

INVESTOR-STATE DISPUTE SETTLEMENT:  
REGULATORY LESSONS FROM *LILLY V CANADA*

*Daniel J. Gervais*<sup>1</sup>

ABSTRACT

*The interface between trade, IP and the right to regulate, including to implement human rights obligations, 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 interest considerations--in particular human rights--can and should be factored into determinations of a state's action compatibility with its trade obligations and commitments in a 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 ISDS context. The Article uses the recent (and pending as of this writing) *Lilly v Canada* case to illustrate several of the various points made. The *Lilly* case deals 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 not just 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.*

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<sup>1</sup> Ph.D., MAE. Professor of Law, Vanderbilt University Law School. Director, Vanderbilt Intellectual Property Program. The Author was an expert retained by Canada in the *Lilly v Canada* arbitration. The views expressed are the author's own. The author is extremely grateful to \_\_\_

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The relationship between human rights and trade is one of the central issues confronting international lawyers at the beginning of the twenty-first century. (Philip Alston<sup>2</sup>)

## I. INTRODUCTION

Investor-State Dispute Settlement (ISDS) is a controversial topic. This Article explores the controversy using an actual case—perhaps the most prominent one—namely the complaint filed by Eli Lilly against Canada under NAFTA Chapter 11.<sup>3</sup> It uses the case to shed light on what could go wrong in the ISDS and intellectual property interface. The Article considers the issue using both human rights and regulatory lenses.

The nineteenth and twentieth century 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.<sup>4</sup> At the same time, however, international lawyers and scholars gradually devised “a programme for the economic and material betterment of the human race.”<sup>5</sup> This effort was eventually “re-cast into one of global freedom of economic intercourse on a liberal capitalist basis.”<sup>6</sup>

The sovereignty of states remained a cornerstone of the international law edifice during this period. It is reflected, *inter alia*, in the *Lotus* doctrine, which lays a basic rule that recognizes the default sovereignty of states. According to this doctrine, all that is not prohibited by a rule of international law is permitted.<sup>7</sup> 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.”<sup>8</sup> The scope of a state’s sovereignty thus depends on what is prohibited by a treaty or other source of international law. A realist

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<sup>2</sup> Philip Alston, *Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann*, EUR. J. INT’L L. (2002) 815, 818.

<sup>3</sup> *Eli Lilly and Co. v. The Gov’t of Canada* [hereinafter *Lilly v. Canada*], ICSID Case No. UNCT/14/2.

<sup>4</sup> *See id.*

<sup>5</sup> *Id.* at 42.

<sup>6</sup> *Id.*

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

<sup>8</sup> *Military and Paramilitary Activities in and Against Nicaragua (Nicaragua v. United States)*, 1986 I.C.J. 14, 135 (June 27, 1986).

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might add that, in practice, this also depends on by who decides what the law is, whether it was violated, and whether decisions are enforceable.

The place that state sovereignty should play is still a matter of much discussion in international law. For example, the Lotus doctrine’ preeminence regularly comes under fire. For example, in an opinion in the *Fisheries* case (opposing the United Kingdom and Norway), 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.<sup>9</sup> It is also true that the Lotus doctrine does not provide a full normatively answer as to the nature of Westphalian order. For instance, is the state “naturally’ sovereign because it sits at the top of the international legal hierarchy, or is the state an organ of international law? Is it international law that determines that attributes of sovereignty? This matters because if the latter is true then an international court could “naturally” be called upon to decide of 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 a court and submit to its findings<sup>10</sup>.

One way to frame the debate is to consider that states have sovereignty but that it *comes with obligations*. It then becomes a matter of enforcement by or on behalf of a supranational institution, such as the United Nations.<sup>11</sup> 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 to maintain peace.<sup>12</sup> Kelsen first voiced this idea in 1934.<sup>13</sup> In the end, however, the Kelsenian dream would not

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<sup>9</sup> Fisheries Case (U.K. v. Nor.), 1951 I.C.J. 116, 152.

<sup>10</sup> Mario Patrono, *Hans Kelsen: A Peacemaker through Law*, 45 VICT. 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.”)

<sup>11</sup> 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.)

<sup>12</sup> *Id.* at 648, 651. Lauterpacht became a member of the United Nations’ International Law Commission from 1952 to 1954 and a Judge of the International Court of Justice from 1955 to 1960.

fully materialize, as the International Court of Justice's jurisdiction is not the "Big Court" he envisaged.<sup>14</sup> For one thing, its jurisdiction is not compulsory for United Nations members.<sup>15</sup>

A more powerful dispute-settlement would 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 them from behaving badly was not limited to war and peace. It 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."<sup>16</sup> Adding to those normative foundations, the economist Friedrich Hayek suggested that free trade as a limit the power of states was one of the best safeguards of peace.<sup>17</sup> In his mind, this included limits on the controls that a state might compose on trade and the economy more broadly.<sup>18</sup> 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.<sup>19</sup>

The first of three inflection points in the trade liberalization debate was the failed attempt to establish an International Trade Organization (ITO) at the Havana conference in 1948 and the establishment of the Bretton Woods institutional framework.<sup>20</sup> Although the ITO negotiations failed to

<sup>13</sup> HANS Kelsen *THE LEGAL PROCESS AND INTERNATIONAL ORDER* (1934), 19 ("[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 [ .].")

<sup>14</sup> Grant Gilmore, *International Court of Justice*, 55 *YALE L J* 1049, 1064 (1946).

<sup>15</sup> 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, June 26, 1945, 59 Stat. 1055, 1060.

<sup>16</sup> Peter-Tobias Stoll, *Constitutional Perspectives on International Economic Law*, in Marise Cremona, Peter Hilpold, Nikos Lavranos, Stefan Staiger Schneider, and Andreas R. Ziegler eds, *REFLECTIONS ON THE CONSTITUTIONALISATION OF INTERNATIONAL ECONOMIC LAW: LIBER AMICORUM FOR ERNST-ULRICH PETERSMANN*, (2014), 201 at 202.

<sup>17</sup> FRIEDRICH A. HAYEK, *THE ROAD TO SERFDOM*, 175 (1944)..

<sup>18</sup> *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).

<sup>19</sup> See Petersmann, n. 104 *supra*, 29. ("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."); and 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).

<sup>20</sup> For a historical account of the GATT as a stand-alone instrument and the failure of the Havana Charter, see JOHN H. JACKSON, *WORLD TRADE AND THE LAW OF GATT* \_\_ ( ). On Bretton Woods, see John C.

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establish a new intergovernmental institution, they did yield one important result, namely the signing of the General Agreement on Tariffs and Trade, better known as GATT.<sup>21</sup> The GATT included a state-to-state dispute settlement system that differs in at least one important respect from many of its international law cousins: it had teeth.<sup>22</sup> 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.<sup>23</sup> 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.<sup>24</sup>

As 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.<sup>25</sup> 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,

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Thomure, Jr. *The Uneasy Case for the North American Free Trade Agreement*, 21 SYRACUSE J. INT'L. L. & COM. 181, 185-6 (1995)

<sup>21</sup> 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, October 30, 1947, 61 Stat. Part 5 at A2051 (1947), T.I.A.S. No. 1700, 55 U.N.T.S. 308 (1950) See Ronald A. Brand, *GATT and the Evolution of United States Trade Law*, 18 Brook. J. Int'l L. 101 (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).")

<sup>22</sup> See Miquel Montana i Mora, *A GATT With Teeth: Law Wins Over Politics in the Resolution of International Trade Disputes*, 31 COLUM. J. TRANSNAT'L L. 103, 128-131 (1993).

<sup>23</sup> 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. See JACKSON, *supra* note 20 \_\_\_\_\_. On the "veto" of a party losing a dispute, see *id.* at \_\_\_\_\_

<sup>24</sup> See ROBERT E. HUDEC, *GATT LEGAL SYSTEM AND WORLD TRADE DIPLOMACY* 185 (1993).

<sup>25</sup> See Pieter Jan Kuijper, *The New WTO Dispute Settlement System: The Impact on the European Community*, in 29:6 J. WORLD TRADE 49, 57 (Dec. 1995); and Joseph H.H. Weiler, *The Rule of Lawyers and the Ethos 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)

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) business. This meant, *inter alia*, enforcing intellectual property rights and establishing rules against expropriation. It led to the shift of 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 its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>26</sup> For our purposes, one question that is particularly relevant 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.<sup>27</sup>

The third and last inflection point represents a major step in the path towards a reduction in state sovereignty. That step is investor-state dispute-settlement (ISDS), a process that form 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.<sup>28</sup> The two main contours of the current 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.”<sup>29</sup> ISDS is a major step in that context: multinational corporations are given a right to sue States in binding and mandatory arbitration proceedings.<sup>30</sup> Specifically, ISDS provides multinational corporations a right to sue

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<sup>26</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1197, arts. 27-34 [hereinafter TRIPS Agreement]. On the shift itself, see Daniel Gervais, \_\_\_\_\_

<sup>27</sup> See Alec Sweet, *Judicialization and the Construction of Governance*, in ON LAW, POLITICS, AND JUDICIALIZATION 63, 64-5 (Martin Shapiro & Alec Stone Sweet eds., 2002); and Shoaib A. Ghias, *International Judicial Lawmaking: A Theoretical and Political Analysis of the WTO Appellate Body*, 24 BERKELEY J. INT'L L. 534, 553 (2006).

<sup>28</sup> 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).

<sup>29</sup> Sweet n. 27 *supra* at 45 (emphasis added).

<sup>30</sup> 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

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States party to an investment treaty (such as 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).<sup>31</sup> Investment protection clauses are now standard in IIAs.<sup>32</sup> According to UNCTAD, as of 2015 there were 3,304 IIAs, 3,304 agreements (2,946 BITs and 358 other treaties with investment provision (TIPs)), including those such as NAFTA and TPP just mentioned.<sup>33</sup>

The emergence of ISDS goes well beyond the mere recognition of international legal personality; 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.<sup>34</sup> The Charter notes *inter alia* that states have the right “to regulate and supervise the activities of transnational corporations within its national jurisdiction [ ] and [to] take measures to ensure that such activities [ ] conform with its economic and social policies.”<sup>35</sup> It imposes a duty on transnational corporations not to “intervene in the internal affairs of a host state.”<sup>36</sup> ISDS is arguably exactly the opposite. ISDS provides a forum that states agree to be bound by in case of a dispute over an investment in state A by a corporation based in State B state with which state A has concluded a treaty containing an ISDS obligation when such corporation disagrees with a measure taken by State A.<sup>37</sup>

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law.); and Glen Kelley, *Multilateral Investment Treaties: A Balanced Approach To Multinational Corporations*, 39 COLUM. J. TRANSNAT'L L. 483, 489-490 (2001). Interestingly, in *Kiobel v. Royal Dutch Petroleum Co.* 621 F.3d 111, 131 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.A. § 1350.

<sup>31</sup> United Nations Conference on Trade And Development, World Investment Report 2016, at 101. Available at [http://unctad.org/en/PublicationsLibrary/wir2016\\_en.pdf](http://unctad.org/en/PublicationsLibrary/wir2016_en.pdf) [hereinafter UNCTAD Report].

<sup>32</sup> 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).

<sup>33</sup> See UNCTD Report, n. 31 *supra*, at 101.

<sup>34</sup> UNGA Resolution 3281 (XXIX) 1974.

<sup>35</sup> *Id.*, art 2(2).

<sup>36</sup> *Id.*

<sup>37</sup> 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



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* have investment protection (including ISDS) may be at a comparative *disadvantage*.<sup>38</sup>

ISDS started in earnest in NAFTA.<sup>39</sup> It forms part of in the Trans-Pacific Partnership.<sup>40</sup> 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).<sup>41</sup> Put differently, ISDS is here, and it seems *here to stay*. Indeed in 2015, “[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.”<sup>42</sup> 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.<sup>43</sup> ISDS has (finally) started to make the

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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.)

<sup>38</sup> See *supra* n. 33 and accompanying text.

<sup>39</sup> North American Free Trade Agreement, Can-Mex-U.S., art. 1105, Dec 17, 1992, 32 I.L.M. 289 [hereinafter NAFTA]. 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 (NY-21) and R. Andrew Fitzpatrick *Investment Arbitration Under NAFTA Chapter 11: A Threat To Sovereignty Of Member States?* (2015) 39 CAN.-U.S. L.J. 55.

<sup>40</sup> See Wendy Miles QC, Kenneth Beale, Peter Barnett, *Investor-State Dispute Settlement under the Recently Concluded Trans-Pacific Partnership*, 21 No. 1 IBA Arb. News 25 (2016).

<sup>41</sup> See Joseph H.H. Weiler *European hypocrisy: TTIP and ISDS*, 25:4 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 of them do. Of the 358 TIPs just mentioned, 132 contained investment provisions similar to those in BITs and another 32 contained “limited” investment protection (for example national treatment with respect to commercial presence or free movement of capital relating to direct investments). See *id.* at 102.

<sup>42</sup> *Id.* at xii.

<sup>43</sup> See Christopher R. Drahozal *New Experiences Of International Arbitration In The United States*, 54 AM. J. COMP. L. 233, 246-7 (2006) (“Although investor-state arbitration dates back at least to the Jay

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headlines, for example in the United States in 2016 when the Keystone XL pipeline project was rejected by President Obama.<sup>44</sup> That example was heralded as evidence of ISDS giving corporations too much power over sovereign public policy decisions.<sup>45</sup>

How does ISDS mesh with a state’s right to regulate its own public policy and to enforce human or fundamental rights within its borders? Limits on state sovereignty are supported by a benevolent world community policing human rights.<sup>46</sup> 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 polices that a state might wish to apply in its own territory. This is the issue at the core of the 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 in 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 possible paths forward.

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Treaty of 1794, in recent years the number of investment arbitration proceedings has increased dramatically.<sup>96</sup> 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 hundreds of millions or even billions of dollars, and the claims may involve sensitive issues of national policy.”)

<sup>44</sup> See Dillon Fowler, *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).

<sup>45</sup> 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.”)

<sup>46</sup> The Rt Hon The Lord Millet, *The Pinochet Case- Some Personal Reflections*, in INTERNATIONAL LAW 2d ed (Malcolm D. Evans, ed.) 10 (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.”)

## 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.<sup>47</sup>

Lilly v Canada was heard at International Centre for Settlement of Investment Disputes (ICSID), the forum of choice for NAFTA investor-state disputes, and according to UNCITRAL Arbitration Rules.<sup>48</sup> ICSID is known for the confidentiality and effectiveness of its services.<sup>49</sup> 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.<sup>50</sup>

## A. The Complaint

Eli Lilly's complaint against Canada was filed under chapter 11 of NAFTA. That chapter is meant to protect investment made in a NAFTA party by a company based in another NAFTA party.<sup>51</sup> 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.<sup>52</sup> The inclusion of intellectual property in the definition of investment is controversial from a normative perspective when it leads to a challenge to a

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<sup>47</sup> Documents concerning the case including briefs submitted by all parties are available at <http://www.italaw.com/cases/1625> (last accessed Dec. 8, 2016).

<sup>48</sup> NAFTA, n. \_\_ *supra*, art. 1120. 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 '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, Mar.18, 1965, 17 U.S.T. 1270. UNCITRAL is the United Nations Commission on International trade law. As of April 1, 2014, UNCITRAL added to its arbitration rules the UNCITRAL Rules on Transparency in Treaty-based Investor-State Arbitration. See [http://www.uncitral.org/uncitral/en/uncitral\\_texts/arbitration/2014Transparency.html](http://www.uncitral.org/uncitral/en/uncitral_texts/arbitration/2014Transparency.html) (last visited October 25, 2016).

<sup>49</sup> 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).

<sup>50</sup> See J. Anthon VanDuzer, *Enhancing the Procedural Legitimacy of Investor-State Arbitration Through Transparency and Amicus Curiae Participation*, 52 MCGILL L.J. 681 (2007).

<sup>51</sup> NAFTA, n. \_\_ *supra*, ch. 11.

<sup>52</sup> See, e.g., the definitions and art 6(5) of the 2012 U.S. Model Bilateral Investment Treaty at <http://www.state.gov/documents/organization/188371.pdf>. 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 art. 1110(7), discussed below. See n. 77 *infra* and accompanying text.

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state’s intellectual property and innovation policy.<sup>53</sup> 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., 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.<sup>54</sup> The claimant (Lilly) contends that the adoption of a “new, radically different standard for determining whether inventions fulfill that requirement” (this is a reference to the “promise of the patent” doctrine discussed below) amounted to an “uncompensated expropriation, in violation of Article 1110 of NAFTA.”<sup>55</sup> Claimant alleges 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.”<sup>56</sup> In other words, Lilly is 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, in is fairly similar to the TRIPS Agreement.<sup>57</sup> 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.

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<sup>53</sup> 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 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.”) The Article returns to this issue in greater depth Parts IV and V *infra*.

<sup>54</sup> Claimants Memorial (on file with author), at 1.

<sup>55</sup> *Id.* at 1-2.

<sup>56</sup> *Id.* at 5-6.

<sup>57</sup> For a discussion see Expert Report of Daniel J. Gervais (Jan 26. 2015) 18-20 (on file with Author) [hereinafter First Report]

A second line of Lilly's argument is 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.<sup>58</sup> Specifically, Lilly alleged that the promise utility 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.<sup>59</sup>

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."<sup>60</sup> These last two arguments, it seems, could be rephrased as arguing that *any invalidation* by a court of an issued patent would amount to expropriation and that any significant change in the interpretation of a patentability criterion would also amount to such an expropriation under NAFTA.

#### B. Canada's Counter-Memorial

In its Counter-Memorial, the Government of Canada notes, first, that 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 Respondent, "[t]he threshold for a violation by a court of the minimum standard of treatment" is set "extremely high" under customary international law<sup>61</sup>. Specifically Canada alleged that 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."<sup>62</sup>

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 "even if the theory of legitimate expectations is now a rule of custom protected under Article 1105(1),

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<sup>58</sup> *Claimant's Memorial*, at 6

<sup>59</sup> *Id.* at 6-7.

<sup>60</sup> *Id.* at 7.

<sup>61</sup> Government of Canada Counter Memorial, Jan. 27, 2015 (on file with Author) at 94.

<sup>62</sup> *Id.* at 115.

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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’.<sup>63</sup>

The United States, in a submission made (as NAFTA Parties not involved in a dispute can do under NAFTA art 1128) 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.<sup>64</sup>

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.<sup>65</sup> It is unnecessary to go into all the details of this discussion. A 1981 quote from the Supreme Court of Canada opinion should suffice to illustrate the validity of Canada’s argument<sup>66</sup>:

There is a helpful discussion in *Halsbury’s Laws of England*, (3<sup>rd</sup> 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:

[T]he practical usefulness of the invention does not matter, nor does its commercial utility, *unless the specification promises commercial utility*, nor does it matter whether

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<sup>63</sup> *Id.* See also Henning Grosse Ruse-Kahn, *Litigating Intellectual Property Rights in Investor State Arbitration: From Plain Packaging to Patent Revocation* 27 (Univ. of Cambridge Faculty of Legal Studies Research Paper Series, Paper No. 52/2014, 27, 2014), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2463711](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711) at 27 (“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.”)

<sup>64</sup> Submission of the United States of America, March 18, 2016, at 4-5 (on file with Author).

<sup>65</sup> See E. Richard Gold and Michael Shortt, “The Promise of the Patent in Canada and Around the World”, 30:1 CAN. INTELL. PROP. REV. 35 (2014); and Expert Report of Ronald E. Dimock Jan. 26, 2015 (on file with Author) [hereinafter Dimock Report].

<sup>66</sup> *Consolboard v. MacMillan Bloedel (Sask) Ltd.*, [1981] 1 SCR 504 at paras. 36 and 37 (Can.)

the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. [Footnotes omitted.]

and concludes:

... 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. [Footnotes omitted.]

*Canadian law is to the same effect.*<sup>67</sup>

It seems plain from the above that promises made by a patent applicant in a patent specifications were considered relevant and clearly were a known factor in Canadian law at least as of 1981. Canada's Counter-Memorial also notes in this context that *even if* the promise of the patent doctrine is 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.<sup>68</sup> This happened recently in several opinions of the United States Supreme Court for example.<sup>69</sup>

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 (a) the US definition is not internationally binding on other nations and (b) 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.<sup>70</sup>

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

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<sup>67</sup> *Consolboard v. MacMillan Bloedel (Sask) Ltd.*, [1981] 1 SCR 504 at paras. 36 and 37 (Can.), quoted in *Dimock Report*, *id.*, at 14. Emphasis added.

<sup>68</sup> US report: Expert Report of Timothy R. Holbrook, Jan. 26, 2015 (on file with author) ([hereinafter *Holbrook Report*]); and for Mexico: Expert Report of Hedwig Lindner, Jan. 26, 2015 (on file with author).

<sup>69</sup> See e.g. *Alice Corp. Pty. Ltd. V. CLS Bank Int'l*, 134 S. Ct. 2347 (2014); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 21707 (2013); *Mayo Collaborative Services. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) (R-110); *Bilski v. Kappos*, 561 U.S. 593; and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

<sup>70</sup> See Counter-Memorial 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); and Second Report of Dr. Daniel Gervais, Dec. 7, 2015 at 3 ("Claimant's argument now seems to be that only certain definitions of utility are acceptable (basically, the current U.S. definition) under NAFTA.") (On file with Author).

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and Europe.”<sup>71</sup> As Vadi notes “this 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.”<sup>72</sup>

## 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<sup>73</sup>. 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 important to understand how Lilly managed to concoct this argument, as this will become relevant in Part IV below.<sup>74</sup> Normally, a disagreement on the application of intellectual property norms contained in the TRIPS Agreement or NAFTA would be subject to a state-to-state dispute under the relevant agreement.<sup>75</sup> 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).<sup>76</sup> Lilly’s argument hangs

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<sup>71</sup> Valentina S. Vadi, *Towards A New Dialectics: Pharmaceutical Patents, Public Health And Foreign Direct Investments*, 5 *NYU J. Intell. Prop. & Ent. L.* 113, 181 (2015)

<sup>72</sup> *Id.* at 181-182.

<sup>73</sup> TRIPS Agreement arts. 27-34. First Report at 18-20.

<sup>74</sup> See \_\_

<sup>75</sup> For NAFTA, this is provided under chapter 20, and specially art. 2004, which provides in part that “the 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 the provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding.” TRIPS Agreement, 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, Legal Instruments--Results of the Uruguay Round, 33 *I.L.M.* 1125 [hereinafter DSU]. See DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* (4<sup>th</sup> ed), 669-675 (2012).

<sup>76</sup> 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, 503-6 (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



on a provision in NAFTA that seems to exclude precisely this type of situation from the purview of investor-state disputes. That provision is Article 1110(7), which reads as follows:

This Article[investor-state arbitration] 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)*.<sup>77</sup>

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)."<sup>78</sup> 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.<sup>79</sup>

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 review a NAFTA Party's measures, each time they arise, for consistency with Chapter Seventeen.<sup>80</sup>

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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).

<sup>77</sup> NAFTA, art. 1110(7). Emphasis added.

<sup>78</sup> Memorial at 108.

<sup>79</sup> Rejoinder at 99.

<sup>80</sup> United States Submission, at 16. Mexico \_\_

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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 art. 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.<sup>81</sup> True, it has also been argued that tribunals should ignore the parties’ views when the text is clear, also on the basis of the VCLT, assuming of course that meaning is clear and unambiguous from the text itself.<sup>82</sup>

The answer is that an ISDS tribunal is not formally bound by the parties’ submissions, but it should think hard and long before ignoring them.<sup>83</sup> 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 (art. 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 has, in an arbitral context.<sup>84</sup> 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 circumstances of its conclusion” as supplementary means of interpretation,<sup>85</sup> an empirical analysis has shown that arbitral tribunals rarely if ever have recourse to such supplementary means, especially the *travaux*.<sup>86</sup>

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<sup>81</sup> Vienna Convention on the Law of Treaties arts.31-32, May 23, 1969, 1115 U.N.T.S. 331 (entered into force Jan. 27, 1980) [hereinafter VCLT]. See UNCTAD, *Interpretation of IIAs: What States Can Do, IIA Issues Note, No. 3*, 3, UNCTAD/WEB/DIAE/IA/2011/10 (Jan. 11, 2012); and James Crawford, *A Consensualist Interpretation of Article 31(3) of the Vienna Convention on the Law of the Treaties*, in TREATIES AND SUBSEQUENT PRACTICE 29, 31 (Georg Nolte ed. 2013).

<sup>82</sup> See Kenneth J. Vandavelde, *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.”)

<sup>83</sup> 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)

<sup>84</sup> See Iran-United States Claims Tribunal, Case No. B1, Interlocutory Award No. ITL 83-B1-FT (Iran-U.S. Cl. Trib. 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.”)

<sup>85</sup> VCLT, n. \_\_ *supra*, art. 32.

<sup>86</sup> See Baiju S. Vassani & Anastasiya Ugale, *Travaux Préparatoires and the Legitimacy of Investor-State Arbitration*, 11 TRANSNAT'L DISPUTE MGMT. (2014)

Multinational companies may rejoice at the thought of being able to challenge a violation of TRIPS or similar norms (such as those obtained in NAFTA Chapter 17) as indirect expropriation. This allows them to circumvent the mechanism by which they can lobby a government to file a state-to-state dispute when they disagree with the implementation of intellectual property norms by a country other than their “home” country. As Vadi notes, states and investors do not necessarily see eye-to-eye in this respect: investors want maximum flexibility for them and little for states; states want to maintain policy flexibility:

The home state may be reluctant to initiate a trade dispute because of political and diplomatic considerations, especially when the alleged IP violation is limited in scope. Even when the home state does bring an ICJ or WTO claim, governments are generally more wary in promoting interpretations of international law that could limit their own regulatory freedom in the future.<sup>87</sup>

#### D. Lilly’s Change of Approach

In its Memorial, Lilly had argued that, as “Robert Armitage, Lilly’s former General Counsel, explains, the utility requirement is “*substantially harmonized* across jurisdictions.”<sup>88</sup> The Author’s initial report demonstrated in no uncertain terms that the harmonization argument was a red herring.<sup>89</sup> All efforts to agree on a definition of utility pre and post NAFTA, including in the Patent law treaty discussions, have failed to produce consensus.<sup>90</sup>

In its Reply Memorial to Canada’s defense, Lilly changed its approach. It abandoned the harmonization argument altogether, 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.<sup>91</sup> One of Lilly’s expert 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.”<sup>92</sup> He further noted that “my experience has also taught me that there are equally important areas where *the practices of member states are*

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<sup>87</sup> Vadi, n. 71 *supra* at 121.

<sup>88</sup> *Memorial*, at 132.

<sup>89</sup> *See* First Report 7-12.

<sup>90</sup> *See id.*

<sup>91</sup> Reply Memorial, Sept. 11, 2015, at 5 (“Canada’s Counter-Memorial seeks to minimize these obligations by arguing that Chapter 17 of NAFTA did not “harmonize” substantive patentability requirements. Yet Lilly never argued that such requirements were harmonized across jurisdictions.”)

<sup>92</sup> Expert Report of Philip Thomas, Sept. 2015, at 4 (on file with Author).

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*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)*.”<sup>93</sup>

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.<sup>94</sup> This WIPO document noted the following:

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’.<sup>95</sup>

The Article lets the reader decide.

#### E. Regulatory flexibility

A significant disagreement between the parties in the Lilly case concerned the flexibility to implement international obligations. Lilly’s argument tugs directly on the “tension between the private interests of foreign investors and the regulatory autonomy of the host state.”<sup>96</sup> Indeed the issue of regulatory flexibility is one of the major issues in the ISDS context. This is not a case of actual or direct expropriation; the notion of indirect expropriation is 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

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<sup>93</sup> *Id.* at 12 (emphasis added).

<sup>94</sup> Their expert noted in his report that “[i]n 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.

<sup>95</sup> WIPO, *The Practical Application of Industrial Applicability/Utility Requirements under National and Regional Laws*, April 2001, quoted in Second Report, note 70 *supra* at 15 (emphasis added).

<sup>96</sup> Vadi, n. 71 *supra*, at 119.

Canada's sovereign ability to regulate its substantive patent law. As noted above, investors want to limit regulatory flexibility and ISDS provides them with a powerful tool to do so.<sup>97</sup>

At bottom, this becomes an argument about state sovereignty. Canada's Reply Memorial notes 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.<sup>98</sup>

True, 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 is 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 any one particular meaning for any of the terms."<sup>99</sup> Canada's argument follows 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.<sup>100</sup> Canada argues 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.

### III. SUBSTANTIVE INTERFACES BETWEEN INTELLECTUAL PROPERTY, HUMAN RIGHTS AND INTERNATIONAL TRADE

The title of this Part could easily be the title of a book. Needless to say, not every nook and cranny of the triangular interface 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

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<sup>97</sup> See *supra* n. 87 and accompanying text.

<sup>98</sup> Reply Memorial, at 64-65 (notes omitted).

<sup>99</sup> *Id.* at 65.

<sup>100</sup> VCLT, *supra* n. 81, arts 31-32; .Reply Memorial at 65.

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

The triangle has institutional aspects: There is a historical connection between the post-World War II establishment of the Bretton Woods institutions and the GATT, on the one hand, and the establishment of the World Health Organization (WHO).<sup>101</sup> The international regime complex contained in the triangle when applied to pharmaceutical regulation is “characterized by institutional density and governed by human rights law, international intellectual property law and international health law.”<sup>102</sup> There may be parallels between some human rights and free trade; there are undoubtedly linkages between access to at least certain pharmaceuticals and human rights.<sup>103</sup> This Part explores each side of the triangle formed by intellectual property, pharmaceuticals, and human rights.

#### 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 and 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.<sup>104</sup> Some core human rights are even considered *jus cogens*, creating obligations from which treaties cannot derogate.<sup>105</sup> Neither intellectual property (discussed in this Section) nor the right to health (discussed in the Section C) are typically considered to form part of *jus cogens*.<sup>106</sup>

Some forms of intellectual property may be seen as (non *jus cogens*) human rights when such rights are aligned with and fulfill the objectives of those human rights. Examples including providing a limited

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<sup>101</sup> Constitution of the World Health Organization, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185. On the Bretton Woods/GATT “system,” see Thomure, Jr. n. 20 *supra*, at 185-6.

<sup>102</sup> Vadi, n. 71 *supra* at 123.

<sup>103</sup> See Petersmann, n. \_\_ *supra*.

<sup>104</sup> Ernst-Ulrich Petersmann, *Human Rights and International Trade Law: Defining and Connecting the Two Fields*, in HUMAN RIGHTS AND INTERNATIONAL TRADE (Th. Cottier, J. Pauwelyn, and E. Bürgi, eds) 32 (2005).

<sup>105</sup> *Id.* at 33.

<sup>106</sup> See Patricia C. Gunn, *Health Care Refugees*, 6 LOY. U. CHI. INT'L L. REV. 339, 361 (2009); and Norman K. Swazo, *The Right to Health, International Law, and Economic Justice*, 5 THE INTERNET J. L., HEALTHCARE AND ETHICS 1, \_\_ (2007).

right to authors in their creations while acknowledging the need for access, as required by the International Covenant on Economic, Social and Cultural Rights.<sup>107</sup> The Charter of Fundamental Rights of the European Union also considers intellectual property as a human right.<sup>108</sup>

At least part of the copyright system can be defended as a human right, for two reasons. First, because it is seen as property, and property is sometimes seen as a human right.<sup>109</sup> Second, as René Cassin (Nobel Peace Prize recipient (1968) and co-drafter of the Universal Declaration of Human Rights) noted, ‘[h]uman beings can claim rights by the fact of their creation.’<sup>110</sup> Human rights principles and analogies can also 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 advancement. Indeed, Article 27 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 he 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.<sup>111</sup> 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

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<sup>107</sup> International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, art. 3 15 (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 <http://indicators.ohchr.org/>.

<sup>108</sup> 2012 O.J. C 326/391 art. 17(2) (“Intellectual property shall be protected.”) [hereinafter EU Charter]. 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*, 31:3 EUR. INT. PROP. REV. 113, 113 and 116 (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.”)

<sup>109</sup> See e.g., EU Charter, art 17(1). There are questions as to whether that human right protection of property extends to *private* property. See D. Gervais, ‘*Spiritual but Not Intellectual? The Protection of Sacred Intangible Traditional Knowledge*’, 11 CARDOZO J. OF INT’L & COMP. L. 467, \_\_\_ (2003).

<sup>110</sup> Quoted in Michel Vivant, *Authors’ Rights, Human Rights?*, 174 REV INT’L DROIT D’AUTEUR (RIDA) 60, 86 (1997).

<sup>111</sup> See Lea Shaver, *The Right to Science and Culture*, 2010 WISC. L. REV. 121-184 (2010).

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a purpose to exceptions, human rights may both serve as guidance to courts<sup>112</sup> and compensate for the excessively economic focus of trade law.<sup>113</sup>

Professor Dessemontet summarized this rather well when he wrote that : “[T]he 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’ view as ensconced in the TRIPS.”<sup>114</sup> Put differently, the trade-economic approach refocused copyright on the industries that produce and distribute copyright 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 is about patents, not copyrights, however, which leads to major normative differences as the Article will now attempt to demonstrate.

#### B. Patents and Human Rights

Like copyright, patents are rights to prohibit use, even in the absence of a viable market. To that extent, they are, like other intellectual property rights, mostly rights to exclude. As noted in the previous pages, denial of access to copyright material may negatively affect the human right 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.<sup>115</sup>

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 has left scars on

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<sup>112</sup> French courts do so on occasion. See JDI 1989, 1005 (note Edelman); and (1989) 143 Rev Intl Droit Auteur 301 (note Sirinelli). See also Daniel Gervais, ‘The Role of International Treaties in the Interpretation of Canadian Intellectual Property Statutes’, in THE GLOBALIZED RULE OF LAW: RELATIONSHIPS BETWEEN INTERNATIONAL AND DOMESTIC LAW. (Oonagh Fitzgerald ed.) 549, \_\_ (2006),

<sup>113</sup> See Jane C. Ginsburg, *Toward Supranational Copyright Law? The WTO Panel Decision and the “Three Step Test” for Copyright Exemptions*, 187 REVUE INTL DROIT D’AUTEUR (RIDA) 3, \_\_ (2001).

<sup>114</sup> Francois Dessemontet, *Copyright and Human Rights*, in INTELLECTUAL PROPERTY AND INFORMATION LAW (Jan J.C. Kabel ed.) 114 (1998).

<sup>115</sup> See Part \_\_



pharmaceutical companies, and impressions on public opinion.<sup>116</sup> Fighting only human rights and their spokespersons such as Médecins sans 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 which should never have been waged. 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. No one is forcing patent holders to produce at or below cost but patents may prevent third parties from producing lower cost versions. 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.<sup>117</sup>

The problem of HIV infection and other severe diseases affecting 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. Many others have until 2016 to adopt pharmaceutical patent protection under WTO rules.<sup>118</sup> 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.

That said, the ripple effect of the clash between patents and human rights is far from over. The WHO, for example, has actively entered the field and broadened the discussion to the entire financing of pharmaceutical research, questioning the predominance of private, profit-driven enterprises. 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 system having adverse human rights

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117 Paragraph 6 system \_\_\_\_

118 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, *Right to Health and Constitutional Imperatives for Regulating the Exercise of Pharmaceutical Patent Rights in Sub-Saharan Africa*, 21:2 AFRICAN J INT’L AND COMP L. 250, 262. (2013)

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impacts.”<sup>119</sup> 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.<sup>120</sup> 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.”<sup>121</sup>.

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.”<sup>122</sup> 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.”<sup>123</sup>

### C. The “Right to Health” in Context

In what is perhaps its clearest articulation, the right to health appears in Article 12 of the ICESCR, which recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>124</sup> According to General Comment 14, this right to health requires access to at least certain medicines.<sup>125</sup> The right also rests on article 25.1 of the 1948 Universal Declaration of Human Rights:

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<sup>119</sup> UN General Assembly, Promotion of a democratic and equitable international order: Note by the Secretary-General, UN Doc A/70/285 (5 August 2015).

<sup>120</sup> Office of the United Nations High Commissioner for Human Rights, Human Rights And World Trade Agreements: Using General Exception Clauses to Protect Human Rights (2005), <http://www.ohchr.org/Documents/Publications/WTOen.pdf> (last visited Oct. 19, 2016)[hereinafter OHCHR Report].

<sup>121</sup> 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 AMER. U. INT’L L. REV. 1333, 1368 (2003).

<sup>122</sup> OHCHR Report, at 5.

<sup>123</sup> *Id.*

<sup>124</sup> ICESCR, n. 107 *supra*, art.12.

<sup>125</sup> Committee on Economic, Social and Cultural Rights (“CESCR”), General Comment 14: The Right to the Highest Attainable Standard of Health (Article 12), ¶ 17, UN Doc. HRI/GEN/Rev.9 (Vol. I) (2000), [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) (“[A]ppropriate treatment of prevalent

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 security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.<sup>126</sup>

The IP/pharmaceutical patent protection relation with the right to health appears to dominate much of the discussions. Normatively, it is hypotenuse of the IP/pharmaceutical/human right (to health) triangle mentioned in the opening paragraph of this Part is. 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.<sup>127</sup> The public interest is protected by access to life-saving or life-improving medicines and 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.<sup>128</sup> Indeed, while there are real debates about the net (in aggregate) positive impact on innovation, if any, of patents in several fields, empirical studies tend to isolate pharmaceuticals as an area in which they produce positive outcomes.<sup>129</sup>

Trade rules *can* accommodate at least some of this triangular policy equation outline 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.<sup>130</sup> The issue that arises

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diseases, illnesses, injuries and disabilities, preferably at community level; the provision of essential drugs; and appropriate mental health treatment and care.”). *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 and Geir Ulfstein eds., 2012).

<sup>126</sup> Universal Declaration of Human Rights, G.A. Res. 217, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948).

<sup>127</sup> Vadi, n. 71 *supra*, at 121.

<sup>128</sup> *See id* and on the value of patent information, *see* Sean B. Seymore *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.”); and 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.”)

<sup>129</sup> 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).

<sup>130</sup> *See* B. K. Baker and K. Geddes, *supra* n. 48, at 28 n.127.

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not on trade but in an ISDS context, however, is that the singular focus on the protection of private interests casts a deep shadow over the public interest component built into the patent system, thus potentially creating a severe policy imbalance.<sup>131</sup> Put differently, in a state-to-state dispute context such as at the WTO Dispute-Settlement Body (DSB), public policy arguments can and are regularly used 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.<sup>132</sup> Not so in ISDS. Hence, Professor Sornarajah seems correct when he suggests that conflicts between private and public interests are prevalent in ISDS, well beyond the few cases involving intellectual property rights.<sup>133</sup> Kate Myles suggested 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.”<sup>134</sup> 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.

Clearly, “property”--in the patent field at least--does not mean quite the same thing as, say, in real estate.<sup>135</sup> Put simply, the grant of a patent right has a clear “social” purpose, and that purpose, seen teleologically (from a policy perspective), is not primarily to create new property rights but rather 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.<sup>136</sup>

The public interest difference between state-to-state and ISDS is clear because, as Susan Sell notes, despite all the rhetoric of economic competitiveness, states are not firms.<sup>137</sup> Firms “only have to

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<sup>131</sup> See Vadi, n. 71 *supra*, at 146.

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<sup>133</sup> See generally Muthu-Cumaraswamy Sornarajah, *Evolution or Revolution in International Investment Arbitration? The Descent into Normlessness*, in *EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION* (Chester Brown and Kate Miles eds., 2011).

<sup>134</sup> Kate Myles, *Reconceptualizing International Investment law: Bringing the Public Interest into Privat Business*, in *INTERNATIONAL ECONOMIC LAW AND NATIONAL AUTONOMY* (Meredith Kolsky Lewis and Susy Frankel, eds) 295, 296 (2010).

<sup>135</sup> 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.”).

<sup>136</sup> See generally Christophe Geiger, *The Social Function of Intellectual Property Rights, or How Ethics can Influence the Shape and Use of IP Law* (Max Planck Institute for Intellectual Property and Competition Law, Working Paper No. 13-06, 2013).

<sup>137</sup> Susan K. Sell, *Remarks* 8 *AM. SOC'Y INT'L L. PROC.* 317 (2014).

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.”<sup>138</sup>

Patent owners using investor-state arbitration to challenge regulatory measures adopted by the host states may directly impact regulatory autonomy, including the state’s ability to make and change innovation policies and to protect human rights.<sup>139</sup> Hence, the risk that some commentators see is that allowing ISDS to interpret the scope of intellectual property obligations 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.”<sup>140</sup>

The risk that this Article sees is that a potential conflict between ISDS and human rights could exacerbate the risk that already tenuous bridges built to allow states to enforce human rights when those 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 now 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.<sup>141</sup> In the ISDS context, the question that arises is, when such conflicts emerge, how will they be handled?

Professor Helfer had offered a vision of interpenetration and cross-pollination of intellectual property and human rights, possibly even a form of integration.<sup>142</sup> ISDS seems to pull in exactly the opposite direction. As Professor Okediji noted in this respect the Lilly case represents “uncharted territory in the increasingly complex and contested landscape of international intellectual property obligations.”<sup>143</sup> In her view, national innovation policy is:

[O]ne of the very few areas still largely insulated from the pervasive economic governance that

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<sup>138</sup> *Id.*, at 318.

<sup>139</sup> *See Vadi, supra* n. 71 at 186.

<sup>140</sup> *Sell, supra* n. 137, at 317.

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<sup>142</sup> *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).

<sup>143</sup> 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, 1122 (2014).

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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.<sup>144</sup>

Professors Dreyfuss and Frankel have rightly noted 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.<sup>145</sup>

In sum, looking at the three sides of our triangle together, policy makers need regulatory autonomy in the public health area both as a matter of public interest protection and human rights implementation. This autonomy was constrained by trade law constrains but only to a limited extent because, as the next part discusses, doctrinal interfaces exist to factor the public interest and human rights in trade disputes, even though some are admittedly only theoretical models. That regulatory autonomy is now directly threatened by ISDS and its very fuzzy interface with both human rights law and regulatory autonomy. Indeed protecting human rights can be seen in this context as a subset of a broader regulatory regime protecting social welfare.<sup>146</sup> The challenge is thus 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, trade and investment rules—at least beyond *jus cogens*. General principles of interpretation apply. Hence, one could argue that

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<sup>144</sup> *Id.*

<sup>145</sup> Rochelle Dreyfuss and 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.”)

<sup>146</sup> See Lone Wandhal Mouyal, *supra* n. \_\_\_\_ at 9.

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.<sup>147</sup>

The WTO dispute settlement body uses the Vienna Convention 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.”<sup>148</sup> DSB reports often limit the scope of their review of WTO Members’ regulatory autonomy, particularly when national government decisions have to take into account complex situations, or when it must ‘weigh and balance’ conflicting rights and obligations.<sup>149</sup> 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?<sup>150</sup> 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 the applicable conflict rules of public international law (eg, *lex posterior* or *lex specialis*), the human rights provision prevails over the WTO provision.<sup>151</sup>

The WTO Appellate Body has not articulated this kind of interface.<sup>152</sup>

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.<sup>153</sup>

#### B. Incorporating human rights in trade and investment disputes

A general balancing test such as the one just mentioned provides a flexible path—though one with murky boundaries. Another option is the incorporation or integration of (some) human rights in

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<sup>147</sup> Petersmann n. 104 *supra* at 33.

<sup>148</sup> *Id.* at 34.

<sup>149</sup> *See id.*

<sup>150</sup> This possibility is explored in Part V.

<sup>151</sup> Joost Pauwelyn, *Human Rights in WTO Dispute Settlement*, in HUMAN RIGHTS AND INTERNATIONAL TRADE *supra* n. 104, at 208.

<sup>152</sup> *Id.* at 210.

<sup>153</sup> *See generally* Alston, n. 2 *supra*.

the trade regime itself. The integration approach can be pushed quite far, as one sees in the work of Professor Petersmann for example. He argues 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.<sup>154</sup> 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.”<sup>155</sup> Petersmann’s view, anchored in Kant’s idea that a *constitutional* law doctrine of fundamental rights and duties of citizens could also apply internationally,<sup>156</sup> 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 (eg, for promoting economic welfare) but also ‘constitutional functions’ (eg, by rendering domestic constitutional principles of freedom, non-discrimination, rule of law, and judicial review more effective in the trade policy area).”<sup>157</sup> Whether free trade rules are designed for that purpose in mind isn’t always clear, however. In his critique of this approach Professor Alston notes, *inter alia*, 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.”<sup>158</sup>

This debate cannot be 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* but indeed a marriage (of convenience?) between human rights and trade, forms the basis for a doctrinal interface worthy of exploration for our purposes. This might explain why this approach, in spite of harsh criticism both in academia and by developing countries, “its currency has persisted.”<sup>159</sup>

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<sup>154</sup> Petersmann, n. 104, at 31.

<sup>155</sup> *Id.* at 26.

<sup>156</sup> Ernst-Ulrich Petersmann, *The Transformation of the World Trading System through the 1994 Agreement Establishing the World Trade Organization*, (1995) 6 EUR. J. INT’L L. 161, at 165.

<sup>157</sup> Ernst-Ulrich Petersmann, n. 19 *supra*.

<sup>158</sup> Alston, n. 2 *supra*, at 822 (emphasis added).

<sup>159</sup> See Deborah Z. Cass, *The ‘Constitutionalization’ of International Trade Law: Judicial Norm-Generation as the Engine of Constitutional Development in International Trade*, 12:1 EUR. J. INT’L L. 39, 40 (2001) (“[E]ven 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.”)



One should be clear about what “constitution” mean in this context. How one defines that term is almost necessarily infused the view one takes of the positive/natural law debate.<sup>160</sup> A constitution may be defined, for example, as “a body of rules that specifies how all other legal rules are to be produced, applied, and interpreted. Constitutional norms are not only higher order rules; they are prior, organic rules: they constitute a given political community.”<sup>161</sup> In a model of liberal constitutionalism, “the constitution establishes a set of electoral rules, and distributes capacities and functions among governmental institutions.”<sup>162</sup> In a different model, such as the United States, a constitution adds “a layer of substantive constraints on the uses of public authority.”<sup>163</sup> In that type of model of a constitutional order, powers are granted different levels of government, or transferred by one level of government to another, thus creating a separation of powers. This separation then 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) from which governments typically cannot (easily) derogate -- acknowledging at the same time that enforcement is key and that, consequently, the existence of words describing such rights does not always mean that they will be applied to preserve the liberties of individual citizens.<sup>164</sup>

The constitutional approach allows one to link higher-level norms at the domestic level and international norms, from example 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.”<sup>165</sup> 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,

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<sup>160</sup> 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.

<sup>161</sup> Alec Stone Sweet. *GOVERNING WITH JUDGES: CONSTITUTIONAL POLITICS IN EUROPE*, 20 (2000).

<sup>162</sup> *Id.*

<sup>163</sup> *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.”)

<sup>164</sup> See Charter of Fundamental Rights of the European Union, 2012 O.J. C 326/391; and John S. Baker, Jr., *The Effectiveness of Bills of Rights*, 15 HARV. J.L. & PUB. POL’Y 55 (1992).

<sup>165</sup> RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 701, n.1, at 154 (1987).

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necessity, and proportionality of government restrictions on transnational trade).”<sup>166</sup> Used in this sense constitutionalization is an approach that can add normative depth to treaty interpretation, in part because it can broaden the range of interpretive tools. Drawing a parallel between international trade law and a *domestic* constitutional approach also seems consonant with “general” international law, where “public international law serves the function that a constitution serves in the domestic legal system: it is a fundamental component governing the production of the remainder and of the institutional environment for international organizations and for states. It provides a limited set of rules regarding the formation of law and its interpretation, application and enforcement.”<sup>167</sup>

Constitutional parallels signal that there are underlying principles that can inform the interpretation and application of rules and standards by tribunals in a given legal order. One could argue for instance that one of the WTO’s governing principles is consider trade liberalization as the main component of its normative backdrop. Such an approach by the Appellate Body could then be seen as informed by an economic trade theory molded with the clay of libertarianism:

There is today universal agreement among economists that liberal trade increases the welfare of domestic consumers (e.g., their choice and purchasing power to buy more, better or less expensive goods from abroad), forces producers to make a more productive use of domestic resources, creates new and more stable employment opportunities in the export sector, and enhances macro-economic gains from trade (such as price stability, technological progress and competition as a decentralized information, allocation and antitrust mechanism).<sup>168</sup>

Is this approach useful then in an ISDS context? Investor-state is not about free trade; it is about investment protection. Moreover, it is hard to argue that investment protection is a human right, unless one takes a very expansive view of the notion property.<sup>169</sup> In *Lilly*, the indirect expropriation argument challenges the criteria used by domestic courts which, after due process, decided that two patents were invalid.<sup>170</sup> It is important to note that patent revocation and invalidation by courts are very common.<sup>171</sup>

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<sup>166</sup> Ernst-Ulrich Petersmann, *Theories of Justice, Human Rights, and the Constitution of International Markets*, 37 LOYOLA LOS ANGELES L REV 407, \_\_\_ (2003).

<sup>167</sup> Joel P. Trachtman, *The Domain of WTO Dispute Resolution* (1999), 40 Harvard International Law Journal 333. See also John K. Setear, *An Iterative Perspective on Treaties: A Synthesis of International Relations Theory and International Law*, 37 HARVARD INT’L L J 139 (1996).

<sup>168</sup> Petersmann, n. 156 supra, at 172.

<sup>169</sup> xref

<sup>170</sup> xref

<sup>171</sup>

This is not surprising: in a patent application context, the discussion is typically limited to the applicant and the examiner. Once the matter goes for review at the request of a third party or to a court of law, new evidence and arguments are advanced by the third party to invalidate the patent.<sup>172</sup> To argue that invalidation is a violation of the patent owner's human rights is a step 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.<sup>173</sup> In an ISDS context, by contrast, if a clash between investment protection and human rights emerges, the "supreme" value of investor protection may be a poor sextant to arbitrate the place of human rights if as a normative lodestar is the rights of multinational investors.

### C. Contractarian approaches

#### 1. Filling normative lacunae

A more neutral way that an ISDS tribunal could use to fill gaps in a text that a state wishes to "fill" with human rights is to use principles of contract law. This seems particularly appropriate 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."<sup>174</sup> 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. That said, 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<sup>175</sup>.

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

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<sup>172</sup>

<sup>173</sup> xref

<sup>174</sup> LONE WANDHAL MOUYAL, *INTERNATIONAL INVESTMENT LAW AND THE RIGHT TO REGULATE: A HUMAN RIGHTS PERSPECTIVE* 223 (2016). Emphasis in original.

The book only briefly mentions public health (*see id.* at 217-218) 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).

<sup>175</sup> *See* Prosper Weil, "The Court Cannot Conclude Definitively ..." *Non Liquet Revisited*, 36 COLUM. J. TRANSN'L L. 109, 10. (1997).

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case of a treaty specifically, this includes taking account of international law, as provided in the VCLT.<sup>176</sup> Depending on the issue, international law can both provide context and constitute “relevant rules of international law applicable in the relations between the parties.”<sup>177</sup>

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.<sup>178</sup> Using external norms as interpretive tools can be done without making law, which panels and the Appellate body are prohibited from doing under the DSU.<sup>179</sup>

As the International Law Commission suggests, international law can “supplement” WTO law, unless the opposite is explicitly stated in the agreement.<sup>180</sup> 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.”<sup>181</sup> Then, as was pointed out by the International Court of Justice (ICJ):

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<sup>176</sup> This often amounts to “interpreting silence” to quote the term used by Lone Wandahl Mouyal in this context. WANDHAL MOUYAL, *supra* n. 174 at 54.

<sup>177</sup> VCLT, art. 31(1) and 31(3)(c).

<sup>178</sup> WTO, *US – Shrimp* – Report of the Appellate Body (Oct. 12, 1998) document WT/DS58/AB/R at ¶¶ 127-131.

<sup>179</sup> 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.” *See also* Susy Frankel and Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement* 46 VAND. J. TRANSNAT’L L. 1149, 1206 (2013).

<sup>180</sup> *See* M Koskenniemi, *Fragmentation of international law: difficulties arising from the diversification and expansion of international law*, Report of the Study Group of the International Law Commission, at ¶ 85 <[http://legal.un.org/ilc/documentation/english/a\\_cn4\\_l682.pdf](http://legal.un.org/ilc/documentation/english/a_cn4_l682.pdf)> accessed Oct. 19, 2016

<sup>181</sup> Resolution No. 5/2008 on International Trade Law, the 73rd Conference of the International Law Association, held in Rio de Janeiro, Brazil, 17-21 August, 2008. Under its Constitution, the ILA is an international non-governmental organisation 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” (art 3.1).

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.<sup>182</sup>

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.<sup>183</sup> Then the WTO is not part of the United Nations, 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.<sup>184</sup> The closest reference one can point to might be that contained in the TRIPS Declaration on Public Health, adopted in 2001, approximately one year after the Millennium Summit in September 2000 at which the MDGs were adopted.<sup>185</sup>

Against this backdrop, at least two contract-based theories have been offered to suggest why trade tribunals may need to use the Vienna Convention go beyond the text of an IIA. 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.”<sup>186</sup> If aligned with evidence that the application of an intellectual property right in a given case interferes unreasonably with trade, then perhaps this argument might have a chance to be considered. That said, the WTO has a number of special and differential provisions (including in the DSU) and it is unlikely that such an normative

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<sup>182</sup> Fisheries Jurisdiction (Federal Republic of Germany v. Iceland), Merits, Judgment, 1974 I.C.J. 181 (July 25).

<sup>183</sup> United States—Standards for Reformulated and Conventional Gasoline, WT/DS2/ AB/R, para.III:B. *See also* Japan—Taxes on Alcoholic Beverages, WT/DS8/AB/R, pt D., fn.19.

<sup>184</sup> Wolfgang Benedek, *The World Trade Organization and Human Rights*, in ECONOMIC GLOBALISATION AND HUMAN RIGHTS (Wolfgang Benedek, Koen De Feyter, Fabrizio Marrella, eds) 150-151 (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, [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (last visited Oct. 19,2016).

<sup>185</sup> WTO Ministerial 2001, Declaration on the TRIPS agreement and public health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm). (last visited Oct. 19, 2016). On the Millennium Development Goals, *see generally* United Nations, Millennium Development Goals Report 2015 (2015).

<sup>186</sup> 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).

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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.<sup>187</sup>

## 2. Incomplete contracts

A second and perhaps more promising contract-based argument not specifically tied to the WTO and possibly useful in an ISDS context was advanced by Professor Trachtman. In the wake of Hadfield's suggested application of the incomplete contracts theory to statutes,<sup>188</sup> he noted that WTO panels and the Appellate Body could do the same to treaties, though not without significant constraints and difficulties.<sup>189</sup> Trachtman 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:

Lacunae 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.<sup>190</sup>

Arbitral tribunals operating in an ISDS context follow the VCLT in interpreting investment treaties (or investment chapters of trade agreements). WTO instruments are not part of the immediate context and tribunals need not follow the approach chosen by the WTO DSB.<sup>191</sup> Yet, as the arbitral tribunal pointed out in *Saluka v. Czech Republic*, the VCLT's direction about *object and purpose* is key in interpreting the scope of obligations, and it includes both an immediate and a broader context.<sup>192</sup> Because

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<sup>187</sup> See Mary Sabina Peters and Manu Kumar R, Introspect "special and differential treatment" given to developing countries under the WTO dispute settlement system, 17:6 INT. A.L.R. 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.”)

<sup>188</sup> Gillian K. Hadfield, *Weighing the Value of Vagueness: An Economic Perspective on Precision in the Law*, 82 CAL L REV 541, 547 (1994).

<sup>189</sup> Trachtman, n 167 above, at 350.

<sup>190</sup> *Id.*, at 376.

<sup>191</sup> RUDOLF DOLZER & CHRISTOPH SCHREUER, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW* 28 (2012).

<sup>192</sup> *Saluka v. Czech Republic*, UNCITRAL Arbitration Rules, Partial Award 67-68 (Mar. 17, 2006), <http://www.italaw.com/sites/default/files/case-documents/ita0740.pdf> (“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

they do follow the VCLT, they consider the plain meaning of the text *in light of its object and purpose*, and the subsequent practice of the parties in its application.<sup>193</sup> As Professor Frankel's work has shown, this opens normative windows.<sup>194</sup> Yet, 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." The WTO Appellate Body itself has been reluctant to look at extrinsic norms, that is norms outside those in covered (WTO) agreements.<sup>195</sup>

### 3. Stipulation for another

A third contract approach specific to the ISDS context reflects the fact that investor-state mechanism are contained in an investment treaty between two or more states (or the investment chapter of a trade agreement) but not for the benefit of any of the parties to the "contract"—at least not directly. 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.<sup>196</sup>

While generally prohibited in French law, there are many cases in which such stipulations

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relevant circumstances") This tribunal operated under UNCITRAL Rules, as did the one in the Lilly case. See \_\_\_\_

<sup>193</sup> 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* n. 81 to 85 and accompanying text.

<sup>194</sup> \_\_\_\_

<sup>195</sup> See Mexico – Tax Measures on Soft Drinks and Other Beverages AB-2005-10, WTO document WT/DS308/AB/R, March 6, 2006 at ¶¶ 13-14 ("Mexico's interpretation would imply that, in order to resolve the case, WTO panels and the Appellate Body would have to assume that there is a violation of the relevant international agreement (such as the NAFTA) by the complaining party, or they would have to assess whether the relevant international agreement has been violated. WTO panels and the Appellate Body would thus become adjudicators of non-WTO disputes. As we noted earlier, this is not the function of panels and the Appellate Body as intended by the DSU. For these reasons, we agree with the Panel that Article XX(d) is not available to justify WTO-inconsistent measures that seek 'to secure compliance' by another WTO Member with that other Member's international obligations.")

<sup>196</sup> A. WEILL & F. TERRÉ, *DROIT CIVIL, LES OBLIGATIONS*, 549. (1986). Translated in Gordon Humphreys and Andrew Higg, *Waybills: a case of common law laissez faire in European commerce*, J. BUS. L. (UK) 453, 465 (1992).

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are allowed.<sup>197</sup> 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.<sup>198</sup> 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.<sup>199</sup> It is 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.”<sup>200</sup> 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.”<sup>201</sup>

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 sell 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. UNIDROIT art. 5.2.1 provides a rule for

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<sup>197</sup>Humphreys and Higg, *id.* at 466. The German civil code (BGB) “provides explicitly in section 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).

<sup>198</sup> Andres Guadamuz Gonzalez *Viral Contracts or Unenforceable Documents? Contractual Validity of Copyleft Licences* 26:8 EUR. INT. PROP. REV. 2331, 3356-7 (2004).

<sup>199</sup> Rutsel Silvestre J. Martha, *Preferred creditor status under international law: the case of the International Monetary Fund*, 39:4 INT’L & COMP. L. QUART. 801, 815-6 (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.”)

<sup>200</sup> VCLT, n. \_\_ *supra*, arts 34 and 36(1). See also Jimenez de Arechaga, *Treaty Stipulations in Favor of Third States*, 50 AM. J INT’L L. 338, 356 (1956)..

<sup>201</sup> William C. Waltera and Michael V. Cory Jr *The Circumvention Of Mississippi's Prohibition Of Direct Actions* 66 MISS. L.J. 493, 501 (1997). For example in my own 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 (citations omitted).” *United American Bank of Memphis v. Gardner*, 706 S.W.2d 639 (Tenn.App.1985).



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.*”<sup>202</sup> 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.”<sup>203</sup>

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. 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 implies certain obligations, including upholding human rights.<sup>204</sup> Put differently, if a corporation gets personality and the right to sue, can the sued state demand compliance with any international obligations, as it could against the state where the corporation is established?

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 jurisgenerative 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.<sup>205</sup>

Other non-state actors (such as the UN itself) have been given legal personality at international

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<sup>202</sup> UNIDROIT Principles of International Commercial Contracts (2010), available at <http://www.unidroit.org/english/principles/contracts/principles2010/integralversionprinciples2010-e.pdf>.

<sup>203</sup> *Id.*

<sup>204</sup> 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)

<sup>205</sup> José E. Alvarez, *Are Corporations “Subjects” of International Law?*, 9 SANTA CLARA J. INT'L L. 1, 11-12 (2011).

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law but “investor-state dispute settlement is a significant paradigm shift.”<sup>206</sup> It creates a “new form of dialectics between the private and public interests in IP governance at the international level.”<sup>207</sup> Enforcement of human rights violations against multinational corporations is not unheard of. Parallels have been drawn in those context to the Alien Tort Statute.<sup>208</sup>

In sum, some 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 at least asking the question 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. These interfaces typically take the form of *specific* human rights exceptions or *general* ones allowing the exercise of the “right to regulate.”<sup>209</sup> This “right to regulate” in relation to IAs 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.” 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.”<sup>210</sup> Specific interfaces in IAs provide for identified regulatory measures to be taken without violating their

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<sup>206</sup> *Id.*

<sup>207</sup> Vadi, *supra* n 71 at 117.

<sup>208</sup> See generally 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 (2006). But see 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) (explain how international standards often fail to restrain the behavior of corporations); and Ilias Bantekas, *Corporate Social Responsibility in International Law*, 22 B.U. INT’L L.J. 309, 310 (2004) (discussing the that immunity from responsibility for human rights violations that corporations have traditionally enjoyed).

<sup>209</sup> AIKATERINI TITI, *THE RIGHT TO REGULATE IN INTERNATIONAL INVESTMENT LAW* 52 (2014).

<sup>210</sup> WANDAH L. MOUYAL, *supra* n. 174 at 8.

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 regulation.

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.’<sup>211</sup> Similar exceptions are found in a number of IIAs.<sup>212</sup> 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.<sup>213</sup> Recourse to general interfaces has not been very successful in the TRIPS context.<sup>214</sup>

The TRIPS Agreement contains 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.”<sup>215</sup> Second, TRIPS contains a specific exception allowing WTO Members to exclude from patentability “the prevention within their territory of the commercial exploitation of which is *necessary* to protect *ordre public* or morality, including to protect human, animal or plant life or health.”<sup>216</sup> Both those TRIPS interfaces are cabined by the use of the term “necessary.”<sup>217</sup> The use of this term seems to posit (as a normative matter) that trade liberalization commitment should trump *but for* necessity to adopt certain regulatory measures. It does not specify the burden of proof (who must show necessity and how) but there

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<sup>211</sup> General Agreement on Tariffs and Trade (GATT), done Oct. 30, 1947, T.I.A.S. No. 1700, 55 U.N.T.S. 187 (entered into force Jan. 1, 1948). The Final Act Embodying The Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, Legal Instruments--Results of the Uruguay Round vol. 1 (1994), 33 I.L.M. 1125 (1994) contains the “GATT 1994” and the General Agreement on Trade in Services (GATS), in its Annexes 1A and 1B, respectively.

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<sup>214</sup> See GRAEME B. DINWOODIE & ROCHELLE COOPER DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME 186 (2012).

<sup>215</sup> TRIPS Agreement, n. \_\_ *supra*, art. 8.1.

<sup>216</sup> *Id.*, art 27.2.

<sup>217</sup> See Frankel and Gervais, *supra* n. 179, at 1205 (reviewing WTO jurisprudence and noting that the “Appellate Body further said, ‘[D]etermination of whether a measure, which is not ‘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.’”)

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is WTO jurisprudence on that point.<sup>218</sup>

As Aikaterina Titi demonstrates in her careful analysis of right to regulate clauses in IIAs, language matters.<sup>219</sup> Providing a “right to regulate,” often in an IIA provision bearing that as its title, can be significantly constrained by a “provided it is consistent with other provisions of this agreement” clause, as in TRIPS Article 8.1 for example.<sup>220</sup> Then the right to regulate might be as 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.<sup>221</sup> Another consideration is that a country that adds this right to regulate (as the US did in its mode BIT in 2004) might prompt an investor to argue that earlier IIAs do not, a contrario, provide regulatory flexibility.<sup>222</sup>

Professors Dinwoodie and Dreyfuss have proposed a “neofederalist” view 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.<sup>223</sup> 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.”<sup>224</sup> 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.”<sup>225</sup> They suggest, *inter alia*, that the DSB make more room for *general* exceptions, which states often paying attention “to access interests safeguarded by commitments outside intellectual property.”<sup>226</sup> They note in that regard that

These provisions [ ] promote the interest in diversity because they allow states to pursue local objectives, including public health, nutrition, and morality. An examination of the methodology of these provisions reveals another important objective: while some are specific, states also employ open exceptions to enable intellectual property law to respond effectively to changing social conditions.”<sup>227</sup>

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<sup>218</sup> *See id.* at 1206-1207.

<sup>219</sup> *See* Titi, *supra* n. 209, at 111-115.

<sup>220</sup> *See id.*

<sup>221</sup> *See id.* at 99-100.

<sup>222</sup> *See id.* at 295.

<sup>223</sup> Dinwoodie and Dreyfuss *supra* n. 214 at 160.

<sup>224</sup> *Id.*

<sup>225</sup> *Id.*

<sup>226</sup> *Id.* at 186.

<sup>227</sup> *Id.* at 187.

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.<sup>228</sup> That however, does not directly solve our ISDS challenge.

## 2. ISDS

Express interfaces between the right to regulate and ISDS increasingly often find their way in 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 CETA and TTIP context, substantive intellectual property is at least partly excluded from ISDS scrutiny, a move informed perhaps by the filing of the Lilly case. Let us see how this was done. A Declaration appended to the expropriation provision of Chapter X of the Comprehensive Economic and Trade Agreement (CETA) provides clearly 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.”<sup>229</sup> 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.”<sup>230</sup> 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.<sup>231</sup>

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<sup>228</sup> See Frankel and Gervais, *supra* n.179 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.”)

<sup>229</sup> Sep. 26, 2014, online <http://ec.europa.eu/trade/policy/in-focus/ceta/>.

<sup>230</sup> *Id.* art. X.11, ¶ 6. See also Vadi, n.71 *supra*, at 191.

<sup>231</sup> See Glyn Moody, *EU-Canada Trade Deal Dodges Belgian Veto For Now, But Faces Multiple Legal Challenges*, TECHDIRT, Oct. 28, 2016, online: <http://bit.ly/2ecPKTw> (accessed Oct. 31, 2016) This reverse a refusal by the European Commission to refer the matter to the court. See James Crisp, *Commission won't ask EU judges to decide on legality of ISDS*, EurActiv.com, Sep. 8, 2015, online

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Similarly, the European text proposal for the Transatlantic Trade and Investment Partnership (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.<sup>232</sup>

The free trade agreement between Australia and the United States contains a general carve out for public health purposes.<sup>233</sup> NAFTA Parties presumably could add a similar one to Chapter 11 (with the risks that any reopening of NAFTA entails<sup>234</sup>), 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.<sup>235</sup>

An interesting change can be seen in the model US BIT.<sup>236</sup> The initial model dates back to 1977. Its main focus was on the protection of foreign investments by US companies.<sup>237</sup> However in the wake of ISDS awards against the United States, the model BIT was revised in 2004 to note that “except 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.”<sup>238</sup>

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<http://bit.ly/2eYxEWB> (accessed Oct. 31, 2016). [THIS NOTE WILL BE IMPROVED DURING EDITING AS BETTER SOURCES BECOME AVAILABLE]

<sup>232</sup> European Union’s proposal for Investment Protection and Resolution of Investment Disputes, Nov. 12, 2015. Transatlantic Trade and Investment Partnership, Trade in Services, Investment and E-Commerce, Chapter II – Investment, art 5(7). Online: [http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc\\_153955.pdf](http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153955.pdf) (accessed Oct. 17, 2016).

<sup>233</sup> Australia–United States Free Trade Agreement, U.S.-Austl., art. 17.9(7), May 18, 2004, 43 I.L.M. 1248.

<sup>234</sup> 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.)

<sup>235</sup> See *supra* n. 77 and accompanying text.

<sup>236</sup> See WANDHAL MOUYAL *supra* n. 174 at 71-73.

<sup>237</sup> See *id.*

<sup>238</sup> US Model BIT (2012), *supra* n. 52. The 2012 language is unchanged on this point from the 2004 model, as a request to remove “except in rare circumstances” was rejected. See WANDHAL MOUYAL, *id.* at 72.

The avenue explored, namely the systematic exclusion of an evaluation of compliance with substantive intellectual property obligations by ISDS tribunals is common in 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.<sup>239</sup> 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.<sup>240</sup> Indeed, 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 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.”<sup>241</sup>

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.”<sup>242</sup> 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.” In addition, paragraph 3 demands that parties “shall not fail to effectively enforce its labour and environmental legislation in a manner affecting trade or investment between the Parties.”<sup>243</sup>

Systematic exclusion is thus a clearly useful tool to consider as we now turn to solutions.

## V. WAYS FORWARD

### A. The challenge

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<sup>239</sup> Articles 22.1, 23.2 and 24.3 of CETA; Article 13.1(1) of the EU FTA with Singapore; Articles 269(3) and 270(2) of the EU FTA with Colombia and Peru; Articles 286(1)-(2), 287 of the EU Association agreement with Central America; and Articles 13.4, 13.5 of the EU FTA with Korea.

<sup>240</sup> *See id.*

<sup>241</sup> A similar provision is contained in Article 13.2(2) of the EU FTA with Singapore and in Article 268 of the EU FTA with Colombia and Peru.

<sup>242</sup> Article 13.1(3) of the EU FTA with Singapore and Article 291(1) of the EU Association Agreement with Central America. Article 291(1) of the EU FTA with Central America contains a similar provision.

<sup>243</sup> EU-Central America Association Agreement (June 29, 2012), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=689> (last visited Oct. 19, 2016).

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The challenge this Article attempts to contribute to meet is to build proper interfaces between a state’s right—indeed often its duty—to regulate to protect human rights, 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 to manoeuvre to promote social welfare [ ] and to live up to international human rights commitments.” If states’ hands are tied in such a way that they 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.<sup>244</sup> The very sustainability of investment protection is at stake.

The challenge is situated at the border of private and public international law. As noted above, ISDS—or at least the BIT regime, which contains a majority of ISDS clauses—was built on a contractual model far removed from public international law.<sup>245</sup> What is required is a reconciliation, not seeing human rights and investment as polar opposites but human rights (not just those that arguably support free trade and free enterprise) as providing legitimacy to investment protection.<sup>246</sup> Avenues discussed in Part IV range from using contractual doctrines to impose a measure of respect for human rights on investors desirous to trigger ISDS to specific regulatory exclusions to employing a VCLT approaches to interpret ISDS clauses using a more open texture. These will now be explored in greater detail to see how they could be used to form part of a viable answer.

#### B. Parameters of an optimal Human Rights/ISDS Interface

Is ISDS now considered by multinational companies as a way to circumvent shortcomings that these companies see in state-to-state multilateral dispute-settlement? The question is worth asking.<sup>247</sup> As far as intellectual property is concerned, as Joost Pauwelyn has observed there have been few TRIPS

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<sup>244</sup> See Peter Muchlinski, *Policy Issues*, in THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW (Peter Muchlinski, Federico Ortino and Christopher Schreuer, eds) 60 (2008).

<sup>245</sup> See *supra* n. 174 and accompanying text.

<sup>246</sup> See WANDAHL MOUYAL, *supra* n. 174 at 227.

<sup>247</sup> See Christopher S. Gibson, *Latent Grounds in Investor-State Arbitration: Do International Investment Agreements Provide New Means to Enforce Intellectual Property Rights?*, Y.B. ON INT’L INV. LAW & POL’Y 397, 398 (2010)



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.<sup>248</sup>

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.<sup>249</sup> ISDS has morphed into a “potent strategic *offensive* tool” to effectuate policy changes to domestic norms concerning environmental protection, intellectual property and other regulatory areas.<sup>250</sup>

This Article suggests that the answer is *not* to oppose the grant to 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 non-governmental organizations (NGO), can supplement the “enforcement” activity of states in this regard.<sup>251</sup> The issue with ISDS is more 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.<sup>252</sup> 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.”<sup>253</sup>

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<sup>248</sup> See generally Pauwelyn, *supra* n. 76.

<sup>249</sup> Howard Mann and Konrad von Moltke, NAFTA Chapter and the Environment: Addressing the Impacts of the Investor-State process on the Environment, International Institute for Sustainable Development, at 15 (1999) <http://www.iisd.org/pdf/nafta.pdf>

<sup>250</sup> *Id.*

<sup>251</sup> See 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); and Steve Charnovitz, *Two Centuries of Participation: NGOs and International Governance*, 18 MICH. J. INT'L L. 183, 285 (1997).

<sup>252</sup> 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 and Frankel, *supra* n. 145 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 ending in 2004 (the panel had determined the damages to be 1,219,900 euros). 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.”) (notes omitted)

<sup>253</sup> Sell, *supra* n. 137 at 177.

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Some commentators have gone a step further and argued that issues expressly left open in trade rules could be “closed” using ISDS, such as exhaustion (parallel imports).<sup>254</sup>

The normative question we need to answer in respect of human rights is whether ISDS should and can interpret and “factor in,” or take account of 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.<sup>255</sup> The constitutional and contract-based approaches reviewed in Part IV are certainly worth investigating even though they lead to a risk that human rights will play second fiddle in an orchestra of norms conducted by trade law.<sup>256</sup> At bottom the interest those approaches hold for our purposes lies in a simple argument: *preventing* ISDS tribunals from considering human rights norms might weaken, both doctrinally and normatively, the case that a state might make that, for example, a measure is “necessary” under a general or specific exception contained in an IIA.<sup>257</sup> For example, a state might want to refer to an obligation under a human right instrument to justify a measure. This implies that it has the right to bring up this norm of international law not contained in the IIA at issue before the ISDS tribunal.

Consequently, this Article suggests that (a) a State should be allowed to bring human rights obligations it is bound by before an ISDS tribunal and (b) these obligations should be fully considered in interpreting the scope and depth of regulatory leeway used by the State. How the second prong could be effectuated is discussed in the next section.

The proposals below tackle both the scope of ISDS and the interpretation of ISDS instruments. The interpretative approach directs ISDS tribunals to avoid consistencies with other (non-investment)

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<sup>254</sup> See B K Baker, K Geddes, *supra* n. 48 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.”)

Under the TRIPS Agreement, WTO members agreed to disagree on exhaustion. Art. 6 of TRIPS provides that “For 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, n. 73 *supra*, art. 6.

<sup>255</sup> xref

<sup>256</sup> See generally Alston, n. 2 *supra*.

<sup>257</sup> xref

instruments whenever possible. It is discussed in the next Section. The scope issue can be approached in two ways. One can reduce the scope of ISDS's jurisdiction by introducing what Professor Okediji has referred to as narrowly tailored provision. Another approach is to keep a fairly broad ISDS provision but add a similarly broad exception for the right to regulate. Both options are discussed below. Finally, a few thoughts on unintended consequences are offered in the last Section of this Part.

### C. Directed interpretation

An optimal solution to the challenge outline in the opening lines of this Part would do more than just require ISDS tribunals to allow states to bring human rights obligations to their attention to justify a public policy measure. One could suggest asking dispute-settlement bodies to *avoid any interpretation of the IIAs that would contravene a human right obligation undertaken by the State whenever possible*, a global Charming Betsy doctrine, as it were.<sup>258</sup> The Charming Betsy doctrine is a US doctrine of statutory interpretation named after the schooner *Charming Betsy* seized in 1800 in open seas by a US frigate. It led to a Supreme Court opinion, *Murray v. Schooner Charming Betsy*.<sup>259</sup> 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.”<sup>260</sup> A VCLT-based approach poses no obstacle. Indeed it can indicate the path to follow for when a text's meaning is obscure or ambiguous a broader context including other relevant instruments can—some might say should-- be factored in.<sup>261</sup> The Article considers the Vienna Convention's role in greater detail below but let us first see what it would mean in practice to use the proposed international “Charming Betsy.”

Applied to the ISDS context, following the Charming Betsy 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 or a state's implementation of its human rights obligations, then that interpretation should be preferred.<sup>262</sup> This would have a “normative stabilizing effect, at a time when

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<sup>258</sup> xref

<sup>259</sup> (1804) 6 U.S. (2 Cranch) 64.

<sup>260</sup> 6 U.S. at 118

<sup>261</sup> xref

<sup>262</sup> The “area of vital socio-economic importance” is taken from TRIPS Article 8.1. *See supra* n. 215 and accompanying text. On the interpretation of regulatory flexibility, *see also* Robert Howse, *The World Trade Organization 20 years On: Global Governance by Judiciary*, 27:7 EUR. J. INT'L L. 9, 76 (2016)

there are few agreed answers about the costs and benefits of globalization or the ideal shape of global economic governance in relationship to differing domestic policy paths.”<sup>263</sup> WTO jurisprudence on the use of regulatory flexibilities within boundaries set by trade commitments and obligations under WTO instruments could inform the scope and reach of the elasticity that an ISDS tribunal should consider before finding an inconsistency when a state credibly raises those matters in response to an ISDS complaint.

How could one effectuate this policy? At the WTO, mechanism exists.<sup>264</sup> In the ISDS context it is admittedly harder. After all there are thousands of existing IIAs that contain investment provisions.<sup>265</sup> They could not all be amended. The idea of amending the Vienna Convention, some provisions of which have achieved quasi-canonical status, also seems far-fetched.<sup>266</sup> Issues of retroactive application of new interpretation norms that have no claim to customary law would emerge.<sup>267</sup>

Another option would be to have a convention on ISDS which would include not just VCLT principles but provisions to compensate for the absence of regulatory and general exceptions in ISDS. The EU has proposed that a permanent court be established for this purpose in TTIP.<sup>268</sup> That new court could theoretically come up with interpretive principles to the same effect as those described above, but

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(“[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.”)

<sup>263</sup> *Id.* at 76.

<sup>264</sup> xref

<sup>265</sup> xref

<sup>266</sup> See Jonathan Pratter, *Treaty Research Basics*, 89 LAW LIBR. J. 407, 408 (1997) (referring to the “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); and Michael B. McDonough *Privileged Outlaws: Diplomats, Crime And Immunity*, 20 SUFFOLK TRANSNAT’L L. REV. 475, 476 (1997).

<sup>267</sup> Although this would require a longer discussion, article 28 VCLT, n. \_\_, *supra*, itself 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. QUART. REV. 78, 80 (2015) (referring to “customary international law of treaty interpretation, as reflected in arts 31–33 of the Vienna Convention.”)

<sup>268</sup> See Ben Stanford, Andreas Yiannaros and Chrispas Nyombi, *TTIP negotiations in the shadow of human rights and democratic values*, INT. COMP’Y COMM. L.R., 27:9 316, 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.”) (notes omitted)

this seems unlikely to the Author given that investment protection is ISDS' normative lodestar.<sup>269</sup> The Article suggests that "Vienna Plus" interpretive principles be included in the convention establishing the court. Naturally if the Court only bound EU-related ISDS it would not bind IIAs not involving the EU. However, jurisprudence might emerge from this court that might influence other arbitral tribunals.<sup>270</sup> 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 dispute arising out of existing IIAs or use it for future ones.

Finally, in the EU context, the referral to the Court of Justice of the European Union about CETA that Belgium obtained in the last minutes before the adoption of the instrument might yield an obligation that ISDS not prevent EU member States from complying with their obligations under the Charter.

#### D. Preserving regulatory autonomy

This suggestion contained at the end of the previous section would be a positive step to be sure, but it will not be enough in all cases. A stronger interface would direct ISDS tribunals to refrain from stepping onto 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 by limiting the scope of ISDS, or by adding to investment instruments an appropriately worded right to regulate clause.

An example of the former is the European Union, which is pushing exclusions of substantive IP rules from ISDS in both CETA and TTIP, as it tries to reconcile human rights and trade in a variety of ways. CETA was the first EU IIA containing an ISDS.<sup>271</sup> It had to be modified even after its initial signature to limit the power of ISDS tribunals. In addition, the Court of Justice of the European Union

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<sup>269</sup> xref

<sup>270</sup> 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 AJIL 48 (2008).

<sup>271</sup> Previous IIAs were bilateral, that is, entered into not by the EU but with individual member States.

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has expressed doubts about the constitutional validity of “external tribunals, especially when those clash with EU fundamental right such as those contained in the EU Charter.”<sup>272</sup>

The European Union is not alone. First, 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.<sup>273</sup>

Australia is also baring its teeth, but in a way that supports 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 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 circumstances where those laws do not discriminate between domestic and foreign businesses.”<sup>274</sup>

At the level of state-to-state disputes at the WTO, multilateral instruments could achieve similar aims. Side agreements on human rights and a Ministerial Declaration have been proposed.<sup>275</sup> How the WTO panel and probably eventually the Appellate Body at the WTO create the interface between public health and intellectual property in the pending plain packaging cases might serve as a good precedent for future state-to-state disputes in the trade realm.<sup>276</sup> If those are formulated using a convincing Vienna Convention approach, it might influence ISDS tribunals.<sup>277</sup> Yet this Article’s approach is rooted in the belief that how the Lilly tribunal structures the award is likely to determine how future ISDS tribunals—absent a change of rules—will proceed in such cases and influence to a larger degree those future awards than the plain packaging reports expected soon at the WTO.<sup>278</sup>

#### E. Imposing corresponding obligations on investors

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<sup>272</sup>

<sup>273</sup> xref

<sup>274</sup> Australian Gov’t, Gillard Government Trade Policy Statement: Trading Our Way to More Jobs and Prosperity 14 (Apr. 2011), available at p [http://blogs.usyd.edu.au/japaneselaw/2011\\_Gillard%20Govt%20Trade%20Policy%20Statement.pdf](http://blogs.usyd.edu.au/japaneselaw/2011_Gillard%20Govt%20Trade%20Policy%20Statement.pdf)

<sup>275</sup> On the former *see* Pauwelyn 206. On the latter *see* Petersmann 71.

<sup>276</sup> *See* Frankel and Gervais, *supra* n. 179 at \_\_\_.

<sup>277</sup> xref

<sup>278</sup> xref

The marked reluctance of international investment law to “take adequate account of the public interest and human rights law is out of step with current trends in public international law.”<sup>279</sup> Would imposing obligations on investors that only claim rights lead to a more balanced outcome? Specifically, does the grant of a right to sue under ISDS create any obligations on these new “international ‘persons’ allowed to sue States directly in their own special court?”<sup>280</sup> 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 services.”<sup>281</sup> 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.”<sup>282</sup> 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.”<sup>283</sup> 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.”<sup>284</sup> India and South Africa have been mentioned in this context as cases demonstrating that domestic courts can impose access obligations based on the right to health.<sup>285</sup>

#### F. Factoring in unintended consequences

Unintended consequences are so common that their existence is said to be a “law.”<sup>286</sup> A win for Lilly in its ISDS claim against Canada could have unintended consequences and could create perverse incentives. For instance, would it be in an investor’s interest to obtain a patent and then have it invalidated

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<sup>279</sup> Miles, *supra* n. 134, at 296.

<sup>280</sup> This issue was explored in Part IV in the discussion of *stipulation pour autrui* and privity. Xref.

<sup>281</sup> David Weissbordt and Muria Kruger, Human Rights Responsibilities of Businesses as Non-State Actors, in NON-STATE ACTORS AND HUMAN RIGHTS (Philip Alston, ed) 315, 335 (2005).

<sup>282</sup> *Id.* at 335-336.

<sup>283</sup> Steven R. Ratner, *Corporations and Human Rights: A Theory of Legal Responsibility*, 111 YALE L. J., 443, 449 (2001).

<sup>284</sup> Lisa Forman & Jillian Clare Kohler, *Introduction: Access to medicines as a human right –What does it mean for pharmaceutical industry responsibilities?* in Lisa Forman & Jillian Clare Kohler, eds.), ACCESS TO MEDICINES AS A HUMAN RIGHT: IMPLICATIONS FOR PHARMACEUTICAL INDUSTRY RESPONSIBILITY 3, 9 (2012)..

<sup>285</sup> See Emmanuel Kolawole Oke, *Using the Right to Health to Enforce the Corporate Responsibilities of Pharmaceutical Companies with Regard to Access to Medicines*. 1 HEALTH DIPL’Y 1, 5-12 (2013).

<sup>286</sup> See Daniel Gervais, *The Regulation of Inchoate Technologies*, 47 HOUST. L REV. 665, 684 (2010) (discussing the “law” of unintended consequences in regulatory theory).

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(and compensated)? Recall that one of Lilly’s arguments was that *any* invalidation might amount to indirect expropriation, not just those happening as a perceived change in the application or interpretation of patentability criteria.<sup>287</sup> It would also create 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.<sup>288</sup>

## CONCLUSION

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<sup>287</sup> Xref

<sup>288</sup> 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 patentable 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, 122 S.Ct. 913 (2002).