. J. TRANSNAT’L L. 1149, 1206–07 (2013).

153. *See* Working Party on Domestic Regulation, *supra* note 111, ¶ 4 (referring to necessity tests (plural) and noting that “in spite of similarities between the wording of necessity tests in different WTO provisions, an interpretation developed in the context of one

contained in a report by the WTO Appellate Body, which explains that the following factors are relevant to test: (i) the degree of contribution made by the measure to the legitimate objective at issue; (ii) the trade-restrictiveness of the measure; and (iii) the nature of the risks at issue and the gravity of consequences that would arise from non-fulfillment of the objective.¹⁵⁴ It adds, “[i]n most cases, a comparison of the challenged measure and possible alternative measures should be undertaken.”¹⁵⁵ This can be a very heavy burden to bear for a state to justify a measure, depending on (a) which party has the burden of proving the degree of contribution and trade-restrictiveness of the impugned measure and the existence of alternative measures and (b) how “necessary” the measure is, as WTO cases reveal falling within broad range, the bookends of which are indispensability and just making a contribution respectively.¹⁵⁶

Similar general exceptions are found in a number of IIAs.¹⁵⁷ General interfaces do not prescribe the type of measure that can be taken by the state, but they do provide a standard against which they can be measured.¹⁵⁸ A normative view of the right to regulate could be used to support the argument that the more a measure targets an area of significant public interest (such as implementing human rights obligations), the easier it becomes to justify its necessity before a trade dispute settlement tribunal.

Actual recourse to either specific or general interfaces not specific to IP to justify a *prima facie* violation of an IP-related commitment contained in a trade agreement is infrequent for two interrelated reasons. First, there is a self-evident reason why specific interfaces *not specific to IP* are not used in IP-related cases. There are specific ones that would usually be applied first as the more targeted *lex specialis*.¹⁵⁹ Second, *lex specialis* also explains why general exceptions are not typically invoked in trade disputes concerning IP.

case cannot be automatically transposable to other provisions. Each provision would have to be interpreted in the light of the object and purpose of the Agreement of which it is part.”)

154. Appellate Body Report, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶ 322, WTO Doc. WT/DS381/AB/R (adopted May 16, 2012).

155. *Id.*

156. See Robert Stumberg, *Safeguards for Tobacco Control: Options for the TPPA*, 39 AM. J.L. & MED. 382, 416 (2013); Eric M. Solovy & Pavan S. Krishnamurthy, *TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines*, 50 GEO. WASH. INT'L L. REV. 69, 109 (2017) (“Article 27.2 [of the TRIPS Agreement] contains a necessity test, which creates a significant burden on the Member taking advantage of this exception.”).

157. See Julien Chaisse, *Exploring the Confines of International Investment and Domestic Health Protections—Is A General Exceptions Clause A Forced Perspective?*, 39 AM. J.L. & MED. 332, 336–41 (2013).

158. See *id.* at 333.

159. *Lex specialis* is a principle of legal text interpretation according to which a law governing a specific subject matter overrides a law that only governs general matters (or *lex generalis*). The Article discusses the interfaces specific to IP below. See *infra* Part V.B. See

The Agreement on Trade-Related Aspects of Intellectual Property (the “TRIPS”) itself contains two interfaces with fundamental rights. First, TRIPS provides its own “general” exception: “Members may . . . adopt measures *necessary* to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”¹⁶⁰ Second, TRIPS contains a specific exception allowing WTO Members to exclude from patentability “the prevention within their territory of the commercial exploitation of which is *necessary* to protect *ordre public* or morality, including to protect human, animal or plant life or health.”¹⁶¹ That second interface is also found in NAFTA.¹⁶² Both TRIPS exceptions use the term “necessary,” a version of the above-mentioned necessity test.¹⁶³

There are alternatives to the necessity test(s). Recall, first, that trade law includes a range of definitions of necessity that varies from being indispensable to simple evidence that a measure is “making a contribution” to the policy objective pursued by the authority that adopted the measure.¹⁶⁴ Tribunals can even go below this range. Arguably, the lowest possible standard is that of rational connection: that is, merely proving that the measure is *rationally connected* to its stated objective would be sufficient to excuse a violation (or a trade obligation or, in the case of an ISDS proceeding, an expropriation or FET violation).¹⁶⁵ The test was used in a negative context by the WTO Appellate Body to explain that a measure that bears “no rational connection to the objective” would be arbitrary and unjustifiable under GATT article XX, which governs general exceptions.¹⁶⁶ At that point, any measure short of an arbitrary one passes the test.

We see something like this highly flexible approach in the 2018 panel report on the WTO dispute between Australia, on the one hand, and Cuba, the Dominican Republic, Honduras, and Indonesia, on the other hand. This dispute addressed whether Australia’s ban on figurative trademarks and

also GRAEME DINWOODIE & ROCHELLE DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME 186 (2012).

160. TRIPS Agreement, *supra* note 50, art. 8.1. This text was not applicable in the Canada dispute because it is not contained in NAFTA, the IP chapter of which otherwise mirrors TRIPS to a large extent. See Shira Perlmutter, *Future Directions in International Copyright*, 16 CARDOZO ARTS & ENT. L.J. 369, 374 (1998) (“The NAFTA intellectual property provisions were negotiated based on an early draft of the TRIPS Agreement, so the two agreements bear a striking resemblance to each other.”)

161. TRIPS Agreement, *supra* note 50, art. 27.2.

162. NAFTA, *supra* note 12, art. 1709, ¶ 2.

163. See Frankel & Gervais, *supra* note 152, at 1205.

164. See Stumberg *supra* note 156 at 408–9.

165. See Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 227, WTO Doc. WT/DS332/AB/R (adopted Dec. 3, 2007). The Appellate Body did not say, however, that this was the only test to determine compatibility with Art. XX.

166. *Id.*

severe restrictions on the use of word marks on cigarette packs—known as “plain packaging” measures—violated article 20 of the TRIPS Agreement prohibition on imposing “special requirements” that “encumber the use” of marks.¹⁶⁷ The Australian measure plainly did. In that case, the panel refused to exclude the possibility that a rational connection might be ample reason to justify the prohibited encumbrance.¹⁶⁸ As noted above, applying a rational connection test is probably the most generous way to provide regulatory flexibility, one which parallels in a positive way the negative test of egregiousness used in the Canada Award.¹⁶⁹ A state authority can, in almost every case, demonstrate a rational connection between a measure and its underlying objective and, hence, any measure short of a purely arbitrary one would pass the test.¹⁷⁰

Consider, in addition, then, that in *Australia – Certain Measures Concerning Trademarks, Geographical Indications And Other Plain Packaging Requirements Applicable To Tobacco Products And Packaging*, the panel imposed on the complainants the burden of proving the absence of justification.¹⁷¹ This means that the case was, for all practical purposes, unwinnable. By imposing a burden on complainants to prove an absence of rational connection—despite acknowledging that the challenged measures were *a priori* prohibited by article 20 but for the justification test—the panel made it all but certain that Australia would win no matter what the evidence showed. The Australia panel report may be overturned or its application and practical import otherwise highly limited on appeal.¹⁷²

2. Application to ISDS

Can language used to formulate exceptions to trade rules, whether IP-specific or not, be used to craft an ISDS/IP interface? Several IIAs already contain sector-specific exclusions, some of which apply to both trade and investment using the same language. For example, the FTA between the EU and Singapore states that “it is inappropriate to encourage trade or investment by weakening or reducing the protections afforded in domestic labour and environment laws.”¹⁷³ The Association Agreement between the

167. See generally WTO Plain Packaging Report, *supra* note 108.

168. See *id.* at 729.

169. See *supra* note 104 and accompanying text.

170. See Stumberg, *supra* note 156.

171. See WTO Plain Packaging Report, *supra* note 108, ¶¶ 7.2169–7.2171, 7.2331. (establishing, at 729, that “unjustifiable discrimination” consists of the absence of justification, and holding at 679–80, that the complainant bears the “initial burden of proof” for establishing “unjustifiable discrimination”).

172. See Notification of an Appeal by Honduras, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435/23 (July 25, 2018).

173. See also Free Trade Agreement Between the European Union and the Republic of Singapore, *supra* note 23, art. 12.1, ¶ 3; Agreement Establishing an Association Between the

EU and Central America goes a step further in its article 291(2), which requires parties “not to waive or derogate from, or offer to waive or derogate from, its labour or environmental legislation in a manner affecting trade or as an encouragement for the establishment.”¹⁷⁴ In addition, paragraph 3 demands that parties “shall not fail to effectively enforce its labour and environmental legislation in a manner affecting trade or investment between the Parties.”¹⁷⁵

To port this type of exclusion to the ISDS/IP context, one must start from the premise that, because the jurisdiction of ISDS tribunals is tied to the text of the IIA, language matters enormously.¹⁷⁶ Hence, a provision recognizing a state’s “right to regulate” its IP policy, for example, would be significantly constrained by attaching a necessity test or language that allows state regulation, “provided it is consistent with other provisions of this agreement,” such as that found in TRIPS article 8.1.¹⁷⁷ Second, a “right to regulate” IP taking the form of a general “public interest” clause would facially offer broad flexibility, but it could be counterproductive if limited to specific public interest sectors, such as public health.¹⁷⁸ Recall the question posed in the introduction: if a state were to add a sector-specific “right to regulate” clause (say, for environmental protection or public health) to an IIA, would this not prompt an investor to argue both that earlier IIAs without this clause do not, *a contrario*, provide the necessary regulatory flexibility and that new IIAs do not provide such flexibility in other, unnamed sectors?¹⁷⁹ This concern is real: intellectual property—and the human rights that support some claims to protect or limit IP—is typically not named in express interfaces in the IP chapters of recent EU IIAs. A limited right to regulate specific to other sectors, such as the protection of the environment, might thus deepen the legal morass for IP because IP sits outside those IIAs’ sector-specific “right to regulate” clauses.

There is, as mentioned above, at least *one* ISDS/IP specific interface: the one contained in the CETA.¹⁸⁰ It is best seen as an exclusion rather than as a filter in that it is meant to exclude an evaluation by an ISDS tribunal of substantive intellectual property rules.¹⁸¹ Both the substance and the timing of the exclusion—occurring after the finalization of the main CETA text but

European Union and Its Member States, on the One Hand, and Central America on the Other, *supra* note 23, art. 291, ¶ 1.

174. Agreement Establishing an Association Between Central America, on the One Hand, and the European Union and Its Member States, of the Other, art 291(2), June 29, 2012, O.J.L. 346 15.12.2012.

175. *Id.* Art. 291(3), ¶ 1

176. *See* TITI, *supra* note 147, at 111–15.

177. *See id.*

178. *See id.* at 99–103.

179. *See id.* at 294–95.

180. CETA, *supra* note 23.

181. *See supra* note 141 and accompanying text.

as *Eli Lilly v. Canada* was proceeding—suggest that it was informed by the filing of the case against Canada by Eli Lilly.¹⁸² The CETA negotiators added to this declaration that investor state dispute settlement tribunals “are not an appeal mechanism for the decisions of domestic courts” and that “the domestic courts of each Party are responsible for the determination of the existence and validity of intellectual property rights.”¹⁸³ CETA also reasserts that “each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement regarding intellectual property within their own legal system and practice.”¹⁸⁴ This exclusionary clause was described as the beginning of a new trend in international investment law.¹⁸⁵ Indeed, the exclusion is mirrored in a more recent text, and an important one: the EU draft of the Transatlantic Trade and Investment Partnership (the “TTIP”).¹⁸⁶

The CETA precedent suggests that express exclusions of a range of IP-related regulatory measures in future IIAs are both possible and desirable. Indeed, CETA could serve as a model due to its exclusion of judicial or other measures concerning the “existence and validity of intellectual property rights.”¹⁸⁷ This Article supports this type of exclusion even though, as noted above, they must be crafted carefully to avoid *a contrario* inclusions of certain measures in the scope of ISDS review, whether in IP or other regulatory areas.¹⁸⁸

182. See *supra* note 24.

183. CETA, *supra* note 23, annex 8-D. This CETA exclusion may never enter into force for two reasons. First, in October 2016, after opposition from, *inter alia*, Wallonia (the French-speaking part of Belgium), it was reportedly agreed that the ISDS provisions of CETA would be submitted to the ECJ to determine their compatibility with EU law, in particular the ability of EU member states to implement and enforce public policy and fundamental rights. See Glyn Moody, *EU-Canada Trade Deal Dodges Belgian Veto for Now, but Faces Multiple Legal Challenges*, TECHDIRT (Oct. 28, 2016), <https://www.techdirt.com/articles/20161027/09490835898/eu-canada-trade-deal-dodges-belgian-veto-now-faces-multiple-legal-challenges.shtml>. Second, unanimous support from all 28 EU member states is required to ratify CETA, and in June 2018, Italy said it would oppose the agreement. See Francesca Landini, *Italy Won't Ratify EU Free-Trade Deal with Canada: Farm Minister*, REUTERS (June 24, 2018 8:55 AM), <https://www.reuters.com/article/us-italy-minister-canada-trade/italy-wont-ratify-eu-free-trade-deal-with-canada-farm-minister-idUSKBN1JA0TR>.

184. CETA, *supra* note 23, annex 8-D; see also Vadi, *supra* note 37, at 191.

185. See Bryan Mercurio, *Safeguarding Public Welfare? Intellectual Property Rights, Health, and the Evolution of Treaty Drafting in International Investment Agreements*, 6 J INT'L DIS. SETL'T 252, 260-1 (2015).

186. *Proposal for Investment Protection and Resolution of Investment Disputes*, Eur. Union (Nov. 12, 2015), http://trade.ec.europa.eu/doclib/docs/2015/Nov/tradoc_153955.pdf (“For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation.”).

187. CETA, *supra* note 23, annex 8-D.

188. See *supra* note 179 and accompanying text.

What if a state wished to go further and design a broader exclusion? Human rights arguments could play a role in that they constitute a good example of a key public policy area in which a state may be expected to act. As noted above, nothing prohibits ISDS tribunals from considering fundamental or human rights norms by the text of IIAs.¹⁸⁹ This lack of prohibition, however, is unlikely to be good enough in this context. How can one ensure that these norms are fully considered in interpreting the scope and depth of the regulatory leeway used by the state? One way to make a human rights argument effective would be to *require that interpretation of the IIAs should not contravene an applicable human rights obligation*.¹⁹⁰ Interpreting the text of a measure challenged by an investor—whether as indirect expropriation or a FET violation—can be directly linked to the state’s implementation of its human rights obligations or even of a key public policy objective. An interpretive rule to that effect could be added to IIAs in addition to specific exclusions.

Following this suggestion would mean that when a *measure challenged* under the notions of indirect expropriation or FET *can be directly reconciled with a state’s regulatory autonomy in an area of vital socioeconomic importance and/or a state’s implementation of its human rights obligations*, then that measure should be presumed to be valid unless it can be shown that it was adopted to circumvent the underlying obligation.¹⁹¹ The proposed approach of applying the anti-circumvention test (well-known in trade law) changes the respondent state’s burden to rely on general notions such as the police powers doctrine, on which there is no consensus among ISDS tribunals. It also offers a clearer analytical path, namely asking, once it has been determined that the policy is in an area of vital socioeconomic importance, whether it was meant to circumvent investment protection obligations.¹⁹² This would have a potent effect that is “normatively stabilizing at a time when there are few agreed answers about

189. See *supra* Part IV.B.

190. This is in line with Professor Wai’s suggestion that “an investment panel should not demand unduly high standards of compensation for regulatory or other legal reform directed towards the achievement of international human rights.” Wai, *supra* note 22, at 71.

191. The phrase “area of vital socio-economic importance” is taken from the TRIPS Agreement, *supra* note 50, art. 8.1.

192. On the application of the anti-circumvention test in trade law, see Diane A. Desierto, *Public Policy in International Investment and Trade Law: Community Expectations and Functional Decision-Making*, 26 FLA. J. INTL. L. 51, 118 (2014):

WTO law purposely delineates between a State’s justifiable exercise of regulatory freedom, from protectionist measures designed to circumvent commitments under the WTO Agreements. These trade agreements purposely accept that a margin of domestic regulatory freedom must continue to be maintained both as a matter of economic efficiency [. . .] as well as to build in a “safety-valve” precaution against unforeseeable contingencies that could disrupt the anticipated or forecasted terms of trade.

the costs and benefits of globalization or the ideal shape of global economic governance in relationship to differing domestic policy paths.”¹⁹³

The suggested approach is not the same as the application of the ECtHR’s margin of appreciation doctrine. It may be supported as an offshoot of the doctrine in that it situates a state’s implementation of its IP policy within a “margin of appreciation” if it passes the above-mentioned contravention test. The approach also does not resemble current trade law, either in the form of the necessity test or the justification test.¹⁹⁴ Rather, it is an explicit presumption of validity in case a measure can be directly reconciled with a state’s regulatory autonomy in an area of vital socioeconomic importance and/or a state’s implementation of its human rights obligations. The mobilizing principle, the Article suggests, should not be one of unimpeded and unaccountable state autonomy. A balance must be found between regulatory autonomy and protection of foreign investors against regulatory measures amounting to an expropriation. The proposed approach would both simplify and make more predictable the outcome of cases such as the two awards reviewed in this Article. It offers tribunals a clearer analytical path that does not rely on fuzzy norms such as egregiousness (which, in any event, is mostly limited to court decisions) or the police powers doctrine. ISDS clauses have legitimate purposes, among them strengthening the rule of law and deterring foreign governments from imposing discriminatory or abusive requirements.¹⁹⁵ The suggested approach, therefore, is not to eliminate ISDS entirely but rather to apply the proper test when ISDS is used to challenge regulatory measures and to carve out policy areas in which ISDS should simply not venture. These carve-outs are required in areas where public interest considerations are likely to outweigh investment or property protection, bearing in mind that, in most cases, the investor still has access to domestic courts.

Such a debate could be had in the context of the preparatory work for the Multilateral Investment Court (the “MIC”) proposed by the EU, as the creation of a new forum provides a significant opportunity to ameliorate the current system.¹⁹⁶ The EU’s commitment to the establishment of this court

193. Robert Howse, *The World Trade Organization 20 Years on: Global Governance by Judiciary*, 27 EUR. J. INT’L L. 9, 76 (2016).

194. On the necessity test, see Solovy & Krishnamurthy, *supra* note 153. On the justification test, see *supra* note 168 and accompanying text.

195. See Ai-Li Chiong-Martinson, *Environmental Regulations and the Trans-Pacific Partnership: Using Investor-State Dispute Settlement to Strengthen Environmental Law*, 7 SEATTLE J. ENVTL. L. 76, 90 (2017) (describing the purpose of ISDS in the TPP).

196. See *Questionnaire on Options for a Multilateral Reform of Investment Dispute Resolution*, EUR. COMM’N: CONSULTATIONS, http://trade.ec.europa.eu/consultations/index.cfm?consul_id=233 (last updated Nov. 17, 2018); see also Ben Stanford et al., *TTIP Negotiations in the Shadow of Human Rights and Democratic Values*, 27 INT’L COMPANY & COM. L. REV. 316, 319 (2016) (“In November 2015, following an extremely critical public consultation into the ISDS model which is commonly used in similar but smaller-scale trade agreements, the Commission revealed that it would instead pursue proposals for an investment

was reaffirmed in its Economic Partnership Agreement with Japan.¹⁹⁷ If one agrees that the new court's credibility depends at least in part on whether its mandate is based on appropriate interpretive principles, then a principle such as the one mentioned in the previous paragraphs could be included in the new court's statute. This is compatible with the EU legal order in which the Charter of Fundamental Rights stands above trade and investment treaty rules.¹⁹⁸ Including the principle in the new court's statute would mean that states that agree to its jurisdiction would agree to be bound by it, as they agree to be bound by UNCITRAL or ICSID rules.¹⁹⁹

The EU is uniquely situated to effectuate reforms of ISDS: it is a major player; it wants to keep ISDS, but it has seen a number of recent cases where the "ability of the [EU member] States to regulate in the public interest" was jeopardized, including a case about Germany's decision to phase out nuclear power.²⁰⁰ The EU can count on other states, both developed (for example, Canada) and emerging (for example, India), to move this debate forward.²⁰¹

Naturally, while the proposed MIC offers an institutional approach to reform ISDS, it is but one of the ways forward. Any ISDS tribunal could adopt the approach suggested in this Article, if it found it useful in its deliberations.

court to be included in the TTIP.") (notes omitted). Notably, observers have criticized the proposal for the high administrative costs it would entail. *See* Jonathan Klett, *National Interest vs. Foreign Investment-Protecting Parties Through ISDS*, 25 TUL. J. INT'L & COMP. L. 213, 236 (2016). It is unclear whether the high costs of proceedings, as things stand now, would in fact be a major obstacle.

197. *See The EU-Japan Agreement Explained*, EUR. COMM'N, <http://ec.europa.eu/trade/policy/in-focus/eu-japan-economic-partnership-agreement/agreement-explained/> (last updated Feb. 06, 2018) ("The EU is committed to integrating its new approach to investment protection and dispute resolution – an investment court system – in *all* its new trade agreements. . . . [I]ncluding an investment court system in its trade agreements will help the EU build support for a public, international investment court with: highly qualified judges [and] transparent working methods[.] An international investment court would replace the current panoply of private arbitration arrangements contained in thousands of bilateral trade deals around the world.") (emphasis in original).

198. *See* Svetlana Yakovleva & Kristina Irion, *The Best of Both Worlds? Free Trade in Services and EU Law on Privacy and Data Protection*, 2 EUR. DATA PROTECTION L. REV. 191, 200–01 (2016) ("In the hierarchy of EU law, [trade agreements are] situated in between EU primary law, such as the Charter and the founding Treaties, and EU secondary law, such as EU regulations, directives and decisions. This approach is based on the principle of the autonomy of the EU legal order vis-a vis international law, which should respect the constitutional values . . .").

199. *See* UNCITRAL, *supra* note 40, at art. 1.3(a) (stating that the arbitral rules of UNCITRAL are binding upon the parties unless otherwise stated by the treaty).

200. Clémentine Baldon & Adèle Azzi, *The New Investment Protection Policy of the EU in the Free-Trade Treaties (CETA, TTIP. . .): New Risks for the EU?*, 2018 INT'L BUS. L.J. 3, 5.

201. *See* Roberts, *supra* note 33, at 4, 6.

VI. CONCLUSION

Eli Lilly lost the gamble it played when filing its C\$500 million investor-state dispute against Canada.²⁰² Philip Morris similarly played and lost against the Oriental Republic of Uruguay. Yet, the cases reviewed and compared in this Article sounded alarm bells among intellectual property scholars. This Article briefly reviewed both cases to explain why IP scholars were taken aback. The Article then reviewed the mechanisms used in the two awards to bridge normative and doctrinal gaps between intellectual property and investment. IP stands at the confluence of public and private law streams. Finding a better way for ISDS tribunals to factor in the broader public interest reflected in IP legislation and jurisprudence is a challenge. The Article, after a review of proposed models to bridge such gap in trade law, general public law, and private law, provides guidance to ISDS tribunals in suggesting new possible approaches and a concrete interpretive principle to minimize conflicts between IP, the broader public interest, and ISDS.

202. Or did it? Eli Lilly undeniably lost the ISDS case, *see* The Canada Award, *supra* note 4, ¶¶ 469–71, but then in a strange twist, the Supreme Court of Canada, having read the Eli Lilly v. Canada ISDS award, threw the promise doctrine out of Canadian patent law in *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 (Can.). The Eli Lilly v. Canada ISDS case is acknowledged in the Canadian Supreme Court opinion's first footnote.