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## New Forms of Dialects between Intellectual Property and Public Health: Pharmaceutical Patent-Related Investment Disputes

Valentina Vadi  
*Lancaster University*

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## New Forms of Dialectics between Intellectual Property and Public Health: Pharmaceutical Patent-Related Investment Disputes

VALENTINA VADI\*

### Introduction

In recent years, the flourishing of investment treaties has furthered the protection of pharmaceutical patents as such treaties consider intellectual property (IP) a form of investment. Besides providing extensive protection to investor's rights, investment treaties provide patent owners direct access to investor–state arbitration. Patent owners can and have used investment treaty arbitration to challenge alleged infringements of those rights by measures of the host state. Investment arbitrators have scrutinized domestic regulatory and judicial measures “for how they define the availability, validity, and scope of IP rights.”<sup>1</sup> Although these questions are “difficult and often elusive substantive questions” of intellectual property law,<sup>2</sup> they can affect a range of important public policy issues, including public access to medicines. Yet arbitration is primarily a private dispute resolution mechanism. Most arbitral tribunals are neither open to the public nor obliged to publish final decisions. They lack the transparency generally afforded by normal judicial proceedings, even in disputes concerning public goods. Arbitrators may not have specific expertise in international intellectual property law. Further, the awards have only limited avenues for annulment and cannot be amended by the domestic courts.

A couple of examples may clarify the issues at stake. Apotex, a Canadian company, recently filed no less than three investor–state arbitrations against the United States of America, claiming that U.S. courts erred in applying federal law violating several provisions of the North American Free Trade Agreement (NAFTA Chapter 11). Allegedly, the erroneous application of the law prevented Apotex from commercializing generic versions

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\* Professor of International Economic Law, Lancaster University, United Kingdom. Visiting Professor, Law Department, European University Institute. Earlier versions of this article were presented at the Society of International Economic Law Fourth Biennial Conference, held at the University of Bern on July 10–12, 2014, and at The City Law School, City University London, on May 11, 2015. The author wishes to thank Oles Andriychuk, Emily Den, Caroline Foster, Michele Potestà, Steven Wheatley, and the participants at the conferences for useful comments on an earlier draft. The usual disclaimer applies.

1. Christine Haight Farley, *TRIPS-Plus Trade and Investment Agreements: Why More May be Less for Economic Development*, 35 U. PA. J. INT'L L. 1061, 1065 (2014).

2. *Id.* (“IP law is notoriously full of grey areas due to finely balanced policy objectives.”).

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of medicines which would be more cheaply available to patients. In turn, Eli Lilly, a major US pharmaceutical company, filed an investor–state arbitration against Canada, after Canadian Federal Courts invalidated a pharmaceutical patent five years before its expiry. The company claimed it suffered damages of at least 100 million Canadian Dollars and requested the arbitral tribunal to award economic compensation for the alleged losses. The patent invalidation, however, made a generic version more cheaply available to patients.

Have arbitral tribunals taken public health considerations into account when adjudicating pharmaceutical patent-related cases? If so, have they considered public health as an exception to investment treaty standards or as a part of the interpretation of the same standards? What techniques are available to avoid regime-collisions between international investment law and other fields including international intellectual property law and public health law? Is investment arbitration a suitable forum to adjudicate pharmaceutical patent-related disputes? Has investment treaty arbitration become an enforcement tool of other areas of international law? Can investment treaty arbitration promote good governance in the pharmaceutical field? Is there convergence or divergence between international investment law and other branches of international law governing pharmaceuticals? Are there mechanisms to promote coherence? Is such coherence ultimately desirable?

This article addresses these questions, discussing recent investment disputes concerning pharmaceuticals. It builds upon, develops, and originally contributes to my previous scholarship which has focused on different aspects of international health law.<sup>3</sup> While earlier studies adopted a more hypothetical stance due to the relative lack of jurisprudence, this article aims to fill this gap in the available literature providing a critical assessment of these emerging arbitrations. These patent-related arbitrations raise important questions regarding the interplay between various international law regimes and international investment law. The outcomes of these arbitrations can shape the development of both international law and international investment law; and the relationship between the two. The intended readership for this article that of specialists in the field of international law. The article is especially relevant to those working in the areas of international economic law, international health law and global governance. The article shows that pharmaceutical corporations have increasingly made use of investment treaty arbitration, and it critically assesses the potential impact of such arbitrations on the development of international investment law and international law more generally.

The article shall proceed as follows. First, it explores what are pharmaceutical patents and how they are governed at the international law level. Second, it briefly describes the basic structure of investment treaty law and arbitration and explores how international investment treaties govern pharmaceutical patents. Third, it analytically assesses the growing tide of pharmaceutical patent-related arbitrations and their potential impact on public health. Fourth, the article puts forwards some interpretative tools that may help adjudicators to reconcile the possible antinomies between the investment treaty regime governing pharmaceuticals and other bodies of international law.

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3. See VALENTINA VADI, PUBLIC HEALTH IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION (2013). For a more technical analysis, adopting a distinct international intellectual property focus, see *idem.*, *Towards a New Dialectic: Pharmaceutical Patents, Public Health and Foreign Direct Investments*, 5 N.Y.U. J. INTELLECT. PROP. & ENT. L. 113 (2015).

The tension between patent holders and state authorities in the governance of pharmaceutical patents is but a specialized example of a broader recurrent interplay in international law: the tension between foreign investors and the host states concerning the appropriate balance between private and public interests. This article argues that arbitrators should not put excessive emphasis on the private interests embodied by pharmaceutical patents, but adequate consideration should be paid to the public interest equally embodied in these rights. An excessive protection of pharmaceutical patents can have a potentially negative impact on the public health policies of the host state. This may seem paradoxical as usually the protection of pharmaceuticals is associated with higher investments in the research and development of new medicines, and thus broader availability of medicines in the long term with positive effects on patients' welfare. However, in some cases, intellectual property has been used in an aggressive fashion by corporations in order to chill public health regulation. This article aims at reconciling potential antinomies between different international treaty regimes exploring the legal mechanisms that may help policy makers and adjudicators to reconcile the protection of pharmaceutical patents and public health in international investment law. The article concludes with the argument that while investor-state arbitration constitutes a major development in international law and facilitates the access of foreign investors to justice, it may endanger the fundamental values of the international community as a whole, unless arbitrators duly take into account the public interest.

### I. Pharmaceutical Patents, Intellectual Property and Public Health in International Law

The patent system is based on a trade-off between promoting knowledge creation on the one hand, and promoting knowledge diffusion on the other.<sup>4</sup> A patent is a type of intellectual property and constitutes a set of exclusive rights granted by a state to an inventor for a limited period of time in exchange for detailed public disclosure of an invention.<sup>5</sup> Patents are granted for inventions that are: (1) new, (2) involve an inventive step (nonobvious), and (3) capable of industrial application (useful).<sup>6</sup> In the pharmaceutical sector, significant research and development costs are associated with the development of new medicines.<sup>7</sup> Therefore, the patent protection of a given medicine aims to ensure the suitable remuneration of the inventor's efforts and an incentive for the invention of new medicines.<sup>8</sup> At the same time, access to medicines plays a vital role in the public health policies of states<sup>9</sup> and has human rights implications.<sup>10</sup> Therefore, patent protection is

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4. Kristen Jakobsen Osenga, *Get the Balance Right!: Squaring Access with Patent Protection*, 25 PAC. MC-GEORGE GLOBAL BUS. & DEV. L.J. 309, 312–13 (2012).

5. Agreement on Trade Related Aspects of Intellectual Property Rights, art. 28, *adopted* Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPs Agreement].

6. *Id.*, art. 27.

7. Keith E. Maskus & Mohan Penubarti, *How Trade Related are Intellectual Property Rights?* 39 J. INT'L ECONOMICS 227, 242 (1995).

8. *Id.*

9. *See generally* INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010).

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limited in scope and time and is not an absolute right in that it may be subject to restrictions, namely, compulsory licenses and limited exceptions.<sup>11</sup>

Pharmaceutical patent protection embodies and merges both private and public interests and is, as stated above, based on a trade-off. On the one hand, the patent system rewards and fosters the inventive efforts of the patent owner awarding her exclusive rights for a limited period of time. On the other hand, the patent system also acknowledges the public interest in a two-fold manner. First, the invented medicines may save lives and improve the quality of life of patients. Second, after the expiry of the patents, competitors may build upon existing knowledge once it has entered the public domain and patients may have access to cheaper generic versions of the same medicine. Even during the patent lifespan, the enjoyment of intellectual property by the patent owner is not absolute: certain rules provide for limited exceptions, other uses of the patent without the patent owner's consent may be allowed, and there are limits to patentability.<sup>12</sup>

However, in recent years, it has been a common criticism that legislatures and judges have expanded the rights of patent owners too far, at the expense of the public interest.<sup>13</sup> This expansion ultimately resulted in the emergence of antinomies between the protection of patents and access to medicines. An absolutist protection of pharmaceutical patents may have a negative impact on public well-being.<sup>14</sup> Pharmaceutical patents create monopoly rights, and high prices may make medicines unaffordable to the poor.<sup>15</sup> "Ever-greening" practices, *i.e.* the various ways in which pharmaceutical companies use regulatory processes to extend their intellectual property rights particularly over highly profitable "blockbuster" medicines, can jeopardize access to medicines for the poor. In the case in which the host state adopts emergency measures to facilitate access to medicines, thus resulting in a reduction of corporate profits, the state's compliance with treaty obligations to protect intellectual property rights may be disputed.<sup>16</sup>

Pharmaceutical patents produce benefits as well as costs, depending on the specifics of the country's situation.<sup>17</sup> The role of pharmaceutical patents in promoting research and development of new medicines differs across countries depending on the amount of resources devoted to creating intellectual assets,<sup>18</sup> and the ratio between knowledge owned and the knowledge needed by a country to develop the pharmaceutical sector.<sup>19</sup> Even in industrialized countries, the regulation of pharmaceuticals is a sensitive field due to its important public policy implications. For instance, the price of vaccines—which help the body to develop immunity to a particular disease—has increased in the last decades,

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10. Hans Morton Haugen, *Patent Rights and Human Rights: Exploring Their Relationship*, 10 J. WORLD INTEL. PROP. 97, 98 (2007).

11. *Id.* at 108.

12. *Id.* at 108-109.

13. Osenga, *supra* note 4, at 315.

14. *Id.*

15. *Id.* at 312.

16. *Id.* at 317.

17. See PETER DRAHOS, *Introduction*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS, AND DEVELOPMENT 1, 4 (Peter Drahos & Ruth Mayne eds., 2002).

18. See Carlos Prima Braga, Carsten Fink & Claudia Paz Sepulveda, *Intellectual Property Rights and Economic Development*, in THE WTO, INTELLECTUAL PROPERTY RIGHTS AND THE KNOWLEDGE ECONOMY—CRITICAL PERSPECTIVES ON THE GLOBAL TRADING SYSTEM AND THE WTO 254 (Keith E. Maskus ed.).

19. See, e.g., David M. Gould & William C. Gruben, *The Role of Intellectual Property Rights in Economic Growth*, 48 J. DEV. ECON. 323, 324 (1996).

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straining public health budgets.<sup>20</sup> The price increase is due to the fact that vaccines are now subject to patentability (which used not to be the case, at least in some countries including the United States).<sup>21</sup> The fact that during the patent term patent holders have monopoly rights of a sort has contributed to the price increase.<sup>22</sup>

Because pharmaceuticals deal with several types of public goods, including knowledge, governance, and public health, they are governed by different fields of international law, including human rights law, international intellectual property law, and international health law. Therefore, pharmaceutical regulation constitutes a regime complex<sup>23</sup> and is characterized by institutional density. This section briefly examines the four main layers of this regime complex: 1) human rights treaties; 2) international intellectual property treaties; 3) investment treaties and 4) international health law.<sup>24</sup>

The human rights component of the pharmaceutical regime complex is provided by a series of provisions of the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>25</sup> On the one hand, even without expressly mentioning intellectual property, Article 15 of the ICESCR<sup>26</sup> identifies the need to protect both public and private interests in knowledge creation and knowledge diffusion.<sup>27</sup> On the other hand, Article 12 of the Covenant recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>28</sup> Access to medicines has been considered to be a component of the right to health.<sup>29</sup> Conceptualized after World War II, “this right was undertheorized due to political reasons.”<sup>30</sup> Since the fall of the Berlin Wall, however, “[e]conomic, social and cultural rights on the one hand, and civil and political rights on the other, have been understood in their unity and complementarity.”<sup>31</sup> The international, regional and national recognition of the right to health requires state au-

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20. Elisabeth Rosenthal, *The Price of Prevention: Vaccine Costs are Soaring*, N.Y. TIMES, July 2, 2014, at A1, available at <http://nyti.ms/1xjfQp2> (last updated July 8, 2014).

21. *Id.*

22. *Id.*

23. See Robert O. Keohane & David G. Victor, *The Regime Complex for Climate Change* 7–8 (Harvard Project on Int’l Climate Agreements, Discussion Paper 2010-33), for a discussion on the notion of “regime complex” as a range of multilevel regulatory frameworks at times diverging and at times converging if not overlapping, introducing the notion of “regime complex” and defining it as a “loosely coupled set of specific regimes.”

24. Alan M. Anderson & Bobak Razavi, *The Globalization of Intellectual Property Rights: TRIPS, BITS and the Search for Uniform Protection*, 38 GA. J. INT’L & COMP. L. 265, 269 (2010) (noting that international intellectual property treaties have been adopted since the nineteenth century.).

25. International Covenant on Economic, Social and Cultural Rights (ICESCR), *adopted* on 16 Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR] (entered into force Jan. 3, 1976).

26. *Id.*, art. 15.

27. *Id.*

28. *Id.*, art. 12.

29. VALENTINA VADI, *PUBLIC HEALTH IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION* (2013).

30. *Id.* at 27 (“Given the political divide between the Eastern and Western blocs determined by the Cold War, the right to health as well as other economic, social and cultural rights were deemed to be politicized as reflecting a socialist perspective. The traditional distinction between civil and political rights and economic, social and cultural rights was also based on the assumption that while the first category of rights was susceptible to immediate realization, the second was deemed to be only of gradual implementation. The dichotomy was formalized by the division of the so-called International Bill of Rights into two Covenants adopted in 1966.”).

31. *Id.*

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thorities to adopt relevant policies to ensure the realization of this right.<sup>32</sup> Moreover, access to medicines has been deemed to be a component of the right to life.<sup>33</sup> Yet, state resistance to proposals of creating a global human rights court and the fragmented landscape of international institutions in the human rights field have inevitably characterized the evolution of the right to health and the right to life.<sup>34</sup>

International intellectual property treaties have been adopted since the nineteenth century. The Paris Convention is the oldest treaty governing aspects of patent regulation.<sup>35</sup> It conceptualizes intellectual property as an incentive to encourage innovation;<sup>36</sup> harmonizes procedures relating to priority, registration, and licensing; and requires national treatment for foreign patent owners.<sup>37</sup> “In theory, a member that failed to comply with its obligations under the Paris Convention could be sued before the International Court of Justice.”<sup>38</sup> But “no such cases have ever been brought.”<sup>39</sup>

Another intellectual property treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) under the World Trade Organization (WTO),<sup>40</sup> is the most comprehensive international treaty setting global standards for medical knowledge governance.<sup>41</sup> It introduced pharmaceuticals as a patentable subject matter, requiring that patents be available in WTO member states “for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>42</sup> While the patent owner is given limited monopoly rights for twenty years, other business competitors may replicate the compound as soon as this term expires.

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32. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) art. 25 (Dec. 10, 1948) (“[E]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including . . . medical care.”); Constitution of the World Health Organization, Preamble, concluded Jul. 22, 1946, 14 U.N.T.S. 185 (“The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”); ICESCR, *supra* note 25, art. 12 (recognizing “the right of everyone to the enjoyment of the highest attainable standard of Physical and mental health. . .”); see generally BRIGIT TOEBES, *THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERNATIONAL LAW* (1999) (discussing the right to health).

33. HOLGER HESTERMEYER, *HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES* (2007); see generally BALANCING WEALTH AND HEALTH: *THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA* (Rochelle C. Dreyfuss & Cesar Rodriguez-Garavito eds., 2014) (on the interplay between access to medicines and intellectual property).

34. Laurence R. Helfer, *Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines*, in *TRANSNATIONAL LEGAL ORDERS* 311, 317 (Terence Halliday & Greg Shaffer eds., 2014).

35. Convention of Paris for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

36. Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property* 5 (New York Univ. Pub. Law and Legal Theory Working Paper No. 478, 2014).

37. Helfer, *supra* note 34, at 314.

38. Paris Convention, *supra* note 35, art. 28.

39. Dreyfuss & Frankel, *supra* note 36, at 5 n. 20.

40. See TRIPS Agreement, *supra* note 5.

41. See also CARLOS CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT*, (1st ed., 2007); DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, (4th ed., 2012).

42. TRIPS Agreement, *supra* note 5, at 331.

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The very adoption of the TRIPS Agreement was controversial: developing countries opposed its adoption, fearing that the introduction of high standards of intellectual property protection would jeopardize access to a wide number of products including pharmaceuticals.<sup>43</sup> Some scholars also doubted that intellectual property could be linked to trade as monopolies—such as those established by intellectual property—can in fact restrict the market.<sup>44</sup> Not by chance, an early reference to intellectual property appears in the General Agreement on Tariffs and Trade (GATT 1947)<sup>45</sup> among the exceptions.<sup>46</sup> Nevertheless, through intense negotiation and what has been named as linkage bargaining—that is, linking negotiations on intellectual property to negotiations in other sectors such as agriculture—the TRIPS Agreement was signed at the Marrakesh Ministerial conference in 1994, as part of a package deal with the other Uruguay Round Agreements, and it came into force in January 1995.<sup>47</sup> Remarkably, the adoption of the TRIPS Agreement “moved from framing IP as a barrier to trade into conceptualizing it as a tradable commodity in the name of facilitating trade . . . and emphasized the rhetoric of ‘rights.’”<sup>48</sup>

The TRIPS Agreement provides for minimum international standards for intellectual property protection, and Members cannot derogate or provide lower ceilings of protection.<sup>49</sup> Members can enforce the provisions of the TRIPS Agreement through the WTO Dispute Settlement Mechanism, which has compulsory jurisdiction over TRIPS-related disputes.<sup>50</sup> WTO Members have the right to provide for more extensive protection than is required by the Agreement, as long as they apply the general principles of the most-favored-nation clause and national treatment under the Agreement,<sup>51</sup> any intellectual

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43. Jerome H. Reichmann, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries*, 32 CASE W. RES. J. INT'L L. 441, 443 (2000) (pointing out that the TRIPS Agreement imposed “relatively high” standards of intellectual property protection which de facto correspond to those used in industrialized countries).

44. Michael Spence, *Which Intellectual Property Rights are Trade-Related?*, in ENVIRONMENT, HUMAN RIGHTS AND INTERNATIONAL TRADE 263, 263–85 (Francesco Francioni ed., 2001).

45. General Agreement on Tariffs and Trade, Oct. 30, 1947, 31 U.S.T. 4919, 55 U.N.T.S. 194 [hereinafter GATT].

46. *Id.*, art. XX (“Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . . (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to . . . the protection of patents, trademarks and copyrights, and the prevention of deceptive practices.”).

47. José E. Alvarez, *The WTO as Linkage Machine*, 96 AM. J. INT'L L. 146, 147 (2002) (“The WTO’s success in ‘nesting’ issues within a broader context so that the ‘fabric’ of one became the foundation for another, as well as in making possible package deals between previously unlinked issues.”).

48. Dreyfuss & Frankel, *supra* note 36, at 3, 32 (also suggesting that the system may be “inclined to interpret proprietary rights broadly while constructing user interests narrowly”).

49. TRIPS Agreement, *supra* note 5, art. 1.1.

50. *Id.*, art. 64; Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 282 (1997) (“Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”).

51. TRIPS Agreement, *supra* note 30, art. 1.1.

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property agreement negotiated subsequent to TRIPS by WTO members can only create similar or higher standards (commonly known as “TRIPS-plus”).<sup>52</sup>

International investment law constitutes “the last wave of IPR protection”, considering IP a form of investment.<sup>53</sup> According to some scholars, the conversion of intellectual property into an investment asset “emphasizes the rhetoric of property.”<sup>54</sup> Has the coalescence of all of these norms and different layers of regulations contributed to creating a strong system of intellectual property protection to the detriment of other public goods, including public health?

By contrast to IP protection, another component of the regime complex governing pharmaceuticals, international health law, is not a particularly well-developed and/or coherent field of international law.<sup>55</sup> While there used to be a discrete number of binding international conventions dealing with various aspects of public health before the World War II, since the inception of the World Health Organization in 1948, this has changed significantly.<sup>56</sup> The World Health Organization has traditionally favored non-legal approaches to health issues.<sup>57</sup> Perceiving itself as a sort of “transnational Hippocratic society”,<sup>58</sup> the institution, mainly composed of health specialists,<sup>59</sup> has principally, if not exclusively, developed medical guidelines and other nonbinding tools. It has developed “an ethos that looks at global health problems as medical-technical issues to be resolved by the application of the healing arts.”<sup>60</sup> Instruments adopted by the WHO have been described as “limited in scope and application”<sup>61</sup> as well as “historically, politically and structurally inadequate to do what is needed.”<sup>62</sup> Such instruments lack coordination and binding force.<sup>63</sup> International health law has not been an effective system, due to its mainly non-legal approach, lack of enforcement powers and consequent states’ failure to

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52. In recent years, states have signed a number of regional and bilateral agreements including TRIPS-plus provisions. On the phenomenon, see, e.g., Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. & TECH J. 125, 141 (2003–2004) (describing the phenomenon of forum shifting as a means of increasing the strength of protection of intellectual property rights).

53. Valentina S. Vadi, *Towards A New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investments*, 5 J. OF INTELL. & ENT. L. 1, 16 (2015).

54. Dreyfuss & Frankel, *supra* note 36, at 3.

55. See generally DAVID P. FIDLER, *INTERNATIONAL LAW AND PUBLIC HEALTH: MATERIAL ON AND ANALYSIS OF GLOBAL HEALTH JURISPRUDENCE* (2000); Shawn H.E. Harmon, *International Public Health Law: Not so Much WHO as Why, and Not Enough WHO and Why Not?*, 12 MED. HEALTH CARE & PHIL. 245, 245 (2009) (“[N]either the WHO . . . nor international law . . . have yet played their necessary part in promoting ‘health for all.’”); Jennifer Prah Ruger, *Normative Foundations of Global Health Law*, 96 GEO. L. J. 423, 424 (2008) (describing international health law as “a relatively new academic field”).

56. Constitution of the World Health Organization, WHO (45th ed. Supp. 2006), [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).

57. David P. Fidler, *International Law and Global Public Health*, 48 U. KAN. L. REV. 1, 22 (1999) (“[The] historical penchant [of the WHO] for dealing with public health problems within a narrow ‘medical-technical’ approach.”).

58. *Id.* at 23.

59. *Id.* at 22 (“WHO has historically been staffed predominantly by physicians, medical scientists, and public health experts.”).

60. David P. Fidler, *The Future of the World Health Organization: What Role for International Law?* 31 VAND. J. TRANSNAT’L L. 1079, 1099 (1998).

61. Harmon, *supra* note 55, at 251.

62. *Id.* (internal citation omitted).

63. *Id.* (noting that such instruments “are being developed . . . in an uncoordinated . . . manner” and “pale in comparison with that of other international [organizations]”).

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comply with its rules.<sup>64</sup> Only in the past decade did the WHO adopt a binding convention in the field of tobacco control.<sup>65</sup> Rarely has the WHO participated in trade negotiations or the resolution of international disputes even when such are linked to public health.<sup>66</sup> Only recently has the WHO cautiously started intervening in investment treaty arbitration as a friend of the court (*amicus curiae*).<sup>67</sup>

In the absence of a well-articulated international health law regime, public health protection has remained a fundamental prerogative and a police power of the state. States have a right and a duty to protect public health. On the one hand, having a population is one of the three elements required for statehood (together with territory and government).<sup>68</sup> On the other hand, the state has assumed duties related to public health “as a result of the social contract between it and its subjects/citizens.”<sup>69</sup> Clearly, the state has the power to adopt measures to protect its population as this protection constitutes one of the conditions of its very existence.

Due to the fragmentation characterizing international law, the asymmetrical development of international intellectual property law and international health law, elements of public health governance have been devolved to a plethora of other organizations “whose primary concerns and objectives are not health.”<sup>70</sup> Given the interconnectedness of health with other global issues including trade and foreign investments (the so-called “issue linkage”)<sup>71</sup> and the lack of a World Health Court, a plethora of international courts, including investment treaty arbitral tribunals, have increasingly governed and/or impacted upon public health. The following sections will examine this interplay focusing on how international investment law governs pharmaceutical patents and how investment treaty arbitral tribunals have adjudicated the relevant disputes.

## II. Pharmaceutical Patents in International Investment Law

While the traditional focus of foreign direct investment used to be on tangible assets, today it could not be more diverse.<sup>72</sup> Not only do investment flows encompass traditional

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64. Jennifer Prah Ruger, *Normative Foundations of Global Health Law*, 96 GEO. L.J. 423, 438 (2008).

65. WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, WHO (2003), <http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf>.

66. Harmon, *supra* note 55, at 251.

67. Clovis Trevino & Luke Eric Peterson, *World Health Organization is Given Green-Light by Arbitrators to Intervene in Philip Morris v. Uruguay Arbitration*, *Investment Arbitration Reporter*, INV. ARB. REP. (Feb. 20, 2015) (noting that “[i]n their request to intervene, the WHO and the FCTC Secretariat contended that their submission ‘may assist the tribunal in the determination of factual and legal issues’ as it w[ould] provide evidence of the relation between health warnings and labeling and the protection of public health, on tobacco control globally which, in their view, may assist the tribunal in assessing the claimant’s legitimate expectations and the legal relation between the FCTC and the Switzerland-Uruguay BIT.”); For a commentary of the specific arbitration, see Valentina Vadi, *Global Health Governance at a Crossroads: Trademark Protection v. Tobacco Control in International Investment Law*, 48 STAN. J. INT’L L. 93 (2012).

68. Convention on the Rights and Duties of States art. 1, Dec. 26, 1933, 49 Stat. 3097, 165 L.N.T.S. 19 (discussing the definition and rights of statehood).

69. Harmon, *supra* note 55, at 247.

70. *Id.* at 251.

71. Allyn L. Taylor, *Global Governance, International Health Law and WHO: Looking Towards the Future*, 80 WHO BULLETIN 975, 976 (2002).

72. Christopher S. Gibson, *Latent Grounds in Investor-State Arbitration*, in YEARBOOK ON INTERNATIONAL LAW INVESTMENT LAW & POLICY 397, 411 (Karl P. Sauvant ed., 2010).

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categories such as mining, oil extraction and infrastructure projects, but they also reach new sectors such as telecommunications, media, health care and pharmaceuticals.<sup>73</sup> International investment agreements (IIAs) do not include detailed regulation of pharmaceutical patents. Rather, they briefly mention intellectual property rights as a form of protected investment. Some IIAs incorporate a broad definition of investment that generally covers both tangible and intangible property.<sup>74</sup> Other international investment treaties generally refer to intellectual property rights, or explicitly indicate the types of intellectual property covered, such as copyright, patents, industrial designs, trade secrets, and trademarks and so on.<sup>75</sup> Notably, the first bilateral investment treaty (BIT) (signed between West Germany and Pakistan in 1959) included “patents and technical knowledge” in the definition of “investment.”<sup>76</sup>

Given the variety of treaty language used in different international investment treaties, the question as to whether intellectual property constitutes an investment requires a case-by-case analysis.<sup>77</sup> Answering this question is crucial because if an intellectual property owner is classified as an investor under the relevant investment treaty, she is entitled to the procedural and substantive protections afforded by the treaty. While registered patents are “covered investments” in most investment treaties, questions arise as to whether patent applications fall within the scope of a covered investment under the relevant investment treaty, given the fact that patents can only be acquired through registration.<sup>78</sup> The expectation of obtaining exclusive rights over an invention is of some value because patent applications “can be sold and assigned to third parties.”<sup>79</sup> Can patent applications be deemed to be a form of intangible property even if it is not a form of intellectual property yet? While some authors argue that applications for a patent fall within the scope of protection offered by international investment agreements to intangible property,<sup>80</sup> cer-

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73. *Id.*

74. For instance, Article 1139(g) of the North American Free Trade Agreement (NAFTA) states that “investment” includes “real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes.” North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 ILM 289, 605 (1993).

75. *See, e.g.*, The Agreement between the Swiss Confederation and the Dominican Republic on the Promotion and Protection of Investments, Switz.-D.M., art. 1.2(d), Aug. 27, 2004, available at <http://investmentpolicyhub.unctad.org/Download/TreatyFile/3264> (“The term ‘investments’ shall include every kind of asset, in particular, though not exclusively: . . . copyrights, industrial property rights (such as patents, utility models, industrial designs or models, trade or service marks, trade names, indications of origin), technical processes, know-how and goodwill.”); *see also* Accordo tra il Governo della Repubblica Italiana e il Governo della Repubblica di Cuba sulla Promozione e Protezione degli Investimenti, It.-Cuba, art. 1.1(d), May 5, 1993, available at <http://investmentpolicyhub.unctad.org/Download/TreatyFile/907> (“Per ‘investimento’ si intende, indipendentemente dalla forma giuridica prescelta e dall’ordinamento giuridico di riferimento, ogni bene investito da persone fisiche o giuridiche di una Parte Contraente nel territorio dell’altra, in conformità delle leggi e dei regolamenti di quest’ultima. In tale contesto di carattere generale il termine ‘investimento’ indica: . . . diritti d’autore, marchi commerciali, brevetti, designs industriali ed altri diritti di proprietà intellettuale ed industriale, know-how, segreti commerciali, la ditta e l’avviamento.”).

76. Bryan Mercurio, *Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements*, 15 J. INT’L ECON. L. 871, 874 n. 8 (2012).

77. Ruth I. Okediji, *Is Intellectual Property “Investment”? Eli Lilly v. Canada and the International Intellectual Property System*, 35 U. PA. J. INT’L L. 1121, 1126 (2013-14).

78. Mercurio, *supra* note 76, at 878.

79. *Id.*

80. *Id.* (suggesting that “applications for IPRs will in fact qualify as a covered investment”).

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tain treaties expressly exclude this possibility.<sup>81</sup> Interpretive uncertainties surround investment treaty provisions protecting “rights with respect to” intellectual property,<sup>82</sup> or even refer to “patentable inventions.”<sup>83</sup> The European Court of Human Rights has held that both registered trademarks and applications to register trade marks were “property rights” within the meaning of Article 1 of Protocol No. 1 of the European Convention on Human Rights.<sup>84</sup> However, the fact that most investment treaties provide protection in the post-establishment phase to both investors and their investments suggests that a case-by-case analysis is needed. This is seemingly confirmed by the growing number of investment treaty arbitrations that have dealt with this question and will be examined below.

The specific protection of pharmaceutical patents through investment treaties not only benefits pharmaceutical corporations,<sup>85</sup> but can induce foreign direct investment (FDI) in research and development of new products, stimulate local inventive activities, and encourage technology transfer into the country.<sup>86</sup> Technological innovation is generally recognized as an important means to stimulate economic development.<sup>87</sup> Moreover, innovation in the health sector is fundamental to human well-being. While intellectual property can be a tool to advance human welfare,<sup>88</sup> excessive protection of the same “may decrease competition in the host country or raise entry barriers for smaller, foreign firms.”<sup>89</sup> Although the notion of investment includes intellectual property rights, the substantive interplay between intellectual property and international investment law remains uncharted.<sup>90</sup> The functioning of investment treaty obligations with regard to intellectual property, the parties’ expectations, and enforcement aspects of these treaties remain largely unexplored.<sup>91</sup> At the procedural level, investment treaties enable foreign investors holding patents to have access to investment treaty arbitration. In doing so, they create a set of procedural rights for the direct benefit of investors.<sup>92</sup> This is a major novelty in international law, as customary international law does not provide such a mechanism.<sup>93</sup>

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81. See, e.g., ASEAN Comprehensive Investment Agreement, art. 4(c), Feb. 26, 2009 (limiting an “investment” to “intellectual property rights which are conferred pursuant to the laws and regulations of each Member State.”).

82. See, e.g., Agreement Between the Government of Hong Kong and the Government of Australia for the Promotion and Protection of Investments, H.K.-Austl., art. 1(e)(iv), Oct. 15, 1993; see also Agreement Between the Government of Canada and the Government of the Republic of Argentina for the Promotion and Protection of Investment Can.-Arg., art. 1(a)(iv), April 29, 1993.

83. Treaty Between the United States of America and Jamaica Concerning the Reciprocal Encouragement and Protection of Investment, U.S.-Jam., March 7, 1997.

84. *Anbeuser-Busch, Inc. v. Portugal*, App. No. 73049/01, (Eur. Ct. H.R. Jan. 11, 2007) (Grand Chamber).

85. Okediji, *supra* note 77, at 1122 (noting that capital exporting countries favored the incorporation of intellectual property obligations in bilateral investment treaties “to provide stronger and more stable protection for firms in developing countries”).

86. John Barton, *New Trends in Technology Transfer: Implications for National and International Policy*, INT’L CTR. FOR TRADE & SUSTAINABLE DEV., Issue Paper No. 18 (Feb. 2007).

87. U.N. CONF. TRADE & DEV. [UNCTAD], WORLD INVESTMENT REPORT FOREIGN DIRECT INVESTMENT AND THE CHALLENGE OF DEVELOPMENT 195 (1999).

88. Okediji, *supra* note 77, at 1133.

89. *Id.* at 1127.

90. For a seminal study, see Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT. L. 163, 170 (1998).

91. Okediji, *supra* note 77, at 1124.

92. See Jan Paulsson, *Arbitration Without Privity*, 10 ICSID REV.-FOREIGN INV. L.J. 232, 256 (1995).

93. See *id.* at 255.

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Investor–state arbitration has become a standard feature in international investment treaties since the 1980s.<sup>94</sup> The rationale for internationalizing investor–state disputes lies in the assumed independence and impartiality of international arbitral tribunals, while national dispute settlement procedures are often perceived as biased or inadequate.<sup>95</sup> Arbitration is also used because of perceived advantages in confidentiality and effectiveness.<sup>96</sup>

The arbitral process in investment arbitration presents characteristics similar to those in a typical international commercial arbitration.<sup>97</sup> The composition of the tribunal is determined by the parties who generally choose law scholars or practitioners. Although the right to choose an arbitrator may be considered the very essence of arbitration,<sup>98</sup> this practice may be problematic from a public policy perspective.<sup>99</sup> As one scholar explains, while arbitrators are “expected to be both independent of the party appointing them and impartial . . . it is usually conceded that without violating in any way this theoretical obligation of independence, the arbitrator may quite acceptably share the political or economic philosophy or ‘legal culture’ of the party who has nominated [her] . . . and may therefore be assumed from the very beginning to be ‘sympathetic’ to that party’s contentions or ‘favorably disposed’ to its positions.”<sup>100</sup>

Confidentiality is one of the main features of arbitral proceedings as generally hearings are held in camera and documents submitted by the parties remain confidential in principle.<sup>101</sup> Final awards may or may not be published, depending upon the parties’ will. Even the names of the parties—much less the details of the dispute—may remain undisclosed. While confidentiality suits commercial disputes well, the same may be problematic in investor–state arbitration, because arbitral tribunals can require states to compensate investors for regulations that hurt the latter. The lack of transparency may hamper efforts to track investment treaty arbitrations, monitor their frequency, and to assess the policy implications that flow therefrom.<sup>102</sup> Because investment disputes are settled using a variety

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94. See David Sedlak, *ICSID’s Resurgence in International Investment Arbitration: Can the Momentum Hold?*, 23 PENN ST. INT’L L. REV. 147, 149 (2004).

95. See, e.g., ANDREW NEWCOMBE & LLUIS PARADELL, *LAW AND PRACTICE OF INVESTMENT TREATIES* (2009) 24.

96. See Ibrahim F.I. Shihata, *Towards a Greater Depoliticization of Investment Disputes: The Role of ICSID and MIGA*, 1 ICSID REV.-FOREIGN INV. L.J.1, 4 (1986).

97. Nigel Blackaby, *Investment Arbitration and Commercial Arbitration (or the Tale of the Dolphin and the Shark)*, in *PERVASIVE PROBLEMS IN INTERNATIONAL ARBITRATION* 217, 232 (Julian Lew & Loukas Mistelis eds., 2006).

98. Pierre Lalive, *Conclusions*, in I.C.C., *THE ARBITRAL PROCESS AND THE INDEPENDENCE OF ARBITRATION* (1991).

99. Kenneth Vandeveld, *The Political Economy of a Bilateral Investment Treaty* (1998) 92 AM. J. INT’ L. 636.

100. Alan S Rau, *Integrity in Private Judging*, 38 S. TEX. L. REV. 485, 507 (1997).

101. Some hearings have been broadcasted in special viewing rooms at the ICSID headquarters in Washington, but were not webcasted. See Lise Johnson, *As Hearings Kick Off in Apotex v. USA Arbitration, New Pleadings Show Continued Sparring Over Canadian Drug Companies’s Claim to Own NAFTA-Protected Investments*, INV. ARB. REP. (Nov. 18, 2013), <https://www.iareporter.com/articles/as-hearings-kick-off-in-apotex-v-usa-arbitration-new-pleadings-show-continued-sparring-over-canadian-drug-companies-claim-to-own-nafta-protected-investments> (subscription required).

102. While more and more awards have been published, some arbitrations and the relevant awards were given minimal publicity. For instance, a redacted version of the *Servier* award, discussed below, was released by a Polish Government agency following a request under the country’s access to information laws. A May 2013 ruling of the Warsaw District Administrative Court directed Poland’s Ministry of Health to release the *Servier* award, subject to any redactions of confidential commercial information. A previously released copy

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of arbitral rules—not all of which provide for public disclosure of claims—there can be no accurate accounting of all such disputes. Yet, arbitral awards rendered under investment treaties should be publicly available. That some portion of the iceberg remains hidden from view should be a matter of concern given the public policy implications of such disputes.

In recent years, there have been various efforts to make investment arbitration more transparent. In response to calls from civil society groups, the three parties to the North American Free Trade Agreement (NAFTA) (including Canada, the United States, and Mexico) have pledged to disclose all NAFTA arbitrations and open future arbitration hearings to the public.<sup>103</sup> Similarly, the International Centre for Settlement of Investment Disputes (ICSID) requires public disclosure of dispute proceedings under its auspices,<sup>104</sup> including the registration of all requests for conciliation or arbitration and an indication of the date and method of the termination of each proceeding. Increasingly, arbitral tribunals have allowed public interest groups to present amicus curiae briefs and have increased access to the arbitral process.<sup>105</sup> These important developments, however, involve the conduct of a limited number of investment dispute proceedings. Indeed, the vast majority of existing treaties do not mandate such transparency, which means that most of the proceedings are resolved behind closed doors. The recent adoption of the United Nations Convention on Transparency in Treaty-based Investor-State Arbitration (the “Mauritius Convention on Transparency”), by which Parties to investment treaties concluded before April 1, 2014, express their consent to apply the UNCITRAL Rules on Transparency in Treaty-based Investor-State Arbitration, may increase the transparency of such disputes.<sup>106</sup>

Finally, awards rendered against host states are, in theory, readily enforceable against host state property worldwide due to the widespread adoption of the New York<sup>107</sup> and Washington Conventions.<sup>108</sup> In arbitrations under the ICSID Convention, awards are only subject to an internal annulment process, and the award is enforced as a local court

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of the 2012 award offered only the cover page and signature page. See Jarrod Hepburn, *Poland Releases a New – Less Redacted – Version of Award from Dispute with French Pharma Companies; MFN Can’t Broaden Investment Treaty’s Arbitration Clause*, INV. ARB. REP. (Oct. 24, 2013), <https://www.iareporter.com/articles/poland-releases-a-new-less-redacted-version-of-award-from-dispute-with-french-pharma-companies-mfn-cant-broaden-investment-treatys-arbitration-clause> (subscription required).

103. *Statement of the Free Trade Commission on Non-Disputing Party Participation*, NAFTA FREE TRADE COMM’N, Oct. 7, 2003, <http://www.state.gov/documents/organization/38791.pdf>.

104. See ICSID, Administrative and Financial Regulations, regulation 22, *as amended and effective* Apr. 10, 2006, available at <https://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/partC-chap04.htm#r22>.

105. ICSID, Rules of Procedure for Arbitration Proceedings, r. 37, *as amended and effective* Apr. 10, 2006, available at <https://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/partF-chap04.htm#r37> [hereinafter ICSID Arbitration Rules].

106. United Nations Convention on Transparency in Treaty-based Investor-State Arbitration, *opened for signature* Mar. 17, 2015, U.N.T.S., [https://treaties.un.org/doc/Treaties/2014/12/20141210%2011-52%20AM/CH\\_XXII\\_3.pdf](https://treaties.un.org/doc/Treaties/2014/12/20141210%2011-52%20AM/CH_XXII_3.pdf). The Convention will enter into force six months after the deposit of the third instrument of ratification [hereinafter Mauritius Convention on Transparency]. The list of the parties to the Convention as well as signatories is available at [http://www.uncitral.org/uncitral/en/uncitral\\_texts/arbitration/2014Transparency\\_Convention\\_status.html](http://www.uncitral.org/uncitral/en/uncitral_texts/arbitration/2014Transparency_Convention_status.html) (last visited Apr. 22, 2016).

107. Convention on the Recognition and Enforcement of Foreign Arbitral Awards, June 10, 1958, 330 U.N.T.S. 38 [hereinafter New York Convention].

108. Convention on the Settlement of Investment Disputes between States and Nationals of Other States, Mar. 18 1965, 575 U.N.T.S. 159 [hereinafter ICSID Convention].

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judgment, thus being exempted from supervision of local courts.<sup>109</sup> In non-ICSID arbitrations, annulment is subject to the supervision of the courts at the seat of arbitration, and enforcement is governed by the New York Convention, which allows for non-recognition and non-enforcement of an award only on limited grounds.<sup>110</sup> Thus, if the arbitration is sited in a country other than the host state, then there may be no capacity whatsoever for the host government to challenge the award in its own legal system.

Given the characteristics of the arbitral process, significant issues arise in the context of disputes involving pharmaceuticals. Arbitration structurally constitutes a private model of adjudication. Yet, arbitral awards ultimately shape the relationship between the state, on the one hand, and private individuals on the other.<sup>111</sup> Arbitrators determine matters such as the legality of governmental activity, the degree to which individuals should be protected from regulation, and the appropriate role of the state.<sup>112</sup> In cases involving public health, one may wonder whether investment arbitration provides an adequate forum. Furthermore, the mere possibility of a dispute with a powerful investor can exert a chilling effect on governments' decisions to regulate in the public interest.

### III. Investor-State Arbitrations Concerning Pharmaceuticals

Until recently, it was rare to hear of any investment dispute concerning pharmaceuticals. This seems to be counterintuitive, given the economic importance of pharmaceutical patents and the flourishing of arbitrations concerning pharmaceuticals among private parties. To solve this puzzle, several considerations need to be taken into account.

First, the available data may represent just the tip of the iceberg, given the limited transparency of investment arbitration. While ICSID makes the existence of all proceedings public and generally encourages the publication of awards, other arbitral institutions do not necessarily disclose their dockets of cases, and even when they do so, they do not publish the awards unless the parties so agree. Finally, other arbitrations are purely ad hoc, and thus their very existence will remain unknown. Therefore, it is likely that the scarcity of cases in this matter is due not to an absence of disputes, but to the lack of transparency of investment treaty arbitration.

Second, with regard to claims concerning pharmaceutical patents, several courts and tribunals are available. The recent process of internationalization of IP protection has not eliminated the traditional judicial remedies, but has added further avenues for dispute settlement. National courts always represent an available option to foreign investors. As pharmaceutical patents are territorial in nature, they are subject to the national laws of each individual country. At the regional level, the Court of Justice of the European Union (CJEU) has adjudicated several cases dealing with intellectual property in general and pharmaceutical patents in particular. Even human rights courts have adjudicated intellectual property related cases. For instance, the European Commission of Human Rights (ECoHR) has deemed that intellectual property is a form of property and is thus protected

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109. *Id.*, art. 52.

110. New York Convention, *supra* note 107, at art. V.

111. GUS VAN HARTEN, INVESTMENT TREATY ARBITRATION AND PUBLIC LAW 70 (2007).

112. M. Sornarajah *The Clash of Globalizations and the International Law on Foreign Investment* 10(2) CAN. FOREIGN POL'Y 1, 12 (2003).

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under Article 1 of the first Protocol of the Convention.<sup>113</sup> Finally, at the international level, the World Trade Organization dispute settlement mechanism constitutes an additional dispute settlement mechanism, in case a state violates its commitments under the TRIPS Agreement.<sup>114</sup>

Third, investment disputes are extremely expensive. Initiating an investment dispute may prove to be a suitable option only for large corporate actors.

Finally, knowledge about pharmaceutical patents is still too limited among investment lawyers and knowledge about investment treaty arbitration is still too limited among IP lawyers. Both intellectual property and foreign direct investment have long been considered to be highly technical subjects and have come to the frontline of legal debate only very recently. Therefore, for a long time, there has been a mutual neglect between international investment law and intellectual property law. In practice, this meant that investment disputes focused mainly on tangible forms of investments.<sup>115</sup>

Recently, however, IP holders have started filing investment treaty arbitrations to protect their patents and other forms of IP. There are several reasons for this change. First, the ICJ and the WTO dispute settlement system are inter-state dispute resolution mechanisms. Recourse to the ICJ requires the exercise of diplomatic protection of the home state of the given corporation. However, diplomatic protection constitutes a prerogative and not a duty for states which may exercise it at their will. While companies lobby their governments to file disputes before the WTO dispute settlement mechanisms, it is up to the states to decide whether to bring a claim. Governments are warier litigators than many companies. They seek to maintain good diplomatic relations, and since they must live by the rules their own litigation establishes, they are cautious in promoting interpretations of international law that could limit their regulatory freedom. When IP violations are limited in scope, the home state will be reluctant to initiate a trade dispute for settling trifles because of political considerations. Furthermore, even if the state brought an international claim for its own injury, it would be under no obligation to pay any reparation to the national actually injured. While remedies under the Uruguay Round Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU)<sup>116</sup> have a prospective character, investment treaties allow the private party to get compensation for past wrongs by the host state. Moreover, the investor would exercise limited, if any, control over the dispute settlement strategy. Finally, the existence of a pending trade dispute does not impede the foreign investor from having recourse to arbitration. Nor does the existence of a pending investment dispute impede the home state from submitting a complaint to the WTO Dispute Settlement Mechanism (DSM).<sup>117</sup> In any case, patent disputes have

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113. See generally Henning Grosse Ruse-Khan, *Overlaps and Conflict Norms in Human Rights Law: Approaches of European Courts to Address Intersections with Intellectual Property Rights*, in RESEARCH HANDBOOK ON HUMAN RIGHTS AND INTELLECTUAL PROPERTY 70 (Christopher Geiger ed., 2015).

114. Joost Pauwelyn, *The Dog That Barked But Didn't Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1 J. INT'L DISP. SETTLEMENT 389 (2010).

115. See, e.g., *AHS Niger & Menzies Mid. E. & Afr. S.A. v. Republic of Niger*, ICSID Case No. ARB/11/11, Award (July 2013) (where Niger was found liable for expropriation of airport services concession, but no damages due for subsequent "misuse" of intellectual property).

116. Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 UNTS 401, 33 ILM 1226 (1994).

117. Even on similar matters the investment treaty dispute and the trade dispute are not identical disputes:

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not been common before the WTO DSM.<sup>118</sup> Scholars have noted that “there remain questions regarding the effectiveness of the WTO DSM in the TRIPS context.”<sup>119</sup> It seems that “the number of TRIPS disputes has consistently decreased over time.”<sup>120</sup> While states may have increasingly complied with their TRIPS obligations<sup>121</sup> and/or increasingly settled potential disputes,<sup>122</sup> “[t]he monitoring role of the Council for TRIPS might explain the reduction in the use of the DSM to resolve IP disputes. The Council’s effectiveness as a monitoring body might be working to pre-empt potential disputes well before they would reach the DSM.”<sup>123</sup>

Second, investment arbitration may be a suitable choice when the host state judiciary does not seem to ensure fair trials or impartiality. In such circumstances, the foreign investor may immediately refer the dispute to arbitration.<sup>124</sup> Otherwise, the investor–state dispute settlement mechanism may constitute the last resort when the case has already been discussed at the national level and the foreign investor is unsatisfied with the result because of discrimination, denial of justice or other reasons.

Third, the dispute settlement chapters of a number of Free Trade Agreements include the possibility of filing non-violation complaints even with regard to intellectual property rights.<sup>125</sup> Any measure that does not appear to directly violate treaty provisions, but is nevertheless sufficiently disadvantageous to the investor’s intellectual property, can fall

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To have identical disputes, three elements are needed: *personae* (same parties), *petitum* (same object) and *causa petendi* (same legal grounds). Not only do investment disputes and trade disputes have different parties, but they also present different *petita* and *causa petendi*. With regard to the parties, while trade disputes are interstate disputes, investor–state arbitrations typically involve a state and a private actor. With regard to the object of the dispute, while WTO cases deal with interstate trade, investment disputes deal with foreign investment in the host state. With regard to the *causa petendi* or legal grounds of the disputes, the legal instruments to be interpreted and applied to the disputes are different. In the case of investment disputes, relevant investment treaties and customary law or, in some cases, the national law will constitute the applicable law. In the case of trade disputes, the DSU empowers the DSB to clarify the provisions of the covered agreements.

VALENTINA VADI, ANALOGIES IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION 151 (2015).

118. *But see Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, Panel Report (Mar. 20, 2000) (holding that the TRIPS permits generic producers to manufacture a given pharmaceutical during the life of the patent; only stockpiling is deemed incompatible with Article 30); *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, Panel Report (Dec. 19, 1997).

119. Yoshifumi Fukunaga, *Enforcing TRIPS: Challenges of Adjudicating Minimum Standards Agreements*, BERKELEY TECH. L.J. 23 (2008) 868, 879 (noting that “the use of the WTO DSM to resolve TRIPS disputes has fallen, while its use to resolve general trade disputes continues unabated”).

120. *Id.* at 887.

121. *Id.* at 888–889 (“[M]ore than half of the disputes concerning TRIPS were settled within the consultation process through a mutually agreed solution’ and that ‘even the number of these settled-before adjudication cases is declining. Perhaps, however, this decline can also be explained as a by-product of the DSM’s effectiveness.”).

122. *See, e.g.*, Request for the Establishment of a Panel by the United States, *Brazil—Measures Affecting Patent Protection*, WT/DS199/3 (Jan. 9, 2001).

123. Fukunaga, *supra* note 119, at 894, 897 (“Compared to adjudication before the DSM, the Council’s monitoring process is less adversarial and thus is less likely to offend the respondent country. . . . [U]nder the TRIPS Agreement the reporting obligations are specific enough and the number of laws to be reviewed is small enough that the Council is able to perform its task effectively.”).

124. However, in case of denial of justice claims, the exhaustion of local remedies is needed.

125. GATT, *supra* note 45, art. XXIII(1)(b)-(c). *See also* Susy Frankel, *Challenging Trips-Plus Agreements: The Potential Utility of Non-Violation Disputes*, 12 J INT ECON. L. 1023 (2009).

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within the category of non-violation complaints. While the aim of the provision is to maintain the balance of benefits struck during negotiations, the vagueness of the clause transfers the authority to decide when the investor has suffered enough disadvantages from the treaty negotiating parties to arbitral panels. In the parallel WTO system, extension of this clause to IP regulation was extremely controversial during the TRIPS negotiations. While the TRIPS Agreement provides for such a remedy,<sup>126</sup> WTO Members have agreed not to use these complaints under the TRIPS Agreement for the time being, adopting a moratorium.<sup>127</sup> From a historical perspective, non-violation complaints were introduced into the GATT 1947 because of the general character of its obligations. There is no such need with regard to intellectual property, whose rules were already detailed in the TRIPS Agreement and other international conventions such as the Paris Convention for the Protection of Industrial Property.<sup>128</sup> There are indications that non-violation complaints have been raised before investment tribunals as well.<sup>129</sup>

Finally, as noted by Gibson, modern economies have become “predominantly ‘conceptual’, reflecting the vital role of ideas in . . . products and services . . .”<sup>130</sup> In a globalized world, science, technology, and creativity generate economic value and increase the significance and centrality of intellectual property.<sup>131</sup> Foreign investments are reflecting the increasing importance of “intellectual capital” as a source of wealth generation and of intellectual property rights protecting knowledge goods.<sup>132</sup>

In recent years, a growing number of investor–state arbitrations concerned the way host states govern the pharmaceutical sector. Some of these disputes are related to the way patents are governed; others relate to various issues ranging from the regulation of competition law and policy,<sup>133</sup> or the implementation of harmonization measures required by the European Union.<sup>134</sup> More generally, these disputes raise the question as to whether, by providing extensive protection to intellectual property, international investment law and arbitration may unduly infringe upon the regulatory autonomy of states in the pharmaceutical sector, potentially affecting fundamental public health issues.

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126. TRIPS Agreement, *supra* note 5, art. 64.2.

127. The 9th WTO Ministerial Conference held in Bali, Indonesia (Dec. 3-7, 2013) reiterated the moratorium until its next session to be held in Nairobi, Kenya, in December 2015. The United States and Switzerland have asked for reconsideration of this issue, and the TRIPS Council is examining the scope and modalities for non-violation complaints.

128. Paris Convention, *supra* note 35.

129. Luke Eric Peterson, *Newly Disclosed Document Shows that Pharma Corp Hopes to Construe Alleged Non-Compliance with Patent Treaties as a Breach of Investment Treaty*, INV. ARB. REP. (Dec. 10, 2012).

130. Gibson, *supra* note 72, at 398.

131. *Id.* at 412.

132. *Id.* at 398.

133. For instance, reportedly Uruguay is facing an arbitration claim over a recent decree that places limits on concentration of ownership in Uruguay’s pharmacy sector. A US investment fund has filed Notices of Dispute pursuant to the Spain–Uruguay and the U.S.–Uruguay bilateral investment treaties respectively, alleging that that the decree harms that company’s recent investment in a chain of local pharmacies. Luke Eric Peterson, *Uruguay Threatened over Decree affecting Ownership of Pharmacies*, INV. ARB. REP. (May 13, 2014).

134. For instance, the *Servier v. Poland* case arose because of regulatory measures adopted by Poland to implement EU law. Luke Eric Peterson, *France’s Second Largest Pharmaceutical Company Quietly Pursues Arbitration against Republic of Poland*, INV. ARB. REP. (Aug. 19, 2011).

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Investment treaty disputes concerning pharmaceutical patents give rise to both jurisdictional, merits and quantum issues. First, some disputes will center on the question as to which economic activities amount to an investment, and thus whether the dispute will be within the arbitral tribunal's jurisdiction. Second, although it may be very difficult to prove, an affected patent owner may claim that an unlawful expropriation has taken place. Third, if an expropriation has occurred, claims may concern the adequacy of the amount, or mode, of compensation. Fourth, the patent owner may also allege violation of the fair and equitable treatment standard. Finally, some claims may concern alleged discrimination suffered by the foreign investor. This section will examine these varieties of claims.

A. THE NOTION OF INVESTMENT

Addressing the question as to whether certain economic activities relating to pharmaceutical products amount to an investment is crucial as a positive answer contributes to establishing the subject matter jurisdiction of the arbitral tribunal.<sup>135</sup> While international investment treaties provide different definitions of investment, the ICSID Convention does not provide a definition of investment.<sup>136</sup> Rather, it provides that ICSID jurisdiction extends "to any legal dispute arising directly out of an investment."<sup>137</sup> In practice this has meant that commentators and arbitral tribunals have elaborated a number of criteria for defining the term.<sup>138</sup> Most notably, the leading test was elaborated by the *Salini* Tribunal, in the context of a dispute arising out of the construction of a highway. The *Salini* test includes four elements: 1) a contribution of money or other assets of economic value; 2) a certain duration; 3) an element of risk; and, 4) a contribution to the host state's development.<sup>139</sup> The need for the last element is sometimes put in doubt.<sup>140</sup>

An interesting case, which shows that the notion of investment should be clarified with reference to the relevant international treaty text rather than domestic notions, is *Servier and Others v. Poland*.<sup>141</sup> While the defendant argued that the claimants did not have any investments in the host state itself under Polish law,<sup>142</sup> Servier argued that "it [was] the Treaty, not Polish law, that [was] relevant in assessing whether Servier's assets [were] protected investments."<sup>143</sup> The Tribunal held that it possessed jurisdiction,<sup>144</sup> acknowledging that the companies were incorporated in France, and therefore it had jurisdiction *ratione*

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135. See ICSID Convention, *supra* note 108, art. 25(1) ("The jurisdiction of the Centre shall extend to any legal dispute arising directly out of an investment.").

136. Alex Grabowski, *The Definition of Investment under the ICSID Convention: A Defense of Salini*, 15 CH. J. INT'L L. 287, 293 (2014) (citing ICSID Arbitration Rules, *supra* note 105, r. 1(1)(3) ("The signatories to the [ICSID] convention purposefully left the term 'investment' undefined when granting the body jurisdiction over matters of international investment.")).

137. ICSID Convention, *supra* note 108.

138. Grabowski, *supra* note 136, at 293 ("A variety of tribunals have applied a plethora of different tests.").

139. *Salini Costruttori S.p.A. v. Morocco*, ICSID Case No. ARB/00/4, Decision on Jurisdiction, ¶ 52 (July 23, 2001), 42 I.L.M. 609 (2003).

140. *Quiborax S. A. v. Bolivia*, ICSID Case No. ARB/06/2, Decision on Jurisdiction, ¶ 220 (Sept. 27 2012) (arguing that while the ICSID Convention attempts to foster economic development via international investment, such development is not a necessary element of investment).

141. *Les Laboratoires Servier, S.A.S., v. Poland*, UNCITRAL, Award, ¶¶ 515, 532 (Feb. 14, 2012).

142. *Id.* at ¶ 222.

143. *Id.*

144. *Id.* at ¶ 510.

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*personae*.<sup>145</sup> On the other hand, it highlighted that under the terms of the treaty, it had jurisdiction *ratione materiae* “only for divestment measures” *i.e.* expropriation claims.<sup>146</sup>

The mere sale of pharmaceutical products does not amount to an investment. In *Italy v. Cuba*, an interstate investment treaty arbitration initiated by the Republic of Italy,<sup>147</sup> an arbitral tribunal recently clarified that the mere trade of medicines does not amount to an investment.<sup>148</sup> Italy espoused the claims of sixteen investors operating in different fields and raised claims in its own name for breach of the BIT.<sup>149</sup> It sought the payment of \$1 from Cuba as symbolic compensation and of several millions of U.S. dollars as compensation for the injury suffered by its investors.<sup>150</sup> One of the investors, Menarini Società Farmaceutica s.r.l., a pharmaceutical company, settled the claim directly and ceased to invoke diplomatic protection.<sup>151</sup> Therefore, Italy informed the tribunal that in light of this circumstance, it withdrew its diplomatic protection.<sup>152</sup> But, it did not withdraw the claim in its own name.<sup>153</sup>

The claimant argued that the agreement between Menarini and Medicuba, an entity affiliated with the Cuban Ministry of Health, did not relate merely to the supply of medicines but also included the research and development of new pharmaceutical products.<sup>154</sup> The claimant also stressed the duration of the contract, the collaboration with local agents, and the particular importance of the given medicines to public health in Cuba.<sup>155</sup> The respondent counter-argued that Menarini was not an “investor” as it merely sold its products to Medicuba and had no subsidiary in Cuba.<sup>156</sup> According to the respondent, contacts with local agents should be considered a normal business practice, and the organization of a cardiology conference was merely aimed at marketing related products and should not be conceived as evidence of an investment.<sup>157</sup> Cuba concluded by stressing that it had reached an agreement with the company, according to which the state would have paid its invoices, while the company would have started its commercial operations with Medicuba again.<sup>158</sup>

The tribunal defined investment as any economic activity carried out by an investor characterized by a contribution to the economic development of the host state of certain

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145. *Id.* at ¶ 518.

146. *Id.* at ¶ 519.

147. See, e.g., Enrico Milano, *The Investment Arbitration between Italy and Cuba: The Application of Customary International Law under Scrutiny*, 11 L. & PRAC. INT'L COURTS & TRIBUNALS 499, 500 (2012) (defining this arbitration as “a landmark case . . . to the extent that it has constituted the first inter-State proceedings in the history of modern BITs.”). See generally Michele Potestà, *Republic of Italy v. Republic of Cuba*, 106 AM. J. INT'L L. 341 (2012). See also Anthea Roberts, *State-to-State Investment treaty Arbitration: A Hybrid Theory of Interdependent Rights and Shared Interpretive Authority*, 55 HARVARD INT'L L. J. 1 (2014).

148. *Italy v. Cuba*, ad hoc State-State Arbitration, Final Award, ¶ 219 (Jan. 1, 2008), available at <http://www.italaw.com/cases/580>.

149. *Id.* at ¶ 46.

150. *Id.* at ¶ 96(1)(e).

151. *Id.* at ¶ 39.

152. *Id.* at ¶ 1.

153. *Id.* at para 93.

154. *Italy*, Final Award, *supra* note 148, at ¶ 89.

155. *Id.* at ¶ 90.

156. *Id.* at ¶ 134.

157. *Id.*

158. *Id.* at ¶ 136.

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duration and involving commercial risks taken on by the investor.<sup>159</sup> Therefore, it dismissed Italy's claims concerning Menarini Società Farmaceutica due to lack of subject matter jurisdiction. After examining the contract between Menarini and Medicuba, tellingly entitled '*Contrato de Compra-Venta*' (contract of sale),<sup>160</sup> the tribunal held that the given commercial activity was not an investment but a sale of pharmaceuticals.<sup>161</sup> As there was neither contribution of resources into Cuba nor assumption of risk (in addition to and beyond the mere risk of nonpayment), the tribunal held that such sale of goods did not constitute an investment protected under the Italy-Cuba BIT.<sup>162</sup> The tribunal added that sponsoring medical congresses does not qualify the subsequent sales of medicines as investments as such activity is a classic marketing practice.<sup>163</sup> The issue as to whether cross-border sales of pharmaceuticals constitute investment was also raised in the *Servier* award.<sup>164</sup> But the heavily redacted award does not allow further clarification on this point.

More recently, in *Apotex Holdings Inc., Apotex Inc. v. United States of America (Apotex III)*,<sup>165</sup> the claimants sought over \$1 billion in damages from the United States after the U.S. Food and Drug Administration (FDA) imposed an Import Alert on certain generic medicines that Apotex Inc. produced in Canada, exported to the United States and a U.S.-based Apotex subsidiary sold in that market.<sup>166</sup> The Import Alert was imposed after FDA inspections of Apotex facilities in Canada found noncompliance with good pharmaceutical manufacturing practices.<sup>167</sup> The respondent emphasized that Apotex produced all its products in Canada.<sup>168</sup> The United States did not view the cross-border trade of pharmaceuticals as an investment.<sup>169</sup> The claimants argued that they had the following investments in the United States: 1) certain intellectual property rights, that is, abbreviated new drug applications (ANDAs), directly held by Apotex Inc. and indirectly held by Apotex Holdings;<sup>170</sup> and 2) Apotex Corp., a U.S.-based subsidiary of Apotex Holdings, that markets pharmaceuticals produced in Canada.<sup>171</sup>

The tribunal held that ANDAs were not "investments" in the United States.<sup>172</sup> In this regard the tribunal followed previous awards (*Apotex I* and *II*), which rejected claims that

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159. Italy v. Cuba, ad hoc State-State Arbitration, Interim Award, ¶ 81 (March 15, 2005) (<http://www.italaw.com/cases/580>) ("[S]auf dispositions contraires spécifiques d'un Traité Bilatéral de protection des Investissements, trois éléments sont requis pour que l'on se trouve en présence d'un investissement: un apport, la durée et une prise de risque de la part de l'investisseur. . . . Ceci permet d'écarter, par exemple, les simples opérations de vente.")

160. Italy, Final Award, *supra* note 148, at ¶ 219.

161. *Id.* at ¶¶ 219, 220.

162. *Id.*

163. *Id.* at ¶ 220 (clarifying that "le fait que Menarini aurait sponsorisé des congrès médicaux, ce qui n'est d'ailleurs pas établi ne permet pas de qualifier d'investissement la vente des médicaments en cause, puisqu'il s'agit d'opérations classiques de promotion des produits vendus").

164. See *Servier*, Award, *supra* note 141.

165. Apotex Holdings Inc, Apotex Inc. v. United States (*Apotex III*), ICSID Case No. ARB(AF)/12/1, Award (Aug. 25, 2014).

166. *Id.* at ¶¶ 2.34, 3.6.

167. *Id.* at ¶¶ 3.52, 3.199.

168. *Id.* at ¶ 2.51.

169. *Apotex III*, *supra* note 165, at ¶ 2.51.

170. *Id.* at ¶ 2.7.

171. *Id.* at ¶¶ 2.5, 2.6.

172. *Id.* at ¶ 7.43.

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applications for the sale of medicines into a host state could be considered investments.<sup>173</sup> The tribunal clarified that even if preparing those applications required significant expenses, the true business activity was the production of the medicines in the home state for export in the host state.<sup>174</sup> One of the three arbitrators dissented from the tribunal's conclusion.<sup>175</sup> He suggested that finally approved ANDAs can be bought and sold and are in other ways treated as property under U.S. law.<sup>176</sup> Therefore, the only investment was the subsidiary Apotex Corp. Commentators criticized the award on the latter point, submitting that it "blurs the line between trade and investment disputes," and argued companies might use their subsidiaries "as a kind of Trojan horse" for obtaining protection under the relevant BIT.<sup>177</sup>

In conclusion, the question as to whether intellectual property constitutes an investment requires a case-by-case assessment. Mere sales of pharmaceutical goods do not amount to investments. In fact, rather than constituting investments in the local economy, such sales can "preserve export markets for the patent owner, leading to welfare losses for the host country," potentially "impeding local innovation" and increasing the costs of medicines.<sup>178</sup> Patent applications create a mere expectation of obtaining a government grant. Unregistered inventions do not constitute patents. Although some argue that the application is a form of intangible property, "the question as to whether a patent application can be considered an investment depends on the precise wording of the relevant [BIT]."<sup>179</sup> For example, the U.S.–Jamaica BIT covers patentable inventions.<sup>180</sup>

More importantly, Okediji points out that "[n]o determination of intellectual property as an 'investment' is per se neutral"; rather, it can affect both domestic and foreign companies.<sup>181</sup> Therefore, it seems crucial that when treating intellectual property as investment, arbitrators consider the relevant policy choices underlying given measures,<sup>182</sup> i.e. the ability of the host state to calibrate national policies to local conditions and needs.

## B. EXPROPRIATION

International investment treaties provide for protection against unlawful expropriation. With regard to expropriation claims, arbitration will be concerned with the issues of what acts of the state may be characterized as amounting to an unlawful expropriation. Treaty provisions lack precise definitions of expropriation and their language encompasses a po-

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173. *Apotex Inc v. United States (Apotex I & II)*, UNCITRAL, Award on Jurisdiction and Admissibility, ¶¶ 243, 245 (June 14, 2013), available at <http://www.italaw.com/sites/default/files/case-documents/italaw1550.pdf>.

174. *Id.* at ¶ 245.

175. *Apotex III*, *supra* note 165, at ¶¶ 7.63-7.66.

176. *Id.* at ¶ 7.66.

177. Lise Johnson, *New Weaknesses: Despite a Major Win, Arbitration Decisions in 2014 Increase the US's Future Exposure to Litigation and Liability*, COLUM. CTR. ON SUSTAINABLE DEV. 1, 4 (2015).

178. Okediji, *supra* note 77, at 1126.

179. Gibson, *supra* note 72, at 433.

180. *Id.*

181. Okediji, *supra* note 77, at 1127.

182. *Id.* at 1136 (illustrating "the dangers of treating intellectual property as 'investment' per se, isolated from its appropriate policy domains").

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tentially wide variety of state activity that may interfere with pharmaceutical patents.<sup>183</sup> Two dichotomies characterize the notion of expropriation: the distinction between lawful and unlawful expropriation, and that between direct and indirect expropriation. Usually international investment agreements clarify that expropriatory measures are lawful if adopted: 1) “for a public purpose;” 2) “on a non-discriminatory basis;” 3) “in accordance with due process of law;” and 4) “on payment of compensation.”<sup>184</sup> A lack of any of these requirements will imply that the expropriation is unlawful and thus requires compensation.

In parallel, expropriation can be direct or indirect. Direct expropriation amounts to a deprivation of property or a taking through formal transfer of title or outright seizure. Cases of direct confiscation of foreign intellectual property rights have taken place in the past. For example, during the First World War, the German-owned Bayer trademark for aspirin [was] assigned to an unrelated U.S. company.<sup>185</sup> In the *Norwegian Shipowners* case, an arbitral tribunal found that U.S. authorities had to pay compensation not only for the requisition of all ships (tangible property) but also for the affected contract rights of Norwegian ship owners (intangible property).<sup>186</sup> In *German Interests in Polish Upper Silesia*, the Permanent Court of International Justice found that a Polish statute which transferred to the Polish Treasury all the properties of the German Reich located in the territory annexed to Poland amounted to a taking not only of the Chorzów factory but also of certain patents that were affected by the legislation.<sup>187</sup> More recently, in *Shell Brand International AG v. Nicaragua*,<sup>188</sup> “two Shell subsidiaries filed a claim against the Government of Nicaragua for breach of the Netherlands–Nicaragua BIT in response to an alleged expropriation of their logo and brand name.”<sup>h</sup> Reportedly, “[a]ccording to Shell, Nicaragua seized its trademarks in an effort to enforce a . . . judgment handed down in 2002 by a Nicaraguan court in, *Sonia Eduarda Franco Franco, et al. v. Dow Chemical, et al.*”<sup>h</sup><sup>189</sup> Accordingly, “[t]hat judgment was in favour of some 500 Nicaraguan citizens who claim to have been affected by the pesticide DBCP, which was manufactured for use on banana plantations in the 1960s and 70s.”<sup>190</sup> As the case was withdrawn, very little information is available about the case.<sup>191</sup>

A more difficult question is whether regulatory measures that do not require the outright seizure of patents can nonetheless amount to a regulatory taking or indirect expropriation. Indirect expropriation indicates measures that do not directly take investment

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183. *Wena Hotels Ltd. v. Egypt*, ICSID Case ARB/98/4, Award, ¶ 98 (Dec. 8, 2000) (noting that “expropriation is not limited to tangible property rights”).

184. Canada–Mexico–United States: North American Trade Agreement art. 1110.1, Dec. 17, 1992, 32 I.L.M. 605, 641.

185. Allen Z. Hertz, *Shaping the Trident: Intellectual Property under NAFTA, Investment Protection Agreements and at the World Trade Organization*, 23 CAN.–U.S. L.J. 261, 276 (1997).

186. *Norwegian Shipowners Claims (Nor. v. U.S.)*, 1 R.I.A.A. 307, 323, 343 (1922); VADI, *supra* note 29, at 74.

187. *Chorzów Factory Case (Ger. v. Pol.)*, Judgment, 1927 P.C.I.J. Series A No. 7 at 44 (May 25, 1926).

188. *Shell Brands Int’l AG v. Nicaragua*, ICSID Case No. ARB/06/14, Request for Arbitration (May 17, 2006).

189. Damon Vis–Dunbar, *Shell Launches Claim Against Nicaragua over Seizure of Intellectual Property*, INV. TREATY NEWS, Oct. 13, 2006, available at [http://www.iisd.org/pdf/2006/itn\\_oct13\\_2006.pdf](http://www.iisd.org/pdf/2006/itn_oct13_2006.pdf).

190. *Id.*

191. See Valentina Vadi, *Trademark Protection, Public Health and International Investment Law: Strains and Paradoxes*, 20 EUR. J. INT’L L. 773 (2009).

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property but which interfere with its use, depriving the owner of its economic benefit.<sup>192</sup> For example, several studies have examined the question as to whether compulsory licenses (when a government allows someone else to exploit the patented product or process without the consent of the patent owner) and parallel imports (importing and selling branded goods into a market there without the consent of the owner of the trademark) can amount to an expropriation of pharmaceutical patents.<sup>193</sup> Both compulsory licenses and parallel imports are flexibilities allowed by the TRIPS Agreement.<sup>194</sup> The issue however, remains theoretical as almost no claims have been brought concerning these specific issues so far.<sup>195</sup> While this does not preclude the possibility that such claims may be brought in the future, this section explores how expropriation claims have been articulated in practice.

In *Servier and Others v. Poland*, the tribunal held Poland liable for expropriation of pharmaceutical marketing authorization in breach of the France–Poland bilateral investment treaty.<sup>196</sup> As part of Poland’s accession to the European Union (EU), the country reviewed its pharmaceutical laws to harmonize them with EU standards.<sup>197</sup> Under one of these harmonization measures, medicines to be sold in Poland required a renewal of their marketing authorization.<sup>198</sup> In late 2008, Polish health authorities did not renew the authorization for two medicines produced by the claimants.<sup>199</sup> The precise reasons for denial of the authorization are redacted from the published award. Around the same time, authorization was granted to Polish companies to market alternatives to these medicines.<sup>200</sup> Against this background, the claimants, three French pharmaceutical companies, commenced UNCITRAL-rules arbitration under the France–Poland BIT; the parties contended that the denial of authorizations amounted to a substantial deprivation of value, and thus a direct or indirect expropriation of their pharmaceutical patents.<sup>201</sup>

Poland argued that its decisions not to renew marketing authorizations for the medicines were adopted “in the normal course of [its] duties as pharmaceutical regulator, and based on the drugs’ failure to comply with EU law requirements.”<sup>202</sup> According to the respondent, these measures did not amount to an expropriation.<sup>203</sup> In particular, Servier could not have expected that authorization would indefinitely be granted in the context of both a heavily-regulated pharmaceutical industry and Poland’s transition to EU

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192. Brigitte Stern, *In Search of the Frontiers of Indirect Expropriation*, in 1 CONTEMPORARY ISSUES IN INTERNATIONAL ARBITRATION AND MEDIATION: FORDHAM PAPERS 35 (Arthur Rovine ed., 2007).

193. For an examination of the question as to whether compulsory licenses can amount to an indirect expropriation, see, e.g., VADI, *supra* note 29, at 52–53, 76–80, 88–91; Christopher S. Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT’L L. REV. 357, 361–63 (2010); Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. OF INT’L L. 331, 362, 367 (2004).

194. TRIPS Agreement, *supra* note 5, art.6 (parallel imports), art. 31 (compulsory licensing).

195. For discussion of an investment treaty arbitration concerning compulsory licensing, see VADI, *supra* note 29, at 78.

196. *Servier*, Award, *supra* note 141, at ¶¶ 574–76.

197. *Id.* at ¶¶ 39–40.

198. *Id.* at ¶¶ 57–58.

199. *Id.* at ¶¶ 80, 89.

200. *Id.* at ¶¶ 108–110, 124.

201. *Servier*, Award, *supra* note 141, at ¶ 215.

202. *Id.* at ¶ 190.

203. *Id.*

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membership.<sup>204</sup> Moreover, Poland contended that its conduct complied with EU law, which was binding on both Poland and France being the “product of a joint French and Polish policy choice.”<sup>205</sup> Poland argued that EU law constituted a “relevant rule of international law applicable between the parties” under Article 31(3)(c) of the Vienna Convention on the Law of Treaties.<sup>206</sup> Therefore, according to Poland, it would be “inappropriate to find that the regulatory requirements which both parties agreed to could give rise to an obligation of compensation.”<sup>207</sup>

Poland contended that it denied marketing authorizations to certain medicines in the exercise of its “police” powers to regulate public health.<sup>208</sup> Poland argued that the display of those powers was proportionate to the public interest to be protected and adopted in good faith.<sup>209</sup> It urged arbitrators to show deference to state regulatory choices.<sup>210</sup> Poland also argued that its laws, recently harmonized with relevant EU law, would not have allowed other regulatory choices, namely approval subject to further information, leaving a denial as the only available response.<sup>211</sup> According to Poland, various delays were due to the claimants’ failure to provide information.<sup>212</sup>

While claimants did not contest the police powers doctrine per se, they contended that the state measures were discriminatory, disproportionate, and unreasonable.<sup>213</sup> According to the claimants, the non-discrimination element was breached when authorizations were granted to local producers while the claimants’ applications were rejected.<sup>214</sup> Servier contended that “neither the EU Treaty, nor the EU Pharmaceuticals Directive, require[d] Poland to favour the local pharmaceutical industry and adopt measures to drive foreign competitors from the market.”<sup>215</sup> Servier argued that the host state aimed at “promot[ing] the local pharmaceutical industry, in particular through the registration of low-cost local generic products.”<sup>216</sup> On proportionality, the claimants suggested that, rather than denying authorization, the health authorities could have limited the indications for use of the medicines, or given conditional approval while requiring further information.<sup>217</sup> According to the claimants, the authorities would allegedly deliberately deliver the decision to deny renewal *after* the authorization had expired, which left the claimants with no re-

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204. *Id.* at ¶¶ 271, 274.

205. *Id.* at ¶ 264.

206. *Id.* at ¶ 265 (citing Vienna Convention on the Law of Treaties, art. 31(3)(c), May 23, 1969, 1155 U.N.T.S. 331).

207. *Servier*, Award, *supra* note 141, at ¶ 265.

208. *Id.* at ¶ 276.

209. *Id.* at ¶ 403.

210. *Id.* at ¶ 279 (“[I]n assessing the measures, [the tribunal] ‘should not embark upon an open-ended enquiry into the scientific correctness of the decisions in question or substitute its own regulatory choices for those made by the competent Polish regulator.’ Rather, the Tribunal should assess whether the measures were ‘motivated by honest belief, held in good faith and based on reasonable scientific grounds,’ that is, whether Poland acted as a reasonable regulator.”); *id.* at ¶ 282 (“A deferential standard of review must be employed by the Tribunal when it comes to regulatory decisions based around science and national regulation.”).

211. *Servier*, Award, *supra* note 141, at ¶ 336.

212. *Id.* at ¶ 347.

213. *Id.* at ¶¶ 276-77.

214. *Id.* at ¶ 310.

215. *Id.* at ¶ 264.

216. *Id.* at ¶ 267.

217. *Servier*, Award, *supra* note 141, at ¶ 344.

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course under Polish law.<sup>218</sup> The claimants alleged that “no serious public health concerns” justified the nonrenewal.<sup>219</sup> In this regard, the claimants noted that while their Eurespal syrup product was denied authorization, the same product in tablet form was authorized.<sup>220</sup>

The tribunal held that, while it should “accord due deference to the decisions of specialized Polish administrators interpreting and applying laws and regulations governing their area of competence,” it would “also consider the manner in which those decisions were taken and their effect on the Claimants’ investments.”<sup>221</sup> The Tribunal found the denial of marketing authorization to be discriminatory, disproportionate, and “not a matter of public necessity,” thus amounting to an unlawful expropriation of the investment.<sup>222</sup> Although the Tribunal’s reasoning on expropriation remains redacted from the award, the specific outcome of this case may depend on the specific wording of the France–Poland BIT, providing that “any” divestment would “give rise to payment of ‘prompt and adequate compensation’ corresponding to the ‘real value’ of the divested investments.”<sup>223</sup>

In another recent dispute, the U.S.-based pharmaceutical company, Eli Lilly, filed a Notice of Intent against the Government of Canada pursuant to NAFTA Chapter 11,<sup>224</sup> claiming that the invalidation of some of its patents by Canadian courts amounted to expropriation.<sup>225</sup> The claimant contends that such judicial decisions deprived the investments of any substantial value and were contrary to the host state’s international treaty obligations.<sup>226</sup> First, the claimant argues that the revocation of the patent constitutes a *direct* expropriation as:

The effect of the promise doctrine and other measures was to revoke the patents *ab initio*, thereby depriving Lilly of its exclusive rights to prevent third parties from making, constructing, using, or selling its patented products during the patent term and to enforce those rights during the patent term or thereafter.<sup>227</sup>

Conversely, the company claims that the host state action amounted to *indirect* expropriation as “[t]he measures in issue have had the effect of destroying the value associated with Lilly’s investments.”<sup>228</sup> The company is seeking US\$500 million in damages.<sup>229</sup>

The facts of the case are the following: the Canadian Federal Court invalidated the Strattera patent, a treatment of attention-deficit hyperactivity disorder (ADHD), upon the request of a generic pharmaceutical company in 2010—six years prior to the patent’s

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218. *Id.* at ¶ 342.

219. *Id.* at ¶ 352.

220. *Id.*

221. *Id.* at ¶ 568.

222. *Id.* at ¶ 575.

223. *Servier*, Award, *supra* note 141, at ¶ 643.

224. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Notice of Intent, ¶ 1 (Nov. 7, 2012) *available at* <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

225. *Id.* at ¶¶ 89–97.

226. *Id.* at ¶¶ 91, 94.

227. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Notice of Arbitration, ¶ 75 (Sept. 12, 2013), *available at* <http://www.italaw.com/sites/default/files/case-documents/italaw1582.pdf>.

228. *Id.*

229. *See* Okediji *supra* note 77, at 1121 (highlighting that “the firm seeks to compel a change in Canadian patent law, an intervention by the Parliament to limit the interpretation of the utility requirement by judges”).

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scheduled expiration—due to its perceived “inutility.”<sup>230</sup> The claimant alleges that it has suffered damages as a result of the invalidation of its patent.<sup>231</sup> Since the declaration of invalidity, the company “no longer had the exclusive right to make, use and sell its patented” medicine.<sup>232</sup> According to the claimant, Canada’s federal courts have developed a doctrine which diverges from patent law in other jurisdictions and which has had the effect of invalidating a large number of patents in recent years.<sup>233</sup> In particular, the company complains that Canadian courts are requiring not only that a given invention have some “scintilla” of usefulness, but also that patent-holders prove, with evidence, that the invention has lived up to the usefulness *promised* by the patent holder at the time of seeking the patent.<sup>234</sup> If the patented invention is found not to meet this promise, the patent can be revoked.<sup>235</sup> According to the claimant, not only would the promise doctrine “unduly impede research and development,”<sup>236</sup> but it would also breach Canada’s obligations under several intellectual property conventions, including Article 27 of the TRIPS Agreement,<sup>237</sup> NAFTA Chapter 17 and the Patent Cooperation Treaty (PCT) “by imposing onerous and additional utility requirements that have had the effect of denying patent rights for inventions which meet the conditions precedent to patentability.”<sup>238</sup>

In its Statement of Defence [sic], Canada countered that a *direct* expropriation only occurs when rights are taken by the state and that no such transfer occurred in this case.<sup>239</sup> Rather, Lilly’s patents were invalidated.<sup>240</sup> Canada argued that “[w]here a court of competent jurisdiction . . . determines that a presumed property right is legally invalid (*i.e.* that it does not exist), this does not amount to a ‘taking’, but rather, constitutes juridical determination of the existence and scope of rights at law.”<sup>241</sup> In other words, according to Canada, the company cannot claim its investments were expropriated because its patents do not even exist under Canadian law.<sup>242</sup> Canada also noted that “[p]atent grants are invalidated each year by courts in all major jurisdictions,” if challenged by other parties and determined by a court not to meet the conditions for patent protection.<sup>243</sup> Therefore, according to Canada, “Article 1110 does not apply to the procedurally fair invalidation of

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230. *Eli Lilly & Co.*, Notice of Intent, *supra* note 224, at ¶¶ 73, 74, 90.

231. *Id.* at ¶ 90.

232. *Id.*

233. *Id.* at ¶¶ 37, 38.

234. *Id.*

235. *Id.* at ¶ 42.

236. *Eli Lilly & Co.*, Notice of Intent, *supra* note 224, at ¶ 16.

237. *Id.* at ¶ 6.

238. *Id.* at ¶ 42.

239. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Canada Statement of Defence, ¶ 108 (June 30, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf>.

240. *Id.*

241. *Id.*

242. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Canada Counter Memorial, ¶ 302 (Jan. 27, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf> (adding that domestic law is the law that determines the existence and nature of property rights and stating that “[i]f there is no valid property right at domestic law, then there is nothing that can be ‘taken’ within the meaning of the international law of expropriation. The only context in which a domestic court ruling on the validity of an asserted property right could amount to an expropriation is if there has been a denial of justice”).

243. *Eli Lilly & Co.*, Canada Statement of Defence, *supra* note 239, at ¶ 106.

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a patent by a domestic court.<sup>244</sup> Moreover, Canada stressed that “[investment tribunals] do not sit as courts of appeal of domestic legal determinations.”<sup>245</sup>

Additionally, Canada argues that there can be no expropriation because Canada’s actions were consistent with NAFTA Chapter 17.<sup>246</sup> According to Article 1110(7) of NAFTA, measures invalidating patents cannot give rise to expropriation claims under Chapter 11 if those measures are consistent with Chapter 17.<sup>247</sup> Canada highlights that, like the TRIPS Agreement, NAFTA Chapter 17 leaves each state party with significant latitude to define the substantive scope of patent protection.<sup>248</sup>

In its Counter-memorial, Canada also highlights the public policy dimension of pharmaceutical patent regulation.<sup>249</sup> According to Canada, the “patent bargain” encompasses a balance between the patent owner and the public:

These rules are intended to ensure that patentees provide the consideration they promised in exchange for the grant of a 20-year monopoly. They seek to ensure that patents are filed on the basis of true invention, rather than of speculation. They verify that disclosure obligations in the patent, which is the basis for the ‘patent bargain’ with the public, are fulfilled. These rules are fundamental to the integrity of the patent system.<sup>250</sup>

Therefore, according to Canada, “such rules in the administration of its domestic patent system” are “legitimate and lawful.”<sup>251</sup>

Canadian commentators argue that there is no such thing as a separate “promise doctrine” in Canadian patent law; rather, these cases relate to the utility test—one of the internationally mandated requirements (with novelty and non-obviousness) under which patents are granted for inventions.<sup>252</sup> In other words, “[a]ll states require that patents be issued only for ‘useful’ inventions.”<sup>253</sup> Canadian scholars point out that enforcing a patentee’s promise contained within a patent specification serves three goals: “(1) holding patentees to account for the public benefit they promise in exchange for the patent monopoly; (2) ensuring that the patentee actually has conducted enough research and development to understand and communicate how the invention works in all its claimed instantiations; and (3) preventing double patenting.”<sup>254</sup> In other words, “the patent sys-

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244. *Id.*

245. *Id.* at ¶ 112.

246. *Eli Lilly & Co.*, Canada Counter Memorial, *supra* note 242, at ¶ 344.

247. *Id.*

248. *Id.* at ¶ 362 (“In the international context, relevant international organizations and States have recognized that neither ‘utility’ nor ‘industrial applicability’ are harmonized terms, and instead bear a range of distinct technical meanings in various national patent law systems.”); *id.* at ¶ 365 (highlighting the NAFTA Parties’ “intention to leave these terms to be applied in a flexible and principled manner, in accordance with national law”).

249. *Id.* at ¶ 7.

250. *Id.*

251. *Id.*

252. E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CAN. INTEL. PROP. REV. 37, 37-39 (2014) (noting that “the ‘promise of the patent’ is probably the most controversial issue in contemporary Canadian patent law” but suggesting that the legal concept has “deep historical roots and global reach” and “is not . . . an independent legal rule”).

253. *Id.* at 37.

254. *Id.* at 40.

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tem is based on a “bargain” or *quid pro quo*: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge.”<sup>255</sup>

Turning to the *indirect* expropriation claim, with regard to the economic impact of the patent invalidation, Canada argues that the invalidated patents were just one component of Lilly’s overall business in Canada.<sup>256</sup> In fact, the company continues to grow and sells a number of products.<sup>257</sup> Therefore, according to Canada, there was no substantial or total destruction of the claimant’s investments.<sup>258</sup> With regard to the character of the invalidation, Canada emphasizes that the decisions of its courts were legitimate.<sup>259</sup> The defendant also highlighted that the “whole notion of judicial expropriation is entirely unsettled even in domestic legal systems, let alone in customary international law.”<sup>260</sup> As the case is pending, it is not possible to foresee how it will be decided.

In *Apotex Inc. v. United States*, Apotex, a Canadian generic pharmaceutical company, alleged, *inter alia*, expropriation of its investments.<sup>261</sup> According to the claimant, the Federal Food, Drug and Cosmetic Act and subsequent amendments provide for “an abbreviated approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-priced generic versions of previously-approved [medicines] on an expedited basis, thereby benefiting the U.S. health-care system and American consumers.”<sup>262</sup> In 2003, the company filed an application with the U.S. Food and Drug Administration (FDA) to obtain the approval of a generic version of an antidepressant before the relevant patent owned by Pfizer expired in 2006.<sup>263</sup> In doing so, Apotex triggered an “artificial” act of patent infringement in an effort to draw the patent owner into a dispute that would provide a judgment, one way or the other, on the legality of Apotex’s application to sell the medicine.<sup>264</sup> When the patent holder declined to file a suit, Apotex filed for a declaratory judgment that it was not infringing on the patent, which, according to the claimant, is a common legal tactic in patent litigation.<sup>265</sup> But the United States District Court for the Southern District of New York dismissed Apotex’s suit for lack of subject matter jurisdiction as it lacked a “reasonable apprehension” that Pfizer would launch a suit for patent infringement.<sup>266</sup> The United States Court of Appeals for the Federal Circuit affirmed the district court’s decision, and the Supreme Court denied Apotex’s petition for *certiorari*.<sup>267</sup> In its Notice of Arbitration, Apotex argues that the U.S. courts “misapplied statutory and constitutional law,” as their reliance on the so-called prudential jurisdictional doctrine or reasonable apprehension doctrine would be contrary

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255. *Id.* at 42.

256. *Eli Lilly & Co.*, Canada Counter Memorial, *supra* note 242, at ¶ 409.

257. *Id.* at 411.

258. *Id.* at 415.

259. *Id.* at 414.

260. *Id.*

261. *Apotex Inc. v. United States (Apotex I)*, UNCITRAL, Notice of Arbitration, ¶ 7 (Dec. 10, 2008), available at <http://www.italaw.com/sites/default/files/case-documents/italaw1323.pdf>.

262. *Id.* at ¶ 29.

263. *Id.* at ¶¶ 14, 16.

264. *Id.* at ¶¶ 16–17.

265. *Id.* at ¶ 19.

266. *Id.* at ¶¶ 20, 36; see generally *Apotex Inc. v. Pfizer, Inc.*, 385 F.Supp.2d 187 (S.D.N.Y. 2005).

267. *Apotex I*, Notice of Arbitration, *supra* note 261, at ¶ 20; see *Apotex Inc. v. Pfizer, Inc.*, 159 Fed.Appx. 1013 (Fed. Cir. 2005), *cert. denied*, 549 U.S. 970 (2006).

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to the U.S. Constitution and Supreme Court jurisprudence.<sup>268</sup> According to the claimant, such a doctrine creates a sort of bottleneck, delaying the expeditious development and manufacture of generics, and thus is contrary to public welfare.<sup>269</sup>

Against this background, Apotex contended that the United States' conduct amounted to an unlawful expropriation, thus violating NAFTA Article 1110.<sup>270</sup> The claimant argued that "[u]nder international law, expropriation occurs where government action unreasonably interferes with an alien's effective use or enjoyment of property."<sup>271</sup> According to the claimant, the U.S. interfered with its property rights in its "abbreviated new drug application" (ANDA) "by unlawfully preventing Apotex from obtaining a federal court decision" assessing the validity of the relevant patent, and "substantially depriving Apotex of the benefits of its investments."<sup>272</sup> The claimant also argued that the defendant "[had] no 'public purpose' for interfering with Apotex's property rights,"<sup>273</sup> and it "failed to provide [the company] with due process of law."<sup>274</sup> Finally, Apotex claimed that it did not receive compensation for the damages it alleged to have suffered.<sup>275</sup> The Arbitral Tribunal dismissed all of the claims and ordered Apotex to pay the United States' legal fees and arbitral expenses.<sup>276</sup>

A parallel dispute,<sup>277</sup> which was joined to the former and heard by the same Arbitral Tribunal,<sup>278</sup> involved the submission of a medicine application seeking approval for a generic version of a heart medication, Pravachol®.<sup>279</sup> In order to obtain approval of its application, Apotex had sued the patent owner, Bristol Myers Squibb (BMS), to obtain a guarantee that it would not file a claim for patent infringement after the launch of Apotex medicines on the market.<sup>280</sup> In response, "BMS moved to dismiss for lack of subject matter jurisdiction on the ground that it had no intention of suing Apotex for infringement."<sup>281</sup> The Court dismissed Apotex's declaratory judgment action for lack of subject matter jurisdiction.<sup>282</sup> According to the claimant, the administrative decision of the FDA, the U.S. District Court for the District of Columbia, and the U.S. Court of Appeals for the District of Columbia, each violated U.S. statutory law and prior controlling precedent.<sup>283</sup> According to Apotex, the United States breached, *inter alia*, NAFTA Article 1110

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268. *Apotex I*, Notice of Arbitration, *supra* note 261, at ¶ 56.

269. *Id.* at ¶¶ 45, 56.

270. *Id.* at ¶ 67.

271. *Id.* at ¶ 65.

272. *Id.* at ¶ 67.

273. *Id.* at ¶ 68.

274. *Apotex I*, Notice of Arbitration, *supra* note 261, at ¶ 69.

275. *Id.* at ¶ 70.

276. *Apotex I & II*, Award on Jurisdiction and Admissibility, *supra* note 173, at ¶ 358.

277. See generally *Apotex Inc. v. United States (Apotex II)*, UNCITRAL, Notice of Arbitration (June 4, 2009), available at <http://www.italaw.com/sites/default/files/case-documents/italaw1229.pdf>.

278. Although there were two different statements of claims, the parties agreed that the tribunal would hear the two claims concurrently, but not consolidated. See *Apotex Inc. v. United States*, UNCITRAL, Procedural Order No. 1, at ¶ 1 (Dec. 16, 2010), available at [http://www.italaw.com/sites/default/files/case-documents/ita0032\\_0.pdf](http://www.italaw.com/sites/default/files/case-documents/ita0032_0.pdf). Therefore, there was only one award dealing with the two different claims. See *Apotex I & II*, Award on Jurisdiction and Admissibility, *supra* note 173, at ¶ 4.

279. *Apotex II*, *supra* note 277, at ¶ 14-15.

280. *Id.* at ¶ 21.

281. *Id.*

282. *Id.* at ¶ 22.

283. *Id.* at ¶ 31.

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(“Expropriation and Compensation”).<sup>284</sup> In its claim, Apotex again alleged that the state action interfered with its property rights in its medicine application.<sup>285</sup> According to the claimant, “[e]xpropriation can occur where the State itself acquires nothing of value, but ‘at least has been the instrument of redistribution.’”<sup>286</sup> Apotex further claimed that because the United States had no “public purpose” for interfering with its property rights and did not provide compensation,<sup>287</sup> the company was entitled to compensatory damages.<sup>288</sup> The Arbitral Tribunal dismissed both claims on jurisdiction because of the failure to exhaust local remedies,<sup>289</sup> time limits,<sup>290</sup> and lack of investment.<sup>291</sup>

In conclusion, there is no “mechanical formula” for determining whether state conduct can amount to a direct or indirect expropriation.<sup>292</sup> Nonetheless, “expropriation requires that there be a ‘substantial deprivation’ to the investor.”<sup>293</sup> The character and regulatory purpose behind the government regulation can carry weight in the assessment as to whether there was a legitimate exercise of the state police powers.<sup>294</sup> As noted by Gibson, “[t]he invalidation or revocation of a patent results in an extreme deprivation of the investor’s IP.”<sup>295</sup> But the act of invalidation or revocation “may constitute a legitimate regulatory activity.”<sup>296</sup>

C. AMOUNT OF COMPENSATION

A further issue that arises in case any breach of the BIT is found is the determination of the amount of compensation. In particular, a specific type of claim concerns the amount of compensation to be paid after an expropriation has taken place. Expropriation rules may be more beneficial to the patent owner than the patent rules. Customary compensation rules, uniformly enshrined in investment protection treaties, do not differentiate between the various public purposes of expropriations, posing a single standard instead. Full compensation is often described as having the characteristics of promptness, adequacy, and effectiveness according to the so-called Hull formula.<sup>297</sup>

In *Servier and Others v. Poland*, the case concerning the alleged expropriation of Servier’s investments, the France–Poland BIT required that any expropriation would “give rise to prompt and adequate compensation” at the “real value of the investment.”<sup>298</sup>

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284. *Id.* at ¶ 77.

285. *Apotex II*, *supra* note 277, at ¶ 277.

286. *Id.* at ¶ 76.

287. *Id.* at ¶¶ 78–80.

288. *Id.*

289. *Apotex I & II*, Award on Jurisdiction and Admissibility, *supra* note 173, at ¶¶ 298–99.

290. *Id.* at ¶ 324.

291. *Id.* at ¶¶ 243, 246.

292. Gibson, *supra* note 72, at 450.

293. *Id.* at 451–52.

294. *Id.* at 452.

295. *Id.* at 453.

296. *Id.* at 454.

297. The Hull formula is named after the American Secretary of State, Cordell Hull, who described a full compensation standard as “prompt, adequate and effective” in a diplomatic exchange of notes with Mexico in 1930. Frank G. Dawson & Burns H. Weston, “Prompt, Adequate and Effective”: A Universal Standard of Compensation?, 30 FORDHAM L. REV. 727, 733–34 (1962), available at <http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=1730&context=flr>.

298. *Servier*, Award, *supra* note 141, at ¶¶ 6, 37.

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Therefore, the Tribunal held that this compensation standard was to be applied, regardless of whether the expropriation was lawful or unlawful.<sup>299</sup> Noting that each side won on some points and lost on others,<sup>300</sup> the Arbitral Tribunal split the costs equally, with parties left to bear their own legal fees.<sup>301</sup> However, not only is the reasoning on valuation of the damages awarded to the claimant redacted, but the claimant's arguments on valuation, including the amount that it sought, are also redacted.<sup>302</sup> The Tribunal stated that it had "discretion to impose additional sanctions to punish Treaty violations of particular seriousness, such as discrimination or breach of specific undertakings."<sup>303</sup> However, the tribunal found that Poland had "not engaged in bad faith behaviour . . . that would require damages beyond the Treaty standard."<sup>304</sup>

D. FAIR AND EQUITABLE TREATMENT

Fair and equitable treatment (FET) has become the most often invoked provision in investment treaty arbitration. Due to its vagueness, it ensures that "even where there is no clear justification for making a finding of expropriation," or any other breach of other investment treaty standards, "there is still a standard which serves the purpose of justice."<sup>305</sup> The fair and equitable treatment standard is an absolute standard of treatment. Absolute standards of treatment are designed to provide a basic safeguard upon which the investor can rely at any time, as opposed to the "relative" standards embodied in "national treatment" and in the "most favored nation" principles, which, on the other hand, define the required treatment by reference to the treatment accorded to other investments. In an attempt to delimit the perimeters of the standard, in the NAFTA context, the Free Trade Commission issued an interpretation of the provision,<sup>306</sup> which is binding on the NAFTA tribunals.<sup>307</sup> The Commission clarified that the FET provision under NAFTA Article 1105 prescribes the minimum standard of treatment in customary international law and does not require any standard of treatment that goes beyond that. Traditionally, the minimum standard of treatment protected investors only in instances of "egregious and shocking" or "manifestly unfair or inequitable conduct." Outside the NAFTA context, however, arbitral tribunals have broadened the notion of fair and equitable treatment significantly. Despite some persisting vagueness, the standard is said to go beyond the minimum standard of treatment and to comprise various elements such as transparency, due process, legitimate expectations, and others.<sup>308</sup> The protection of legitimate expectations

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299. *Id.* at ¶ 644.

300. *Id.* at ¶ 669.

301. *Id.* at ¶ 672.

302. *See id.* at ¶ 646-62.

303. *Servier*, Award, *supra* note 141, at 645.

304. *Id.* at ¶ 642.

305. *Id.*; *Sempra Energy Int'l v. Argentine Republic*, ICSID Case No. ARB/02/16, Award ¶ 300 (Sept. 28, 2007), <http://www.italaw.com/sites/default/files/case-documents/ita0770.pdf>.

306. NAFTA Free Trade Comm'n, Notes of Interpretation of Certain Chapter 11 Provisions (July 31, 2001).

307. NAFTA, *supra* note 74, art. 1131 ("An interpretation by the [FTC] of a provision of the Agreement shall be binding on a Tribunal established under this Section.")

308. Christoph Schreuer, *Fair and Equitable Treatment in Arbitral Practice*, 6 J. OF WORLD INVESTMENT & TRADE 357, 386 (2005), available at <http://www.univie.ac.at/intlaw/pdf/77.pdf>.

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is not absolute; rather, it must be balanced against the state right to regulate in the public interest.<sup>309</sup>

With regard to claims concerning alleged violations of fair and equitable treatment, it is worth recalling the NAFTA case *Signa S.A. v. Canada*.<sup>310</sup> Signa, a Mexican generic pharmaceutical company, established a joint venture with the Canadian Apotex, Inc., for the production of the generic version of Bayer Inc.'s top-selling ciprofloxacin hydrochloride, an antibiotic that treats a number of bacterial infections.<sup>311</sup> In order to sell the pharmaceutical in Canada, an authorization was required by the relevant authorities.<sup>312</sup> Signa contended that the regulations governing the authorization process included "improper requirements."<sup>313</sup> According to the claimant, the *Patented Medicines (Notice of Compliance) Regulations* provided that "by merely purporting to have a relevant patent, a person can obtain a mandatory prohibition against a generic competitor for a period of about 3 years."<sup>314</sup> As Bayer, the patent holder company, prevented Apotex and Signa from using ciprofloxacin hydrochloride for a period of about three years, Signa claimed loss of revenues and market share.<sup>315</sup> Signa, *inter alia*, claimed that the *Patented Medicines (Notice of Compliance) Regulations* constituted a breach of Article 1105 of the NAFTA, which provides for the fair and equitable treatment of foreign investors.<sup>316</sup> As the parties quickly settled this case, there is no publicly available information on the dispute. This withdrawal was probably due to the inception of the TRIPS Agreement that extended the pharmaceutical patent protection to twenty years. Whether the filing of the Notice of Intent to Arbitrate had any strategic or other impact is unknown.

In *Eli Lilly v. Canada*, the case relating to the invalidation of patents for treatments used for attention deficit disorder and schizophrenia, the claimant contends that the allegedly unexpected and arbitrary adoption by the Canadian courts of a new, stricter approach to patent invalidation is contrary to the company's "reasonable investment-backed expectations,"<sup>317</sup> and in breach of NAFTA Article 1105 which sets out a minimum standard of treatment owed to foreign investors.<sup>318</sup> The company argues that it "could not have anticipated that the requirement for utility at the time of its investment . . . would be so drastically altered by the adoption . . . of the doctrine of the 'promise of the patent'" into Canadian law and practice.<sup>319</sup> The claimant also contends that by allegedly violating a number of international law instruments governing patentability requirements, the Cana-

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309. *Saluka Investments BV (The Netherlands) v. Czech Republic*, UNCITRAL, Partial Award, ¶ 305 (Mar. 17, 2006). ("No investor may reasonably expect that the circumstances prevailing at the time the investment is made remain totally unchanged. In order to determine whether frustration of the foreign investor's expectations was justified or reasonable, the host State's legitimate right subsequently to regulate domestic matters in the public interest must be taken into consideration as well.")

310. *Signa S.A. de C.V. v. Canada*, Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 22 of the North American Free Trade Agreement (Mar. 4, 1996), available at <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/signa-01.pdf>.

311. *Id.* at paras. 1-3.

312. *Id.* at para. 4.

313. *Id.*

314. *Id.* at para. 6.

315. *Id.* at para. 9.

316. *Signa S.A.*, *supra* note 310, at para. 12.

317. See *Eli Lilly & Co.*, Notice of Intent, *supra* note 224, at ¶¶ 49, 70, 99-102.

318. *Id.* at ¶ 98.

319. *Id.* at ¶ 101.

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dian measures are in breach of the fair and equitable treatment standard.<sup>320</sup> The company stresses its legitimate expectations that Canada complies with international IP norms,<sup>321</sup> including the TRIPS Agreement, the Patent Cooperation Treaty and NAFTA Chapter 17.<sup>322</sup>

In its Statement of Defence, the Government of Canada counter-argues that the claimant received due process before Canadian courts and that the mere fact that the claimant was disappointed with the outcomes of two patent trials does not amount to a breach of the relevant obligations.<sup>323</sup> Canada stresses that “NAFTA tribunals are not courts of appeal for disappointed domestic litigants.”<sup>324</sup> Rather, according to the 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>325</sup> Canada highlights that the FET standard does not prevent the evolution of a State’s legal framework<sup>326</sup> as NAFTA Chapter 11 was “never meant ‘as a kind of insurance policy against the risk of any changes in the host State’s legal and economic framework.’”<sup>327</sup> In its Counter Memorial, Canada also points out that NAFTA’s FET provision does not go beyond the minimum standard of treatment required under customary international law.<sup>328</sup> According to Canada, “a violation of Article 1105(1) will not be found unless there is evidence of serious malfeasance, manifestly arbitrary behavior or denial of justice by the respondent NAFTA Party.”<sup>329</sup> Therefore, Canada argues that a violation of investors’ legitimate expectations does not establish a breach of the minimum standard of treatment, as the theory of legitimate expectations has not become a rule of customary international law.<sup>330</sup>

The respondent also maintains that the Tribunal lacks jurisdiction “over alleged breaches of Canada’s international intellectual property obligations.”<sup>331</sup> In particular, the respondent highlights that the Tribunal “lacks jurisdiction to rule on alleged violations of any of TRIPS, PCT or NAFTA Chapter Seventeen” and that enforcement of obligations under these other international IP agreements may only be brought before other venues.<sup>332</sup>

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320. *Id.* at ¶¶ 93, 99.

321. *Id.* at ¶ 93.

322. *Id.* at ¶¶ 93, 96.

323. *Eli Lilly & Co.*, Canada Statement of Defence, *supra* note 239, at ¶ 90.

324. *See id.* at ¶ 98.

325. *Id.* at ¶ 99.

326. *Id.* at ¶ 104.

327. *Id.* (quoting EDF (Services) Ltd. v. Romania, ICSID Case No. ARB/05/13, Award, ¶ 217 (Oct. 8, 2009)).

328. *See Eli Lilly & Co.*, Canada Counter Memorial, *supra* note 242, at ¶ 15.

329. *Id.* at ¶ 227.

330. *Id.* at ¶ 266.

331. *Eli Lilly & Co.*, Canada Statement of Defence, *supra* note 239, at ¶¶ 83-84 (“The Tribunal’s jurisdiction in this matter relates only to alleged breaches of NAFTA Chapter Eleven obligations. Chapter Eleven does not grant this Tribunal jurisdiction ‘at large’ to rule on alleged breaches of any and all of Canada’s other international obligations.”).

332. *Id.* at ¶ 84 (“Disputes in respect of an alleged breach of TRIPS obligations may only be brought pursuant to the Dispute Settlement Understanding of the World Trade Organisation. Allegations of a breach of the PCT are, in accordance with that Treaty, to be brought before the International Court of Justice. Allegations of a breach of NAFTA Chapter Seventeen are to be brought on a State-to-State basis before a tribunal constituted pursuant to NAFTA Chapter Twenty.”).

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In any case, Canada also stresses that it is in compliance with NAFTA Chapter 17.<sup>333</sup> In fact, according to the respondent, “the language of NAFTA Article 1709(1) was drawn from the TRIPS negotiations, where broad terms were used due to the lack of consensus on substantive law and the desire to maintain flexibility.”<sup>334</sup> Due to “substantial differences in their respective intellectual property regimes . . . the NAFTA Parties were unable to agree even on common terminology for core concepts of patentability.”<sup>335</sup> While Article 1709(1) includes the criteria “new,” “result[ing] from an inventive step,” and “capable of industrial application” as criteria for patentability of a given compound, it also notes that “a Party may deem the terms ‘inventive step’ and ‘capable of industrial application’ to be synonymous with the terms ‘non-obvious’ and ‘useful,’ respectively.”<sup>336</sup> According to Canada, the TRIPS Agreement reinforces this line of argument, as it “did not attempt to create a uniform or deeply harmonized patent regime and left ample room for national variations and approaches to substantive patent issues.”<sup>337</sup> Finally, the state notes the irrelevance of the PCT to the case. In fact, according to the state, “[t]he PCT expressly does not govern either substantive conditions of patentability or the invalidation of patents.”<sup>338</sup> It “simply facilitates the international filing of patent applications.”<sup>339</sup> Yet, Canada stresses that “[f]iling in accordance with the PCT is no guarantee that a patent application will result in a successful patent grant, or that any grant of a patent will withstand judicial scrutiny.”<sup>340</sup>

In *Apotex v. United States (Apotex I and II)*, the disputes concerning the approval for generic versions of given antidepressant and anti-cholesterol medicines, the claimant described the courts’ judgments as a “substantive ‘denial of justice’” in violation of NAFTA Article 1105, in addition to contending that they were “unjust” and amounted to an expropriation of its investment.<sup>341</sup> In particular, the claimant contended that it was denied justice when U.S. courts “render[ed] manifestly unjust decisions by misapplying constitutional, statutory, and common law relevant to the justiciability of declaratory judgment actions” brought by the generics company against the patent-owner.<sup>342</sup> The company claimed that there was a breach of the minimum standard of treatment required by NAFTA Article 1105.<sup>343</sup> The claim of denial of justice was brought in conjunction with the claim for expropriation that was examined above.<sup>344</sup> Under customary international law, and under certain circumstances, a manifestly unjust judgment may constitute a “denial[] of justice,”<sup>345</sup> or a type of indirect expropriation.<sup>346</sup>

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333. *Id.* at ¶ 82.

334. *Id.* at ¶ 87.

335. *Id.*

336. *Id.*

337. *Eli Lilly & Co.*, Canada Statement of Defence, *supra* note 239, at ¶ 91.

338. *Id.* at ¶¶ 93-94.

339. *Id.* at ¶ 94.

340. *Id.*

341. *See Apotex I*, Notice of Arbitration, *supra* note 261, at ¶¶ 13-14, 61-67.

342. *Id.* at ¶ 63.

343. *Id.* at ¶¶ 61, 61.

344. *Id.* at ¶¶ 64, 67.

345. *See Loewen Grp. Inc. v. United States*, ICSID Case No. ARB(AF)/98/3, Award, ¶ 129, (June 26, 2003) <http://www.state.gov/documents/organization/22094.pdf>.

346. *See Saipem S.p.A. v. Bangladesh*, ICSID Case No. ARB/05/07, Award, ¶ 127 (June 30, 2009) <http://www.italaw.com/sites/default/files/case-documents/ita0734.pdf>.

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As mentioned above, the Arbitral Tribunal upheld all preliminary objections raised by the United States of America, including that the claimant had not made a covered investment in the U.S., and that it had failed to exhaust local remedies that were available and not obviously futile.<sup>347</sup> In particular, the respondent noted that “[w]ith respect to its Sertraline Claim, Apotex sought, and was denied, review from the U.S. Supreme Court with regard to the lower court decisions rejecting its declaratory judgment action.”<sup>348</sup> Therefore, with regard to this claim, “[a]ll avenues of recourse within the U.S. court system were thereby exhausted.”<sup>349</sup> However, it noted that “[w]ith respect to its Pravastatin Claim . . . Apotex elected not to pursue all potentially available avenues before the U.S. Courts. In particular, it did not seek U.S. Supreme Court review of the court decisions rejecting its efforts to enjoin application of the FDA decision.”<sup>350</sup> Both parties agreed that “‘judicial finality’ must first be reached in the host State’s domestic courts, unless such recourse is ‘obviously futile.’”<sup>351</sup> But they disagreed on the meaning of “obviously futile.”<sup>352</sup> Apotex submitted that “it [was] wholly unrealistic to suppose that the Supreme Court would not only have granted the petition, but could have scheduled argument and render an opinion in Apotex’s favour. . . . Any efforts to achieve such a result would have been ‘objectively futile.’”<sup>353</sup>

After stating that this objection concerned its jurisdiction *ratione materiae*,<sup>354</sup> the Tribunal concluded that the judicial acts complained of lacked sufficient finality to form the basis of claims under NAFTA Chapter Eleven.<sup>355</sup> It expressed “sympathy for Apotex’s position”, and appreciated that “petitioning the U.S. Supreme Court was unlikely to secure the desired relief.”<sup>356</sup> However, it held that “under established principles, the question whether the failure to obtain judicial finality may be excused for ‘obvious futility’ turns on the unavailability of relief by a higher judicial authority, not on measuring the likelihood that the higher judicial authority would have granted the desired relief.”<sup>357</sup> The national court system—explained the Tribunal—must be given a chance to correct errors before its perceived failings can constitute an international wrong.<sup>358</sup>

In *Apotex III*, concerning the import ban on certain pharmaceuticals produced in Canada, the claimant contended that the U.S. had breached the minimum standard of treatment due to the perceived lack of due process in issuing the issue alert, and delays experienced in reinspecting the facilities. The claimant also contended that the FET standard is an evolving standard and includes due process in administrative decision-making processes.<sup>359</sup> In its counter-memorial,<sup>360</sup> the U.S. countered that the import alert was a

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347. *Apotex I & II*, Award on Jurisdiction and Admissibility, *supra* note 173, at ¶ 135.

348. *Id.* at ¶ 249.

349. *Id.*

350. *Id.* at ¶ 250.

351. *Id.* at ¶ 257.

352. *Id.*

353. *Apotex I & II*, Award on Jurisdiction and Admissibility, *supra* note 173, at ¶ 274.

354. *Id.* at ¶ 260.

355. *Id.* at ¶ 267.

356. *Id.* at ¶ 276.

357. *Id.*

358. *Id.* at ¶¶ 281–282.

359. *Apotex III*, Award, *supra* note 165, at ¶ 2.26.

360. *Apotex III*, ICSID Case No. ARB(AF)/12/1, U.S. Counter-Memorial (Dec. 14, 2012), available at <http://www.italaw.com/sites/default/files/case-documents/italaw1242.pdf>.

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lawful measure to prevent the import of adulterated medicines and ensure the safety of imported products in an increasingly globalized world. The U.S. also argued that domestic agencies such as the FDA are given discretion with regard to enforcement action because of its specialized expertise. The Tribunal noted that “[w]hen interpreting and applying the ‘minimum standard’, a Chapter 11 tribunal does not have an open-ended mandate to second-guess government decision making.”<sup>361</sup> But, while the Tribunal dismissed some claims on jurisdictional grounds, it did not find any breach of the substantive obligations of NAFTA Chapter 11.<sup>362</sup>

IP-related FET claims have raised a number of questions: does the grant of the patent by the host state constitute state representations which in turn create legitimate expectations the patent holder may rely upon?<sup>363</sup> Can an investor rely upon international intellectual property norms as a source of legitimate expectations?<sup>364</sup> Does investment treaty arbitration provide new means to enforce international intellectual property agreements?<sup>365</sup> What is the relationship between denial of justice claims and claims of judicial indirect expropriation?<sup>366</sup> The next subsections will address these questions.

1. *IP Rights as a Basis for Investor’s Legitimate Expectations?*

The grant of a patent does not confer absolute rights.<sup>367</sup> As Grosse Ruse-Khan points out, such conferral “certainly does not and cannot create any legitimate expectation that the exclusivity it confers is absolute and will remain without interference from accepted checks and balances inherent in the IP system.”<sup>368</sup> Not only does the international IP framework provide for commonly used regulatory controls on the utilization and exploitation of patents, and such tools should not be considered as a breach of FET, but patents are territorial in nature.<sup>369</sup> Therefore, it is within a host state’s competence to determine the patentability and scope of protection offered for patents granted pursuant to national law. Patents exist by virtue of legal recognition from the state. Moreover, intellectual property rights are not positive rights; rather they are negative rights, which prevent other competitors from exploiting a given invention for a limited time. They cannot prevent the states from regulating the use of such rights in the pursuit of legitimate public policy objectives.<sup>370</sup> Vice versa, if the host state had granted specific assurances to the investor

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361. *Apotex III*, Award, *supra* note 165, at ¶ 9.39.

362. *Id.* at ¶ 9.72.

363. Henning Grosse Ruse-Khan, *Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation 3* (Max Plank Inst. for Intellectual Prop. & Competition Law, Working Paper No. 2014/21), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2463711](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711).

364. *Id.*

365. See Gibson, *supra* note 72, at 397.

366. *Id.*

367. See Ruse-Khan, *supra* note 363, at 13.

368. *Id.*

369. *Id.* at 13-14 (referring to Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WTO Doc. WT/DS/174R (adopted Mar. 15, 2005) [hereinafter EC-Geographical Indications Panel Report]).

370. EC-Geographical Indications Panel Report, *supra* note 367, at ¶¶ 7.210, 7.246.

[T]he TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members

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regarding the exploitation of her investment in the host state, the adoption of new regulatory measures affecting the economic value of her investment might amount to a breach of fair and equitable treatment.<sup>371</sup>

2. *International IP Norms as a Source of Legitimate Expectations?*

In several investment arbitrations, investors claim that measures adopted by the host state and affecting their investments are illegal under a number of international IP agreements and therefore violate the fair and equitable treatment standard. They allege that as the host state is a party to international intellectual property agreements such as the TRIPS Agreement, the Paris Convention and the Patent Cooperation Treaty, they expect that the host state will not violate such agreements. For instance, Eli Lilly argues that “[t]he Government of Canada has a positive obligation to ensure Canadian law complies with Canada’s international treaty obligations, as well as the reasonable investment-backed expectations of the investor.”<sup>372</sup> Can investors legitimately expect that the host state complies with its international obligations? Or are these claims plainly outside the scope of protection of international investment treaties?

In *Eli Lilly v. Canada*, while the claimant contended that the possible violation of the TRIPS provisions constitutes a violation of the FET standard, the respondent argued that the Tribunal lacks jurisdiction over the question as to whether the host state complied with its obligations under international IP treaties.<sup>373</sup> As Grosse Ruse-Khan points out, “[w]ithout any explicit reference to such treaty obligations in an IIA, it appears difficult to assume that the IIA parties wished to interpret the FET standard in such a wide-ranging manner.”<sup>374</sup> In fact had the IIA parties wished to expand the subject matter jurisdiction of the Tribunal, arguably they would have included explicit reference to other international treaties. In addition, if the Arbitral Tribunal accepted such an extensive interpretation of the FET standard, there would be a conflict or overlap between the jurisdiction of the same Tribunal and other international courts, as the same dispute or related aspects of the same could be brought to two different dispute settlement systems. But the WTO dispute settlement mechanism has exclusive jurisdiction in settling disputes over breaches of WTO law.<sup>375</sup>

In any case, Canada also discusses the substantive provisions of the TRIPS Agreement, NAFTA Chapter 17 and the PCT to show that, in any event, it is in compliance with such instruments.<sup>376</sup> The key issue here is that international intellectual property treaties “include deliberate gaps, reflecting areas of non-convergence and the residual sovereignty of states to legislate specific rules.”<sup>377</sup> How countries achieve a competitive balance between public and private interests remains a national prerogative, provided that they comply with

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freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.

371. Ruse-Khan, *supra* note 363, at 14.

372. *Eli Lilly & Co.*, Notice of Intent, *supra* note 224, at ¶ 95.

373. *Eli Lilly & Co.*, Canada Statement of Defence, *supra* note 239, at ¶ 82.

374. Ruse-Khan, *supra* note 363, at 15.

375. DSU, *supra* note 116, Annex 2, art. 23.

376. *Eli Lilly & Co.*, Canada Statement of Defence, *supra* note 239, at ¶¶ 86-94.

377. Okediji, *supra* note 77, at 1132.

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their international obligations.<sup>378</sup> Yet, “it is well recognized that domestic implementation of international intellectual property standards will take distinctive twists across countries.”<sup>379</sup> As Okediji points out, “[o]ften countries calibrate across patentability standards to achieve net policy goals in specific sectors. The ultimate question is whether the inventor has provided enough in exchange for the patent grant.”<sup>380</sup> And, as Reichman explains:

[N]either TRIPS nor any other international agreement attempts to establish the substantive content of industrial applicability (utility), or for that matter, of novelty and non-obviousness. The reason is that there is no consensus on how to apply these doctrines: state practices differ. What we find here are open-ended standards, not rules, whose content continues to evolve over time.<sup>381</sup>

Analogously, other scholars have highlighted that the current international intellectual property regime is “by design, rooted in the disparate practices . . . of different nations. As such, non-uniformity pervades the very fabric of the TRIPS regime.”<sup>382</sup> Article 1.1 of TRIPS clarifies that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”<sup>383</sup> Moreover, Article 19.2 of the DSU provides that WTO panels and the Appellate Body (AB) “cannot add to or diminish the rights and obligations provided for in the covered agreements.”<sup>384</sup> WTO jurisprudence has confirmed this “space reserved for state sovereignty.”<sup>385</sup>

3. *A New Tool to Enforce International Intellectual Property Agreements?*

Can investment treaty arbitration constitute a new tool to enforce international intellectual property agreements? Can it provide investors with an alternative venue to challenge the consistency of domestic regulations with the TRIPS Agreement, instead of lobbying their governments to bring a WTO dispute? And if parallel proceedings are brought before the WTO dispute settlement mechanism and investment treaty arbitral tribunals respectively, will arbitral tribunals, WTO panels and the AB show any deference to the other dispute settlement mechanism? In some exceptional cases, foreign investors have attempted to use international investment law to indirectly protect other values by requiring a state to respect its international law obligations that are critical to the success of the investment.<sup>386</sup> For instance, a Canadian investor filed an investment treaty claim against Barbados for alleged failure to enforce its own environmental law implementing interna-

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378. *See id.* at 1132-33.

379. *Id.*

380. *Id.* at 1134.

381. Jerome Reichman, Compliance of Canada’s Utility Doctrine with International Minimum Standards of Patent Protection, Panelist Presentation at ASIL Panel Proceedings (April 11, 2014) (transcript available on p. 8 at [http://frederickabbott.com/sites/default/files/ASIL%20-%202014%20-%20FA-SS-JR%20consolidated\\_1.pdf](http://frederickabbott.com/sites/default/files/ASIL%20-%202014%20-%20FA-SS-JR%20consolidated_1.pdf)).

382. Anderson & Razavi, *supra* note 24, at 289.

383. TRIPS Agreement, *supra* note 5, art.1.1.

384. *Id.* art. 19.2.

385. Anderson & Razavi, *supra* note 24, at 289.

386. VALENTINA VADI, CULTURAL HERITAGE IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION 129-31 (2014).

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tional obligations.<sup>387</sup> As the investor acquired wetlands and subsequently developed them into an ecotourism facility, he claimed that Barbados had failed to prevent the discharge of raw sewage into the wetlands and to investigate or prosecute polluters, thus reducing the profitability of its investment.<sup>388</sup> The way this claim is formulated illustrates a novel form of interplay between international investment law and other branches of international law.

When adjudicating intellectual property-related investment disputes, the question arises as to whether arbitral tribunals can take into account and/or apply other bodies of law in addition to international economic law. Can a breach of the TRIPS Agreement provide basis for an independent claim in investment treaty arbitration? Investment treaty arbitral tribunals are of limited jurisdiction and cannot adjudicate on the eventual violation of international intellectual property law, unless the relevant investment treaty requires them to do so. In *Grand River v. United States*, the tribunal held that the fair and equitable treatment standard in NAFTA Chapter 11 “does not incorporate other legal protections that may be provided investors or classes of investors under other sources of law”—otherwise, the standard would become “a vehicle for generally litigating claims based on alleged infractions of domestic and international law.”<sup>389</sup> In another recent case,<sup>390</sup> the tribunal agreed with the Claimants that the applicable law “does not incorporate the universe of international law into the BITs or into disputes arising under the BITs.”<sup>391</sup>

Yet, when interpreting a treaty, the tribunal can take account of other international obligations of the parties according to customary rules of treaty interpretation as restated by the Vienna Convention on the Law of Treaties (VCLT).<sup>392</sup> Article 31.3(c) of the VCLT provides that there shall be taken into account, together with the context, any relevant rules of international law applicable in the relations between the parties.<sup>393</sup> That is how the intellectual property international obligations of states can be considered in the adjudication of disputes before arbitral tribunals.<sup>394</sup> The TRIPS Agreement can thus provide “interpretive background” to inform investment treaty standards.<sup>395</sup> In this manner, intellectual property obligations would not mean one thing under investment treaties and a completely different thing under trade or other international intellectual property agreements.<sup>396</sup>

Given their institutional mandate to settle investment disputes, there is a risk that investment treaty tribunals water down or overlook noteworthy intellectual property aspects. Arbitrators may be perceived as detached from local communities and their concerns. They may not have specific expertise in intellectual property law, as their ap-

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387. Peter A. Allard v. Barbados, UNCITRAL, Notice of Dispute (Sept. 8, 2009).

388. *Id.* at ¶ 16.

389. *Grand River Enter. v. United States*, UNCITRAL, Award, ¶ 219 (Jan. 12, 2011), available at <http://www.italaw.com/sites/default/files/case-documents/ita0384.pdf>.

390. *Bernhard von Pezold v. Zimbabwe*, ICSID Case No. ARB/10/15, Procedural Order No. 2, at ¶ 57 (June 26, 2012), available at <http://www.italaw.com/sites/default/files/case-documents/ita1044.pdf>.

391. *Id.* at ¶ 57.

392. Vienna Convention on the Law of Treaties, *supra* note 206, art. 31(3)(c).

393. *Id.*

394. For an analogous argument with regard to international cultural law, see Valentina Vadi, *Crossed Destinies: International Economic Courts and the Protection of Cultural Heritage*, 18 J. INT'L ECON. L. 51, 56 (2015).

395. Gibson, *supra* note 72, at 472.

396. Okediji, *supra* note 77, at 1136 (arguing that “[i]t simply cannot be the case that intellectual property obligations mean one thing under investment treaties and a completely different thing under trade agreements”).

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pointment requires expertise in international investment law. The “interpretative tradition” of arbitral tribunals has “its own language; way of speaking, expressing ideas, and defining problems and solutions.”<sup>397</sup> Arbitral tribunals have their own “inherited interpretative culture”—their own approach to reasoning with rules, a world of shared meanings.<sup>398</sup> Furthermore, due to the emergence of a *jurisprudence constante* in international investment law, there is a risk that tribunals will conform to these *de facto* precedents without necessarily considering analogous intellectual property-related cases adjudicated before other international courts and tribunals. This is not to say that consistency in decision-making is undesirable; obviously, it can enhance the coherence and predictability of the system contributing to its legitimacy. Yet, the selection of the relevant precedents matters as it can have an impact on the decision.<sup>399</sup>

Have arbitral tribunals paid any attention to the specificities of intellectual property? Are they imposing standards of good intellectual property governance, by adopting general administrative law principles, such as proportionality, due process, reasonableness and others? The critical assessment of such jurisprudence is a fertile endeavour as it may help in detecting common patterns, leading to the coalescence of general principles of law and/or customary law requiring an equilibrated balance between the protection of intellectual property and related investments on the one hand and public welfare on the other. While international investment law should not be used to enforce intellectual property law, this is not to say that arbitral tribunals can avoid dealing with intellectual property in some instances.<sup>400</sup>

4. *Denial of Justice Claims and Claims of Judicial Indirect Expropriation*

Another important issue raised by the parallel invocation of the fair and equitable treatment standard and the indirect expropriation provision is the interplay between denial of justice claims and claims of judicial expropriation.<sup>401</sup> Denial of justice does not occur if state courts made a mere error of law. Investment treaty tribunals are not an appeal mechanism for the decisions of domestic courts. Rather, denial of justice implies the failure of a national legal system as a whole to satisfy minimum standards of treatment. A number of arbitrations show that denial of justice is very difficult to prove and that rarely

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397. Vadi, *supra* note 53, at 176-77.

398. For an analogous argument with regard to the WTO Law, see Fiona Smith, *Power, Rules and the WTO*, 36 B.C. INT'L & COMP. L. REV. 1063, 1080 (2013) (“[I]n this ‘world’ . . . ideas from outsiders, like human rights and environmental scholars, about how WTO law should be regulated are often rejected as ‘wrong’ or misguided by trade lawyers and policymakers. These ideas often place the individual at the heart of the analysis and address her diverse and complex needs in ways that simply do not translate readily into the language of comparative advantage and trade liberalization. We should not really be surprised therefore when trade experts dismiss them as wrong or misguided, or when such ideas are castigated as ‘protectionist.’”).

399. See VALENTINA VADI, *ANALOGIES IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION* (2016).

400. For an analogous argument concerning trade law and human rights, see Christopher McCrudden, *International Economic Law and the Pursuit of Human Rights: A Framework for Discussion of the Legality of “Selective Purchasing” Laws under the WTO Government Procurement Agreement*, 2 J. INT'L ECON. L. 3, 47 (1999).

401. See generally Mavluda Sattorova, *Denial of Justice Disguised?: Investment Arbitration and the Protection of Investors from Judicial Misconduct*, 61 INT'L COMP. L. Q. 223 (2012); Mavluda Sattorova, *Judicial Expropriation or Denial of Justice? A Note on Saipem v Bangladesh*, 2 INT'L ARB. L. REV. 35 (2010). On denial of justice in general, see generally JAN PAULSSON, *DENIAL OF JUSTICE IN INTERNATIONAL LAW* (2005).

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has such a claim been successful. Moreover, to invoke denial of justice successfully, the claimant must exhaust local remedies first, giving the judicial system of the host state a chance to redress its failure before filing a claim before an investment treaty arbitral tribunal.<sup>402</sup>

By contrast, claims of judicial expropriation have not required exhaustion of local remedies.<sup>403</sup> For instance, the *Saipem* Tribunal found the host state responsible for expropriation resulting from the judicial intervention in arbitral proceedings dismissing the respondent's objection that the exhaustion of local remedies was a substantive condition for challenging judicial acts in investment arbitration. Rather, the tribunal clarified that the local remedies rule would apply in the case of denial of justice, but not in the case involving judicial expropriation.

The finding that a judicial expropriation has occurred precludes the successful invocation of denial of justice and, vice versa, the successful invocation of denial of justice precludes the successful invocation of judicial expropriation. Nonetheless, investors often make both claims as a matter of strategy. The claim of judicial expropriation can be easier to substantiate and can be more investor-friendly in terms of eventual compensation. Therefore, the emergence of this claim in the recent arbitral jurisprudence can affect the state judiciary autonomy in the pharmaceutical sector.

E. NON-DISCRIMINATION

The non-discrimination principle is a cornerstone of international investment law.<sup>404</sup> It is typically reflected in two investment treaty provisions: the principles of national treatment (NT) and most-favored-nation (MFN) treatment. The basic purpose of the MFN and NT clauses is to avoid discrimination and to guarantee equal competitive opportunities for foreign investors in the host state. These two standards do not guarantee a specific level of protection but are *relative* standards that require a host country to treat a foreign investor in the same way that a domestic investor or an investor from another country in like circumstances would be treated. In order to ascertain whether companies are in "like circumstances", one should first consider whether they are in the same sector and whether those comparators have been accorded more favorable treatment than the claimant. Then in order to ascertain whether there is improper discrimination or a legitimate distinction, one should consider the impact and objective of the given state measure in the particular field.<sup>405</sup>

In *Eli Lilly v. Canada*, the case relating to the invalidation of patents, the claimant also alleges that Canada denied the company national treatment.<sup>406</sup> First, the company contends that it faces more arduous patent standards in Canada than a Canadian investor might face in other jurisdictions, such as the United States and Europe.<sup>407</sup> Yet, this form of extraterritorial analogy is highly unusual in national treatment claims before arbitral

402. PAULSSON, *supra* note 401, at 130.

403. Sattorova, *Note on Saipem*, *supra* note 401, at 35-42; *idem.*, *Denial of Justice Disguised*, *supra* note 401, at 223-46.

404. Ruse-Khan, *supra* note 363, at 17.

405. *Id.* at 18.

406. *See Eli Lilly*, Notice of Intent, *supra* note 224, at ¶¶ 105-07.

407. *Id.* at ¶ 106.

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tribunals.<sup>408</sup> Second, the company argues that domestic generic pharmaceutical companies received more favorable treatment as they benefitted from the invalidation of the patent.<sup>409</sup> Third, the claimant highlights that only pharmaceutical companies bear the burden of the promise doctrine, rather than patent holders in other economic sectors. According to the claimants, the judicial decisions amount to *de facto* discrimination against pharmaceutical patents, contrary to the obligation not to discriminate among different fields of technology under Article 27(1) of the TRIPS Agreement. While the case is still pending, it can have a significant impact on access to medicines. In fact, if the arbitral tribunal upheld the claim of the investor, it would be more difficult for generic pharmaceutical companies to enter into the relevant market.

In *Apotex I*, the dispute concerning the approval for generic versions of antidepressant and anti-cholesterol medicines,<sup>410</sup> the claimant contended *inter alia* that the host state violated the non-discrimination provision by “failing to treat Apotex in the same fashion as US investors.”<sup>411</sup> As the case was dismissed on jurisdiction, the discrimination claim became moot. The significance of non-discrimination claims should not be understated. While, in some arbitrations, arbitral tribunals have upheld such claims as a distinct violation of the non-discrimination provision in the relevant BIT, in other cases, discrimination can constitute evidence of the breach of fair and equitable treatment, or be one of the relevant factors of unlawful expropriation.

In *Apotex III*, concerning an import ban on certain pharmaceuticals produced in Canada, Apotex contended that it had been discriminated against as comparable national and foreign manufacturers had received better treatment. According to the claimant, the FDA inspected a competitor’s facilities in Israel and found many violations. But it did not issue an import alert against the Israeli manufacturer. Therefore, according to the claimants, they were treated more severely than other comparable investors. The United States countered that manufacturers in the United States are subject to even more regular inspections and enforcement due to their location. With regard to foreign comparators, the U.S. rejects the idea that there should be a lowest common denominator when ensuring the health and safety standards of medicines.<sup>412</sup> The tribunal held that there was no violation of national treatment, as the claimant and the domestic competitors were not in “like circumstances.”<sup>413</sup> But, the Tribunal held that the U.S. had treated the Canadian company less favorably than other foreign companies.<sup>414</sup> According to the Tribunal, since the U.S. had *de facto* discriminated against the company, the claimants would prevail on their most-favored-nation claim, unless the U.S. could establish that it had legitimate reasons for the different treatment.<sup>415</sup> The Tribunal concluded that the FDA actions were “materially influenced by the FDA’s genuine concerns over shortages of essential drugs manu-

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408. Luke Eric Peterson, *U.S. Pharma Corp Puts Canada on Notice of NAFTA Claim Following Patent Invalidation at Hands of Canadian Court; More Such Claims in Wings?*, INV. ARB. REP. (Dec. 3, 2012) (“This unusual form of extra-territorial comparison is not commonly seen in National Treatment claims under investment treaties.”).

409. *Eli Lilly*, Notice of Intent, *supra* note 224 at ¶¶ 105-07. .

410. *Apotex I*, Notice of Arbitration, *supra* note 261, at ¶¶ 58-60.

411. *Id.* at ¶ 60(f).

412. *See Apotex III*, Award, *supra* note 165, at ¶ 3.28.

413. *Id.* at ¶ 8.57.

414. *Id.* at ¶ 8.62.

415. *Id.* at ¶ 8.65.

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factured” by the Israeli manufacturer.<sup>416</sup> Therefore the Tribunal concluded that since the companies were not in like circumstances, there was no discrimination.<sup>417</sup>

#### IV. Critical Assessment

What impact can these arbitrations have on the development of international law? These arbitrations raise important questions regarding the interplay between various international law regimes and international investment law. The outcomes of these arbitrations can shape the development of both international law and international investment law; and the relationship between the two.

In general terms, according to a range of international conventions protecting various aspects of IP and other international law instruments, states have the right and duty to adopt regulation governing pharmaceutical products.<sup>418</sup> The right to regulate is “an inherent power of sovereign States,” part and parcel of their sovereign prerogatives.<sup>419</sup> This is particularly the case with regard to public health which is a salient public value and lies at the heart of state sovereignty not only because of practical reasons—national authorities are better placed to appreciate local societies’ needs—but also because public health is central to the very existence of the state: population is recognized to be one of the constituting elements of statehood.<sup>420</sup> Therefore, protecting public health is a primary duty of states.<sup>421</sup> Inevitably, public health policy making is “highly political,” as what best serves the commonwealth may not always be in the interests of all its members.<sup>422</sup> In some circumstances, the protection and preservation of public health is not possible without constraining a wide range of private activities.<sup>423</sup> For instance, in early 2000, the U.S. FDA adopted rules that “created considerable unrest amongst international pharmaceutical companies.”<sup>424</sup> The FDA adopted “Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products . . . out of concern about the ‘Mad Cow Disease’ (BSE) that had erupted in the UK.”<sup>425</sup> Blood preparations processed by the pharmaceutical companies using blood from “donors who had spent more than six months in the UK between 1980 and 1986 could no longer be accepted in the US.”<sup>426</sup> Reportedly, “according to German scientists, the health risk posed by the targeted blood trans-

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416. *Id.* at ¶¶ 8.71, 8.73.

417. *Id.* at ¶ 8.77.

418. Chang-fa LO, *External Regime Coherence: WTO/BIT and Public Health Tension as an Illustration*, 7 ASIAN J. WTO & INT’L HEALTH L. & POL’Y 263, 276 (2012) (noting that “the host country has an inherent right to regulate”).

419. *Id.*

420. VADI, *supra* note 29, at 30.

421. *Id.*

422. LAWRENCE GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 6 (2008).

423. VADI, *supra* note 29, at 31.

424. Marco C. E. J. Bronckers, *More Power to the WTO?*, 4 J. INT’L ECON. L. 41, 42 (2001).

425. *Id.*; see U.S. Food & Drug Admin., *Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products* 1, (Jan. 2002), <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory-Information/Guidances/Blood/ucm074089.htm>.

426. Bronckers, *supra* note 424, at 42.

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fers was ‘theoretical’” and the regulation lacked scientific basis.<sup>427</sup> But, other countries followed the example.<sup>428</sup>

While the industry often asserts that economic principles militate against state interference, public health has historically constrained the rights of individuals and businesses so as to prevent nuisance.<sup>429</sup> At the same time there is a risk that governmental authorities abuse their authority and unnecessarily infringe upon investor rights.<sup>430</sup> The question is whether measures limiting pharmaceutical companies’ ability to fully exploit their patents comply with the relevant provisions of international investment agreements. While commentators have noted that “[f]or a long time, the practical relevance of the IP and investment overlap seemed negligible,” this is no longer the case.<sup>431</sup> Rather, a number of arbitrations have emerged where investors have challenged host state measures affecting pharmaceutical patents, contending that these various regulatory measures amounted to breaches of the relevant investment treaty provisions. In this context, treaty making and interpretation play a crucial role.

Some international investment agreements expressly clarify that the exercise of state regulatory autonomy in the pharmaceutical sector does not per se amount to a breach of investment treaty provisions. For instance, the U.S. Model BIT of 2012 states that:

This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the TRIPS Agreement.<sup>432</sup>

Analogously, Article 6.5.6 of the Singapore-India FTA reads:

This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights to the extent that such issuance, revocation, limitation or creation is consistent with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights.<sup>433</sup>

These provisions require interpretation of the TRIPS Agreement. “Failure to comply with the TRIPS Agreement” provisions “would result in the expropriation clause remaining applicable.”<sup>434</sup>

Yet, the issuance of compulsory licenses, or the creation, limitation, or revocation of intellectual property rights is regulated only in very broad brushes by the TRIPS Agreement. For instance, with regard to the creation of patents, some fields can be excluded

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427. *Id.*

428. *Id.*

429. VADI, *supra* note 29, at 31.

430. *Id.*

431. Ruse-Khan, *supra* note 363, at 2.

432. Model Bilateral Investment Treaty, art. 6(5) (2012), available at <https://ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf>.

433. Agreement Between the Government of the Republic of Korea and the Government of Japan for the Liberalisation, Promotion and Protection of Investment, Japan-Korea, art. 6.1, March 22, 2002, Treaty No. 17 and Ministry of Foreign Affairs Notification No. 430

434. Mercurio, *supra* note 76, at 905.

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from patentability and the question of what deserves to be patented is left for countries to determine. For example, to protect public order or morality, plants, animals and methods for treatment of humans or animals are matters that can be excluded. The TRIPS Agreement only requires that patents should be granted for new, inventive and useful inventions—but it does not define these terms.<sup>435</sup> Deciding whether a new formulation (producing a pill version of a drug that formerly came as a powder, for instance), or a new combination (combining two or more existing molecules into a new pill), or a new use of a medicine deserves a new twenty-year patent for example is a prerogative of states and is not determined by the TRIPS Agreement. Countries can therefore determine what kinds of inventions deserve patents in the area of pharmaceuticals, in light of their own social and economic conditions.<sup>436</sup> During the patent lifespan, the enjoyment of intellectual property rights by the patent owner is not absolute: certain rules provide for limited exceptions and other uses of the patent without the patent owner's consent.<sup>437</sup> With regard to revocation, the TRIPS Agreement only requires member states to provide judicial review for every decision to revoke a patent.<sup>438</sup> Traditionally, patents can be revoked for lack of use, lack of payment of annual fees or abuse of dominant position. More recently, several developing and least developed countries—being depositaries of mega biodiversity—have enacted legislation to prevent biopiracy according to which noncompliance with disclosure of origin rules leads to the revocation of a patent.<sup>439</sup>

In this scenario, “TRIPS consistency is tested in proceedings outside the (state-to-state) WTO dispute settlement” mechanism.<sup>440</sup> While WTO jurisprudence can provide some guidance, only a limited number of IP-related disputes have been brought before the WTO.<sup>441</sup> Therefore, the arbitrations examined above can pave the way to subsequent WTO decisions. But there is no binding precedent in international law, and both WTO panels and arbitral tribunals are not bound to follow “precedents” of other jurisdictions.<sup>442</sup>

The TRIPS Agreement expressly presents clauses regulating the interface between public health protection and intellectual property. Notoriously, Article 7 of the TRIPS Agreement provides that:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.<sup>443</sup>

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435. See TRIPS Agreement, *supra* note 5, art. 27(1).

436. See TRIPS Agreement, *supra* note 5, art. 27(1)-(2).

437. See *id.*, art. 27.

438. *Id.*, art. 32.

439. Antonietta Di Blase, *Traditional Knowledge: Cultural Heritage or Intellectual Property Right?*, in *CULTURE AND INTERNATIONAL ECONOMIC LAW* 145, 157 (Valentina Vadi & Bruno De Witte eds., 2015).

440. See Ruse-Khan, *supra* note 363, at 19 (highlighting the risk that “the interpretative result may well be different from the result achieved in a ‘pure’ WTO setting”).

441. *Id.* at 20; see generally Pauwelyn, *supra* note 114.

442. See VADI, *supra* note 117 (pinpointing that although there is no binding precedent in international law, both WTO panels and arbitral tribunals are not bound to follow “precedents” of other jurisdictions, they refer to each other's jurisprudence.).

443. TRIPS Agreement, *supra* note 5, art. 7.

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In parallel, Article 8 of the TRIPS Agreement states that:

Members may, in formulating or amending their laws and regulations, 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>444</sup>

Such provisions are not exceptions but set forth as fundamental principles of IP governance that need to be taken into account when interpreting the Agreement as a whole. The mentioned provisions provide space for reconciliation between private and public interests in IP regulation. But Article 8 of the TRIPS Agreement imposes some limits.<sup>445</sup> In particular, the measures to be adopted need to be consistent with the TRIPS Agreement.<sup>446</sup> Prima facie, this clause might be interpreted as giving precedence to intellectual property over other interests. However, a closer reading suggests that it merely requires taking the whole agreement into account. The Doha Declaration on the TRIPS Agreement and Public Health has further reinforced state regulatory space to adopt public health measures.<sup>447</sup> As WTO members have experienced difficulties in reconciling patent protection with access to essential medicines, the Doha Declaration on the TRIPS Agreement and Public Health recognized the WTO members' right to protect public health and to use the flexibilities provided by the TRIPS Agreement.<sup>448</sup> Where clear reference is made to the TRIPS Agreement, international investment agreements incorporate TRIPS, Articles 7 and 8, entitled "Objectives" and "Principles" respectively, as well as the relevant interpretative background provided by the Doha Declaration. They then become applicable and may provide guidance in the context of investment disputes.

In some cases, the investment chapters of U.S. FTAs do not refer to compliance with TRIPS as a safeguard against expropriation claims. Rather they refer to compliance with their own IP chapters.<sup>449</sup> For instance, Article 1110(7) of NAFTA exempts "the issuance of compulsory licensing" and "the revocation, limitation or creation of intellectual property rights" from expropriation protection, if such measures are consistent with NAFTA Chapter 17 governing intellectual property.<sup>450</sup> NAFTA Chapter 17 contains "TRIPS-plus" provisions on intellectual property rights, which strengthen the intellectual property regimes of NAFTA countries beyond the global standards established by the TRIPS Agreement. For instance, NAFTA Chapter 17 does not include provisions analogous to

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444. *Id.*, art. 8.

445. See TRIPS Agreement, *supra* note 5, art. 8.

446. *Id.* at art. 8(1).

447. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

448. *Id.* at ¶ 4 ("We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we affirm the right of WTO members to use, to the full, the provisions of the TRIPS Agreement which provide flexibility for this purpose."). For commentary, see Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L ECON. L. 469, 493 (2002).

449. See Ruse-Khan, *supra* note 363, at 19.

450. NAFTA, *supra* note 74, art. 1110(7)

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Articles 7 and 8 of the TRIPS Agreement. But Article 1709, which governs patents, includes a number of flexibilities which also appear in the TRIPS Agreement as NAFTA Chapter 17 was based on a draft of the TRIPS Agreement.<sup>451</sup> For instance, states can exclude certain inventions from patentability, introduce limited exceptions and compulsory licenses, as well as revoke the patents.<sup>452</sup>

In more recent agreements, parties have appended declarations clarifying the interplay between the expropriation provision (included in the investment chapter) and various IP provisions (included in the relevant chapter). For instance, in the Canada–EU Comprehensive Economic and Trade Agreement (CETA), the parties appended a declaration to the expropriation provision of Chapter X, which governs foreign direct investment.<sup>453</sup> The declaration clarifies 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>454</sup> The Parties reasserted that “each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement regarding intellectual property within their own legal system and practice.”<sup>455</sup> The parties also reserved the possibility to issue binding interpretations at a later stage.<sup>456</sup> Moreover, Article 3 of Chapter 22, which governs intellectual property, refers to the Doha Declaration.<sup>457</sup>

In most cases, however, bilateral investment treaties make no reference to the TRIPS Agreement. In the absence of an express reference to the TRIPS Agreement, can arbitral tribunals assert jurisdiction to define the obligations that the host state has entered into under the TRIPS Agreement and, for that purpose, to interpret the provisions of that agreement? Unless the applicable BIT refers to the TRIPS Agreement, providing investors with the possibility of asserting violations of the TRIPS Agreement against host states

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451. See Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, ¶ 4.6, WTO Doc. WT/DS114/R (Apr. 7, 2000) (“While the Uruguay Round negotiations were somewhat in limbo in 1991/1992, the negotiations on a North American Free Trade Agreement (NAFTA) between Canada, Mexico and the United States of America were concluded in 1992 and the agreement was signed at the end of 1992. NAFTA contained in Chapter Seventeen extensive disciplines on the protection of intellectual property rights. The provisions of Chapter Seventeen were largely based on, and in many instances were a verbatim reproduction of, the provisions of the then draft TRIPS Agreement. Article 31 of the TRIPS Agreement was reproduced almost identically in Article 1709(10) of NAFTA.”).

452. NAFTA, *supra* note 74, arts. 1706(10), 1706(6), 1706(10), 1706(8).

453. Canada–EU Comprehensive Economic and Trade Agreement (CETA), Sept. 24, 2014 (not yet in force).

454. *Id.*, art. X.11, ¶ 6.

455. *Id.*

456. *Id.* (“The Parties agree to review the relation between intellectual property rights and investment disciplines within 3 years after entry into force of the agreement or at the request of a Party. Further to this review and to the extent required, the Parties may issue binding interpretations to ensure the proper interpretation of the scope of investment protection under this Agreement in accordance with the provisions of Article X.27: Applicable Law and Rules of Interpretation of Chapter x (Investment).”).

457. See CETA, *supra* note 453, at ch. 22, art. 3 (recognizing “the importance of the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the World Trade Organisation,” and providing that “In interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with this Declaration” and that “The Parties shall contribute to the implementation and respect the Decision of the WTO General Council of 30 August 2003 on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as well as the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005”).

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would be a “radical departure” from the text of the BIT and the Dispute Settlement Understanding of the WTO.<sup>458</sup> As Gibson points out, “[s]hould a country fail to fulfill its TRIPS Agreement obligations, the WTO’s dispute-settlement mechanism . . . provides procedures for the resolution of state-to-state disputes arising from non-compliance.”<sup>459</sup> In the absence of a reference to the TRIPS Agreement in the text of the relevant BIT, the argument that investors can challenge state measures on the basis of the TRIPS Agreement proves to be too much. A state’s violation of the TRIPS Agreement cannot provide a basis for an independent claim under the relevant BIT in investor–state arbitration.

But this does not mean that the TRIPS Agreement is irrelevant. The TRIPS Agreement can provide interpretive guidance and context.<sup>460</sup> If the applicable law is national law—as is the case for intellectual property which is territorial in nature—and national law implements the TRIPS Agreement, the interpretation of the relevant TRIPS provisions may help the arbitral tribunal to ascertain the legitimacy of the same state measures, their rationality and reasonableness, and their eventual conformity with international practice. In turn, this could foster a coherent international framework of IP rules.

Arbitrators have a maieutic role, as they give birth to the meaning of treaty provisions, having to identify the applicable rules, clarify their meaning and relate them to the specific facts of the case. Their expertise on intellectual property may be limited. But experts and amici curiae may be consulted to facilitate sound decision-making.<sup>461</sup> In any case, arbitrators must be mindful of the two equilibria that characterize IP regulation. While the intrinsic equilibrium concerns the very structure or architecture of IP norms, the extrinsic equilibrium indicates the search for balance between IP and other norms. The intrinsic equilibrium is evident in the conceptual matrix of certain norms of the patent regime. These provisions do not forbid limitations to intellectual property *tout court*, but give a certain margin of appreciation to policy makers and adjudicators to determine what a lawful delimitation is.

In parallel, the extrinsic equilibrium appears in the interplay between the intellectual property regime and other fields of law. If one adopts an instrumentalist view of intellectual property, the international IP system should function for the good of all. The notion that intellectual property regime serves a social function is widely accepted in international law, as expressly indicated by Articles 7 and 8 of the TRIPS Agreement.<sup>462</sup> In scrutinizing the complex regime that governs intellectual property, it appears that intellectual property is never absolute.<sup>463</sup> Rather, intellectual property rights must be put into

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458. See Charles Owen Verrill, *Are WTO Violations also Contrary to the Fair and Equitable Treatment Obligations in Investor Protection Agreements?* 11 ILSA J. INT’L & COMP. L. 287, 288-89 (2005).

459. See Gibson, *supra* note 72, at 422.

460. Gaetan Verhoosel, *The Use of Investor-State Arbitration Under Bilateral Investment Treaties to Seek Relief for Breaches of WTO Law*, 6 J. INT’L ECON. L. 493, 503-06 (2003).

461. See, e.g., *Eli Lilly v. Canada*, Case No. UNCT/14/2, Procedural Order No. 4 (Feb. 23, 2016), available at <http://www.italaw.com/sites/default/files/case-documents/italaw7145.pdf> (accepting the intervention of selected amici curiae, including IP professors).

462. 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 INST. FOR INTELL. PROP. & COMP. L., Research Paper No. 13-06 (2013).

463. *Id.*, at 5 (“[T]here cannot be an ‘absolute’ right that can be exercised in a totally selfish manner with no consideration for the consequences that this exercise involves, but only rights that are ‘relativized’ by the rights of others and the well-being of the community.”).

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perspective, as they are part of a broader legal system.<sup>464</sup> They “must always be harmonized with other rights of equally significant value and with the interests of the community”.<sup>465</sup> According to Professor Gervais, “one should not protect beyond what is necessary to achieve policy objective(s) because the risk of a substantial general welfare impact is too high.”<sup>466</sup> Similarly, Professor Cornides points out that “property is not an end in itself. Obviously, it must be used in a way that contributes to the realisation of the higher objectives of human society.”<sup>467</sup>

Can the TRIPS Agreement provide arbitral tribunals with some interpretive context? Certainly, pursuant to Article 31(3)(c) of the VCLT, adjudicators should take into account “any relevant rules of international law applicable in the relations between the parties.”<sup>468</sup> Therefore, “[e]very treaty provision must be read not only in its own context, but in the wider context of general international law, whether conventional or customary.”<sup>469</sup> A number of international organizations play an active role in the governance of pharmaceutical patents, creating a sort of institutional density or regime complex.<sup>470</sup> As all these organizations receive almost worldwide consensus, a broader perspective of the legal environment which surrounds a given dispute should be adopted in investor–state arbitration.<sup>471</sup> In particular, the TRIPS Agreement can provide interpretive context for investment disputes.<sup>472</sup> In this sense, arbitrators should acknowledge their responsibility for the charting of the contours of international law norms and, more broadly, as cartographers of the international legal order.

### Conclusion

Pharmaceutical patent-related investment disputes constitute a new and uncharted development of the increasingly complex and contested interplay between international investment law and other fields of public international law. A tension can arise between the protection of investor’s rights and state regulatory autonomy. In some circumstances, the excessive protection of investors’ rights may have negative effects on public health. There is a risk that the protection of pharmaceutical patents provided by investment treaties over-emphasizes the private interest and neglects the public interest equally embodied in intellectual property. Is international investment law a self-contained regime, or is it a component of public international law? Should it be responsive to other areas of international law?

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464. *Id.* at 4.

465. *Id.*

466. Daniel J. Gervais, *The Changing Landscape of International Intellectual Property*, in *INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS* 49, 60 (Christopher Heath & Anselm Kamperman Sanders eds., 2007) (cautioning that “one should not protect beyond what is necessary to achieve policy objective(s) because the risk of a substantial negative general welfare impact is too high”).

467. See Jakob Cornides, *Human Rights and Intellectual Property: Conflict or Convergence?* 7 *J. WORLD INTEL. PROP.* 135, 143 (2004).

468. Vienna Convention on the Law of Treaties, *supra* note 206, art. 31(3)(c).

469. IAN SINCLAIR, *THE VIENNA CONVENTION ON THE LAW OF TREATIES* 139 (1984).

470. *Id.*

471. *Id.*

472. Verhoosel, *supra* note 460, at 503.

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The new dialectics between intellectual property and public health in patent-related investment treaty disputes confirms the idea that investment treaty arbitration is a form of governance, and raises two different issues: 1) the extent to which investment governance can take into account public interests; and 2) regime collision between different areas of international law. International investment law and arbitration views the interrelationship between private corporate actors and the host state as a central issue, and contributes to building up the international legal status of private actors. At the same time, the proliferation of international investment agreements and the tremendous success of investment arbitration as a dispute settlement mechanism raise questions as to whether investment governance is an autonomous system or a component of public international law. Combined, these two dynamics raise far-reaching issues. Can investment treaty arbitration uphold/reinforce national policies giving effect to the aims and content of international law in fields tangential to investment law, such as international health law or human rights law? To the extent that investment treaty arbitration declines to do so, deemphasizes these policies and leaves them to one side, this is problematic for moving forward globally important policy issues through the vehicle of public international law.

This article suggests that international investment law and arbitration should be considered an important emerging part of public international law and should retain the ideal of public international law as we know it, as a unitary whole, built on inter-state relations, and intended to further the common good internationally. Against this theoretical background, this article submits that interpretation can supply a mechanism for balancing IP rights against other values. Arbitrators should focus on the nature and purpose of that which is being protected. Intellectual property rights should not be considered as absolute rights, but should be interpreted in the light of their goals and limits. Regulations adopted to protect public health and a range of human rights, depending on the specific circumstances of the case, might be viewed as an intrinsic limit to the rights associated with intellectual property. Foreign investments, including pharmaceutical patents, should not be considered an end in itself, but as one of the available tools to promote human welfare. Whether arbitrators shall adopt a holistic approach to public health related IP disputes, as directed by customary rules of treaty interpretation, remains to be seen.