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Investor-State Dispute Settlement: Human Rights and Regulatory Lessons from "Lilly v. Canada"

Daniel J. Gervais

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Investor-State Dispute Settlement: Human Rights and Regulatory Lessons from *Lilly v. Canada*

Daniel J. Gervais*

*The triangular interface between trade, intellectual property (IP) and human rights has yet to be fully formed, both doctrinally and normatively. Adding investor-state dispute settlement (ISDS) to the mix increases the complexity of the equations to solve. Two resultant issues are explored in this Article. First, the Article considers ways in which broader public policy objectives—in particular, the protection of human rights—can and should be factored into determinations of whether a state's action is compatible with its trade obligations and commitments in the state-to-state dispute settlement context. Second, the Article examines whether doctrinal tools used in state-to-state, trade-dispute settlement to make room for public interest considerations port to the investment/ISDS context. The Article uses the recent *Lilly v. Canada* case as backdrop to illustrate the points made. The *Lilly* case dealt with an ISDS complaint filed after the revocation of two Canadian patents on pharmaceutical products. The Article approaches the above-mentioned triangular interface from a policy perspective that factors in innovation and investment protection, but also public health, a policy area supported by a human right (to health), and in which states need regulatory autonomy.*

* Ph.D., MAE, Professor of Law, Vanderbilt University Law School. Disclaimer: the Author was an expert retained by Canada in the *Lilly* arbitration. The views expressed are the Author's own, however. The Author is grateful to participants at the "IP and Human Rights" symposium at UC Irvine School of Law (October 2016); participants in the Institute of European Studies of Macau "IP as Property" seminar (November 2016); and attendees at my public lecture on the *Lilly* case at the Centre for International Intellectual Property Studies in Strasbourg (January 10, 2017) for their useful comments on an early draft of this Article. Thanks also to Jose Alvarez, Joel Trachtman and Susy Frankel. All errors are entirely mine.

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INTRODUCTION

Investor-State Dispute Settlement (ISDS) is a controversial topic. Its foray into the area of intellectual property (IP) has increased the scope and depth of the controversy. This incursion in the field of IP is the topic of this Article, which explores the resulting controversy using an actual case—perhaps the most prominent one to date—namely the complaint filed by Eli Lilly against Canada

under NAFTA Chapter 11.¹ The Article uses this recently decided case to shed light on what could go wrong in the ISDS and intellectual property interface.²

The Article considers the issues using two lenses. First, the Article uses a human right lens, echoing Philip Alston's sentiment that the "relationship between human rights and trade is one of the central issues confronting international lawyers at the beginning of the twenty-first century. . . ."³ Second, the Article uses a regulatory lens to see how ISDS might impact a state's ability to regulate not just human rights, but also other key areas of public policy.

Let us first situate ISDS in its international legal context. The nineteenth and twentieth centuries saw international law progress along two axes. First, maintaining state sovereignty as a fundamental tenet, international law began to function in a more "business-like" fashion, getting states to make bargains in which they would limit their sovereign powers in exchange for similar concessions by other states.⁴ At the same time, however, international lawyers and scholars gradually devised "a programme for the economic and material betterment of the human race."⁵ This effort was eventually "re-cast into one of global freedom of economic intercourse on a liberal capitalist basis."⁶

The sovereignty of states remained a cornerstone of the international law edifice erected during this period. This is reflected, *inter alia*, in the *Lotus* doctrine, according to which all that is not prohibited by a rule of international law is permitted.⁷ Similarly the International Court of Justice stated, in *Military and Paramilitary Activities in and Against Nicaragua (Nicaragua v. United States)*, that "in international law there are no rules, other than such rules as may be accepted by the State concerned, by treaty or otherwise. . . ."⁸ The theoretical scope of a state's sovereignty thus depends on what is prohibited by a treaty or other source of international law. A realist might add that, in practice, this also depends on who decides what the law is, whether it was violated, and whether those decisions are enforceable.

The role that state sovereignty should play is still a matter of much discussion in international law, and the *Lotus* doctrine's preeminence regularly comes under

1. North American Free Trade Agreement, Can.-Mex.-U.S., Dec. 17, 1992, 107 Stat. 2057, 32 I.L.M. 605 [hereinafter NAFTA]. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Judgment (Mar. 17, 2017).

2. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Final Award (Mar. 16, 2017), http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf [<https://perma.cc/UJ6Q-ZXSK>] [hereinafter *Eli Lilly & Co. v. Canada*, Final Award].

3. Philip Alston, *Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann*, 13 EUR. J. INT'L L. 815, 818 (2002).

4. Stephen C. Neff, *A Short History of International Law*, in INTERNATIONAL LAW 31, 37-42 (Malcolm D. Evans ed., 2d ed. 2006).

5. *Id.* at 42.

6. *Id.*

7. *S.S. Lotus (Fr. v. Turk.)*, Judgment, 1927 P.C.I.J. (ser. A) No. 10, at 18-19 (Sept. 7).

8. *Military and Paramilitary Activities in and Against Nicaragua (Nicar. v. U.S.)*, Judgment, 1986 I.C.J. Rep. 14, ¶ 269 (Jun. 27).

fire. In his opinion in the *Fisheries* case (*United Kingdom v. Norway*), for example, Judge Alvarez of the International Court of Justice wrote that the principle reflected in the doctrine “formerly correct, in the days of absolute sovereignty, is no longer so at the present day: the sovereignty of States is henceforth limited not only by the rights of other States but also by other factors . . . which make up what is called the new international law,” including the Charter of the United Nations and resolutions passed by the Assembly of the United Nations.⁹

The *Lotus* doctrine certainly does not provide a full normative key to understanding the nature of the Westphalian order.¹⁰ For instance, it does not explain whether a state is “naturally” sovereign because it sits at the top of the international legal hierarchy or is a mere organ—and thus also a subject—of international law. If the latter is true, then an international court can “naturally” be called upon to decide if a state is acting within the bounds of the law. If one considers the former option to be correct, then states must *willingly* accept the jurisdiction of an international court and submit to its findings.¹¹

One way to frame this debate more productively is to consider that states have sovereignty, but that the exercise of sovereignty can come with obligations. A key question is then the enforcement of such obligations by, or on behalf of a supranational institution, such as the United Nations (UN). The question whether states have willingly accepted the jurisdiction or because one considers this supranational institution as having a natural role in doing so is pushed towards the background of the doctrinal picture.¹² Hans Kelsen and his former student, Sir Hersch Lauterpacht, argued that the United Nations system should include a court with *compulsory jurisdiction* with a limited mandate to maintain peace.¹³ Kelsen first voiced this idea in 1934.¹⁴ In the end, however, the Kelsenian dream would not fully materialize, as the International Court of Justice’s jurisdiction is not the “Big Court”

9. *Fisheries (U.K. v. Nor.)*, Judgment, 1951 I.C.J. Rep. 116, at 152 (Dec. 18).

10. The Westphalian order or system emerged after the Peace of Westphalia (1648). It is based on the principle of territorial integrity of sovereign states, which is seen as the primary institutional agent of international law and relations. See Joanna Kulesza & Roy Balleste, *Signs and Portents in Cyberspace: The Rise of Jus Internet as a New Order in International Law*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1311, 1317–18 (2013).

11. Mario Patrono, *Hans Kelsen: A Peacemaker Through Law*, 45 VICTORIA U. WELLINGTON L. REV. 647, 649 (2014) (“According to Kelsen, the sovereignty becomes an attribute of the state as the supreme legal order, that is, the sole legal order that doesn’t derive its validity from a superior legal order, but enjoys its own independent validity. . . . If we admit the supremacy of international law over domestic law, the ‘sovereignty’ would fade because the state, in Kelsen’s view, would become a mere organ of the international legal community.”).

12. See Roger Myers, *A New Remedy for Northern Ireland: The Case for United Nations Peacekeeping Intervention in an Internal Conflict*, 11 N.Y.L. SCH. J. INT’L & COMP. L. 1, 69–74 (1990) (discussing the conditions for armed UN interventions in its member States).

13. Patrono, *supra* note 11, at 651. Lauterpacht became a member of the United Nations’s International Law Commission from 1952 to 1954 and a Judge of the International Court of Justice from 1955 to 1960.

14. HANS KELSEN, *THE LEGAL PROCESS AND INTERNATIONAL ORDER* 19 (1934) (“[T]he greater the authority of an international court having jurisdiction over all disputes, the less necessary it is to empower it expressly to apply any other than the positive law.”).

he envisaged.¹⁵ For one thing, its jurisdiction is not compulsory for United Nations members.¹⁶

A more powerful form of enforcement would indeed emerge—not in the field of war and peace, but rather in the world of trade law. This is not altogether a huge surprise. Indeed, the impulse to limit state sovereignty to prevent states from behaving badly extended early on into the economic realm. Trade rules are viewed in this context as a means to ensure that states, like Ulysses, limit their sovereignty to withhold “protectionist sirens.”¹⁷ Adding to those normative foundations, the economist Friedrich Hayek suggested that free trade, viewed as a limit to the power of states, was one of the best safeguards of peace.¹⁸ In his mind, this included limits on the controls that a state might compose on trade and the economy more broadly.¹⁹ To that extent, human rights and trade could be said to share some high-level objectives, and trade and foreign investment can be said to work hand-in-hand with development.²⁰

International economic liberalization and the enforcement of decisions against states that fail to live up to their liberalization obligations can be traced along three inflection points. The first was the failed attempt to establish an International Trade Organization (ITO) at the Havana conference in 1948, coupled with the successful establishment of the Bretton Woods institutional framework.²¹ Although the ITO negotiations failed to establish a new intergovernmental institution, they did yield

15. Grant Gilmore, *International Court of Justice*, 55 YALE L.J. 1049, 1064 (1946).

16. States adhering to the Court *may* recognize the Court’s jurisdiction as “compulsory ipso facto and without special agreement, in relation to any other state accepting the same obligation.” Statute of the International Court of Justice art. 36, para. 2, Jun. 26, 1945, 59 Stat. 1055, 1060, 33 U.N.T.S. 993.

17. Peter-Tobias Stoll, *Constitutional Perspectives on International Economic Law*, in REFLECTIONS ON THE CONSTITUTIONALISATION OF INTERNATIONAL ECONOMIC LAW: LIBER AMICORUM FOR ERNST-ULRICH PETERSMANN 201, 202 (Marise Cremona et al. eds., 2014).

18. FRIEDRICH A. HAYEK, *THE ROAD TO SERFDOM* 175 (1944).

19. *Id.* Professor Ernst-Ulrich Petersmann, in his noted 1991 book, advocated limiting the power of states, inter alia, to guarantee free trade but he offered a different argument, or at least a different version of Hayek’s argument. See ERNST-ULRICH PETERSMANN, *CONSTITUTIONAL FUNCTIONS AND CONSTITUTIONAL PROBLEMS OF INTERNATIONAL ECONOMIC LAW* 221–44 (1991).

20. See Ernst-Ulrich Petersmann, *Human Rights and International Trade Law: Defining and Connecting the Two Fields*, in HUMAN RIGHTS AND INTERNATIONAL TRADE 29 (Thomas Cottier, Joost Pauwelyn & Elisabeth Bürgi Bonanomi eds., 2005) (“From the point of view of human rights, the history of international law, including international trade law, could be written as a history of abuses of foreign policy powers to the detriment of general citizen-interests.”); Reuven S. Avi-Yonah, *The Cyclical Transformations of the Corporate Form: A Historical Perspective on Corporate Social Responsibility*, 30 DEL. J. CORP. L. 767, 768 (2005) (arguing that corporations are often in a better position than states to promote development).

21. For a historical account of the General Agreement on Tariffs and Trade (GATT) as a stand-alone instrument and the failure of the Havana Charter, see Thomas J. Dillon, Jr., *The World Trade Organization: A New Legal Order for World Trade?*, 16 MICH. J. INTL. L. 349, 353 (1995) (“With the failure of the Havana Charter and the ITO, the GATT became the principal international agreement regulating trade between nations.”). On Bretton Woods, see John C. Thomure, Jr., *The Uneasy Case for the North American Free Trade Agreement*, 21 SYRACUSE J. INT’L. L. & COM. 181, 185–86 (1995).

one important result, namely the signing of the General Agreement on Tariffs and Trade (GATT).²² The GATT included a state-to-state dispute settlement system that differed in at least two important respects from many of its international law cousins: it was mandatory for GATT Contracting Parties and had “teeth,” in the form of trade-based retaliation against a party failing to implement an adverse ruling.²³ Those teeth were a bit fragile, however, because the losing party in a dispute could oppose adoption of the dispute settlement report by the GATT Contracting Parties and thus compromise its enforceability.²⁴ According to Professor Hudec, a number of disputes were not filed in the first place for political and other reasons, thus further limiting the impact of the GATT dispute-settlement system.²⁵

A second inflection point in the strengthening of enforceability was the establishment in 1995 of the World Trade Organization (WTO), which includes an enhanced dispute-settlement system.²⁶ The WTO’s teeth, compared to those of the previous GATT system, grew significantly longer. Clearly, “sovereignty” lost a sizeable share of its normative heft in the WTO exercise. A number of key actors, including multinational corporations, were pushing for tough norms to be imposed on and enforced against states where they were doing (or were planning to do)

22. Havana Charter for an International Trade Organization, Mar. 24, 1948, U.N. Doc. E/CONF 2/78. The GATT was never ratified as a stand-alone treaty by the United States. It was adopted by the Protocol of Provisional Application of the General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-2051, 55 U.N.T.S. 308. See Ronald A. Brand, *GATT and the Evolution of United States Trade Law*, 18 BROOK. J. INT’L L. 101, 142 n.72 (1992) (“[B]oth the GATT and the Protocol receive their authority in United States law, not as a result of any direct congressional act, but rather through Presidential agreement to and proclamation of the effectiveness of the Protocol of Provisional Application. Proclamation No. 3513, 28 Fed.Reg. 107, 115 (1963).”).

23. See Miquel Montaña i Mora, *A GATT with Teeth: Law Wins Over Politics in the Resolution of International Trade Disputes*, 31 COLUM. J. TRANSNAT’L L. 103, 128–31 (1993).

24. Because the GATT was basically a contract and not a typical intergovernmental organization with “members,” states party to it were simply called contracting parties. Acting together (as a group) to take a collective decision, the capitalized plural CONTRACTING PARTIES was used. GATT Article XXV.1 uses “CONTRACTING PARTIES,” in all capital letters, to mean “the contracting parties acting jointly.” Oct. 30, 1947, 61 Stat. A-3, at A-68, 55 U.N.T.S. 187, at 272. On the “veto” of a party losing a dispute, see Curtis Reitz, *Enforcement of the General Agreement on Tariffs and Trade*, 17 U. PA. J. INTL. ECON. L. 555, 564 (1996) (“General GATT practice was that the CONTRACTING PARTIES, or the Council, would take action only if all parties agree; any individual nation could block action. Thus, even the losing party to a dispute could block action by the CONTRACTING PARTIES or the Council.”).

25. See ROBERT E. HUDEC, *GATT LEGAL SYSTEM AND WORLD TRADE DIPLOMACY* 185 (1993).

26. See Pieter Jan Kuijper, *The New WTO Dispute Settlement System: The Impact on the European Community*, 29 J. WORLD TRADE 49, 57 (1995); Joseph H.H. Weiler, *The Rule of Lawyers and the Ethics of Diplomats: Reflections on the Internal and External Legitimacy of WTO Dispute Settlement*, 13 AM. REV. INT’L ARB. 177, 197 (2002) (“Inevitably, then, with ever increasing sophistication, the WTO legal paradigm shift occasioned by the acceptance of compulsory adjudication with binding outcomes has attracted most comment. And with good empirical justification. Measured in quantitative terms, Panel and the Appellate Body activity under the new DSU can be described as frenetic. Equally inevitably WTO dispute settlement in general and the Appellate Body and its jurisprudence in particular are taking their rightful place as objects of reflection alongside other major transnational and international courts.”) (notes omitted).

business. This meant, *inter alia*, enforcing intellectual property rights and establishing rules against expropriation. It led to the shift in the entire field of intellectual property from a set of technical rules administered by its own UN specialized agency (the World Intellectual Property Organization (WIPO), the origins of which date back to the 1880s) to the world of trade, and eventually the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).²⁷ A question that emerges in connection with this shift is whether the WTO dispute settlement system is self-contained, or whether—and if so how—it can consider norms extrinsic to the WTO regime, including human rights.²⁸

The third and last inflection point represents a major step in the path towards a further reduction in state sovereignty. That step is investor-state dispute settlement (ISDS), a process that forms part of most recent trade and investment agreements. While all steps in the story systematically whittled away state sovereignty, ISDS marks a paradigmatic shift. ISDS is the result of a move towards recognizing the role of multinational corporations as international legal persons that compete with states for the policy space or have a special say in policy setting notably because they can offer direct investment in exchange for policy decisions.²⁹ The two main contours of the so-called “post-Westphalian” system are: “1) limited international legal personality for *non-state actors*; 2) *qualified sovereignty* for state actors, partly but not exclusively due to a) *devolution of sovereignty* to local or *private* entities (localization and privatization) and b) *sublimation of sovereignty* into transnational international organizations.”³⁰ ISDS is a major step in that context: multinational corporations are given a right to sue states in binding and mandatory arbitration proceedings.³¹

27. Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27–34, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]. On the impacts of the shift of IP to trade, see Daniel Gervais, *Human Rights and the Philosophical Foundations of Intellectual Property*, in RESEARCH HANDBOOK ON HUMAN RIGHTS AND INTELLECTUAL PROPERTY 89, 92–93 (C. Geiger ed., 2016).

28. See Shoab A. Ghias, *International Judicial Lawmaking: A Theoretical and Political Analysis of the WTO Appellate Body*, 24 BERKELEY J. INT'L L. 534, 553 (2006); Alec Sweet, *Judicialization and the Construction of Governance*, in ON LAW, POLITICS, AND JUDICIALIZATION 63, 64–65 (Martin Shapiro & Alec Stone Sweet eds., 2002).

29. See Christen Broecker, Note, “Better the Devil You Know”: Home State Approaches to Transnational Corporate Accountability, 41 N.Y.U. J. INT'L L. & POL. 159, 184–85 (2008) (showing how corporations use the investment carrot to affect poorer states' policies).

30. Eric Allen Engle, *The Transformation of the International Legal System: The Post-Westphalian Legal Order*, 23 QUINNIPIAC LAW REV. 23, 45 (2004) (emphasis added).

31. See José E. Alvarez, *Are Corporations “Subjects” of International Law?*, 9 SANTA CLARA J. INT'L L. 1, 31 (2011) (suggesting that “international lawyers should spend their time addressing which international rules apply to corporations rather than whether corporations are or are not “subjects” of international law); Glen Kelley, *Multilateral Investment Treaties: A Balanced Approach To Multinational Corporations*, 39 COLUM. J. TRANSNAT'L L. 483, 489–90 (2001). Interestingly, in *Kiobel v. Royal Dutch Petroleum Co.*, 621 F.3d 111, 131 (2d Cir. 2010), the Court of Appeals for the Second Circuit decided that corporate liability was not a rule of customary international law applicable under the Alien Tort Statute (ATS), 28 U.S.C. § 1350 (2012).

Specifically, ISDS provides multinational corporations a right to sue states that are parties to an investment treaty (such as a bilateral investment treaty or BIT) or a trade agreement containing an investment protection chapter for direct or indirect expropriation, referred to together as international investment treaties (IIAs).³² Investment protection clauses are now standard in IIAs.³³ According to the United Nations Conference on Trade and Development (UNCTAD), as of 2015 there were 3,304 known IIAs (2,946 BITs and 358 other treaties with investment provision (TIPs)), not all of which are in force, however.³⁴

The emergence of ISDS goes well beyond the mere recognition of international legal personality for multinational corporations: it marks a sharp turn in the regulation of the activities of such corporations by individual states where they invest and do business. The scope of the shift compared to state-to-state dispute settlement (i.e., among “equals”) can be measured by comparing ISDS with the 1974 Charter of Economic Rights and Duties of States adopted by the UN General Assembly.³⁵ The Charter notes, *inter alia*, that states have the right “[t]o regulate and supervise the activities of transnational corporations within [their] national jurisdiction and [to] take measures to ensure that such activities . . . conform with [their] economic and social policies.”³⁶ It imposes a duty on transnational corporations not to “intervene in the internal affairs of a host State.”³⁷ ISDS is arguably exactly the opposite. Where states A and B have agreed to an ISDS obligation in a treaty, ISDS provides a binding forum where a corporation in state A can challenge a measure taken by the government of state B affecting the corporation’s investments in state B.³⁸

ISDS was and probably still is a good idea to attract foreign investment, especially in countries where the legal system may not be effective at imposing remedies against the state. It is so widespread, however, that it no longer marks a comparative advantage (over states that do not provide it); instead states that do *not*

32. UNITED NATIONS CONFERENCE ON TRADE & DEV., WORLD INVESTMENT REPORT 2016: INVESTOR NATIONALITY: POLICY CHALLENGES 101, U.N. Sales No. E.16.II.D.4 (2016), http://unctad.org/en/PublicationsLibrary/wir2016_en.pdf [<https://perma.cc/2TMX-24B3>] [hereinafter UNCTAD REPORT].

33. See 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) (investor-state arbitration is a standard feature of IIAs concluded since the 1980s).

34. See UNCTAD REPORT, *supra* note 32, at 101. Not all of those instruments are currently in force.

35. G.A. Res. 3281 (XXIX) (Dec. 12, 1974).

36. *Id.* art. 2(2).

37. *Id.*

38. See Timothy J. Feighery, *Rule of Law in the Emerging Development Agenda: On Finding the Optimal Role for Investment Treaties*, 21 SW. J. INT’L L. 297, 299 (2015) (“The ISDS may broadly be defined as an international law-based system that is founded mostly on thousands of bilateral investment treaties (BITs) and some multilateral investment-related treaties that protect, on a reciprocal basis, the investors of each state when they make investments in other states. . . . By this system, sovereigns agree to *privatize* the dispute resolution process for covered investments. In this way, foreign investors are protected against the traditional *home field advantage* that sovereigns may enjoy via their national court systems.”).

have investment protection (including ISDS) may be at a comparative disadvantage.³⁹

The first plurilateral agreement to contain ISDS provisions was NAFTA.⁴⁰ ISDS forms part of the second version of the Trans-Pacific Partnership.⁴¹ It likely will form part of the Transatlantic Trade and Investment Partnership (TTIP)—if that agreement is ever finalized—which itself is modeled after a vast number of bilateral investment agreements (BITs).⁴² Put differently, ISDS is here, and it seems *here to stay*. Indeed, “[w]ith 70 cases initiated in 2015, the number of new treaty-based investor-state arbitrations set a new annual high. Following the recent trend, a high share of cases (40 per cent) was brought against developed countries.”⁴³ ISDS provisions already bind (or soon may) the United States with most of its significant trading partners, including Canada, Mexico, and the EU, and its importance is growing.⁴⁴ ISDS has (finally) started to make the headlines, for example in the

39. See *supra* note 34 and accompanying text.

40. NAFTA, *supra* note 1; see Vivian H.W. Wang, Note, *Investor Protection or Environmental Protection? “Green” Development under CAFTA*, 32 COLUM. J. ENVTL. L. 251, 260 (2007) (“The inclusion of an ISDS-type mechanism within a BIT was first adopted in NAFTA and was heralded as an advancement in the resolution of international trade disputes as it ‘grant[ed] individual foreign investors standing to sue host governments without requiring the participation or acquiescence of the investor’s home government.’”) (notes omitted); see also William L. Owens & R. Andrew Fitzpatrick, *Investment Arbitration Under NAFTA Chapter 11: A Threat to Sovereignty of Member States?*, 39 CAN.—U.S. L.J. 55 (2015). Investment protection emerged in the bilateral investment treaty between Germany and Pakistan of Nov. 25, 1959. Treaty for the Promotion and Protection of Investments (with Protocol and Exchange of Notes), Ger.-Pak., Nov. 25, 1959, 457 U.N.T.S. 24. As far as the United States is concerned, ISDS provisions were first used in the Treaty between the United States of America and the Republic of Panama Concerning the Treatment and Protection of Investments of Oct. 27, 1982, art. VII. Treaty Between the United States of America and the Republic of Panama Concerning the Treatment and Protection of Investments, U.S.-Pan., Oct. 27, 1982, S. TREATY DOC. No. 99-14 (1991).

41. The “new version” refers to the new text reportedly agreed in January 2018 by eleven countries following the withdrawal of the United States from the pact in January 2017. See James Fernyhough, *The TPP is Going Ahead, and Not Everyone in Australia is Happy*, THE NEW DAILY (Jan. 28, 2018, 3:48 PM), <https://thenewdaily.com.au/money/finance-news/2018/01/24/tpp-going-ahead/> [<https://perma.cc/8JZU-W23F>].

42. See Joseph H.H. Weiler, Editorial, *European Hypocrisy: TTIP and ISDS*, 25 EUR. J. INT’L L. 963, 964 (2014) (“The ISDS chapter in the TTIP is essentially modelled (for good and for bad) on similar regimes in thousands (!) of BITs in force all over the world. Almost all European Member States, among them the shrillest objectors to the ISDS in the TTIP, are not only signatories to such agreements but are heavy users thereof.”). While BITs by definition contain “investment protection” in the form of ISDS, not all TIPs contain them, though a clear majority do. Of the 358 TIPs just mentioned, 132 contained investment provisions similar to those in BITs, and another thirty-two contained “limited” investment protection (for example, national treatment with respect to commercial presence or free movement of capital relating to direct investments). See UNCTAD REPORT, *supra* note 32, at 102.

43. UNCTAD REPORT, *supra* note 32, at xii.

44. See Christopher R. Drahozal, *New Experiences of International Arbitration in the United States*, 54 AM. J. COMP. L. 233, 246–47 (2006) (“Although investor-state arbitration dates back at least to the Jay Treaty of 1794, in recent years the number of investment arbitration proceedings has increased dramatically. To illustrate: claimants filed a total of three treaty-based cases with the World Bank’s International Centre for Settlement of Investment Disputes (ICSID) from its inception through 1994. In the next ten years—through November 2004—claimants filed an additional 103 cases. Investment arbitrations also are notable for their high stakes: claimants regularly seek to recover

United States in 2016 when the Keystone XL pipeline project was rejected by President Obama.⁴⁵ That specific example was heralded as evidence of ISDS giving corporations too much power over sovereign public policy decisions.⁴⁶ One can fairly ask, therefore, whether and if so how ISDS meshes with a state's right to regulate its own public policy within its borders.

Limits on state sovereignty are often well-grounded, for example, when they are supported by a benevolent world community policing human rights.⁴⁷ But what happens when international law is used to *limit* the protection of human or fundamental rights that a state (or supranational body, such as the European Union) wants to protect (in the form of a limit on an intellectual property right or restriction on the use of personal data, for example) because it could amount to an alleged expropriation? This is where ISDS takes us now, as it is used to enforce investment protection with little or no doctrinal space to acknowledge—let alone defer to—human rights and other public interest norms and associated policies that a state might wish to apply in its own territory. That, in a nutshell, is the issue at the core of this Article.

The Article proceeds as follows. In Part II, the Article presents the *Lilly* case, which it uses to explicate how human rights issues might arise in the context of ISDS cases involving intellectual property. In Part III, the Article examines various aspects of the substantive interface between trade, investment, intellectual property, and human rights. This includes the (human) right to health and the regulation of pharmaceutical products from a public health perspective. Part IV reviews various doctrinal mechanisms used (with varying degrees of success) in a trade context to solve this complex equation and considers whether these mechanisms can be used in an ISDS context. Part V offers paths forward.

II. LILLY V. CANADA

This Part provides the reader not familiar with the details of the *Lilly* case with a glimpse into the arguments made by the parties that are relevant for the purposes of this Article. It is not intended to provide a full picture of the case.⁴⁸

hundreds of millions or even billions of dollars, and the claims may involve sensitive issues of national policy.”) (footnotes omitted).

45. See Dillon Fowler, Comment, *Keystonewalled: TransCanada's Discrimination Claim Under NAFTA and the Future of Investor-State Dispute Settlement*, 31 AM. U. INT'L L. REV. 103, 105 (2016).

46. See *id.* at 130 (“[T]he fact that TransCanada is suing the United States government at all shows that Chapter 11 provides corporations with too much leverage over elected governments through the current model of ISDS.”).

47. Peter Millet, *The Pinochet Case — Some Personal Reflections*, in INTERNATIONAL LAW 10 (Malcolm D. Evans ed., 2d ed. 2006) (“No longer is international law a matter which concerns sovereign States alone. It marches with human rights law to protect individuals from State action. The world community has finally decided that the way a sovereign State treats its own nationals is not a purely internal matter.”).

48. For documents concerning the case, including briefs submitted by all parties, see *Eli Lilly and Company v. the Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, ITALAW, <http://www.italaw.com/cases/1625> [https://perma.cc/EM3H-GJYT] (last visited June 21, 2018).

Lilly v. Canada was heard at the International Centre for Settlement of Investment Disputes (ICSID), the forum of choice for NAFTA investor-state disputes, and according to the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules.⁴⁹ ICSID is known for the confidentiality and effectiveness of its services.⁵⁰ Hearings are not public and calls for more transparency have been made, although memorials (briefs) and expert reports, as well as tribunal orders are generally made available to the public on the ICSID website.⁵¹

The award (decision) of the tribunal was made available in March 2017.⁵² Let us examine Lilly's claims and Canada's response.

A. The Complaint

Eli Lilly's complaint against Canada was filed under chapter 11 of NAFTA.⁵³ That chapter is meant to protect investments made in a NAFTA party by a company based in another NAFTA party.⁵⁴ Interestingly, although "intellectual property" is often mentioned in IIAs in the definition of "investment," this is not the case in NAFTA, at least not directly.⁵⁵ The inclusion of intellectual property in the definition of the term "investment" is controversial from a normative perspective when it leads to a challenge to a state's intellectual property and innovation policy.⁵⁶

49. See NAFTA, *supra* note 1, art. 1120, at 643; see also 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. INTELL. PROP. L. 1, 14 (2015) (ICSID handles the "vast majority of investor-state dispute resolution claims."). ICSID was established by the Convention on the Settlement of Investment Disputes Between States and Nationals of Other States art. 1, Mar. 18, 1965, 17 U.S.T. 1270, 575 U.N.T.S. 159. UNCITRAL is the United Nations Commission on International Trade Law. As of April 1, 2014, UNCITRAL has added to its arbitration rules. See UNITED NATIONS COMM'N ON INT'L TRADE LAW, UNCITRAL RULES ON TRANSPARENCY IN TREATY-BASED INVESTOR-STATE ARBITRATION (2014), <http://www.uncitral.org/pdf/english/texts/arbitration/rules-on-transparency/Rules-on-Transparency-E.pdf> [<https://perma.cc/JA44-XD79>].

50. 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).

51. See generally J. Anthony VanDuzer, *Enhancing the Procedural Legitimacy of Investor-State Arbitration Through Transparency and Amicus Curiae Participation*, 52 MCGILL L.J. 681 (2007) (advocating for the formal adoption of transparency rules by NAFTA to address legitimacy concerns in investor-state arbitration).

52. Eli Lilly & Co. v. Canada, Final Award, *supra* note 2, ¶¶ 198, 310, 349. The Award was made available to the parties on March 16, 2017. The Parties had ten days to identify confidential information, if any, in the award before its release to the public ten days later.

53. See *id.* at ¶ 95.

54. See NAFTA, *supra* note 1, ch. 11.

55. See, e.g., U.S. DEPT. OF STATE, 2012 U.S. MODEL BILATERAL INVESTMENT TREATY arts. 1 (Definitions), 6.5 (2012), <http://www.state.gov/documents/organization/188371.pdf> [<https://perma.cc/SLP2-ED99>] [hereinafter 2012 U.S. MODEL BIT]; see also Susan K. Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28 LIVERPOOL L. REV. 41, 41 (2007). In NAFTA, the "indirect" mention is in Article 1110(7), discussed below. See *infra* notes 83–89 and accompanying text.

56. See 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, 1124 (2014) ("Although the

One could argue that it would be much less so, or even not controversial at all, if the inclusion of intellectual property were limited to actual expropriation (e.g., when state A takes the title to a patent or copyright belonging to company B to keep it or transfer it to a third party).

Actual expropriation is not the fact pattern in *Lilly v. Canada*. The *Lilly* case relates to the *invalidation* of two Canadian patents on its drugs Zyprexa and Strattera (atomoxetine and olanzapine) by Canadian courts for failure to meet one of the core patentability criteria, namely the utility requirement, one of the basic patentability criteria in U.S. and Canadian patent law.⁵⁷ The claimant (Lilly) contended that the adoption of a “new, radically different standard for determining whether inventions fulfill that requirement” (the “promise of the patent” doctrine discussed below) amounted to an “uncompensated expropriation, in violation of Article 1110 of NAFTA.”⁵⁸ The claimant alleged that the promise of the patent doctrine violated the intellectual property chapter (Chapter 17) of NAFTA, which “requires Canada to provide patents to inventions, in all fields of technology, that are ‘new, result from an inventive step, and are capable of industrial application [*i.e.*, have utility],” arguing that if “Canada can *unilaterally* reinterpret a core legal term in such a stark manner and with such severe consequences, legally operative words in NAFTA with internationally-accepted meanings could be susceptible to *unilateral* re-definition, such that NAFTA will no longer establish foundational requirements for patent protection.”⁵⁹ In other words, Lilly was trying to use investment chapter of NAFTA to challenge the compatibility of the application of a patentability criterion by Canadian courts (in which it undeniably received due process) with Canada’s substantive IP obligations in the patent section of chapter 17 of NAFTA, which are broadly similar to those in the TRIPS agreement.⁶⁰ The word “unilateral” used twice in the short quotation above betrays Lilly’s thinking: the exercise of state sovereignty is seen as a “unilateral” measure.

A second line of Lilly’s argument was that the interpretation of the notion of utility by Canadian courts violated Canada’s obligations to afford “fair and equitable treatment” (FET) to Lilly’s investments under Article 1105 of NAFTA.⁶¹

definition of ‘investment’ contained in most investment treaties mention intellectual property, the obligations, expectations, and enforcement aspects of these treaties are largely undeveloped. Moreover, the doctrinal, policy, and structural differences between BITs and the TRIPS Agreement have rarely been meaningfully analyzed, leaving a gap in the international law of intellectual property. That is the gap Eli Lilly now seeks to exploit.”) This Article returns to this issue in greater depth *infra* Parts IV, V.

57. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Claimant’s Memorial, at 1 (Sept. 29, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw4046.pdf> [<https://perma.cc/N22P-587H>] [hereinafter *Eli Lilly & Co. v. Canada*, Claimant’s Memorial].

58. *Id.* at 1–2.

59. *Id.* at 5–6 (emphasis added).

60. For a discussion of NAFTA Chapter Seventeen and TRIPS, see *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Expert Report of Daniel J. Gervais, at 18–20 (Jan. 26, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4139.pdf> [<https://perma.cc/69GZ-5BP9>] [hereinafter *Eli Lilly & Co. v. Canada*, Expert Report of Daniel J. Gervais].

61. *Eli Lilly & Co. v. Canada*, Claimant’s Memorial, *supra* note 57, at 6.

Specifically, Lilly alleged that the promise of the patent doctrine violated: (i) protection against arbitrary treatment (the doctrine is completely unpredictable and unreasonably difficult to satisfy); (ii) protection of legitimate, investment-backed expectations; and (iii) protection against discriminatory treatment.⁶²

Lilly also 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 had been issued “after a careful review by Canada’s patent examiners in light of Canada’s utility requirement at the time.”⁶³ These last two arguments, it seems, could be rephrased as arguing that *any invalidation* by a court of an issued patent amounts to expropriation, and that any significant change in the interpretation of a patentability criterion could also amount to expropriation under NAFTA.

B. Canada’s Counter-Memorial

In its counter-memorial, the Government of Canada noted, first, that the claimant received due process before Canadian courts (a fact not in dispute) and was simply disappointed with the outcome of two patent trials. That did not amount to a breach of the relevant obligations. Rather, according to the respondent, “[t]he threshold for a violation of the minimum standard of treatment is high and requires a finding of egregious or manifestly unfair behaviour” under customary international law.⁶⁴ Specifically, Canada alleged that the claimant had failed “to prove that the theory of ‘legitimate expectations’ has become a rule of customary international law” protected by NAFTA Article 1105(1) and, moreover, that “regardless of its status generally in international law, it is a doctrine which fundamentally cannot be applied to judgments of the domestic judiciary acting in an adjudicative function of domestic statutory interpretation.”⁶⁵

On the issue of the alleged change in the interpretation of the utility requirement by Canadian courts, Canada countered on several fronts. It noted that:

[E]ven if the theory of legitimate expectations is now a rule of custom protected under Article 1105(1), Claimant could not have had a “legitimate expectation” of how a court would rule in the future in light of the law, facts, evidence and other considerations presented before the court at the time of challenge. To assert otherwise would give every disappointed litigant an automatic remedy in international law against any adverse domestic ruling that it “expected” to win.⁶⁶

62. *Id.* at 6–7.

63. *Id.* at 7.

64. Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Government of Canada Counter Memorial, at 94. (Jan. 27, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf> [<https://perma.cc/P3K3-LTMB>] [hereinafter *Eli Lilly & Co. v. Canada*, Government of Canada Counter Memorial].

65. *Id.* at 115.

66. *Id.*; see also Henning Grosse Ruse-Kahn, *Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation* (Univ. of Cambridge Faculty of Law

The United States, in a submission noted along similar lines that:

The concept of “legitimate expectations” is not a component element of “fair and equitable treatment” under customary international law that gives rise to an independent host State obligation. An investor may develop its own expectations about the legal regime governing its investment, but those expectations impose no obligations on the State under the minimum standard of treatment. The United States is aware of no general and consistent State practice and *opinio juris* establishing an obligation under the minimum standard of treatment not to frustrate investors’ expectations Moreover, the concept of “legitimate expectations” is particularly inapt in the context of judicial measures.⁶⁷

Canada also argued that the “promise of the patent” doctrine was not new in Canadian law, as Canadian academics and a well-known Canadian expert retained by the government of Canada demonstrated.⁶⁸ A 1981 quote from the Supreme Court of Canada opinion should suffice to illustrate the validity of Canada’s argument:⁶⁹

There is a helpful discussion in *Halsbury’s Laws of England*, (3rd ed.), vol. 29, at p. 59, on the meaning of ‘not useful’ in patent law. It means ‘that the invention will not work, either in the sense that it will not operate at all or, more broadly, *that it will not do what the specification promises* that it will do’. . . . The discussion in *Halsbury’s Laws of England* . . . continues:

. . . the practical usefulness of the invention does not matter, nor does its commercial utility, *unless the specification promises commercial utility*, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. . . .

and concludes:

Legal Studies Research Paper Series, Paper No. 52, 2014), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711 [<https://perma.cc/9RW3-PU3A>] (“In *Eli Lilly vs. Canada*, the investor hence cannot legitimately expect from the grant of patents by the Canadian Patent Office (CPO) that those remain free from any validity challenges in the courts. Also a change in how the Canadian courts apply patentability standards such as utility or the disclosure obligation as such does not affect legitimate investor expectations . . .”).

67. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Submission of the United States of America, at 4–5 (Mar. 18, 2016), <http://www.italaw.com/sites/default/files/case-documents/italaw7175.pdf> [<https://perma.cc/29U3-ET6V>] [hereinafter *Eli Lilly & Co. v. Canada*, Submission of the United States of America] (footnotes omitted) (made as NAFTA parties not involved in a dispute can do under NAFTA Article 1128).

68. *See Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Expert Report of Ronald E. Dimock (Jan. 26, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4138.pdf> [<https://perma.cc/6PBP-YZYP>] [hereinafter *Eli Lilly & Co. v. Canada*, Expert Report of Ronald E. Dimock]; Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CANADIAN INTEL. PROP. REV. 35, 35 (2014).

69. *See Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, 524 (Can.).

. . . it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice. . . .

Canadian law is to the same effect. . .⁷⁰

It seems plain from the above that promises made by a patent applicant in patent specifications were considered relevant and clearly were a known factor in utility analyses in Canadian law, at least as far back as 1981. The tribunal agreed with Canada on that point.⁷¹ Canada's counter-memorial also noted in this context that, *even if* the promise of the patent doctrine was considered to change the interpretation of the utility criterion, changes in the interpretation of patentability criteria by courts in all three NAFTA parties are common, and sometimes significant.⁷² This happened recently in several opinions of the United States Supreme Court for example.⁷³ Here again, the tribunal agreed.⁷⁴

Lilly tried to argue that the notion of utility in Canada should be defined basically the same way that it is in the United States (and therefore practically nonexistent as a substantive threshold). Canada countered that (i) the U.S. definition is not internationally binding on other nations and (ii) that the notion of utility does different normative work (if any) in the United States because the notions of written description and enablement (which do not exist as such in Canadian law) perform essentially the same function as the Canadian notion of utility.⁷⁵

Relatedly, Lilly argued, as Valentina Vadi explains, that it faced "more arduous patent standards in Canada than a Canadian investor might face in other

70. *See id.* (emphasis added), *quoted in* Eli Lilly & Co. v. Canada, Expert Report of Ronald E. Dimock, *supra* note 68, at 14 (original emphasis removed; emphasis added).

71. *See* Eli Lilly & Co. v. Canada, Final Award, *supra* note 2, ¶¶ 318–323.

72. *See* Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Expert Report of Timothy R. Holbrook, at 27–30 (Jan. 26, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4137.pdf> [<https://perma.cc/CX7L-JP6K>]; Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Expert Report of Hedwig Lindner, at 4 (Jan. 26, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4136.pdf> [<https://perma.cc/S9K4-FDQL>] (discussing Mexican law).

73. *See, e.g.*, Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Mayo Collaborative Servs. v. Prometheus Labs, Inc., 566 U.S. 66 (2012); Bilski v. Kappos, 561 U.S. 593 (2010); KSR Int'l v. Teleflex Inc., 550 U.S. 398 (2007).

74. *See* Eli Lilly Co. v. Canada, Final Award, *supra* note 2, ¶¶ 310, 386 (noting that "evolution of the law through court decisions is natural, and departures from precedent are to be expected" and referring to "incremental and evolutionary changes" in the interpretation of the utility criterion).

75. *See* Eli Lilly & Co. v. Canada, Government of Canada Counter Memorial, *supra* note 64, at 5 ("Claimant also fails to acknowledge that U.S. law reaches many of the same results as do Canada's utility rules, through its analogous 'enablement' and 'written description' requirements."); Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Second Report of Dr. Daniel Gervais, at 3 (Dec. 7, 2015), <https://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207018.pdf> [<https://perma.cc/QZP8-ZV37>] [hereinafter Eli Lilly & Co. v. Canada, Second Report of Dr. Daniel Gervais] ("Claimant's argument now seems to be that only certain definitions of utility are acceptable (basically, the current U.S. definition) under NAFTA.").

jurisdictions, such as the United States and Europe.”⁷⁶ As Vadi notes, “[T]his form of extraterritorial analogy is highly unusual in national treatment claims before arbitral tribunals, given the regulatory diversity of IP laws across the globe, and is likely not going to be accepted by the Arbitral Tribunal.”⁷⁷ Indeed, the Tribunal noted that it was “difficult to see how a comparison across jurisdictions can demonstrate a change over time within a single jurisdiction.”⁷⁸

C. The Role of Chapter 17

Canada disagreed both that there was a violation of the substantive intellectual property chapter (Chapter 17) of NAFTA and the ISDS tribunal should consider that alleged violation to begin with. The patent-related provisions contained in that chapter, which was negotiated at about the same time as the TRIPS agreement, are largely similar to those found in TRIPS.⁷⁹ Lilly’s argument was not about investment protection proper, but about the compatibility of Canadian law with obligations undertaken vis-a-vis other states (Mexico and the United States).

It is necessary to explain how Lilly managed to concoct this argument, as this understanding will become relevant below.⁸⁰ Normally, a disagreement on the application of intellectual property norms contained in the TRIPS Agreement or NAFTA would be subject to state-to-state dispute settlement under the relevant agreement.⁸¹ ISDS in this context is viewed as a way to achieve indirectly what a corporation cannot do directly (because it cannot convince its host state to file a WTO case).⁸² Lilly’s argument hangs on a provision in NAFTA that seems to exclude precisely this type of situation from the purview of investor-state disputes.

76. Valentina S. Vadi, *Towards a New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investments*, 5 N.Y.U. J. INTELL. PROP. & ENT. L. 113, 181 (2015).

77. *Id.* at 181–82.

78. *Eli Lilly & Co. v. Canada*, Final Award, *supra* note 2, ¶ 377.

79. *See Eli Lilly & Co. v. Canada*, Expert Report of Daniel J. Gervais, *supra* note 60, at 18–20 (comparing Chapter Seventeen of NAFTA to TRIPS); *see also* TRIPS Agreement, *supra* note 27, arts. 27–34.

80. *See infra* Part IV.

81. For NAFTA, this is provided under chapter 20, and especially article 2004, which provides in part that “[t]he dispute settlement provisions of this Chapter shall apply with respect to the avoidance or settlement of all disputes between the Parties regarding the interpretation or application of this Agreement.” *See* Laurinda L. Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U. J. INT’L L. & POL’Y 769, 799–800 (1997). The TRIPS Agreement provides that disputes between WTO Members shall be settled under “[t]he provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding.” TRIPS Agreement, *supra* note 27, art. 64.1; *see also* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU]; DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 669–75 (4th ed. 2012).

82. *See* Gaetan Verhoosel, *The Use of Investor-State Arbitration Under Bilateral Investment Treaties to Seek Relief for Breaches of WTO Law*, 6 J. INT’L ECON. L. 493, 503–06 (2003). It is true that there have been few TRIPS disputes and that many did not provide relief for the corporations that had requested that the cases be brought. *See* Joost Pauwelyn, *The Dog that Barked but Did Not Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1 J. INT’L DISP. MGMT. 389, 393, 395 (2010).

That provision is Article 1110(7), which reads as follows:

This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).⁸³

Lilly's argument in this respect was that it had "demonstrated that Canada's measures were cognizable expropriations because they violated Canada's obligations in Chapter 17 of NAFTA (a basis for liability that Article 1110(7) contemplates)."⁸⁴ Basically, the argument rests on the fact that, if the investor can demonstrate that the revocation (or other measure) mentioned in article 1110(7) was not "consistent with Chapter Seventeen," then it was fair game under Chapter 11 (ISDS).

Canada disagreed. It noted in its rejoinder that:

The inference that Claimant is asking the Tribunal to draw is a logical fallacy, known as the fallacy of denying the antecedent. In essence, the problem with the reasoning is that it ignores the other reasons why something may or may not have occurred. The most classic example involves the following syllogism: "If it is raining, then the streets are wet." . . . Applied to this case, the relevant conditional statement would be: "If a measure is consistent with Chapter 17, then it is consistent with Article 1110." From this, one cannot infer, as Claimant suggests, that because a measure is inconsistent with Chapter 17, it is inconsistent with Article 1110. There could be many other reasons why the measure is consistent with Article 1110. Claimant's interpretation perverts the logic of Article 1110(7) by transforming what was intended to be a shield for the NAFTA Parties in a sensitive area into a sword for disappointed patent litigants to wield.⁸⁵

Mexico and the United States agreed. The US 1128 submission argues that:

Article 1110(7) therefore should not be read as an element of an investor's claim under Article 1110(1) or as a jurisdictional hook that allows a Chapter Eleven tribunal to examine whether alleged breaches of Chapter Seventeen by a NAFTA Party constitute an expropriation of intellectual property rights. Nor should Article 1110(7) be read as an invitation to

83. NAFTA, *supra* note 1, art. 1110(7) (emphasis added).

84. Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Claimant's Reply Memorial, at 109 (Sept. 11, 2014), <https://www.italaw.com/sites/default/files/case-documents/italaw4384.pdf> [<https://perma.cc/V9VG-Q2JS>] [hereinafter Eli Lilly & Co. v. Canada, Claimant's Reply Memorial].

85. Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Respondent's Rejoinder on the Merits, at 99 (Dec. 8, 2015), <https://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207014.pdf> [<https://perma.cc/T6R5-BVW2>] [hereinafter Eli Lilly & Co. v. Canada, Respondent's Rejoinder on the Merits].

review a NAFTA Party's measures, each time they arise, for consistency with Chapter Seventeen.⁸⁶

Can an investment tribunal disregard the fact that all parties to the "contract" called NAFTA agree on its meaning? After all, it has been said that "states which are bound by [a treaty] at the relevant time, own the treaty," which is consonant with Article 31 of the Vienna Convention, because the parties' understanding both illuminates the "object and purpose" of the treaty and may provide evidence of the subsequent practice of the parties.⁸⁷ True, it has also been argued that tribunals should ignore the parties' views when the text is clear, also on the basis of the Vienna Convention on the Law of Treaties (VCLT), assuming of course that the meaning is clear and unambiguous from the text itself.⁸⁸

The answer is that an ISDS tribunal is not formally bound by those submissions, but it should think hard and long before ignoring them.⁸⁹ Indeed the Tribunal did pay great heed to the American and Mexican submissions.⁹⁰ If the parties provide convincing evidence of their intention *at the time of entering into the treaty*, then that should have significant force because, using Vienna Convention (Article 31(1)) terminology, it provides powerful evidence of the object and purpose of the agreement. Evidence of uniform subsequent practice should also matter, and in practice it often has, in an arbitral context.⁹¹ This method of determining object and purpose and subsequent practice matters because even though Article 32 of the Vienna Convention allows use of "preparatory work of the treaty and the

86. *Eli Lilly & Co. v. Canada*, Submission of the United States of America, *supra* note 67, at 16 (footnotes omitted); *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, NAFTA Article 1128 Submission of United Mexican States, at 3 (Mar. 18, 2016), <https://www.italaw.com/sites/default/files/case-documents/italaw7174.pdf> [<https://perma.cc/F3WT-TAKN>] ("[B]ecause of the particular role of the adjudicative power within the organization of states, Mexico agrees with Canada that, with respect to judicial acts, denial of justice is the only rule of customary international law clearly identified and established so far as part of the minimum standard of treatment of aliens . . .").

87. Vienna Convention on the Law of Treaties art. 31(1), May 23, 1969, 1115 U.N.T.S. 331 (entered into force Jan. 27, 1980) [hereinafter VCLT] (providing 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 purpose"); see United Nations Conference on Trade & Dev., *Interpretation of IAs: What States Can Do, IIA Issues Note, No. 3*, at 3, UNCTAD/WEB/DIAE/IA/2011/10 (Jan. 11, 2012); James Crawford, *A Consensualist Interpretation of Article 31(3) of the Vienna Convention on the Law of Treaties*, in TREATIES AND SUBSEQUENT PRACTICE 29, 31 (Georg Nolte ed., 2013).

88. See Kenneth J. Vandeveld, *Treaty Interpretation from a Negotiator's Perspective*, 21 VAND. J. TRANSNAT'L L. 281, 296 (1988) ("The cornerstone of the Vienna Convention is its requirement that courts refrain from inquiring into the parties' actual intentions if the provision to be interpreted is clear on its face.").

89. See Margie-Lys Jaime, Note, *Relying upon Parties' Interpretation in Treaty-Based Investor-State Dispute Settlement: Filling the Gaps in International Investment Agreements*, 46 GEO. J. INT'L L. 261, 293 (2014).

90. See *Eli Lilly & Co. v. Canada*, Final Award, *supra* note 2, ¶ 158.

91. See *Iran v. United States*, Case No. B1 (Counterclaim), Interlocutory Award, Award No. ITL 83-B1-FT (September 9, 2004) ("[F]ar from playing a secondary role in the interpretation of the treaties, the subsequent practice of the Parties constitutes an important element in the exercise of interpretation.").

circumstances of its conclusion” as supplementary means of interpretation,⁹² an empirical analysis has shown that arbitral tribunals rarely if ever have recourse to such supplementary means, especially the *travaux* (the preparatory work for a treaty, including conference records and draft texts).⁹³

D. Lilly’s Change of Approach

In its memorial, Lilly argued that, as “Robert Armitage, Lilly’s former General Counsel, explains, the utility requirement is ‘*substantially harmonized* across jurisdictions.”⁹⁴ The Author’s initial report demonstrated in no uncertain terms that the harmonization argument was a red herring.⁹⁵ Every effort to agree on a definition of utility pre- and post-NAFTA, including in the patent law treaty discussions, failed to produce consensus.⁹⁶

In its reply memorial to Canada’s defense, Lilly changed its approach. It abandoned the harmonization argument, even denying, despite having made it very openly as can be seen above from the mouth of its own General Counsel, that it had never claimed there had been substantive harmonization of patent law.⁹⁷ One of Lilly’s experts hired in support of its reply—a former WIPO patent official—argued instead that “the industrial applicability (utility) standard is, as further discussed below, applied in a manner that is *remarkably similar* around the world.”⁹⁸ He further noted that his “experience has also taught [him] that there are equally important areas where *the practices of member states are consistent*. I disagree with Professor Gervais’s attempt to place industrial applicability (utility) in the first category (of divergence) *rather than the second category (of consistency)*.”⁹⁹

The Author’s second report, in reply to Lilly’s expert, quoted, *inter alia*, a report prepared by WIPO, indeed by the very division of which their WIPO expert was director when the report was produced.¹⁰⁰ This WIPO document noted the following:

92. VCLT, *supra* note 87, art. 32.

93. See Baiju S. Vassani & Anastasiya Ugale, *Travaux Préparatoires and the Legitimacy of Investor-State Arbitration*, 11 TRANSNAT’L DISP. MGMT. 1 (2014).

94. Eli Lilly & Co. v. Canada, Claimant’s Memorial, *supra* note 57, at 132.

95. See Eli Lilly & Co. v. Canada, Expert Report of Daniel J. Gervais, *supra* note 60, at 7–12.

96. See *id.*

97. Eli Lilly & Co. v. Canada, Claimant’s Reply Memorial, *supra* note 84, at 5.

98. Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Expert Report of Philip Thomas, at 4 (Sept. 7, 2015), <https://www.italaw.com/sites/default/files/case-documents/italaw4375.pdf> [<https://perma.cc/5LZU-NKWE>].

99. *Id.* at 12 (emphasis added).

100. Their expert noted the following in his report:

In 1990, I joined the World Intellectual Property Organization (“WIPO”) as a Senior Legal Officer. Over the next 20 years, I served in a range of senior positions, including as Director of the PCT Legal Development Division and Director of the Patent Policy Department. I retired in 2010 as Senior Director-Advisor (PCT and Patents).

Id. at 2. In his testimony (the Author was present at the hearing), he confirmed that the report was produced by his division while he worked there.

Information received by [WIPO] members, reveals that *there is a wide range of differences among SCP members concerning the interpretation and practice relating to the 'industrial applicability/utility' requirement*. It also shows that the industrial applicability/utility requirement is closely linked, or sometimes overlaps, with other substantive patentability requirements, such as the sufficient disclosure (enablement) requirement, inventive step, exclusions from patentable subject matter and the definition of 'invention'.¹⁰¹

This Article lets the reader decide. Unfortunately, the Tribunal neither discussed, nor opined on, the matter of harmonization.

E. Regulatory Flexibility

A significant disagreement between the parties in the *Lilly* case concerned the flexibility to implement international obligations. Lilly's argument tugged directly on "the tension between the private interests of foreign investors and the regulatory autonomy of the host state."¹⁰² Indeed the issue of regulatory flexibility is one of the major issues in the ISDS context. This was not a case of actual or direct expropriation; instead, the notion of *indirect expropriation* was used to challenge the judicial application of a patent doctrine to specific inventions, thus arguably amounting to a challenge by a private non-state actor to Canada's sovereign ability to regulate its substantive patent law and evolve its patent law through court interpretations. As noted above, investors want to limit regulatory flexibility and ISDS can provide them with a powerful tool to do so. At bottom, this becomes an argument about state sovereignty. Canada's reply memorial noted the following in this respect:

[A]s Claimant itself acknowledges, the NAFTA Parties have flexibility in deciding how to implement the obligations of NAFTA Chapter Seventeen. Accordingly, even if NAFTA Article 1709(1) required the NAFTA Parties to impose the specific "low threshold" utility standard Claimant alleges (it does not), it has nothing to say about how the NAFTA Parties are permitted to implement the requirement, particularly with regard to issues of evidence and disclosure.¹⁰³

Parties to a treaty can agree to definitions that must then be applied in the event of a dispute according to the Vienna Convention rules, but there is no definition of "utility" in either NAFTA or TRIPS. Hence, Canada was correct to argue that NAFTA left to each party "the flexibility to define and implement the specific legal standard under each of the enumerated criteria of novelty, non-obviousness or inventiveness, and utility or industrial applicability. It does not adopt

101. WORLD INTELLECTUAL PROP. ORG., *THE PRACTICAL APPLICATION OF INDUSTRIAL APPLICABILITY/UTILITY REQUIREMENTS UNDER NATIONAL AND REGIONAL LAWS* (2001), *quoted in* *Eli Lilly & Co. v. Canada*, Second Report of Dr. Daniel Gervais, *supra* note 75, at 15 (emphasis added).

102. Vadi, *supra* note 76, at 119.

103. *Eli Lilly & Co. v. Canada*, Respondent's Rejoinder on the Merits, *supra* note 85, at 65-66 (notes omitted).

any one particular meaning for any of the terms.”¹⁰⁴ Canada’s argument followed the Vienna Convention because the VCLT considers: (1) the ordinary meaning of the terms “useful” and “capable of industrial application” as understood in the patent law field in the NAFTA parties; (2) the context of Article 1709(1); (3) the subsequent practice of the NAFTA parties; (4) other relevant rules of international law; and (5) to the extent necessary to eliminate ambiguity, any relevant supplemental means of interpretation.¹⁰⁵ Canada argued that none of these points supports Lilly’s argument that a single or baseline notion circumscribing the meaning of utility or other patentability criteria (including those not named in NAFTA, such as enablement) bound the NAFTA parties or their domestic courts. The Tribunal agreed with Canada that ISDS tribunals were not courts of appeal of domestic courts, but noted that courts are organs of the state and that egregious errors by a court could be subject to an ISDS proceeding, thus refusing a categorical exclusion.¹⁰⁶

In the end, all of Lilly’s claims were rejected, but the case remains relevant. First, much of the outcome relied on Lilly’s inability to provide evidence to support its case¹⁰⁷ because the tribunal had no difficulty accepting that patents at issue were investments.¹⁰⁸ It also accepted that acts of courts as judicial organs of a state would be scrutinized by an ISDS tribunal—especially those that might “crystallize” an expropriation—but only if there was “clear evidence of egregious and shocking conduct” by the court.¹⁰⁹ This means that future ISDS claims could be filed on the basis of patent invalidations. The panel also left open the possibility that a sudden change in the law might have led to a different outcome by referring to the progressive nature of the change in Canadian law—some degree of change through judicial interpretation is to be expected, particularly in a common law environment.¹¹⁰

III. INTERFACES BETWEEN INTELLECTUAL PROPERTY, HUMAN RIGHTS, INTERNATIONAL TRADE & INVESTMENT

The title of this Part could easily be the title of a book. Needless to say, not every nook and cranny of the substantive interfaces between intellectual property, human rights and international trade can be explored in these pages. It gets worse: add the investment dimension and one must now square new normative and

104. *Id.* at 65.

105. VCLT, *supra* note 87, arts. 31–32; *Eli Lilly & Co. v. Canada*, Respondent’s Rejoinder on the Merits, *supra* note 85, at 66.

106. *See Eli Lilly & Co. v. Canada*, Final Award, *supra* note 2, ¶ 221 (“[A] NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of national judiciaries.”); *see also supra* note 56 and accompanying text.

107. *See Eli Lilly & Co. v. Canada*, Final Award, *supra* note 2, ¶¶ 308, 349, 366, 376, 379, 385.

108. *See id.* ¶ 167 (referring to “the investments at issue in this arbitration (the Zyprexa and Strattera Patents)”).

109. *See id.* ¶¶ 221, 224.

110. *See id.* ¶¶ 198, 310, 349.

doctrinal circles. The purpose of this Part is thus only to provide the necessary context on the elements of the interface to allow this Article to make concrete doctrinal recommendations in Part V.

This Part explores the linkages between intellectual property protection in trade and investment agreements, on the one hand, and access to (at least certain) pharmaceuticals and human rights, on the other. When applied to pharmaceutical regulation the international regime in which interfaces must be built is “characterized by institutional density and governed by human rights law, international intellectual property law and international health law.”¹¹¹

A. Intellectual Property and Human Rights

The UN Charter, the texts establishing some UN specialized agencies (such as the International Labour Organization (ILO) and the UN Educational, Scientific, and Cultural Organization (UNESCO)), the International Covenant on Civil and Political Rights, the Universal Declaration on Human Rights, the European Convention on Human Rights (ECHR), and international human rights law more generally commit member states to the protection and promotion of human rights.¹¹² Some core human rights are even considered *jus cogens*, creating obligations from which treaties cannot derogate.¹¹³ Neither intellectual property (discussed in this Section) nor the right to health (discussed in Section III.C.) are typically considered to form part of *jus cogens*.¹¹⁴

Some forms of intellectual property may be seen as (non-*jus cogens*) human rights when such intellectual property rights are aligned with and fulfill human rights’ objectives. This means that investors can, and do, rely on property protections or other fundamental rights in investment disputes. Infusing human rights into such disputes is this far from a one-way street.¹¹⁵ A first example is the right of authors in their creations while acknowledging the need for access, as required by the International Covenant on Economic, Social and Cultural Rights.¹¹⁶ At least part of the copyright system can be defended as a human right, for two

111. Vadi, *supra* note 76, at 123.

112. Petersmann, *supra* note 20, at 32.

113. *Id.* at 33.

114. See Patricia C. Gunn, *Health Care Refugees*, 6 LOY. U. CHI. INT’L L. REV. 339, 361 (2009).

115. See Jose A. Alvarez, *The Use (and Misuse) of European Human Rights Law in Investor-State Dispute Settlement*, in THE IMPACT OF EU LAW ON INTERNATIONAL COMMERCIAL ARBITRATION 519, 605 (Franco Ferrari ed., 2017) (discussing the protection of investment as property or a possession under European human rights law).

116. International Covenant on Economic, Social and Cultural Rights art 15, Dec. 16, 1966, S. Treaty Doc. No. 95-19, 6 I.L.M. 360 (1967), 993 U.N.T.S. 3 [hereinafter ICESCR] (providing both the right of everyone to take part in cultural life and to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author). As of 2016, the Covenant has 164 parties. The United States has signed, but has not ratified the Covenant. See *Status of Ratification Interactive Dashboard*, UNITED NATIONS HUM. RTS. OFF. HIGH COMMISSIONER, <http://indicators.ohchr.org/> [<https://perma.cc/7BYH-UY7E>] (last visited June 21, 2018).

reasons. First, because it is seen as property, and property is sometimes seen as a human right.¹¹⁷ Second, as René Cassin (Nobel Peace Prize recipient (1968) and co-drafter of the Universal Declaration of Human Rights (UDHR)) noted, human beings “can claim rights by the fact of their creation.”¹¹⁸ The Charter of Fundamental Rights of the European Union also considers intellectual property as a fundamental right.¹¹⁹

Human rights principles and analogies provide normative boundaries to the age-old quest for intrinsic equilibrium in copyright policy: the protection of interests resulting from expressed creativity, on the one hand, and the right to enjoy and share the arts and scientific advancements, on the other. Indeed, Article 27 of the UDHR is an interesting normative tool to balance copyright policy. It offers a solid justificatory theory beyond the practicalities of trade: Article 27 UDHR protects both the right to the protection of the moral and material interests resulting from and scientific, literary or artistic production of which an individual is the author and users’ right freely to participate in the cultural life of the community, to enjoy the arts, and to share in scientific advancement and its benefits.¹²⁰ Copyright protection can thus serve to protect interests resulting from scientific, literary, or artistic production, while securing the objective of access, which is expressed teleologically as a tool to allow everyone to enjoy the arts and to share in scientific advancement and its benefits. By giving a purpose to exceptions, human rights may both serve as guidance to courts and compensate for the excessively economic focus of trade law.¹²¹

Professor François Dessemontet summarized this rather well when he wrote that “the Universal Declaration and the UN Covenant [on Economic, Social and Cultural Rights adopted on 16 December, 1966] mark the apex of the French vision of literary and artistic property, as opposed to the Anglo-American ‘mercantilist’

117. See, e.g., Charter of Fundamental Rights of the European Union art. 17(1), 2012 O.J. (C326/391). There are questions as to whether that human right protection of property extends to private property. See Daniel Gervais, *Spiritual but Not Intellectual? The Protection of Sacred Intangible Traditional Knowledge*, 11 CARDOZO J. INT’L & COMP. L. 467, 483–484 (2003).

118. Michel Vivant, *Authors’ Rights, Human Rights?*, 174 REVUE INTERNATIONALE DU DROIT D’AUTEUR [RIDA] 60, 86 (1997).

119. E.U. Charter art. 17(2) (“Intellectual property shall be protected.”). For a discussion, see Christophe Geiger, *Intellectual Property Shall Be Protected!? Article 17 (2) of the Charter of Fundamental Rights of the European Union: A Mysterious Provision with an Unclear Scope*, 31 EUR. INT’L PROP. REV. 113, 113–16 (2009) (“On December 7, 2000, intellectual property (IP) entered the ‘Pantheon’ of European fundamental rights protection. . . . [T]his provision (or at least the way it seems to be understood) could contribute to amplifying the crisis of legitimacy that IP is currently facing in public opinion. For sure, IP would have been better off without this badly-drafted provision.”).

120. G.A. Res. 217 (III) A, art. 27, Universal Declaration of Human Rights (Dec. 10, 1948). For a discussion, see Lea Shaver, *The Right to Science and Culture*, 2010 WISC. L. REV. 121.

121. For example, French courts have done so on occasion. See B. Edelman, Bulletin, *Propriété Intellectuelle*, 4 JOURNAL DU DROIT INTERNATIONALE [J.D.I.] 1005 (1989); Pierre Sirinelli, Note, 143 REVUE INTERNATIONALE DE DROIT AUTEUR [R.I.D.A.] 301 (1989) (Fr.); Jane C. Ginsburg, *Toward Supranational Copyright Law? The WTO Panel Decision and the “Three Step Test” for Copyright Exemptions*, 187 R.I.D.A. 3, 51–56 (2001) (Fr.).

view as ensconced in the TRIPS.”¹²² Put differently, the trade-economic approach refocused copyright on the industries that produce and distribute copyrighted content. From a purely policy-oriented perspective, this ‘de-centering’ of copyright away from creators reduces the moral imperative of users, whose sympathy for large distribution multinationals (assuming for the sake of this discussion that this is a widespread perception of how the music and film industry are structured) is far from infinite.

The *Lilly* case was about patents, not copyrights, however, which leads to major normative differences from the copyright analysis above, as this Article will now attempt to demonstrate.

B. Patents and Human Rights

Like copyright, patents are rights to prohibit the use of protected material (works in the case of copyright; inventions in the case of patents). If seen as a form of property, they may benefit from fundamental or human right to the protection of private property. This is so even in the absence of a viable market. To that extent, they are, like other property rights, rights to exclude. Yet, as noted in the previous pages, denial of access to copyrighted material may negatively affect the human rights balance between creation and access to culture and information. Denial of patented pharmaceuticals to patients who cannot afford them, however, when they, or their government, could afford those products at a generic rate (that is, without patent rent) may be an affront to another human right, namely the right to health.¹²³ The Preamble to the World Health Organization (WHO) Constitution provides that the “enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”¹²⁴

Battles between pharmaceutical companies, on the one hand, and AIDS and public health activists advocating flexibility on behalf of developing countries, on the other hand, have left scars on pharmaceutical companies, notably in the form of negative impressions on public opinion.¹²⁵ Fighting public health interests perceived and presented as human rights and spokespersons such as *Médecins sans*

122. François Dessemontet, *Copyright and Human Rights*, in *INTELLECTUAL PROPERTY AND INFORMATION LAW* 113, 114 (Jan J.C. Kabel ed., 1998).

123. See *infra* Section C.

124. Constitution of the World Health Organization, Preamble, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185. A number of proposals have been made at the World Health Organization (WHO) not only to limit patent protection but to “delink” drug prices from the underlying R&D costs. See *WORLD HEALTH ORG., AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS* 18 (2016) (“Consultations with WHO Member states highlighted that any new funding mechanism should take into account the main principles for equitable R&D . . . [including] open knowledge innovation and delinkage of R&D costs from product price in order to ensure equitable access.”).

125. See Martin L. Hirsch, *Side Effects of Corporate Greed: Pharmaceutical Companies Need a Dose of Corporate Social Responsibility*, 9 *MINN. J.L. SCI. & TECH.* 607, 632 (2008) (observing that “PhrMA may be forced to consider the negative impact that opposing human rights and consumer protection laws will have on public opinion of drug companies.”).

Frontières (Doctors Without Borders) and Nelson Mandela, against a backdrop of dying children to defend a “trade-related” right was a difficult public relations battle, one that should never have been waged. Moreover, an ethical, human rights approach to public health dictates limits on patent rights, especially when no real market benefit is possible because patients are too poor to afford the medication. To put it differently, no one is forcing patent holders to produce at or below cost, but patents may prevent third parties from producing lower cost versions and thus prevent availability. At its most basic level, the human rights balance argument is thus as follows: when the patent holder cannot reasonably hope to have a significant market in a territory for a product that has life-saving potential, there is no legitimate reason to prevent access to that product if someone (a public or private entity) is willing to produce it at a cost that the country can afford. There are legitimate concerns on the part of patent holders about re-exportation, and those should be adequately addressed, as they have been at the WTO.¹²⁶

The problem of HIV infection and other severe diseases affecting the least-developed countries does not lie entirely with patents, far from it. In several African countries where patent protection would be available, antiretroviral drugs are not patented.¹²⁷ Many others have until 2016 to adopt pharmaceutical patent protection under WTO rules.¹²⁸ Problems often lay elsewhere, such as in the absence of a capacity of production and the lack of distribution networks. The latter can be solved, though with colossal efforts, by setting up distribution mechanisms, local clinics, etc. Concerns about interrupted treatments and the possible emergence of more aggressive viruses must be taken very seriously.

The ripple effects of the clash between patents and human rights are far from over. The WHO, for example, has actively entered the field and broadened the discussion to the entire financing of pharmaceutical research, questioning whether current models are optimal to generate “research into communicable diseases and poverty and inequity in health.”¹²⁹ The WHO is not alone. The United Nations has generally taken a dim view of the interface between trade and human rights, especially when ISDS is factored in. A report presented in 2015 to the UN General Assembly concluded that ISDS “should be abolished as a fundamentally flawed

126. See World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 6, WTO Doc. WT/MIN(01)/DEC/2, 41 ILM 746 (2002) (commenting on the TRIPS Agreement and Public Health); Marla L. Mellino, *The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals?*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1349, 1388 (2010).

127. See Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to Aids Treatment in Africa?*, 286 JAMA 1886, 1887 (2001) (“This study demonstrates that patent protection for antiretroviral drugs in Africa is not extensive.”).

128. Some commentators believe that this flexibility is “merely academic” because many sub-Saharan countries comply with TRIPS even if they are under no obligation to do so. See Poku Adusei, *The Right to Health and Constitutional Imperatives for Regulating the Exercise of Pharmaceutical Patent Rights in Sub-Saharan Africa?*, 21 AFR. J. INT'L & COMP. L. 250, 262 (2013).

129. WORLD HEALTH ORG., THE WHO STRATEGY ON RESEARCH FOR HEALTH 44 (2012), http://apps.who.int/iris/bitstream/handle/10665/77935/9789241503259_eng.pdf [<https://perma.cc/45X3-SVS9>].

system having adverse human rights impacts.”¹³⁰ Ten years earlier, the High Commissioner for Human Rights offered a less radical solution, based in part on the above-mentioned references to “public morals” in GATT and GATS.¹³¹ The report quotes Robert Howse, who suggested that:

In the modern world, the very idea of public morality has become inseparable from the concern for human personhood, dignity, and capacity reflected in fundamental rights. A conception of public morals or morality that excluded notions of fundamental rights would simply be contrary to the ordinary contemporary meaning of the concept.¹³²

On that basis, the report argued, “the exclusion of the norms and standards of international human rights on the basis of the ordinary meaning of the terms would be very difficult to sustain.”¹³³ As to the meaning of “human life or health”, the report takes the view that “according to its ordinary meaning, is also very broad and has considerable potential to include a number of human rights. Certainly, the right to life and right to health fall within its scope.”¹³⁴

C. The “Right to Health” in Context

In what is perhaps its clearest articulation, the right to health appears in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”¹³⁵ According to General Comment 14, this right to health requires access to at least certain medicines.¹³⁶ The right also rests on Article 25.1 of the 1948 Universal Declaration of Human Rights:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and *medical care* and necessary social services, and the right to

130. U.N. Secretary-General, *Rep. of the Independent Expert on the Promotion of a Democratic and Equitable International Order*, U.N. Doc. A/70/285 (Aug. 5, 2015).

131. Office of the United Nations High Comm’r for Human Rights, *Human Rights and World Trade Agreements: Using General Exception Clauses to Protect Human Rights*, U.N. Doc. HR/PUB/05/5 (2005), <https://www.ohchr.org/Documents/Publications/WTOen.pdf> [<https://perma.cc/2W3G-EK79>] [hereinafter OHCHR Report].

132. Robert Howse, *Back to Court After Shrimp/Turtle? Almost but Not Quite Yet: India’s Short Lived Challenge to Labor and Environmental Exceptions in the European Union’s Generalized System of Preferences*, 18 AM. U. INT’L L. REV. 1333, 1368 (2003).

133. OHCHR Report, *supra* note 131, at 5.

134. *Id.*

135. ICESCR, *supra* note 116, art. 12.

136. United Nations Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 14 (2000): The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)*, ¶ 17, UN Doc. E/C.12/2000/4 (Aug. 11, 2000), <http://undocs.org/E/C.12/2000/4> (including the provision of equal and timely access to “appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at community level; the provision of essential drugs; and appropriate mental health treatment and care” as state obligations); see also Helen Keller & Lena Grover, *General Comments of the Human Rights Committee and Their Legitimacy*, in UN HUMAN RIGHTS TREATY BODIES: LAW AND LEGITIMACY 116, 132 (Helen Keller & Geir Ulfstein eds., 2012).

security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.¹³⁷

The IP/pharmaceutical patent protection relation with this “right to health” appears to dominate much of the discussions. Normatively, it is the hypotenuse of the IP/ pharmaceutical/human right (to health) triangle mentioned in the opening paragraph of this Part. It is not just about providing property-like rights to pharmaceutical research companies. As Valentina Vadi notes, pharmaceutical protection reflects both private and public interests, namely the private interest of the patent owner (that is, exclusive rights for the term of the patent and possible extensions), but also the public interest.¹³⁸ The public interest is protected by access to (new) life-saving or life-improving medicines, of course, and that is a fundamental part of the bargain. But the public interest is also served by the possibility (afforded by the patent disclosure) for other innovators to build on inventions disclosed to develop their own, including in markets where no patent is in force and in which there is thus no need to wait for the expiration of the patent.¹³⁹ Indeed, while there are real debates about the net (in aggregate) positive impact of patents on innovation writ large, empirical studies tend to isolate pharmaceuticals as an area in which they produce positive outcomes.¹⁴⁰

How does this nuanced grouping of private and public interests translate into trade rules? Such rules *can* accommodate at least some of the triangular policy equation outlined in the previous paragraphs, as the adoption of the Ministerial Declaration on TRIPS and Public Health and the subsequent 2003 establishment of the “paragraph 6 system” at the WTO illustrate.¹⁴¹ The issue that arises not in trade, but in an ISDS context, however, is the singular focus on the protection of private interests. This casts a deep shadow over the public interest component built into the patent system, thus potentially creating a severe policy imbalance.¹⁴² Put differently, in a state-to-state dispute settlement context, such as at the WTO Dispute-Settlement Body (DSB), public policy arguments can and are regularly used

137. G.A. Res. 217 (III) A, *supra* note 120.

138. Vadi, *supra* note 76, at 121.

139. *See id.* On the value of patent information, see Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 601 (2012) (noting that “the technical value of patent disclosures is greater than many legal scholars have appreciated, but also that many patents probably fail to meet the existing disclosure requirements.”); Sean B. Scymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 661 (2010) (suggesting an improvement in patent documentation because “[a] more technically robust patent document, replete with working examples, will allow follow-on innovators to more easily and quickly create second-generation products and processes.”).

140. Outside the pharmaceutical and chemical industries, James Bessen and Michael Meurer “safely conclude that during the late 1990s, the aggregate cost of patents exceeded the aggregate private benefits of patents for United States public firms.” JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 141 (2008). The classic study might still be Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 174 (1986).

141. *See* Baker & Geddes, *supra* note 49, at 28 n.127.

142. *See* Vadi, *supra* note 76, at 146.

to justify (e.g., under general exceptions clauses in GATT or GATS) a prima facie violation of a trade-related commitment contained in a WTO instrument.¹⁴³

Does the same reasoning apply to ISDS? Professor Sornarajah suggests that conflicts between private and public interests are likely to be structurally prevalent in ISDS due to panels' use of "low-order sources of international law like decisions of tribunals and the writings of 'highly-qualified publicists' who are no more than hired guns," thus not leaving states to address "issues involving economic development, poverty, welfare needs [and] the environment."¹⁴⁴ Kate Miles suggests in the same vein that there is "little room for the consideration of the public interest in a regime so heavily weighted towards investor protection."¹⁴⁵ If patents are seen as property, then their revocation, even where fully justified under domestic law, may appear at first glance like an expropriation, absent the broader normative context that typically informs patent and innovation policies.

Professor Susy Frankel notes in connection that:

Investment tribunal arbitrators when making decisions (including the interpretation of the agreements at issue) are likely to focus on the function of IP as a set of property rights rather than as equally important parts of the international IP structure, which enables tailoring of those rights to reward innovation appropriately (rather than excessively) and to maintain regarding interests, such as when property rights need to be balanced with affordability and availability of medicines [T]hat does not require and should not result in detaching the property aspects of IP from its other functions and objectives.¹⁴⁶

True, "property" in the patent field does not mean quite the same thing as, say, in real estate, even if all property rights arguably have a societal function.¹⁴⁷ For example, property rights are sometimes described as absolute.¹⁴⁸ Intellectual

143. In the specific case of intellectual property, a WTO dispute-settlement panel discussing TRIPS Article 8 noted the following: "This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement." Panel Report, *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, ¶ 7.210, WTO Doc. WT/DS174/R (Mar. 15, 2005).

144. See Muthu-Cumaraswamy Sornarajah, *Evolution or Revolution in International Investment Arbitration? The Descent into Normlessness*, in *EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION* 631, 654–55 (Chester Brown & Kate Miles eds., 2011).

145. Kate Miles, *Reconceptualizing International Investment Law: Bringing the Public Interest into Private Business*, in *INTERNATIONAL ECONOMIC LAW AND NATIONAL AUTONOMY* 295, 296 (Meredith Kolsky Lewis & Susy Frankel eds., 2010).

146. Susy Frankel, *Interpreting the Overlap of International Investment and Intellectual Property Law*, *J. INT'L ECON. L.* 1, 5 (2016).

147. See Jakob Cornides, *Human Rights and Intellectual Property: Conflict or Convergence?*, 7 *J. WORLD INTELL. PROP.* 135, 143 (2004) ("[P]roperty is not an end in itself. Obviously, it must be used in a way that contributes to the realization of the higher objectives of human society.").

148. See generally Robert P. Burns, *Blackstone's Theory of the "Absolute" Rights of Property*, 54 *U. CIN. L. REV.* 67, 72 (1985) ("Of all the absolute rights, the most essential are those of personal security, personal liberty, and private property.").

property by contrast has inherent limitations (e.g., term) and exceptions (e.g., fair use) built into the system. They are “part of the framework of rights, rather than being something that gnaws away at them.”¹⁴⁹ Those broader societal objectives related to innovation and access provide “both boundaries and the framework of the scope of the property rights.”¹⁵⁰

Then the grant of a patent right has a specific purpose, and that purpose, seen teleologically (from a policy perspective), is primarily an instrument to create an incentive that will be in the (private) interest of the patent holder but for the greater public interest in access to innovation.¹⁵¹ The public interest component present, to a certain extent at least, in state-to-state dispute settlement is not the same when a party to the dispute is a multinational company. As Susan Sell notes, despite all the rhetoric of economic competitiveness, states are not firms.¹⁵² Firms “only have to worry about one thing—shareholder value. The bottom line is always to earn a profit, and they have one clear goal—to increase shareholder value. Policymakers face a much more complicated array of issues and priorities.”¹⁵³ Yet, as noted above, patent holders use human rights, such as private property protection in their favor.¹⁵⁴

Still, patent owners using ISDS to challenge regulatory measures adopted by host states can directly impact regulatory autonomy, including the state’s ability to make and change innovation policies and to protect human rights.¹⁵⁵ Hence, the risk is that allowing ISDS to interpret the scope of intellectual property obligations as private property and well beyond issues of actual expropriation “stand to disrupt regulations governing everything from public health, energy, finance, education, privacy, and free expression. Under these provisions investors can attack domestic social bargains and, if successful, override legitimate sovereign regulatory discretion.”¹⁵⁶ As far as evolution of the law in court opinions are concerned, the Tribunal in the *Lilly* case found that such evolutions were normal and that investors should expect them to happen.¹⁵⁷

149. Frankel, *supra* note 146, at 14.

150. *Id.* at 16.

151. See Christophe Geiger, *The Social Function of Intellectual Property Rights, or How Ethics Can Influence the Shape and Use of IP Law* 12 (Max Planck Inst. for Intellectual Prop. & Competition Law, Research Paper No. 13-06, 2013), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2228067 [<https://perma.cc/MP2X-C9JE>] (“Society has a need for intellectual productions in order to ensure its development and cultural, economic, technological and social progress and therefore grants the creator a reward in the form of an intellectual property right, which enables him to exploit his work and to draw benefits from it. In return, the creator, by rendering his creation accessible to the public, enriches the community. Intellectual property law is thus the product of a type of ‘social contract’ between the author and society.”).

152. Susan K. Sell, Remarks, 8 AM. SOC’Y INT’L L. PROC. 317 (2014).

153. *Id.* at 318.

154. See *supra* Section III.A.

155. See Vadi, *supra* note 76, at 186.

156. Sell, *supra* note 152, at 317.

157. See *Eli Lilly & Co. v. Canada*, Final Award, *supra* note 2, ¶¶ 198, 310, 349.

The potential conflict between ISDS and human rights exacerbates the risk that tenuous bridges built to allow states to enforce human rights when those rights conflict with trade commitments will collapse. The chink in the post-Westphalian armor is that supranational mechanisms meant to cabin states to avoid bad actions may be used to prevent them from performing good ones. Although this claim could be made with respect to trade law—especially with the more powerful WTO DSB (compared to its GATT predecessor)—direct conflicts have thus far been reasonably well handled—often by avoidance.¹⁵⁸ In the ISDS context, the question that arises is, when such conflicts emerge, how will they be handled?

The arc of trade law is moving in a positive direction, towards at least conflict avoidance and perhaps even some form of reconciliation. Professor Helfer has offered a vision of interpenetration and cross-pollination of intellectual property and human rights, possibly even a form of integration.¹⁵⁹ Will ISDS go in the opposite direction? As Professor Okediji commented, this is a “stunning change” as she noted that the *Lilly* case represented “uncharted territory in the increasingly complex and contested landscape of international intellectual property obligations.”¹⁶⁰ In her view, national innovation policy is:

[O]ne of the very few areas still largely insulated from the pervasive economic governance that conditions contemporary international economic relations. Intellectual property obligations in the investment context thus pose a new threat to states’ traditional lawmaking powers by providing foreign actors a singular opportunity to challenge laws that have been enacted with the domestic public interest in full view.¹⁶¹

Professors Dreyfuss and Frankel have noted (rightly in this Article’s view), along similar lines, that the TRIPS Agreements may contain upper limits to justify limits on intellectual property in the public interest, such as those contained in Articles 1.1, 7 and 8 of the TRIPS Agreement.¹⁶² Those are for the most part absent from NAFTA and many other IIAs.¹⁶³

In sum, regulatory autonomy in the public health area is constrained by trade law, but only to a limited extent because, as the next Part explicates, doctrinal

158. The GATT was weaker because a losing party could veto adoption of the report. Not so under the WTO. *See supra* note 24.

159. *See* Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 71–78 (2004).

160. Okediji, *supra* note 56, at 1122.

161. *Id.*

162. Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property*, 36 MICH. J. INT’L L. 557, 588 (2015) (“While the Basic Principles of the TRIPS Agreement permit states to implement more extensive protection, there is a proviso: they may not go so far as to ‘contravene the provisions of the Agreement.’ Now that it is clear how easily theories of commodification and assetization can unravel the rationale behind IP protections, the proviso could play a more prominent role in the future. The Objectives provision of TRIPS recognizes that IP protection should be to the mutual advantage of producers and users, create a balance of rights and obligations, and promote technical transfer. Thus, agreements that undermine those objectives should not be regarded as legitimately made.”).

163. The text of NAFTA chapter 17 contains no equivalent provision. NAFTA, *supra* note 1.

interfaces exist to factor in the public interest and human rights in trade disputes. In the ISDS context, that regulatory autonomy may be threatened due to the very fuzzy interface with both human rights law and regulatory autonomy. Panels in ISDS disputes can and often do consider human rights arguments put forward by a party as they would any other argument brought to their attention. Is that a sufficient guarantee? The answer is certainly not a clear yes.

Protecting human rights can be seen in this context as a subset of a broader regulatory regime protecting social welfare and other key public policy objectives.¹⁶⁴ The challenge is to integrate regulatory autonomy and the public interest that underpins it into the ISDS equation, a task to which the last Part now turns its attention. Before doing so, let us see which interfaces have been used in the area of trade law and whether they can be ported to the ISDS context.

IV. DOCTRINAL INTERFACES

A. Balancing Human Rights, Trade and Investment

There is no recognized supremacy or hierarchy of human rights and trade and investment rules—at least beyond *jus cogens*. General principles of interpretation apply, however. Hence, one may argue that an IIA signed after the conclusion of an instrument protecting human right may have priority under the *lex posterior derogat legi priori* canon, or that an IIA should take precedence over more general human rights obligations under the *lex specialis derogat legi generali* canon.¹⁶⁵

The WTO Dispute Settlement Body (DSB) uses the VCLT and “general balancing principles (such as transparency, non-discrimination, necessity, and proportionality) in deciding on whether national restrictions of freedom of trade are necessary for the protection of public interests.”¹⁶⁶ DSB reports often limit the scope of their review of WTO Members’ regulatory autonomy.¹⁶⁷ This raises directly the interface question: can a WTO Member use an obligation to comply with its human rights obligations to derogate from a trade commitment, absent a direct possibility to do so in the text containing the commitments?¹⁶⁸ Professor Pauwelyn, for example, has advocated allowing:

[T]he use of human rights as a *defence* against a claim of WTO violation in WTO dispute settlement but only if (i) both disputing parties are bound by the human rights provision in question, (ii) there is an irreconcilable conflict between the WTO obligation, on the one hand, and the human right, on the other, and (iii) pursuant to a conflict clause in either treaty or

164. See LONE WANDAHL MOUYAL, INTERNATIONAL INVESTMENT LAW AND THE RIGHT TO REGULATE: A HUMAN RIGHTS PERSPECTIVE 9, 223 (2016).

165. Petersmann, *supra* note 20, at 33. According to the *lex posterior derogat (legi) priori* canon, a later law prevails over an earlier one. According to the *lex specialis derogat legi generali* canon, a more specific law prevails over a general one.

166. *Id.* at 34.

167. *See id.*

168. This possibility is explored in Part V.

the applicable conflict rules of public international law (eg, *lex posterior* or *lex specialis*), the human rights provision prevails over the WTO provision.¹⁶⁹

The WTO Appellate Body has not articulated this interface quite that way.¹⁷⁰ Professor Petersmann, opining on the dispute on Australian plan packaging legislation, suggested a more flexible balancing:

Just as national courts tend to “balance” economic and health rights on the basis of constitutional principles of non-discrimination, good faith, necessity and proportionality of governmental restrictions, also regional and WTO dispute settlement jurisdictions must interpret IEL “in conformity with principles of justice” and “human rights and fundamental freedoms” as accepted by all WTO members, notwithstanding the fact that the differences among the applicable laws in different jurisdictions may entail different procedures (e.g. regarding burden of proof, judicial standards of review) and legitimately different interpretations of HRL, constitutional laws, health law and IEL. The WTO panel [in the plain packaging case] should therefore repeat and clarify in respect of the TRIPS Agreement what the Appellate Body has already indicated with regard to the TBT Agreement, *i.e.* that the legal and judicial “balancing methods” for interpreting the specific WTO agreements should proceed from the same “principles of justice” underlying WTO law as well as the human rights obligations of WTO members.¹⁷¹

Other commentators balk at the thought of having human rights obligations taken on board in trade tribunals, fearing a “take over” of human rights by trade law.¹⁷²

Like the WTO DSB, ISDS tribunals apply the VCLT. This suggests that the arguments used to support the VCLT-based approach to human rights and balancing tests used in trade may port to the investment area, if credible and useful parallels can be established.¹⁷³

B. Incorporating Human Rights in Trade and Investment Disputes

An option to operationalize the interface between human rights, on the one hand, and international trade and investment law, on the other hand, is the incorporation or integration of (specific) human rights in the trade or investment

169. Joost Pauwelyn, *Human Rights in WTO Dispute Settlement*, in HUMAN RIGHTS AND INTERNATIONAL TRADE, *supra* note 20, at 205, 208.

170. *Id.* at 210.

171. Ernst-Ulrich Petersmann, *How to Reconcile Health Law and Economic Law with Human Rights? Administration of Justice in Tobacco Control Disputes*, 10 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 27, 60 (2015).

172. See Alston, *supra* note 3, at 837 (noting that the WTO is not “designed, structured, or suitable to operate in the way that [an institution] with major human rights responsibilities would.”).

173. See Jaime, *supra* note 89, at 287–88 (“[I]n the absence of express rules in a particular IIA . . . it is appropriate to turn to the general rules of interpretation, as set forth by Articles 31–33 (Interpretation of Treaties) of the VCLT.”).

regime itself. Such an integrative approach can be pushed quite far, as one sees in the work of Professor Petersmann, for example. He argued (in the case of trade) that free trade forms part, or at least is aligned with, the international human rights framework, in particular in advocating respect for human dignity, individual autonomy, and the free development of one's personality through enterprise or business.¹⁷⁴ Free trade can help an "individual's right to trade the fruits of her labour in exchange for foreign goods and services needed for personal self-development in dignity."¹⁷⁵ Petersmann's view, anchored in Kant's idea that a *constitutional* law doctrine of fundamental rights and duties of citizens could also apply internationally,¹⁷⁶ is that GATT and other international trade rules, typically viewed as policy instruments designed to improve access to foreign markets, should also be viewed as "*domestic policy instruments* that could serve not only economic functions (e.g., for promoting economic welfare), but also 'constitutional functions' (e.g., by rendering domestic constitutional principles of freedom, non-discrimination, rule of law, and judicial review more effective in the trade policy area)."¹⁷⁷ In his critique of this approach Professor Alston notes that the subset of rules enshrined in international trade law are *not* those that are "recognized as economic rights within the framework of international human rights law."¹⁷⁸

This debate can be neither resolved nor even fully investigated here. Whether or not it is correct to assert that free trade meshes with the international human rights framework, however, the idea that a "constitutional" approach advocating not just a rapprochement between human rights and trade (possibly adding investment), forms the basis for a doctrinal interface worthy of a bit more exploration. Indeed, this might explain why the "currency [of this approach] has persisted," in spite of harsh criticism both in academia and by developing countries.¹⁷⁹

How one defines constitutionalism is often infused with the view one takes of the positive/natural law debate.¹⁸⁰ In a model of liberal constitutionalism, "the constitution establishes a set of electoral rules, and distributes capacities and functions among governmental institutions."¹⁸¹ In a different model, such as the

174. Petersmann, *supra* note 20, at 31.

175. *Id.* at 26.

176. Ernst-Ulrich Petersmann, *The Transformation of the World Trading System Through the 1994 Agreement Establishing the World Trade Organization*, 6 EUR. J. INT'L L. 161, 165 (1995).

177. Petersmann, *supra* note 20.

178. Alston, *supra* note 3, at 822 (emphasis added).

179. See Deborah Z. Cass, *The 'Constitutionalization' of International Trade Law: Judicial Norm-Generation as the Engine of Constitutional Development in International Trade*, 12 EUR. J. INT'L L. 39, 40 (2001) ("[I]ts currency has persisted even after it became apparent that the claim was considered provocative not only by the trade law establishment, but also by developing countries and non-governmental organizations with interests ranging from business regulation through environmental standards, to labour reform.").

180. What I mean here, in very succinct fashion, is that a constitution is a highest norm in Kelsen's theory but there are higher organic norms in a natural law approach.

181. ALEC STONE SWEET, *GOVERNING WITH JUDGES: CONSTITUTIONAL POLITICS IN EUROPE* 20 (2000).

United States, a constitution adds “a layer of substantive constraints on the uses of public authority.”¹⁸² This typically limits what (each level of) government can do, either by granting exclusive power over a certain area to one level of government (thereby excluding others) or by imposing a set of “higher” rules and principles (such as those contained in the US Bill of Rights or the EU Charter). Typically, governments cannot (easily) derogate from such rules and principles—acknowledging at the same time that enforcement is key. Consequently, the existence of words describing such rights in a constitutional text does not always mean that they will be applied to preserve the liberties of individual citizens.¹⁸³

A constitutional approach allows one to link higher-level norms at the domestic level and international norms, such as customary international law. For example, the Restatement (Third) of the Foreign Relations Law of the United States notes that “there is a willingness to conclude that prohibitions [against human rights violations] common to the constitutions or laws of many states are general principles that have been absorbed into international law.”¹⁸⁴ As used in the context of international trade, “constitutionalizing” might thus be translated as promoting “an increasing ‘internationalization’ of formerly domestic constitutional law concepts (like non-discrimination, necessity, and proportionality of government restrictions on transnational trade).”¹⁸⁵ Used in this sense “constitutionalization” of trade law is an approach that can add normative depth to treaty interpretation, in part because it can broaden the range of interpretive tools.

How would such an approach work in an ISDS context? The answer is far from clear. Investor-state is not about free trade; it is about investment and “property” protection.¹⁸⁶ In *Lilly*, the indirect expropriation argument applied to a very specific type of “property,” however, Lilly’s complaint challenges the criteria used by domestic courts, after due process, to decide that two patents were invalid.¹⁸⁷ To argue that invalidation is a violation of the patent owner’s human rights (protection of property) is a huge step, one that this Article refuses to take. This explains why a constitutional approach seems risky in an ISDS context. Alston’s critique of a possible normative and institutional takeover of human rights by trade law and trade tribunals resonates louder here than in trade, even if at least some aspects and normative underpinnings of international trade law are aligned with a number of economic and developmental human rights.¹⁸⁸ In an ISDS

182. *Id.* at 21 (“Guatemala, Iran, the Soviet Union and various authoritarian regimes elsewhere have had wonderfully worded bills of rights that produced no discernible increase in respect for individual liberties in those countries.”).

183. *See* Charter of Fundamental Rights of the European Union, 2012 O.J. C 326/391; John S. Baker, Jr., *The Effectiveness of Bills of Rights*, 15 HARV. J.L. & PUB. POLY 55 (1992).

184. RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 701, Reporters’ Notes 1, at 154 (AM. LAW. INST. 1987).

185. Ernst-Ulrich Petersmann, *Theories of Justice, Human Rights, and the Constitution of International Markets*, 37 LOYOLA L.A. L. REV. 407, 437 (2003).

186. *See* Alvarez, *supra* note 115.

187. *See supra* Part II.A.

188. *See supra* note 3 and accompanying text.

context, by contrast, if a clash between investment protection and human rights emerges, the “supreme” value of investor and property protection may be a poor sextant to arbitrate the place of human rights if the normative lodestar is the rights of multinational investors. In sum, although private property protection is consistent with human rights, it is one of many such rights that should be considered in that context.¹⁸⁹

C. Contractarian Approaches

Contract-based approaches have been suggested to broaden the scope and nature of norms that international trade tribunals can use to interpret trade agreements. This seems particularly relevant in an ISDS context because a significant part of the IIAs, namely the BIT regime, “was developed on the basis of a *contractual way of thinking*, lifting contractual claims out of a domestic context and into an international law context.”¹⁹⁰ Put differently, ISDS is perhaps best seen as private law while trade law as public law.

1. Filling Normative Lacunae

Any court interpreting a legal text, whether a contract, statute or treaty, may be called upon not just to interpret it, but also to fill lacunae.¹⁹¹ Lacunae may be said to exist for several reasons, including that terms are left undefined; that definitions they contain are unclear; or that there are missing elements and interstices in the texts. In the case of a treaty specifically, this includes taking account of relevant rules of international law, as provided in the VCLT.¹⁹² Depending on the issue, international law can both provide context and constitute “relevant rules of international law applicable in the relations between the parties.”¹⁹³

As was done for constitutional approaches, let us see first how this applies in the trade law context. Non-WTO international agreements may provide context to interpret the provisions of WTO agreements, as the WTO Appellate Body did in the *Shrimp-Turtle* case.¹⁹⁴ Using external norms as interpretive tools can be done

189. See Alvarez, *supra* note 115.

190. MOUYAL, *supra* note 164, at 223. The book only briefly mentions public health, *see id.* at 217–18, and NAFTA, *see id.* at 68–73, but constitutes a most helpful study of the general interface between human rights and investment law, including a detailed list of extant BITs and model BITs. *See id.* at 223.

191. A lacuna in a specific treaty does not mean a lacuna in international law, in the sense that international law beyond the text of the treaty can “fill” the lacuna. *See* Prosper Weil, “*The Court Cannot Conclude Definitively . . .*” *Non Liquet Revisited*, 36 COLUM. J. TRANSN’L L. 109, 110 (1997).

192. This often amounts to “interpreting silence” to quote the term used by Lone Wandahll Mouyal in this context. MOUYAL, *supra* note 164, at 54.

193. VCLT, *supra* note 87, arts. 31(1), 31(3)(c).

194. Panel Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc. WT/DS58/AB/R, ¶¶ 127–131 (adopted Oct. 12, 1998).

without making law, which panels and the Appellate Body are prohibited from doing under the DSU.¹⁹⁵

As the International Law Commission suggests, international law can “supplement” WTO law, unless the opposite is explicitly stated in the agreement.¹⁹⁶ Along similar lines, in its 2008 resolution No. 5/2008 on International Trade Law the International Law Association declared that “WTO members and bodies are legally required to interpret and apply WTO rules in conformity with the human rights obligations of WTO members under international law.”¹⁹⁷ Then, as was pointed out by the International Court of Justice (ICJ):

It being the duty of the Court itself to ascertain and apply the relevant law in the given circumstance of the case, the burden of establishing or proving rules of international law cannot be imposed upon any of the parties for the law lies within the judicial knowledge of the Court.¹⁹⁸

It is often noted in this regard that the Appellate Body has said that WTO norms are not to be read in “clinical isolation” from international law.¹⁹⁹ The WTO is not part of the United Nations and, although its former Director General Supachai Panitchpakdi “affirmed the vital importance” of the UN Millennium Development Goals (MDGs), including the goal to combat HIV/AIDS, malaria and other diseases, those goals were not formally incorporated into the WTO framework.²⁰⁰ The closest reference one can point to might be that contained in the

195. DSU Article 3(2) provides:

The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

DSU, *supra* note 81, art. 3(2); *see also* Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46 VAND. J. TRANSNAT'L L. 1149, 1206 (2013).

196. *See* Martti Koskeniemi (Chairman of the Int'l Law Comm'n), *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, ¶ 85, U.N. Doc. A/CN.4/L.682 (Apr. 13, 2006).

197. Int'l Law Ass'n Res. No. 5/2008 (Aug. 17–21, 2008). Under its Constitution, the International Law Association (ILA) is an international non-governmental organisation and has consultative status. Its objectives are “the study, clarification and development of international law, both public and private, and the furtherance of international understanding and respect for international law.” Int'l Law Ass'n Constitution art. III, § 1.

198. *Fisheries Jurisdiction (Ger. v. Ice)*, Judgment, 1974 I.C.J. Rep. 181 (July 25).

199. Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, ¶ III:B, WTO Doc. WT/DS2/AB/R (adopted May 20, 1996); *see also* Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, at 12 n.19, WTO Doc. WT/DS8/AB/R (adopted Oct. 4, 1996).

200. Wolfgang Benedek, *The World Trade Organization and Human Rights*, in ECONOMIC GLOBALISATION AND HUMAN RIGHTS 137, 150–51 (Wolfgang Benedek, Koen De Feyter & Fabrizio Marrella eds., 2007). The WTO website, however, notes that the “WTO, in co-operation with UNCTAD and ITC, monitors the achievement of trade-related Millennium Development Goals.” *See The WTO and the Sustainable Development Goals*, WORLD TRADE ORG., <https://www.wto.org/>

TRIPS Declaration on Public Health, adopted in 2001, approximately one year after the Millennium Summit in September 2000 at which the MDGs were adopted.²⁰¹

At least two contract-based theories have been offered to suggest how *trade* tribunals should use the VCLT. Some suggestions are infused with normative objectives, such as Professor Harris suggestion that the WTO Appellate Body “may nevertheless take the Agreement’s unfairness into account by using the treaty of adhesion doctrine to interpret its provisions more favorably to developing countries.”²⁰² The WTO has a number of special and differential provisions (including in the DSU) and it is unlikely that such a normative overlay will be applied in the context of a dispute absent support in a negotiated text, whether that be a WTO-negotiated agreement or a ministerial or decision.²⁰³ The second is the doctrine of incomplete contracts, on which we now turn the spotlight.

2. *Incomplete Contracts*

In the wake of Hadfield’s suggested application of the incomplete contracts theory to statutes,²⁰⁴ Joel Trachtman suggested that WTO panels and the Appellate Body could do the same to treaties, though not without significant constraints and difficulties.²⁰⁵ He pointed to the role of adjudication bodies, especially when interpreting standards instead of rules. A standard is not a lacuna; it needs to be interpreted and applied to a specific fact pattern, however. As Trachtman explained, “[l]acunae are circumstances where there is no law and no constraint. This is quite different from a standard, where there is law applicable by a dispute resolution tribunal but less explicit guidance to the tribunal as to how to decide.”²⁰⁶

Now let us see how this might apply in an ISDS context. As already noted, arbitral tribunals operating in an ISDS context follow the VCLT in interpreting

english/thewto_e/coher_e/mdg_e/mdg_e.htm [https://perma.cc/Z3CV-WGD4] (last visited June 21, 2018).

201. Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 (2001), https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf [https://perma.cc/QV5H-SFL6]. On the Millennium Development Goals, see generally UNITED NATIONS, *THE MILLENNIUM DEVELOPMENT GOALS REPORT 2015* (2015).

202. Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PENN. J. INT’L ECON. L. 681, 687 (2006).

203. See Mary Sabina Peters & Manu Kumar, Annotation, *Introspect “Special and Differential Treatment” Given to Developing Countries Under the WTO Dispute Settlement System*, 17 A.L.R. INT’L 123, 124 (2014) (“[T]he DSU included some provisions that referred to developing countries’ special needs. However, these Special and Differential Treatment (SDT) measures have turned out to be of very limited value to developing countries . . . Most of the clauses in DSU regarding developing countries have turned out to be declarative rather than operative.”).

204. Gillian K. Hadfield, *Weighing the Value of Vagueness: An Economic Perspective on Precision in the Law*, 82 CALIF. L. REV. 541, 547 (1994).

205. Joel P. Trachtman, *The Domain of WTO Dispute Resolution*, 40 HARV. INT’L L.J. 333, 350 (1999).

206. *Id.* at 376.

investment treaties (or investment chapters of trade agreements).²⁰⁷ The *Lilly* Award makes a very interesting series of points in that regard:

[T]he phrase “applicable rules of international law” addresses not simply, for example, rules of interpretation of treaties, such as those reflected in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (“VCLT”), but also any other applicable rules of international law that may be relevant to the case before it. . . . It will be a matter for each tribunal constituted under Section B of NAFTA Chapter Eleven to evaluate, with the assistance of submissions of the parties on the matter, the precise scope of the phrase “applicable rules of international law” in the circumstances of the case of which it is seised.²⁰⁸

The VCLT directs tribunals to consider the plain meaning of the text. Yet, as the arbitral tribunal pointed out in *Saluka v. Czech Republic*, the VCLT’s direction about *object and purpose* is also key in interpreting the scope of obligations, and it includes both an immediate and a broader context.²⁰⁹ Because they do follow the VCLT, ISDS panels thus consider the plain meaning of the text *in light of its object and purpose*, and the subsequent practice of the parties in its application.²¹⁰

True, it may be difficult to argue before an ISDS tribunal that it must consider human rights texts because an investment treaty (or the investment chapter of a trade treaty like NAFTA) is “incomplete.” Yet, the conflict between the *object and purpose* of the investment chapter (to protect property) and the *object and purpose* of the IP chapter of an IIA (forming part of a balanced and effective innovation policy) must be reconciled. Petersmann suggests a balancing test similar to his proposal in the WTO context:

Investment arbitral tribunals should likewise aim at reconciling the general principles of law underlying the almost 3,000 investment treaties with the governmental duties to protect public health not only on the basis of the specific treaty commitments, but also with due regard to the progressive judicial clarification of their underlying “principles of justice” acknowledging sovereign rights to give priority to existential public health values over utilitarian justifications of trade and investment law.²¹¹

207. See *supra* note 173 and accompanying text.

208. *Eli Lilly & Co. v. Canada*, Final Award, *supra* note 2, ¶ 106; see also RUDOLF DOLZER & CHRISTOPH SCHREUER, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 28 (2012).

209. *Saluka v. Czech Republic*, Partial Award, at 66–67 (Perm. Ct. Arb. 2006), <http://www.italaw.com/sites/default/files/case-documents/ita0740.pdf> [<https://perma.cc/MP4U-JRQ8>] (“The ‘fair and equitable treatment’ standard in Article 3.1 of the Treaty is an autonomous Treaty standard and must be interpreted, in light of the object and purpose of the Treaty. . . . In applying this standard, the Tribunal will have due regard to all relevant circumstances.”). This tribunal operated under UNCITRAL Rules, as did the one in the *Lilly* case. See *supra* note 49.

210. Arbitral tribunals are not bound by the parties’ statements about their intention when entering into the agreement and tend not to pay much attention to the *travaux*. See *supra* notes 87–92 and accompanying text.

211. Petersmann, *supra* note 171, at 65.

This opens a door for an ISDS tribunal to bring human rights and other key public policy objectives in its analytical mix, especially in cases where the specific solutions proposed in the last Part of this Article have not been applied to the applicable IIA.

3. *Stipulation for Another*

Another contract-based approach reflects the fact that investor-state mechanisms contained in investment treaties between two or more states (or the investment chapter of a trade agreement) are not for the benefit of any of the parties to the “contract.” This doctrinal mechanism is specific to the ISDS context and, hence, there is no need to compare its application in the trade and investment realms.

ISDS is arguably what French law calls a “*stipulation pour autrui*” (stipulation for another), which French law defines as follows:

There is stipulation for another where, in a contract, one of the parties, called the stipulator, stipulates to the other, called the promisor that the latter shall give or do something for the benefit of an extraneous third party, the beneficiary who thereby becomes a creditor without having been a party to the contract.²¹²

While theoretically prohibited in French law, there are many cases in which such stipulations are allowed.²¹³ In a common law context, establishing a third party right of suit in a contract may be said to offend the privity of contract. Privity implies that “a third party cannot be subjected to a burden by a contract to which he is not a party,” but this does not fully answer the question whether *allowing* a third party to benefit from the contract, may imply, if the third party chooses to accept this benefit, also an obligation on that third party.²¹⁴ A privity-based approach has been applied in a treaty context in asking, for example, whether Paris Club practice of not requiring the rescheduling of bilateral obligations to the International Monetary Fund and the World Bank creates a right to sue for the Fund and the Bank.²¹⁵ It is

212. A. WEILL & F. TERRÉ, *DROIT CIVIL, LES OBLIGATIONS* 549 (1986), translated in Gordon Humphreys & Andrew Higg, *Waybills: A Case of Common Law Laissez Faire in European Commerce*, J. BUS. L. (UK) 453, 465 (1992).

213. Humphreys and Higg, *supra* note 212, at 466. The German civil code (BGB) “provides explicitly in § 328 that a contract may be made for the benefit of a third party, thus giving the third party a right to demand performance.” Fabrizio Cafaggi, *The Regulatory Functions of Transnational Commercial Contracts: New Architectures*, 36 *FORDHAM INT’L L.J.* 1557, 1595 (2013); see also Hendrik Verhagen, *Contemporary Law*, in *CONTRACTS FOR A THIRD PARTY BENEFICIARY: A HISTORICAL AND COMPARATIVE ACCOUNT* 137 (Jan Hallebeek & Harry Dondorp eds., 2008).

214. Andres Guadamuz Gonzalez, *Viral Contracts or Unenforceable Documents? Contractual Validity of Copyleft Licences*, 26 *EUR. INTELL. PROP. REV.* 331, 336–37 (2004).

215. Rutsel Silvestre J. Martha, *Preferred Creditor Status Under International Law: The Case of the International Monetary Fund*, 39 *INT’L & COMP. L.Q.* 801, 815–16 (1990) (noting also that “[w]ith respect to the law of treaties the view has been taken that the beneficiary of a ‘*stipulation pour autrui*’ can only in the case of an actual right invoke directly and on its own account the provision conferring the benefit.”).

also reflected in the VCLT itself, which provides both that “[a] treaty does not create either obligations or rights for a third State without its consent,” and that a “right arises for a third State from a provision of a treaty if the parties to the treaty intend the provision to accord that right either to the third State . . . and the third State assents thereto.”²¹⁶ At common law, third party beneficiary status arises “when parties make a valid contract which contains provisions evidencing a clear intent to operate for the benefit of the third party.”²¹⁷

This is not radical thinking. If A sells her house to B, but stipulates that C can live in part of the house if C pays rent, then C can “trigger” the right to live in the house, but has the corresponding obligation to pay rent. Similarly, if D takes insurance for E’s benefit, then the insurance company can claim unpaid premiums from E before paying the benefit. Article 5.2.1 of the International Institute for the Unification of Private Law’s (UNIDROIT) Principles of International Commercial Contracts provides a rule for contracts in favor of third parties, which states in part that the “existence and content of the beneficiary’s right against the promisor are determined by the agreement of the parties and *are subject to any conditions or other limitations under the agreement.*”²¹⁸ The Comment to this Article notes in this respect that “the promisor and promisee enjoy broad powers to shape the rights created in favour of the beneficiary.”²¹⁹

Would it be conceivable to use this notion to suggest that corporations using ISDS must comply with certain obligations? This is a possibly fruitful dimension to explore further. Providing corporations with a right to sue states under an IIA implies that corporations have a legal *personality* at international law. The argument one could make is that this attribution of legal personality comes with a very important right (to sue states in a separate tribunal), but it could also imply certain obligations, including upholding human rights.²²⁰ Put differently, if a corporation gets personality and the right to sue, can the sued state demand compliance with

216. VCLT, *supra* note 87, arts. 34, 36 ¶ 1; see also Jimenez de Arechaga, *Treaty Stipulations in Favor of Third States*, 50 AM. J. INT’L L. 338, 356 (1956).

217. William C. Walter & Michael V. Cory, Jr., *The Circumvention of Mississippi’s Prohibition of Direct Actions*, 66 MISS. L.J. 493, 501 (1997). For example, in my Law School’s jurisdiction (Tennessee) “the requisites necessary to establish a third party beneficiary relationship are: (1) a valid contract made upon sufficient consideration between the promisor and promisee; and (2) the clear intent to have the contract operate for benefit of a third party.” *United Am. Bank of Memphis v. Gardner*, 706 S.W.2d 639 (Tenn. Ct. App. 1985) (citations omitted).

218. UNIDROIT, PRINCIPLES OF INTERNATIONAL COMMERCIAL CONTRACTS art. 5.2.1(2), at 161 (2010) (emphasis added), <http://www.unidroit.org/english/principles/contracts/principles2010/integralversionprinciples2010-e.pdf> [<https://perma.cc/R4R7-CTTU>].

219. *Id.* at 163.

220. Glen Kelley, *Multilateral Investment Treaties: A Balanced Approach to Multinational Corporations*, 39 COLUM. J. TRANSNAT’L L. 483, 527 (2001) (“[I]n the Reparations Case the International Court of Justice found that the United Nations enjoyed international legal personality but did not have the same rights and duties as a state under international law. This principle of limited international legal personality could be applied to MNCs as well. A duty for MNCs to uphold selected human rights, created by an investment treaty, would be enforceable by states under international law without expanding the rights of MNCs under international law.”) (notes omitted).

any international obligations, as it could against the state where the corporation is established? Enforcement of human rights violations against multinational corporations is not unheard of: parallels have been drawn in that context to the Alien Tort Statute.²²¹

As Professor Alvarez observed in that respect:

Under investor-state arbitration, therefore, states are mostly passive participants in a game controlled by corporate plaintiffs in which the latter play the jurisprudential role that in the WTO and throughout much of international law is formally reserved to states [M]ost BITs and FTAs . . . explicitly provide investors with the ability to pursue their claims vis-à-vis states at the international level. To the extent the ICJ concluded in the Reparation Case that the ability to act as a person is the principal determinant of personhood status, the same conclusion can even more readily be drawn with respect to corporations and other investors under the international investment regime.²²²

In sum, contract-based approaches can, in keeping with the VCLT, provide a means to fill gaps in texts by using international norms not contained in the text but part of the context at the time of its establishment, or relevant to the parties for other reasons, including subsequent practice. A *stipulation pour autrui*/privity doctrinal approach goes a step further and allows one at least to ask whether corporations meant to be the beneficiaries of ISDS may also, when given the right to sue states, have certain obligations. In contrast, efficient breach does not seem a promising way forward. In Part IV, the notion of obligations imposed on corporations will form part of the discussion on ways forward.

D. Express Interfaces

1. Trade

IAs can and often do contain *express* interfaces with human rights and public policy writ large. These interfaces typically take the form of *specific* human rights exceptions or *general* ones allowing the exercise of the “right to regulate.”²²³ This

221. See Carolyn A. D’Amore, *Sosa v. Alvarez-Machain and the Alien Tort Statute: How Wide Has the Door to Human Rights Litigation Been Left Open*, 39 AKRON L. REV. 593, 626–27 (2006) (“Human rights activists will seize on to the [Alien Tort Statute] as a means to redress the violations of the host nations where multinational corporations are often immersed in human rights predicaments.”). But see Ilias Bantekas, *Corporate Social Responsibility in International Law*, 22 B.U. INT’L L.J. 309, 310 (2004) (discussing the immunity from responsibility for human rights violations that corporations have traditionally enjoyed); Christiana Ochoa, *Towards a Cosmopolitan Vision of International Law: Identifying and Defining CIL Post Sosa v. Alvarez-Machain*, 74 U. CIN. L. REV. 105, 106 (2005) (arguing that multinational corporations are not socially responsible); David Weissbrodt, *Business and Human Rights*, 74 U. CIN. L. REV. 55, 55 (2005) (explaining how international standards often fail to restrain the behavior of corporations).

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

223. AIKATERINI TITI, *THE RIGHT TO REGULATE IN INTERNATIONAL INVESTMENT LAW* 52 (2014).

“right to regulate” in relation to IIAs may be defined as “a legal right that permits a departure from specific investment commitments assumed by a State on the international plane without incurring a duty to compensate.”²²⁴ At least 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.”²²⁵ Specific interfaces in IIAs provide for identified regulatory measures to be taken without violating their commitments and obligations contained in bilateral, regional or multilateral trade agreements. By contrast, general interfaces take the form of an open-ended exception affirming the state’s right to adopt certain regulations.

The most important *general* interfaces in international trade law are arguably the exceptions contained in GATT Article XX and GATS Article XIV. The latter targets, *inter alia*, measures “necessary to protect public morals or to maintain public order”, ‘necessary to protect human . . . life or health.’²²⁶ Similar exceptions are found in the trade portion of a number of IIAs.²²⁷ General interfaces do not prescribe the type of measure that can be taken by the state, only a standard against which they can be measured.²²⁸ Admittedly, recourse to general interfaces has not been very successful in the TRIPS context at the WTO, but then there have been relatively few cases.²²⁹

The TRIPS Agreement does contain both general and specific interfaces with human rights. It states, first, a 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.”²³⁰ Second, TRIPS contains a specific exception allowing WTO members to exclude from patentability inventions “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.”²³¹ Both those TRIPS interfaces are cabined by the use of the term “*necessary*.”²³² The use

224. *Id.*

225. MOUYAL, *supra* note 164, at 8.

226. General Agreement on Tariffs and Trade 1994 art. XX, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994).

227. 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) (discussing instruments incorporating the WTO “General Exceptions” clause in one form or another in IIAs).

228. See *id.* at 333 (“[A] new trend is emerging in treaty practice consisting of including a ‘general exceptions’ clause, which governments hope will provide greater regulatory flexibility and serve pursuing public interest objectives . . .”).

229. See GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, *A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME* 186 (2012).

230. TRIPS Agreement, *supra* note 27, art. 8.1.

231. *Id.* art. 27.2.

232. See Frankel & Gervais, *supra* note 195, at 1205 (reviewing WTO jurisprudence and noting that the “Appellate Body further said, ‘[D]etermination of whether a measure, which is not

of this term seems to posit (as a normative matter) that trade liberalization commitments should trump *but for* the necessity to adopt certain regulatory measures. It does not specify the burden of proof (who must show necessity and how), but there is WTO jurisprudence on that point.²³³

Language matters.²³⁴ Providing a “right to regulate,” often in an IIA provision bearing that as its title, can be significantly constrained by a “provided that such measures are consistent with provisions of this Agreement” clause, as in TRIPS Article 8.1 for example.²³⁵ Then the right to regulate might be a general “public interest” clause offering broad flexibility, but it may also limit the scope to specific public interests (plural), such as labor or environmental standards.²³⁶ Another consideration is that a country that adds this right to regulate (as the United States did in its model BIT in 2004) might prompt an investor to argue that earlier IIAs do not, a *contrario*, provide regulatory flexibility.²³⁷

Professors Dinwoodie and Dreyfuss proposed a “neofederalist” model of international IP in the TRIPS context that offers additional guidance on the interpretation of exceptions. Their approach considers an international *acquis* that the DSB should incorporate into the TRIPS framework using both general and specific interfaces.²³⁸ As they note, now that trade and intellectual property were joined at the hip (by the TRIPS Agreement) “linkage to a broader array of norms is inevitable.”²³⁹ They argue “detaching TRIPS adjudication from the rich fabric of other international initiatives would distort the creative environment and ignore important values, such as commitments to free speech and distributive justice.”²⁴⁰ They suggest, *inter alia*, that the DSB make more room for *general* exceptions, which states often use to safeguard interests outside intellectual property.²⁴¹

Clearly, there is still work to be done—some of it by the WTO Appellate Body—to clarify the trade and intellectual property interface. Yet doctrinal avenues have been ploughed, at least at the theoretical level. The pending plain packaging cases at the WTO may present an occasion for the Appellate Body to put some of them in actual motion.²⁴² Can that help solve our ISDS challenge?

“indispensable”, may nevertheless be “necessary” . . . involves in every case a process of weighing and balancing a series of factors which prominently include the contribution made by the compliance measure to the enforcement of the law or regulation at issue, the importance of the common interests or values protected by that law or regulation, and the accompanying impact of the law or regulation on imports or exports.”).

233. *See id.* at 1206–07.

234. *See* TITI, *supra* note 223, at 111–15.

235. *See id.*

236. *See id.* at 99–100.

237. *See id.* at 295.

238. DINWOODIE & DREYFUSS, *supra* note 229, at 160.

239. *Id.*

240. *Id.*

241. *See id.* at 186.

242. *See* Frankel & Gervais, *supra* note 195, at 1214 (“[T]here is a need for a balanced and methodical approach by the WTO. Both the VCLT and previous panel and Appellate Body reports contain the tools that are needed to get to a balanced outcome.”).

2. ISDS

Express interfaces between the right to regulate and ISDS increasingly often find their way in the investment chapter of IIAs, sometimes with the specific purpose to exclude an evaluation by an ISDS tribunal or substantive intellectual property rules, or to maintain regulatory flexibility (and in the latter case sometimes a link is made with human rights, as the examples discussed in the following lines should demonstrate). In both the Comprehensive Economic and Trade Agreement (CETA) and Transatlantic Trade and Investment Partnership (TTIP), substantive intellectual property is at least partly excluded from ISDS scrutiny, for example, a move perhaps informed by the filing of the *Lilly* case. Indeed the Tribunal in that case did not hesitate to equate patents with investment—even though a patent may be issued in a country where none of the expenses related to the development of the invention took place.²⁴³ The exclusion of IP was done in CETA by adding a declaration that provides both 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.”²⁴⁴ Moreover, CETA reasserts “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.”²⁴⁵ In October 2016, after opposition from the French-speaking part of Belgium, it was agreed that the ISDS provisions of CETA would be submitted to the Court of Justice of the European Union to determine their compatibility with EU law, in particular the ability of EU member States to implement and enforce public policy and fundamental rights.²⁴⁶

Similarly, the European text proposal for the TTIP provides that:

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.²⁴⁷

243. *Eli Lilly & Co. v. Canada*, Final Award, *supra* note 2, ¶ 167.

244. Comprehensive Economic and Trade Agreement Between Canada of the One Part, and the European Union, of the Other Part, Annex 8-D, Can.-E.U., Oct. 30, 2016, http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf [<https://perma.cc/64AC-NJCM>] [hereinafter CETA].

245. *Id.* art. X.11, ¶ 6; *see also* Vadi, *supra* note 76, at 191.

246. *See* Laurens Ankersmit, *Investment Court System in CETA to Be Judged by the ECJ*, EUR. L. BLOG (Oct. 31, 2016), <http://europeanlawblog.eu/2016/10/31/investment-court-system-in-ceta-to-be-judged-by-the-ecj/> [<https://perma.cc/XSM8-JH5J>].

247. EUROPEAN UNION, PROPOSAL FOR INVESTMENT PROTECTION AND RESOLUTION OF INVESTMENT DISPUTES: TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP, TRADE IN SERVICES, INVESTMENT AND E-COMMERCE, CHAPTER II – INVESTMENT art. 5(7), at 6 (2015),

The free trade agreement between Australia and the United States also contains a general carve out in ISDS for public health purposes.²⁴⁸ NAFTA parties presumably could add a similar one to Chapter 11 (with the risks that any reopening of NAFTA entails),²⁴⁹ or one similar to the exclusion added to CETA, and in the EU-proposed TTIP text if doubts as to the intent and meaning of Article 1110(7) remain.²⁵⁰

An interesting change can also be observed in the model U.S. BIT.²⁵¹ The initial model dates back to 1977 and its main focus was on the protection of foreign investments by U.S. companies.²⁵² In the wake of ISDS cases against the United States and the increasing recognition that “bilateral” implies that foreign companies can invest in, and sue the government of, the United States, the model BIT was revised in 2004 to note that “[e]xcept in rare circumstances, non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations.”²⁵³ The avenue explored there—namely the systematic exclusion of an evaluation of compliance with substantive intellectual property obligations by ISDS tribunals—is common in more recent trade agreements concerning other key areas, such as labor, environment and sustainable development. Indeed, they are contained in the majority of post-WTO (1995) trade agreements negotiated by the EU.²⁵⁴ They often refer to a list of international conventions setting out applicable standards that a state (or the EU itself) has the right to implement.²⁵⁵ Safeguards for labor, environment and sustainable development often explicitly demand a “high level of protection” and put these interests expressly above that of liberalization of trade. For example, under Article

http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153955.pdf [<https://perma.cc/CKQ8-Y5HA>].

248. Australia–United States Free Trade Agreement art. 17.9(7), Austl.-U.S., May 18, 2004, 43 I.L.M. 1248.

249. See Melissa Long, *Recent Developments in NAFTA*, 14 L. & BUS. REV. AM. 875, 879 (2008) (noting that under President George W. Bush, the “Administration has been and will continue to be clear and consistent in strongly opposing requests to reopen this agreement” due to risk to US exporters).

250. See *supra* note 87 and accompanying text.

251. See MOUYAL, *supra* note 164, at 71–73.

252. See *id.*

253. 2012 U.S. MODEL BIT, *supra* note 55, annex B(4)(b). The 2012 language is unchanged on this point from the 2004 model, as a request to remove “except in rare circumstances” was rejected. See MOUYAL, *supra* note 164, at 72.

254. CETA, *supra* note 244, arts. 22.1, 23.2, 24.3; Free Trade Agreement Between the European Union and the Republic of Singapore art. 13.1(1), May 2015 [hereinafter E.U.-Singapore FTA]; Trade Agreement Between the European Union and Its Member States, of the One Part, and Colombia and Peru, of the Other Part arts. 269(3), 270(2), 2012 O.J. (L 354) 3 [hereinafter E.U.-Peru & Columbia FTA]; Agreement Establishing an Association Between Central America, on the One Hand, and the European Union and Its Member States, on the Other art. 286(1)–(2), 2012 O.J. (L 346) 3 [hereinafter E.U.-Central America Association Agreement]; Free Trade Agreement Between the European Union and its Member States, of the One Part, and the Republic of Korea, of the Other Part arts. 13.4, 13.5, 2014 O.J. (L 140) 3 [hereinafter E.U.-Korea FTA].

255. See articles of agreements cited *supra* note 254.

23.2 of 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 improve such laws and policies with the goal of providing high levels of labour protection.”²⁵⁶

In addition to these provisions, some IIAs include recognition by the parties that “it is inappropriate to encourage trade or investment by weakening or reducing the protections afforded in domestic labour and environment laws.”²⁵⁷ The Association Agreement 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, acquisition, expansion or retention of an investment or an investor in its territory.”²⁵⁸ In addition, paragraph three demands that a party “shall not fail to effectively enforce its labour and environmental legislation in a manner affecting trade or investment between the Parties.”²⁵⁹

Systematic exclusion of certain policy areas, in whole or in part (that is, by applying a stricter test), is thus a clearly useful tool to consider as we now turn to this Article’s proposed solutions.

V. SPECIFIC WAYS FORWARD

A. *The Puzzle*

The puzzle this Article attempts to contribute to solving is to build proper interfaces between a state’s right—indeed often its duty—to regulate to protect human rights and key public policy areas, on the one hand, and the protection of investment contained in thousands of IIAs when this protection takes the form of a complaint filed by a multinational corporation against a host state in an ISDS proceeding. States need “regulatory space of manoeuvre to promote social welfare . . . and to live up to international human rights commitments.”²⁶⁰ If the state’s hands are tied in such a way that it can no longer respond adequately to changing circumstances—whether those changes be social, environmental or technological—by adapting their social and economic policies, then the advantages that states see in encouraging foreign investment through ISDS will fade and trigger public opinion backlash—as recent European events have demonstrated.²⁶¹ The sustainability of investment protection is at stake.

256. A similar provision is contained in E.U.-Singapore FTA, *supra* note 254, art. 13.2(2), and E.U.-Peru & Columbia FTA, *supra* note 254, art. 268.

257. E.U.-Singapore FTA, *supra* note 254, art. 13.1(3); E.U.-Central America Association Agreement, *supra* note 254, art. 291(1).

258. E.U.-Central America Association Agreement, *supra* note 254, art. 291(2).

259. *Id.*

260. MOUYAL, *supra* note 164, at 19.

261. See Peter Muchlinski, *Policy Issues*, in THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW 60 (Peter Muchlinski, Federico Ortino & Christopher Schreuer eds., 2008).

B. Parameters of an Optimal Human Rights/ISDS Interface

Is ISDS a way to circumvent shortcomings that companies see in state-to-state multilateral dispute settlement? The question is worth asking.²⁶² Recall that ISDS was originally meant as *defensive* measure for companies stripped of assets by expropriation, often for purposes of nationalization of those assets by a state.²⁶³ ISDS has morphed into a “potent *offensive* strategic tool” to effectuate policy changes to domestic norms concerning environmental protection, intellectual property, and other regulatory areas.²⁶⁴ As far as intellectual property is concerned, as Joost Pauwelyn has observed, there have been few TRIPS cases, and some of them left a bitter after taste in the mouths of corporate actors who had pushed for the cases to be filed.²⁶⁵ Those cases were not rejected on the basis of human rights or extrinsic (non-WTO) norms, however.

The answer is *not* to oppose the grant to corporations (non-state actors) of a right to sue states. Governments may have incentives not to file cases against other governments, including lack of resources, diplomatic relations, etc. Non-state actors, including well-organized nongovernmental organizations (NGO), can supplement the “enforcement” activity of states.²⁶⁶

The issue with ISDS is different and specific. It is that only a very narrow category of non-state actors (multinational investors) have been given an extraordinary lever to achieve policy aims; tribunals with broad powers and dedicated to the task of investment protection have been established with a sole purpose: to hear their grievances about states.²⁶⁷ The risk is that those firms will use ISDS as “vertical forum-shifting to achieve results that they know would be unacceptable if debated and considered openly and multilaterally.”²⁶⁸ Some

262. See Christopher S. Gibson, *Latent Grounds in Investor-State Arbitration: Do International Investment Agreements Provide New Means to Enforce Intellectual Property Rights?*, 2010 Y.B. INT'L INV. L. & POL'Y 397, 398.

263. HOWARD MANN & KONRAD VON MOLTKE, INT'L INST. SUSTAINABLE DEV., NAFTA'S CHAPTER 11 AND THE ENVIRONMENT: ADDRESSING THE IMPACTS OF THE INVESTOR-STATE PROCESS ON THE ENVIRONMENT 15 (1999), <http://www.iisd.org/pdf/nafta.pdf> [<https://perma.cc/6XH7-DFPG>].

264. *Id.*

265. See generally Pauwelyn, *supra* note 82.

266. See Steve Charnovitz, *Two Centuries of Participation: NGOs and International Governance*, 18 MICH. J. INT'L L. 183, 285 (1997); Antonio F. Perez, *The International Recognition of Judgments: The Debate Between Private and Public Law Solutions*, 19 BERKELEY J. INT'L L. 44, 87 (2001).

267. ISDS “remedies” are not an obligation to change the law but rather an obligation for the state at fault to compensate the complainant. However, the imposition or risk of imposition of very large awards (Lilly's claim is in the order of C\$500 million) will likely lead governments to effect policy changes or not make ones that multinational investors do not want to see implemented to avoid the disputes. See Dreyfuss & Frankel, *supra* note 162, at 574 (“[W]hen the United States failed to conform to the 1999 US-110(5) decision, it paid the EU, pursuant to further WTO arbitration, \$3.3 million to cover a three-year period In an investment dispute Eli Lilly brought against Canada over its patent rights, it demanded CDN \$500 million. That difference could have a considerable impact on the willingness of countries to draft laws that test the limits of international flexibilities.”) (citations omitted).

268. Sell, *supra* note 152, at 318.

commentators have gone a step further and argued that flexibilities in trade rules could be “closed” using ISDS, such as exhaustion (parallel imports).²⁶⁹

The question with respect to human rights is whether ISDS should interpret and “factor in” human rights obligations to “balance” investment protection in a deeper normative pool. As explicated in Part IV, some scholars believe that trade tribunals *must* consider human rights (including those that mesh with trade liberalization). Others carefully explicate how and why under the VCLT they *can* do so.²⁷⁰ In this Article’s view, they most certainly can do so. The constitutional and contract-based approaches reviewed in Part IV are certainly worth investigating, even though they lead to a risk that human rights and other key public policy objectives will play second fiddle in an orchestra of norms conducted by trade law.²⁷¹

This Article suggests that human rights obligations brought to the attention of an ISDS tribunal should be fully considered in interpreting the scope and depth of the regulatory leeway used by the State before an unjustified (that is, one that leads to an obligation to compensate the investor) violation of its investment obligations is found. How the second prong can be effectuated is discussed in the next section.

C. Directed Interpretation

An optimal solution to the puzzle described in the opening section of this Part would do more than just require ISDS tribunals to “consider” human rights obligations: dispute settlement bodies should be directed to *avoid any interpretation of the IAs that would contravene a human rights obligation undertaken by the State whenever possible*, a global “Charming Betsy” doctrine, as it were.²⁷² The VCLT indicates the path to follow: when a text’s meaning is obscure or ambiguous a broader context,

269. See Baker & Geddes, *supra* note 49, at 32 (“Article 6 prohibits resort to interstate dispute settlement with respect to IP exhaustion rules, but it does not directly permit or authorize international exhaustion, otherwise known as parallel importation. Accordingly, a disgruntled pharmaceutical company could very easily object to the importation and sale of a medicine it had sold more cheaply elsewhere claiming that parallel importation had violated its expectation of patent-based market segmentation and higher profits in certain markets.”) (footnote omitted).

Under the TRIPS Agreement, WTO members agreed to disagree on exhaustion. Article 6 of TRIPS provides that “[f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” TRIPS Agreement, *supra* note 27, art. 6.

270. Bruno Simma & Theodore Kill, *Harmonizing Investment Protection and International Human Rights: First Steps Towards a Methodology*, in INTERNATIONAL INVESTMENT LAW FOR THE 21ST CENTURY: ESSAYS IN HONOUR OF CHRISTOPH SCHREUER 678, 692-97 (Christine Binder et al., eds., 2009).

271. See generally Alston, *supra* note 3.

272. The Charming Betsy doctrine is a U.S. doctrine of statutory interpretation named after the schooner *Charming Betsy* seized in 1800 in open seas by a U.S. frigate. It led to a Supreme Court opinion, *Murray v. Schooner Charming Betsy*, 6 U.S. 64 (1804). The Supreme Court stated that an “act of Congress ought never to be construed to violate the law of nations if any other possible construction remains.” *Id.* at 118.

including other relevant instruments can—some might say should—be factored in.²⁷³

Applied to the ISDS context, following this proposed canon would mean that when an interpretation of the notions of direct or indirect expropriation and fair and equitable treatment in an investment protection chapter can be reconciled with a state's regulatory autonomy in an area of vital socio-economic importance and/or a state's implementation of its human rights obligations, then that interpretation should be preferred.²⁷⁴ This would have a “normative stabilizing effect, at a time when there are few agreed answers about the costs and benefits of globalization or the ideal shape of global economic governance in relation to differing domestic policy paths.”²⁷⁵ WTO jurisprudence on the use of regulatory flexibilities within boundaries set by trade commitments and obligations under WTO instruments could inform the determination of the appropriate scope and reach of the state's regulatory elasticity.

As already detailed, an explicit mechanism exists at the WTO to effectuate this policy.²⁷⁶ In the ISDS context, it is admittedly harder. After all, there are thousands of existing IIAs that contain investment provisions.²⁷⁷ Realistically they cannot all be amended, although bulk actions, such as pulling out of all of them at once has been used.²⁷⁸ The idea of amending the VCLT itself, the provisions of which have achieved canonical status, also seems far-fetched.²⁷⁹ Issues of retroactive application of new interpretation norms that have no claim to customary law would emerge.²⁸⁰

273. See *supra* Section II.C.

274. The “area of vital socio-economic importance” is taken from Article 8.1 of TRIPS. See *supra* note 230 and accompanying text (“Members may, in formulating or amending their laws and regulations, adopt measures necessary . . . to promote the public interest in sectors of vital importance to their socio-economic and technological development . . .”). On the interpretation of regulatory flexibility, see Robert Howse, *The World Trade Organization 20 Years On: Global Governance by Judiciary*, 27 EUR. J. INT'L L. 9, 76 (2016) (“[T]he Appellate Body sought to discern in the corpus of WTO treaties an equilibrium between domestic regulatory autonomy and trade liberalization very much inspired by, or anchored in, the original GATT – a respect for regulatory diversity and flexibility towards domestic policy interventions . . .”).

275. Howse, *supra* note 274, at 76.

276. Namely the general exception. See Chaisse, *supra* note 227.

277. See *supra* note 34 and accompanying text.

278. For example, in answer to questions at the Indian Parliament (Lok Sabha) on July 25, 2016, the Indian Minister of Trade and Industry noted that “[o]ut of the total 83 [bilateral investment] treaties signed by India so far, 58 treaties are being terminated.” See GOV'T OF INDIA, DEP'T OF INDUS. POLICY & PROMOTION, UNSTARRED QUESTION NO. 1290. TO BE ANSWERED ON MONDAY, THE 25TH JULY, 2016. (2016), <http://dipp.nic.in/sites/default/files/lu1290.pdf> [<https://perma.cc/L8KY-R9US>].

279. See Jonathan Pratter, *Treaty Research Basics*, 89 L. LIBR. J. 407, 408 (1997) (referring to the “canonical definition of ‘treaty’ found in the Vienna Convention on the Law of Treaties”). Proposals to amend the VCLT surface regularly but they strike the Author as unlikely. See, e.g., Christopher J. Borgen, *Resolving Treaty Conflicts*, 37 GEO. WASH. INT'L L. REV. 573, 637 (2005); Michael B. McDonough, *Privileged Outlaws: Diplomats, Crime and Immunity*, 20 SUFFOLK TRANSNAT'L L. REV. 475, 476 (1997).

280. Although this would require a longer discussion, VCLT art. 28 provides for non-retroactivity of treaties. As to the status of VCLT interpretive rules as customary international law, see Eirik Bjorge, *The Vienna Rules on Treaty Interpretation Before Domestic Courts*, 131 L. Q. REV. 78, 80

A different option would be to have a special convention. In early 2017, the EU launched consultations on a Multilateral Investment Court, a permanent court to be established for this purpose in TTIP.²⁸¹ That new court could theoretically come up with interpretive principles to the same effect as those described above, but this seems unlikely to the Author given that investment protection is ISDS' normative lodestar.²⁸² This Article suggests that "Vienna Plus" interpretive principles could be included in the convention (statute) establishing the new court to reflect recent understandings about ISDS. Naturally, if the new court only bound EU-related ISDS it would not directly affect IIAs not involving the EU. However, jurisprudence might emerge from this court that might influence other arbitral tribunals.²⁸³ If the court was established not as a "pure" EU court, but instead a multilateral one, it could attract other nations that would either reorient existing investor-state disputes arising out of existing IIAs or use it for future ones.

In the EU context, one must keep an eye on the referral to the Court of Justice of the European Union about CETA's ISDS mechanism that the Walloons (French-speaking Belgians) obtained.²⁸⁴ The Court has already expressed doubts about the constitutional validity of "external" tribunals, especially when those tribunals' findings may clash with the fundamental rights contained in the EU Charter.²⁸⁵

(2015), for a reference to "customary international law of treaty interpretation, as reflected in arts 31–33 of the Vienna Convention" (footnote omitted).

281. See *Questionnaire on Options for a Multilateral Reform of Investment Dispute Resolution*, EUR. COMMISSION, http://trade.ec.europa.eu/consultations/index.cfm?consul_id=233 [<https://perma.cc/DV9J-AHWW>] (last visited June 21, 2018); see also Ben Stanford, Andreas Yiannaros, & Chrispas Nyombi, *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 court to be included in the TTIP.") (citations omitted).

282. See *supra* text accompanying note 189.

283. See David A. Gantz, *Settlement of Disputes Under the Central America-Dominican Republic-United States Free Trade Agreement*, 30 B.C. INT'L & COMP. L. REV. 331, 344–47 (2007) (referring to NAFTA's ISDS jurisprudence). It should be noted also that cross-fertilization between trade and investment jurisprudence has been modest, sometimes for good reasons. See Joost Pauwelyn & Nicolas DiMascio, *Non-Discrimination in Trade and Investment Treaties: Worlds Apart or Two Sides of the Same Coin?*, 102 A.J.I.L. 48 (2008).

284. Wallonia obtained that the EU Commission should ask the Court of Justice of the European Union to examine the compatibility of the ISDS provisions contained in CETA with EU Law, in particular the EU Charter of Fundamental Rights. See Milan Schreuer, *How Dairy Farmers in Belgium Held Up a Big E.U. Trade Deal*, N.Y. TIMES, Oct. 28, 2016, https://www.nytimes.com/2016/10/29/world/europe/belgium-farmers-block-eu-trade-deal.html?_r=0 [https://web.archive.org/web/20161109092440/https://www.nytimes.com/2016/10/29/world/europe/belgium-farmers-block-eu-trade-deal.html?_r=0].

285. See Ernst-Ulrich Petersmann, *Can the EU's Disregard for "Strict Observance of International Law" (Article 3 TEU) Be Constitutionally Justified?*, in *TRADE AND COMPETITION LAW IN THE EU AND BEYOND* (Inge Govaere, Reinhard Quick & Marco Bronckers eds., 2011).

D. Expressly Reserving Regulatory Autonomy

A strongly worded interface should direct ISDS tribunals to refrain from stepping on the regulatory autonomy of States promoting their population's public health, both because these are sectors of "vital importance"—to use the terminology of TRIPS Article 8.1—and because the regulatory measures at issue are a means of implementing the right to health. This is particularly true in patent cases concerning pharmaceuticals because in such cases looking solely at an investor's alleged losses misses several key parts of the policy picture. This can be done negatively by limiting the scope of ISDS, or positively by adding to investment instruments an appropriately worded "right to regulate" clause.

A good example is the exclusion of substantive IP rules from ISDS in both CETA and TTIP.²⁸⁶ The European Union is not alone. Recall that both Mexico and the United States came to Canada's defense in the *Lilly* case, not as much on the interpretation of the patent provisions of NAFTA, but in the role of ISDS in this context.²⁸⁷ Australia supported the inclusion of a countervailing right to regulate to limit the reach of "pure" investment rules rather than by restricting the scope of ISDS. In a statement on trade policy issued in 2011, the government of Australia noted that it "does not support provisions that would confer greater legal rights on foreign businesses than those available to domestic businesses. Nor will the Government support provisions that would constrain the ability of Australian governments to make laws on social, environmental, and economic matters in circumstances where those laws do not discriminate between domestic and foreign businesses."²⁸⁸

E. Imposing Obligations on Investors

The marked reluctance of international investment law to "take adequate account of the public interest and to integrate principles from international environmental and human rights law is out of step with current trends in public international law."²⁸⁹ Would imposing obligations on investors—perhaps using the doctrine of stipulation for another—that at present claim rights under ISDS provisions lead to a more balanced outcome?²⁹⁰ Weisbrodt and Kruger asked whether it was "appropriate to place human rights obligations upon organizations whose primary purpose is to produce profit or effectively deliver goods or

286. Previous IIAs were bilateral, that is, entered into not by the E.U. but with individual member states.

287. Interestingly, CETA was the first E.U. IIA containing an ISDS mechanism. See *supra* note 244 and accompanying text.

288. AUSTRALIAN GOV'T, DEPT OF FOREIGN AFF. & TRADE, GILLARD GOVERNMENT TRADE POLICY STATEMENT: TRADING OUR WAY TO MORE JOBS AND PROSPERITY 14 (2011), http://blogs.usyd.edu.au/japaneselaw/2011_Gillard%20Govt%20Trade%20Policy%20Statement.pdf [<https://perma.cc/832N-F6VT>].

289. Miles, *supra* note 145, at 296.

290. See *supra* Section IV.C.3.

services.”²⁹¹ They answer in the affirmative, noting that a “widely accepted” set of human rights norms would create more predictability and “establish a level playing field for business competition.”²⁹² Ratner has argued along similar lines that “business enterprises will have duties both insofar as they cooperate with those actors whom international law already sees as the prime sources of abuses—states—and insofar as their activities infringe upon the human dignity of those with whom they have special ties.”²⁹³ Yet, one must admit that, as Forman and Kohler rightly note, “the application of human rights to non-state actors like the pharmaceutical industry is not a settled question within international law.”²⁹⁴ Still, at the domestic level at least, India and South Africa have cases demonstrating that domestic courts can impose access obligations on patent holders based on the human right to health.²⁹⁵ A possible forum for further discussion on this issue is the Organisation for Economic Co-operation and Development (OECD), which is discussing National Action Plans on Business and Human Rights (NAPs) as part of its Responsible Business Conduct Initiative.²⁹⁶

F. Factoring in Unintended Consequences

Unintended consequences are so common that their existence is said to be a “law.”²⁹⁷ A win for Lilly in its ISDS claim against Canada would likely have had unintended consequences. A win for Lilly would have created a strong incentive for patent offices to be extremely (or at least more) careful in the pharmaceutical sector in the case of dubious applications—perhaps such as the “species within a genus” type of application at issue in the *Lilly* case—and possibly other industrial fields where major multinational players have the wherewithal to challenge a state’s invalidation decisions in an ISDS and claim compensation from its taxpayers.²⁹⁸ A

291. David Weissbordt & Muria Kruger, *Human Rights Responsibilities of Businesses as Non-State Actors*, in NON-STATE ACTORS AND HUMAN RIGHTS 315, 335 (Philip Alston ed., 2005).

292. *Id.* at 335–36.

293. Steven R. Ratner, *Corporations and Human Rights: A Theory of Legal Responsibility*, 111 YALE L. J. 443, 449 (2001).

294. Lisa Forman & Jillian C. Kohler, *Introduction: Access to Medicines as a Human Right – What Does It Mean for Pharmaceutical Industry Responsibilities?*, in ACCESS TO MEDICINES AS A HUMAN RIGHT: IMPLICATIONS FOR PHARMACEUTICAL INDUSTRY RESPONSIBILITY 3, 9 (Lisa Forman & Jillian C. Kohler eds., 2012).

295. See Emmanuel K. Oke, *Using the Right to Health to Enforce the Corporate Responsibilities of Pharmaceutical Companies with Regard to Access to Medicines*, 1 J. HEALTH DIPL. 1, 5–12 (2013).

296. See ORG. FOR ECON. CO-OPERATION & DEV., SUMMARY REPORT: 2017 ROUNDTABLE FOR POLICY MAKERS (2017), <https://mneguidelines.oecd.org/global-forum/2017-RBC-Roundtable-for-Policy-Makers-Summary-Report.pdf> [<https://perma.cc/CPW2-EPRC>].

297. See Daniel Gervais, *The Regulation of Inchoate Technologies*, 47 HOUS. L. REV. 665, 684 (2010) (discussing the “law” of unintended consequences in regulatory theory).

298. The rule against double-patenting prevents an applicant from claiming a genus if an earlier-issued patent contains claims to a species of the genus because the genus is anticipated by the species but a claim to a genus does not prevent a claim to a species within the genus. As the Federal Circuit noted in a case (involving Lilly in fact): “[C]ase law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.” *Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001), *cert. denied*, 534 U.S. 1109 (2002).

second incentive logically created by a win would have been that patent offices should look long and hard before issuing pharmaceutical patents if their state coffers are then tapped for compensation in case of invalidation seen as indirect expropriation or a failure to meet some FET standard in an ISDS context. How this would have benefited Lilly and other pharmaceutical companies is not entirely obvious.

CONCLUSION

Lilly lost the gamble it played when filing its C\$500 million investor-state dispute against Canada.²⁹⁹ The case did, however, provide scholars and the investment law community with a unique opportunity to reflect on the balancing of intellectual property, investment, human rights and regulatory autonomy. This Article briefly reviewed the arguments made by both parties, the award, and mechanisms that exist to bridge the normative and doctrinal gaps between intellectual property, human rights, trade, and investment, bearing in mind important differences between trade (state-to-state) and investor-state disputes. It proposes several paths forward to prevent future disputes from taking investment state disputes outside proper channels.

299. Although Lilly's loss was followed by a win, namely the surprising and weakly supported reversal of policy by the Supreme Court of Canada a few months later. *See AstraZeneca Canada Inc. v. Apotex Inc.*, [2017] 1 S.C.R. 943 (Can.).

