

THE PROPOSED MULTILATERAL INVESTMENT COURT  
HUMAN RIGHTS AND REGULATORY LESSONS FROM *LILLY V CANADA*

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A. Introduction

International economic liberalization and the enforcement of decisions against States that fail to live up to their trade and investment liberalization obligations can be traced along three inflection points. The first was the failed attempt to establish an International Trade Organization (ITO) at the Havana conference in 1948 coupled with the successful establishment of the Bretton Woods institutional framework (IMF, World Bank). The 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. The WTO's teeth, compared to those of the previous GATT system<sup>2</sup>, grew significantly longer. The third and last inflection point represents a major step in the path towards a further reduction in state sovereignty. That step is investor-state dispute-settlement (ISDS), a process that forms part of most recent trade and investment agreements.

The emergence of ISDS goes well beyond the mere recognition of international legal personality for multinational corporations; it marks a sharp turn in the ability of States to regulate the activities of corporations by individual states where such corporations invest and do business. It is the result of a move towards recognizing the role of multinational

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<sup>2</sup> See note 25 below.

corporations as international legal persons that compete with states for the policy space or have a special say because they can offer direct investment in exchange for favorable policy outcomes. Specifically, ISDS provides multinational corporations a right to sue 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>3</sup> As noted in the document introducing this consultation on a Multilateral Investment Court (MIC), investment protection clauses are now standard in IIAs. 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>4</sup>

ISDS emerged in NAFTA.<sup>5</sup> It is *here to stay*. In 2015, “[w]ith 70 cases initiated in 2015, the number of new treaty-based investor-State arbitrations set a new annual high. A high share of cases (40 per cent) are brought against developed countries.”<sup>6</sup> ISDS made headlines, for example, in 2015 when Phillip Morris sued Uruguay to contest its plain packaging (tobacco) regulations; in the United States in 2016 when the Keystone XL pipeline project was rejected by President Obama; and recently during CETA’s adoption by EU Bodies. One can fairly ask whether, and if so how, ISDS meshes 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 often well-grounded, for example when they are supported by a benevolent world community policing human rights.<sup>7</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 cross-border transfer of personal data for example) because it could amount to an alleged expropriation? The Lilly case, which is pending as of this writing (March 2017) offers interesting lessons as the EU considers a MIC.

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<sup>3</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>4</sup> UNCTAD Report at 101.

<sup>5</sup> North American Free Trade Agreement, Can-Mex-U.S., art. 1105, Dec 17, 1992 [hereinafter NAFTA].

<sup>6</sup> UNCTAD Report at xii.

<sup>7</sup> The Rt Hon The Lord Millet, ‘The Pinochet Case- Some Personal Reflections’, in MD. Evans, ed., *International Law*, 2nd ed. (2006) at 10.

## B. The Lilly v Canada case

Eli Lilly's complaint against Canada was filed under chapter 11 of NAFTA. That chapter is meant to protect against expropriation investments made in a NAFTA party by a company based in another NAFTA party. The case was heard in 2016 at International Centre for Settlement of Investment Disputes (ICSID) according to UNCITRAL Rules.<sup>8</sup> ICSID is known for the confidentiality and effectiveness of its services. Memorials (briefs) and expert reports as well as tribunal orders are generally made available to the public on the ICSID website.

The case is not about actual expropriation. 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>9</sup> The claimant alleged that the legal doctrine used to justify the invalidation of the patents (for lack of utility, a rough equivalent of the notion of industrial applicability in European patent law) violated the intellectual property chapter (Chapter 17) of NAFTA. Lilly argued 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>10</sup> Lilly tried 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 this respect is fairly similar to the TRIPS Agreement. The word "unilateral" used twice in the short quotation above betrays Lilly's thinking: the exercise of state sovereignty (by domestic courts following what they deem to be Canadian law and after due process) is seen as a "unilateral" measure.

A significant disagreement between the parties in the Lilly case concerned the flexibility to implement international obligations. Lilly's argument tugs directly on the

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<sup>8</sup> NAFTA, art. 1120. 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)

<sup>9</sup> Claimant's Memorial at 1. Memorials and expert reports are available at [italaw.com](http://italaw.com)

<sup>10</sup> *Ibid.* at 5-6.

“tension between the private interests of foreign investors and the regulatory autonomy of the host state.”<sup>11</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; rather 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 Canada’s sovereign ability to regulate substantive patent law.

### C. 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>12</sup> Some forms of intellectual property may be seen as human rights when such rights are aligned with and fulfill the objectives of those human rights. Examples including providing a limited 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>13</sup> The Charter of Fundamental Rights of the European Union also considers intellectual property as a fundamental right.<sup>14</sup>

In the context of the Lilly case, other rights, such as the (human) right to health seems relevant. This right appears in Article 12 of the International Covenant on Economic, Social and Cultural Rights, which recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>15</sup> According to General Comment 14, this

<sup>11</sup> Valentina S. Vadi, ‘Towards A New Dialectics: Pharmaceutical Patents, Public Health And Foreign Direct Investments’ (2015), 5 *NYU J. Intell. Prop. & Ent. L.* 113, at 119.

<sup>12</sup> Ernst-Ulrich Petersmann, ‘Human Rights and International Trade Law: Defining and Connecting the Two Fields’, in Th. Cottier, J. Pauwelyn, and E. Bürgi, eds, *Human Rights and International Trade* (2005) at 32.

<sup>13</sup> International Covenant on Economic, Social and Cultural Rights [ICESCR], Dec. 16, 1966, 993 U.N.T.S. 3, art.s 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. See <http://indicators.ohchr.org/>.

<sup>14</sup> 2012 O.J. C 326/391 art. 17(2) (“Intellectual property shall be protected.”) [hereinafter EU Charter]. 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’, (2009).31:3 *Eur. Int. Prop. Rev.* 113, at 113 and 116

<sup>15</sup> ICESCR, art.12.

right to health requires access to at least certain medicines.<sup>16</sup> The right to health also rests on article 25.1 of the 1948 Universal Declaration of Human Rights. How can an ISDS factor it into a decision on pharmaceutical patent? More broadly, how do patents on pharmaceuticals fit into this picture?

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>17</sup> The private interest is protected by providing the patent holder with exclusive rights, allowing the imposition of higher prices ('patent rent') to recoup investments made to develop new products that, in EU parlance, are the result of an inventive step and are industrially applicable. The public interest is protected by limiting patents to actual inventions and by providing access to such new inventions, including life-saving or life-improving medicines. The public interest is also served by the possibility afforded by the patent disclosure for other innovators to build on inventions disclosed to develop their own, including in markets where no patent is in force and in which there is thus no need to wait for the expiration of the patent. Indeed, while there are real debates about the net (in aggregate) positive impact of patents on innovation writ large, empirical studies tend to isolate pharmaceuticals as an area in which they produce positive outcomes.<sup>18</sup>

The issue that arises in an ISDS context, however, is the singular focus on the protection of private interests and the scant regard paid to the broader public interest(s). In the Lily case, this casts a shadow over the public interest component built into the patent system, thus potentially creating a significant policy imbalance.<sup>19</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. In ISDS, as Professor Kate Myles has noted, there is "little room for the

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<sup>16</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.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En)

<sup>17</sup> Vadi, loc. cit., at 121.

<sup>18</sup> According to two US law professors, outside the pharmaceutical and chemical industries, one can "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* (2008) at 141.

<sup>19</sup> See Vadi, loc. cit. at 146.

consideration of the public interest in a regime so heavily weighted towards investor protection.”<sup>20</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.

As Professor Susy Frankel rightly notes,

Investment tribunal arbitrators when making decisions (including the interpretation of the agreements at issue) are likely to focus on the function of IP as a set of property rights rather than as equally important parts of the international IP structure, which enables tailoring of those rights to reward innovation appropriately (rather than excessively) and to maintain regarding interests, such as when property rights need to be balanced with affordability and availability of medicines [...] [T]hat does not require and should not result in detaching the property aspects of IP from its other functions and objectives.<sup>21</sup>

Recall that ISDS was originally meant as *defensive* measure for companies stripped of assets by expropriation, often for purposes of nationalization of those assets by a state.<sup>22</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.

The proper solution is, in my submission, *not* to oppose the grant to corporations (non-state actors) a right to sue states. Non-state actors, including well-organized non-governmental organizations (NGO), can supplement the “enforcement” activity of States in this regard. The issue with ISDS is different and specific: It is that only a very narrow category of non-state actors (multinational investors) have been given an extraordinary lever to achieve policy aims; tribunals with broad powers and dedicated to the task of investment protection have been established with a sole purpose: to hear their grievances about states. And while ISDS “remedies” are not an obligation to change the law but rather an obligation for the state at fault to compensate the complainant, the imposition or risk of imposition of very large awards (Lilly’s claim is in the order of C\$500 million) will likely lead

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<sup>20</sup> Kate Myles, ‘Reconceptualizing International Investment law: Bringing the Public Interest into Private Business’, in M Kolsky Lewis and S Frankel, eds, *International Economic Law and National Autonomy* (2010) at 296.

<sup>21</sup> Susy Frankel, ‘Interpreting the Overlap of International Investment and Intellectual Property Law’, (2016).*J. Int. Econ. L.* 1, 5

<sup>22</sup> Howard Mann and Konrad von Moltke, *NAFTA Chapter 11 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>

governments to make policy changes or not make ones that multinational investors do not want to see implemented to avoid the disputes.

#### D. Incorporating human rights in investment disputes

IAs can and sometimes 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>23</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>24</sup> Specific interfaces in IAs provide for identified regulatory measures to be taken without violating their commitments and obligations contained in bilateral, regional or multilateral trade agreements. By contrast, general interfaces take the form of an open-ended exception affirming the state’s right to adopt certain regulation.

The most important *general* interfaces in international trade law are 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>25</sup> Similar exceptions are found in the trade portion of a number of IAs. 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. Admittedly, recourse to general interfaces has not been very successful in the TRIPS context at the WTO, but there have been relatively few cases.<sup>26</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

<sup>23</sup> Aikaterini Titi, *The Right to Regulate in International Investment Law* (2014) at 52.

<sup>24</sup> Lone Wandhal Mouyal, *International Investment Law and the Right to Regulate: A Human Rights Perspective* (2016), at 8.

<sup>25</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.

<sup>26</sup> See Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime* (2012) at 186.

measures are consistent with the provisions of this Agreement.”<sup>27</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>28</sup> Both those TRIPS interfaces are constrained by the use of the term “*necessary*.” 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 is WTO jurisprudence on that point.

The interface may take the form of a sector-by-sector exclusion. In both the Comprehensive Economic and Trade Agreement (CETA) and the draft TTIP text, substantive intellectual property is at least partly excluded from ISDS scrutiny, for example, a move perhaps informed by the filing of the Lilly case. This was done in CETA by adding a Declaration that provides 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>29</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>30</sup>

Yet exclusions will not always be present and even when they exist they will be subject to interpretation by an ISDS tribunal. This is the main reason why this paper argues that interpretation principles are the best way forward.

#### E. Lessons for the proposed Multilateral Investment Court

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>31</sup> Some commentators have gone a step further and argued that issues expressly left open as flexibilities in trade rules could be “closed” using ISDS, such as exhaustion (parallel imports).

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<sup>27</sup> TRIPS Agreement, art. 8.1.

<sup>28</sup> *Ibid.* art 27.2.

<sup>29</sup> Sep. 26, 2014, online <http://ec.europa.eu/trade/policy/in-focus/ceta/>.

<sup>30</sup> Art. X.11, ¶ 6.

<sup>31</sup> Susan K. Sell, ‘Remarks’, (2014) 8 *Am. Soc’y Int’l L. Proc.* at 317.



At bottom the argument is simple: *preventing* ISDS tribunals from considering human rights norms and a proper exercise of the right to regulate 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. For example, a state might want to refer to an obligation under a human right instrument to justify a public policy 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.

From the foregoing analysis, one can draw a few lessons, namely that (a) a State should be allowed to bring human rights obligations before an ISDS tribunal; and (b) these obligations should be fully considered in interpreting the scope and depth of the regulatory leeway used by the State. An optimal solution would do more than just require ISDS tribunals to consider human rights obligations 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*. This would mean that when an interpretation of the notions of direct or indirect expropriation and fair and equitable treatment in an investment protection chapter can be reconciled with a state’s regulatory autonomy in an area of vital socio-economic importance and/or a state’s implementation of its human rights obligations, then that interpretation should be preferred.<sup>32</sup> This would have a “normative stabilizing effect, at a time when there are few agreed answers about the costs and benefits of globalization or the ideal shape of global economic governance in relationship to differing domestic policy paths.”<sup>33</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.

A new Multilateral Investment Court could and should be based on solid and convincing interpretive principles. What I am suggesting is that such a set of principles be included in the Statute establishing the new 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. If the MIC was

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<sup>32</sup> The phrase “area of vital socio-economic importance” is taken from TRIPS Article 8.1.

<sup>33</sup> Robert Howse, ‘The World Trade Organization 20 Years On: Global Governance by Judiciary’, (2016) 27:7 *Eur. J. Int’l L.* 9, at 76.

established not as a “pure” EU court but instead a true 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.