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TOWARDS A NEW DIALECTICS: PHARMACEUTICAL
PATENTS, PUBLIC HEALTH AND FOREIGN DIRECT
INVESTMENTS

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This article highlights the emergence of a new dialectics between the protection of intellectual property and public health in international investment law and arbitration. International investment law is a vital area of international law, which has furthered the protection of intellectual property, considering it a form of investment and providing intellectual property owners access to investor-state arbitration. 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 their role as “cartographers” of international law within their role as “adjudicators.” Have arbitral tribunals taken public health considerations into account when adjudicating pharmaceutical patent-related cases? If so, have they considered public health either 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 public health law? This article offers a primer on recent investment disputes concerning pharmaceuticals. The underlying assumptions of this article are that adjudication is a mode of governance, and it has a fundamental importance with regard to the concrete implementation of a given legal regime. The article argues that arbitrators

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should not put an 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.

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INTRODUCTION

In nature we never see anything isolated, but everything in connection with something else...

Johann Wolfgang von Goethe¹

In recent years, international investment agreements (IIAs)² have flourished, furthering the protection of intellectual property (IP) as a form of

¹ Johann Peter Eckerman, *Conversations of Goethe with Eckermann and Soret* 266, 266-67 (John Oxenford trans., Smith, Elder & Co. 1850).

² International investment agreements (IIAs) – a term encompassing both bilateral investment treaties (BITs) and Free Trade Agreements (FTAs) or Regional Trade Agreements (RTAs) with investment chapters – are “agreements concluded between states

investment.³ In general terms, most bilateral investment treaties (BITs) only refer to IP rights in their definitions of protected investments.⁴ These treaties do not provide a detailed and specific regulation of IP rights. However, they do formally and substantively raise the level of IP protection from the pre-treaty status. In fact, by considering IP rights as protected investments, BITs enable IP holders to enjoy the substantive and procedural protections of foreign investments provided by the applicable treaty. Substantive protections granted by IIAs include fair and equitable treatment, national and most favoured nation treatment and protection against unlawful expropriation, among others.⁵

Besides providing substantive protection to investors' rights, investment treaties also provide IP owners with direct access to investor-state arbitration, which can be a powerful dispute settlement mechanism to resolve claims of alleged IP infringement.⁶ This is a novel development in international law because investors are no longer required to exhaust local remedies or depend on diplomatic protection to defend their interests against the host state. The claims are heard by *ad hoc* arbitral tribunals whose arbitrators are selected by the

for the promotion and protection of reciprocal investments." See Bertram Boie, *The Protection of Intellectual Property Rights Through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?* 4 (NCCR Trade Regulation, Working Paper No. 2010/19, 2010).

³ See, e.g., State Dep't, U.S. Model Bilateral Investment Treaty, art. 1 (2012) [hereinafter US Model BIT] (listing "intellectual property rights" among the "forms that an investment may take"); Treaty Concerning the Encouragement and Reciprocal Protection of Investments, Ger.-Burundi, art. 1(d), Sept. 10, 1984, 1517 U.N.T.S. 287 [hereinafter Germany-Burundi BIT] (noting that "[f]or the purposes of the present treaty, the term 'investments' shall comprise every kind of asset, in particular . . . [c]opyrights, industrial property rights, technical processes, trademarks, trade names, know-how and goodwill . . ."); Agreement Concerning the Encouragement and Reciprocal Protection of Investments, Peru-China, art. 1(d), June 9, 1994, 1901 U.N.T.S. 257 (affirming that "[f]or the purpose of this agreement, the term 'investment' means every kind of asset invested by investors of one Contracting Party in accordance with the laws and regulations of the other Contracting Party in the territory of the Latter, and in particular, though not exclusively, includes: . . . copyrights, industrial property, know-how and technological process . . .").

⁴ FTAs, however, can include both investment and IP chapters and provide a detailed regulation of IP, tightening their protection beyond current international standards. See Susan K. Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28 LIVERPOOL L. REV. 41, 41 (2007) (highlighting that pharmaceutical companies have "succeeded in getting extremely restrictive TRIPS-Plus . . . intellectual property provisions into regional and bilateral free trade agreements."). On the impact of FTAs on access to medicines, see generally Carlos María Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 BULL. WORLD HEALTH ORG. 399, 399 (2006).

⁵ ANDREAS KULICK, *GLOBAL PUBLIC INTEREST IN INTERNATIONAL INVESTMENT LAW* (2012); see, e.g., US Model BIT arts. 3–7; see also Germany-Burundi BIT, *supra* note 3, at arts. 2–3, 4(2).

⁶ See, e.g., US Model BIT art. 2.

disputing parties or appointing institutions. Depending on the arbitral rules chosen, the proceedings occur behind closed doors (*in camera*) and the very existence of the claim and the final award may never become public.⁷

These arbitrations have recently been used by patent owners to challenge alleged infringements of their patents by measures of the host state.⁸ Arbitral tribunals have scrutinized how domestic legal systems govern the availability, validity and scope of patents.⁹ These arbitrations have involved “difficult and often elusive substantive questions” of intellectual property law,¹⁰ and can affect a range of important public policy issues, such as public access to medicines.

Despite the important social and political implications, investment treaty arbitration is lacking in transparency, expertise, and arguably, legitimacy.¹¹ Most arbitral tribunals are neither open to the public nor obliged to publish final decisions, and hence 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, as they are mostly experts in international investment law. There are even disputes over whether or not norms external to investment law, such as IP law, should be relevant in investment treaty arbitration. Finally, according to some authors, investment treaty law and arbitration face a “legitimacy crisis” as arbitral awards seem to affect public policy “in a vacuum.”¹² While arbitral tribunals consider important public policy issues, they are detached from the local polities’ needs. Have IIAs “become a charter of rights for foreign investors, with no concomitant responsibilities or liabilities, no direct legal links to

⁷ Kate Miles, *Reconceptualising International Investment Law: Bringing the Public Interest Into Private Business*, in INTERNATIONAL ECONOMIC LAW AND NATIONAL AUTONOMY 295, 295–96 (Meredith Kolsky Lewis and Susy Frankel eds., 2010) (noting that “[a]lthough [investment disputes] resolve questions that can affect significant matters of public policy, the public generally does not have access to the documents, the proceedings are conducted behind closed doors, and the submission of amicus curiae briefs is restricted, if permitted at all.”).

⁸ See *infra* Parts III and IV below for a comprehensive account of the current investor-state arbitrations of pharmaceutical patents.

⁹ Christine Haight Farley, *TRIPS–Plus Trade and Investment Agreements: Why More May Be Less for Economic Development*, 35 U. PA. J. OF INT’L L. 1061, 1065 (2014) (stating that arbitral tribunals review state regulatory and judicial measures “for how they define the availability, validity and scope of IP rights”).

¹⁰ *Id.* (noting that “IP law is notoriously full of grey areas due to finely balanced policy objectives . . .”).

¹¹ See, e.g., Susan Franck, *The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521, 1537–38 (2005) (discussing the alleged legitimacy crisis of international investment law and arbitration).

¹² See *id.* at 1571.

promoting development objectives, and no protection for public welfare in the face of environmentally or socially destabilizing foreign investment?”¹³ Has international investment law become a “corporate bill of rights”¹⁴ or a “system of corporate rights without responsibility”?¹⁵

Recent examples illustrate that investor-state arbitration can affect state autonomy in making important public policy decisions in the pharmaceutical sector, including making cheap generic medicines widely available and ensuring their safety. In 2008, Apotex, a Canadian company, filed an investor-state arbitration against the United States, claiming that the U.S. courts had erred in applying federal law violating several provisions of the North American Free Trade Agreement (NAFTA).^{16, 17} According to the claimant, the erroneous application of the law prevented Apotex from commercializing generic versions of medicines, and this amounted, *inter alia*, to an expropriation of its investments.¹⁸ In a parallel dispute,¹⁹ the company 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 were produced in Canada, then exported to the U.S. and sold by a U.S.-based Apotex subsidiary.²⁰ The FDA issued the alert after its inspections of Apotex facilities in Canada found noncompliance with good pharmaceutical manufacturing practices.²¹ In parallel, Eli Lilly, a major U.S. pharmaceutical company, filed an investor-state arbitration against Canada after Canadian Federal Courts invalidated a pharmaceutical patent on the ground of inutility.²² Eli Lilly requested the Tribunal award economic compensation of at least 100 million

¹³ United Nations Conference on Trade and Development, Nov. 6–8, 2002, *The Development Dimension of FDI: Policy and Rule-Making Perspectives*, 212, UNCTAD/ITE/IIA/2003/4 (Aug 31, 2003) [hereinafter UNCTAD].

¹⁴ Todd Weiler, *Balancing Human Rights and Investor Protection: A New Approach for a Different Legal Order*, 1 TRANSNAT'L DISP. MGMT. 2 (2004).

¹⁵ UNCTAD, *supra* note 13, at 215.

¹⁶ North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA].

¹⁷ Apotex Inc. v. U.S., ICSID Case No. ARB(AF)/12/1, Notice of Arbitration, ¶ 22 (Dec. 10, 2008), <http://www.state.gov/documents/organization/115447.pdf>.

¹⁸ *Id.* ¶ 7.

¹⁹ Apotex Holdings Inc, Apotex Inc. v. United States of America (Apotex III), ICSID Case No. ARB(AF)/12/1, Award (Aug. 25, 2014), <http://www.state.gov/documents/organization/233043.pdf>.

²⁰ *Id.* ¶ 2.24.

²¹ *Id.* ¶ 2.40.

²² Eli Lilly and Company v. The Government of Canada (U.S. v Can.), ICSID Case No. UNCT/14/2, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven, ¶ 35 (Nov. 7, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

Canadian dollars for alleged damages.²³ Not only do these cases show the clash between the national regulatory measures of the states to regulate IP in the public interest on the one hand and international investment law on the other, but they also highlight the emergence of a new form of dialectics between the private and public interests in IP governance at the international level.

Have arbitral tribunals taken public health considerations into account when adjudicating pharmaceutical patent 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? Can investment treaty arbitration promote good governance in the pharmaceutical field? Is there a convergence or a divergence between international investment law and other branches of international law governing pharmaceuticals? Are there mechanisms to promote coherence? And is such coherence ultimately desirable?

This article addresses these questions, providing a comprehensive account of current investment treaty arbitrations, highlighting their significance for global intellectual property governance. It shows that investment arbitration serves as a new avenue for the ongoing dialectics between private and public interests in IP regulation. Conflicts between private and public interests are endemic in IP regulation. These take the form of disputes before various tribunals at the national, regional and even international levels. Investment treaty arbitration constitutes a new avenue for settling IP disputes. Far from being a neutral development of the increasing pervasiveness of international law in different areas of regulation, the attraction of IP disputes by investment treaty tribunals have the potential to revolutionize the current landscape of IP governance.

While a dialogue between public and private interests is intrinsic to any form of regulation and dispute resolution of IP rights, what is new in the emerging IP-related investment disputes is the articulation of *private* economic interests by *private transnational* actors against *public national* entities before *international* tribunals. In fact, while traditionally international law has only enabled states to file claims before international courts and tribunals, international investment law has empowered foreign investors to file claims against states before international tribunals. This development has the potential

²³ *Id.* ¶ 108.

revolutionize IP governance at the national and international levels.²⁴ On the one hand, investment arbitration provides a valuable avenue for foreign investors to be heard. Although a private investor could complain through its home state, inter-state disputes concerning IP have been rare, mainly because states are careful not to initiate proceedings and advance arguments that may backfire in the future.²⁵ Investor-state arbitration enables nongovernmental actors such as multinational corporations to directly file claims against states before international tribunals. On the other hand, eminent scholars warn against potential abuse of this mechanism,²⁶ as investment arbitration could emphasize private interests at the expense of the public interest. Non-state actors may adopt a different approach to litigation than state actors. They may strategically use investment arbitration to receive monetary compensation for state regulatory action,²⁷ and simply by filing an arbitration claim, they may have a chilling effect on domestic policy makers. The emerging dialectics between private actors and states in investment arbitration needs to be scrutinized given the public policy implications it can have on crucial areas of IP governance.

The tension between patent holders and state authorities in the governance of pharmaceutical patents is one example of a broader recurrent interplay in international law: the tension between the private interests of foreign investors and the regulatory autonomy of the host state. This article argues that arbitrators should not put excessive emphasis on the private interests in pharmaceutical patents, but must pay adequate consideration to the public interest equally embodied in these rights. Excessive protection of pharmaceutical patents can have a negative impact on the public health policy of the host state. This may seem paradoxical, as usually the protection of

²⁴ M. Sornarajah, *Evolution or Revolution in International Investment Arbitration? The Descent into Normlessness*, in *EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION* (Chester Brown and Kate Miles eds., 2011) [hereinafter Sornarajah, *Evolution or Revolution*] (arguing that “disparate trends” in international investment law and arbitration “show neither evolution nor revolution but an ongoing conflict [between private and public interests] that either will bring a new system – resulting in a revolution – or will keep the old, simply because one or the other of the camps wins the tussle.”).

²⁵ See Joost Pauwelyn, *The Dog that Barked but did not Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1 J. INT’L DISP. MGMT. 389, 393, 395 (2010) (showing that IP complaints amount to only 3 per cent of all claims under the World Trade Organization agreements, and that such disputes have a higher settlement rate and lower appeal rate than average WTO disputes).

²⁶ See Sornarajah, *Evolution or Revolution*, *supra* note 24, at 631 (arguing that “the law is hurtling into ‘normlessness’ as a result of State reactions to expansive interpretations placed on treaty prescriptions.”).

²⁷ See Pauwelyn, *supra* note 25, at 41 (explaining both the low number and the systemic type of IP disputes by the limited prospective remedies that the WTO offers to the winning complainants).

pharmaceuticals is associated with higher investments in the research and development of new medicines, and a corresponding broader availability of medicines that lead to positive effects on patient welfare. However, in some cases, corporations have used intellectual property to chill public health regulation. 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 their role as “cartographers” of international law.

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. Third, it illustrates the rise of investor-state arbitrations concerning pharmaceuticals. Fourth, it highlights the emergence of a new dialectics between intellectual property and public health in international investment law and arbitration, examining recent investment disputes concerning pharmaceuticals. Fifth, it critically assesses the potential impact of such arbitrations on the public health policies of the host state, and proposes some legal mechanisms that can help adjudicators to strike a suitable balance between the protection of pharmaceutical patents and public health in international investment law and arbitration.

I

PHARMACEUTICAL PATENTS AND PUBLIC HEALTH IN INTERNATIONAL LAW

The patent system is based on a trade-off between promoting knowledge creation and knowledge diffusion.²⁸ A patent is a type of intellectual property constituting a set of exclusive rights granted by a state for a limited period of time in exchange for detailed public disclosure of an invention.²⁹ Patents are granted for inventions that are: (1) new, (2) nonobvious (involving an inventive step), and (3) capable of industrial application (useful).³⁰ In the pharmaceutical sector, the invention of new medicines entails significant research and

²⁸ Org. for Econ. Co-operation and Development [OECD], *Patents and Innovation: Trends and Policy Challenges*, 9 (2004), <http://www.oecd.org/sti/sci-tech/24508541.pdf> (noting that patents are “considered to represent a trade-off between incentives to innovate on one hand, and competition in the market and diffusion of technology on the other.”).

²⁹ *Id.* at 8 (defining patents as “exclusive right[s] to exploit (make, use, sell, or import) an invention over a limited period of time (20 years from filing) within the country where the application is made.”).

³⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, 1 Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 1869 U.N.T.S. 299, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

development costs.³¹ The patent protection of a given medicine aims to ensure the remuneration of the inventor's efforts and provide an incentive for the invention of new medicines.³²

Through this trade-off, pharmaceutical patent protection reflects both private and public interests. The patent system rewards the private interest and fosters the inventive efforts of the patent owner by awarding her exclusive rights for a limited period of time. At the same time, the patent system acknowledges the public interest in a two-fold manner. First, medicines invented under the incentive of patents may save lives and improve the quality of life of patients. Second, competitors may build upon existing knowledge inventing new medicines and contributing to the development of science. In addition, patients may have access to cheaper generic versions of the same medicine after the patent expires. During the patent lifespan, a balance between private and public interests is also embodied in the patent regime. The enjoyment of IP rights by the patent owner are not absolute, they are limited in consideration of the public interest. For example, certain rules provide for exceptions to the patent right;³³ some uses of the patent may be allowed without the patent owner's consent;³⁴ and there are limits to patentability.³⁵

However, in recent years, a common criticism has been that legislatures and judges have expanded the rights of patent owners too far³⁶ at the expense of the global public interest.³⁷ An absolute protection of pharmaceutical patents has

³¹ Matthew Herper, *The Cost Of Creating A New Drug Now \$5 Billion, Pushing Big Pharma To Change*, FORBES (Aug. 11, 2013, 11:10 AM), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/> (“A company hoping to get a single drug to market can expect to have spent \$350 million before the medicine is available for sale.”).

³² Keith E. Maskus & Mohan Penubarti, *How Trade Related Are Intellectual Property Rights?* 39 J. INT'L ECON. 227 (1995).

³³ TRIPS Agreement art. 30.

³⁴ *Id.* at art. 31.

³⁵ *Id.* at art. 27.

³⁶ See Rachel Sachs, *The New Model of Interest Group Representation in Patent Law*, 16 YALE J.L. & TECH. 344, 345 (2014) (“The various fields of intellectual property (IP) law have been marked by seemingly ever-increasing levels of protection.”).

³⁷ See, e.g., Kristen Jakobsen Osenga, *Get the Balance Right!: Squaring Access With Patent Protection*, 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 309 (2012); CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 9 (2000) (mentioning the “general concern that such legislative reform can have a major impact on people's access to drugs and on public health policies in the South.”); Victoria E. Hopkins, *Analysis of International Patent Protection and Global Public Health*, 17 J. PUB. AND INT'L AFF. 83, 83 (2006) (noting that the TRIPS Agreement “has elicited public health concerns in developing countries, worried that they will be unable to access essential medicines as a result of increasing patented drug costs.”).

a negative impact on public well-being. Pharmaceutical patents create welfare-reducing monopoly rights, which often lead to higher prices due to a lack of competition, making medicines less affordable to the poor. Moreover, by engaging in “ever-greening” practices, pharmaceutical companies often use regulatory processes to extend their monopoly over highly profitable “blockbuster” medicines and further jeopardize access to medicines for the poor.³⁸ Even where a state adopts emergency measures to limit IP rights to facilitate access to medicines, the state’s compliance with international treaty obligations to protect IP rights may be disputed.³⁹

Pharmaceutical patents produce benefits and costs, the extent of which are country dependent.⁴⁰ The role of pharmaceutical patents in promoting research and development of new medicines depends on the amount of resources a country devotes to creating intellectual assets⁴¹ and the country’s ratio between knowledge owned and the knowledge needed to develop the pharmaceutical sector.⁴² Historical evidence suggests that strong patent protection can “kick away the ladder” to development for low- and middle-

³⁸ Symposium, *Enabling Patent Law’s Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1106–07 (2008) (explaining that “evergreening refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents on modified forms of the same drug, new delivery systems for the drug, new uses of the drug, and the like.”); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 348–49 (2007) (noting that in recent years pharmaceutical companies have become “quite creative about strategies to secure ‘evergreening’ patents in order to defer the date their products go off-patent.”).

³⁹ An infamous case is that of *South African Pharmaceutical Manufacturers Ass’n v. South Africa*, Case No. 4183 (1998). In 1998, the South African Pharmaceutical Manufacturers Association (PMA) submitted a legal complaint to the High Court of Pretoria challenging the legality of relevant provisions of the (South African) Medicines Act in light of the TRIPS Agreement. The Medicines Act had been enacted to cope with a public health emergency and enabled the state to issue compulsory licenses and use parallel imports to make medicines affordable. Due to international protests and public outcry, the claim was withdrawn. For a detailed account of the case, see DUNCAN MATTHEWS, *INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT — THE ROLE OF NGOS AND SOCIAL MOVEMENTS* 97-99 (2011).

⁴⁰ See Peter Drahos, *Introduction to GLOBAL INTELLECTUAL PROPERTY RIGHTS — KNOWLEDGE, ACCESS AND DEVELOPMENT* 1, 4 (Peter Drahos & Ruth Mayne eds., 2002).

⁴¹ See Carlos Primo 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* 245, 254 (Keith E. Maskus ed., 2004).

⁴² 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).

income countries,⁴³ and that even industrialized countries did not adopt strong pharmaceutical patent policies until recently.⁴⁴ Regulation of pharmaceuticals is a sensitive field with important public policy implications. Given that medicines and vaccines are now subject to patent protection worldwide,⁴⁵ their price increase has strained public health budgets.⁴⁶

Pharmaceutical regulation constitutes a *regime complex*, which involves sets of multilevel regulatory frameworks that are at times diverging and at times converging, if not overlapping.⁴⁷ As a regime complex, pharmaceutical regulation is characterized by institutional density and governed by human rights law, international intellectual property law and international health law.

A. *Pharmaceuticals and Human Rights Law*

The International Covenant on Economic, Social and Cultural Rights (ICESCR)⁴⁸ provides the human rights component of the pharmaceutical regime complex. Article 15 of the ICESCR identifies the need to protect both public and private interests in knowledge creation and diffusion.⁴⁹ Namely, it recognizes the right of everyone “[t]o benefit from the protection of the moral and material interests resulting from any scientific ... production of which he is the author,”⁵⁰ including pharmaceutical patents, on the one hand and the “right of everyone ... to enjoy the benefits of scientific progress and its applications”

⁴³ HA-JOON CHANG, KICKING AWAY THE LADDER: DEVELOPMENT STRATEGY IN HISTORICAL PERSPECTIVE 1–5 (2003) (providing a historical overview of the economic development of industrialized countries and arguing that through the Washington Consensus such countries prescribe policies for the developing countries which they have not used themselves during their period of economic growth).

⁴⁴ Ha-Joon Chang, *Intellectual Property Rights and Economic Development: Historical Lessons and Emerging Issues*, 2 J. HUM. DEV. 287, 305–06 n.8 (2001) (noting that pharmaceutical products “remained unpatentable until 1967 in West Germany and France, 1979 in Italy, and 1992 in Spain. Pharmaceutical products were also unpatentable in Canada into the 1990s.”).

⁴⁵ See TRIPS Agreement art. 27 (The TRIPS Agreement has required the patentability of pharmaceuticals).

⁴⁶ Elisabeth Rosenthal, *The Price of Prevention: Vaccine Costs Are Soaring*, N.Y. TIMES, July 2, 2014, at A1.

⁴⁷ See Robert O. Keohane & David G. Victor, *The Regime Complex for Climate Change*, 9 PERSP. ON POL. 7, 7 (2011) (introducing the notion of “regime complex” and defining it as a “loosely coupled set of specific regimes.”).

⁴⁸ International Covenant on Economic, Social and Cultural Rights, art. 15, Dec. 16, 1966, 993 U.N.T.S. 3, 6 ILM 36 [hereinafter ICESCR]. As of 2015, the Covenant has 164 parties. The United States has signed but has not ratified the Covenant. See Philip Alston, *The US Ratification of the Covenant on Economic, Social and Cultural Rights: The Need for an Entirely New Strategy*, 84 AM. J. INT’L L. 365, 365 (1990).

⁴⁹ ICESCR, *supra* note 48, at art. 15.

⁵⁰ *Id.* art. 15.1.c.

on the other.⁵¹ In parallel, Article 12 of the ICESCR recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” The right to health requires access to medicines, according to General Comment 14.⁵² While general comments are not binding instruments, they are deemed to constitute authoritative interpretation of states commitments under the ICESCR and can reflect emerging norms of customary law.⁵³ Although conceptualized after World War II, the right to health was under-theorized due to political reasons.⁵⁴ However, since the fall of the Berlin Wall, like other economic, social and cultural rights, it has had a renaissance, being understood in its “unity and complementarity” with civil and political rights.⁵⁵

Yet, the lack of a World Human Rights Court (WHRC)⁵⁶ and the fragmentation of international human rights institutions have inevitably affected

⁵¹ *Id.* art. 15.1.b.

⁵² Committee on Economic, Social and Cultural Rights (“CESCR”), General Comment 14: The Right to the Highest Attainable Standard of Health (Article 12), ¶ 17, UN Doc. HRI/GEN/Rev.9 (Vol. I) (2000), [http://www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) (“The creation of conditions which would assure to all medical service and medical attention in the event of sickness [in] (art. 12.2 (d) [of the ICESCR]), both physical and mental, includes the provision of equal and timely access to basic preventive, curative, rehabilitative health services and health education; regular screening programmes; appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at community level; the provision of essential drugs; and appropriate mental health treatment and care.”).

⁵³ Helen Keller & Lena Grover, *General Comments of the Human Rights Committee and Their Legitimacy*, in UN HUMAN RIGHTS TREATY BODIES: LAW AND LEGITIMACY 116, 132 (Helen Keller and Geir Ulfstein eds., 2012).

⁵⁴ VALENTINA VADI, PUBLIC HEALTH IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION 27 (2012) [hereinafter VADI] (“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.”).

⁵⁵ *Id.*

⁵⁶ On the desirability of a World Human Rights Court, see generally Stefan Trechsel, *A World Court for Human Rights?* 1 NW. J. INT’L HUM. RTS. 3 (2004); Int’l Comm. of Jurists, *Towards a World Court of Human Rights: Questions and Answers*, 2 (Dec. 2011) [hereinafter Int’l Comm. of Jurists] (highlighting “a glaring gap in th[e] . . . human rights architecture: a World Court of Human Rights, that would make available a judicial mechanism to provide enforceable and effective justice to individual victims of human rights violations.”).

the realization of the right to health.⁵⁷ States maintain the prime duty of providing access to remedies at the domestic level.⁵⁸ However, effective remedies should be available at both the national and international levels,⁵⁹ because international remedies are essential in those cases where domestic remedies are not available or inadequate.⁶⁰ Several UN bodies deal with human rights,⁶¹ but they do not fulfill the tasks of a world court for human rights.⁶² Moreover, the institutional fragmentation of the human rights system — the existence of different UN bodies and monitoring frameworks with converging and diverging competences,⁶³ — and its substantive fragmentation — the existence of different treaties and regimes — can create obstacles to the effective realization of the right to health.⁶⁴

B. Pharmaceuticals and International Intellectual Property Law

Several sources of international intellectual property law govern patent regulation. The Paris Convention⁶⁵ conceptualizes intellectual property as an

⁵⁷ 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).

⁵⁸ Int'l Comm. of Jurists, *supra* note 56, at 2 (pinpointing that states have “the primary responsibility for providing access to remedies at the national level.”).

⁵⁹ *Id.* at 2 (arguing that “victims of human rights violations should have access to effective remedies at both the national and international levels.”).

⁶⁰ *Id.* (stressing that “a complementary system of remedies at the international level is necessary to address instances where a State is unable or unwilling to provide remedies for violations or where such remedies are ineffective.”).

⁶¹ Trechsel, *supra* note 56, at 4 (noting that “[t]here is already quite an impressive list of bodies which deal with human rights within the framework of the United Nations.”).

⁶² *Id.* at 5 (pinpointing that “none can be regarded as a substitute for a world court for human rights” as “[e]ither [such UN bodies] are not judicial bodies—this applies in particular to the various commissions and committees—or they are not directly dealing with human rights issues, which applies to the Criminal Tribunals”).

⁶³ On the institutional fragmentation of the human rights system, see, e.g., Marjan Ajevski, *Fragmentation in International Human Rights Law – Beyond Conflict of Laws*, 32 *NORDIC J. OF HUMAN RIGHTS* 87, 88 (2014).

⁶⁴ Mehrdad Payandeh, *Fragmentation within International Human Rights Law*, in *A FAREWELL TO FRAGMENTATION: REASSERTION AND CONVERGENCE IN INTERNATIONAL LAW* 297 (Mads Andenas and Eirik Bjorge eds., 2015) (stigmatizing the risks of conflicting jurisprudence among different monitoring bodies due to “structural biases of the different human rights treaty bodies.”).

⁶⁵ Paris Convention for the Protection of Industrial Property, Mar. 20 1883, last revised at Stockholm on July 14 1967, and amended on Sep. 28 1979, 828 U.N.T.S. 305 [hereinafter Paris Convention].

incentive to encourage innovation.⁶⁶ It harmonizes procedures relating to priority, registration, and licensing and requires national treatment for foreign patent owners.⁶⁷ In theory, a member that has failed to comply with its obligations under the Paris Convention could be sued before the International Court of Justice,⁶⁸ but no such cases have ever been brought.⁶⁹ Nonetheless, the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) under the World Trade Organization (WTO),⁷⁰ incorporates some provisions of the Paris Convention and can be implemented through the WTO Dispute Settlement Mechanism (DSM).⁷¹

The TRIPS Agreement is the most comprehensive international treaty setting global standards for medical knowledge governance.⁷² It requires WTO member states to provide patent protection for pharmaceuticals.⁷³ The patent owner is given limited monopoly rights over the patented medicine for twenty years,⁷⁴ and after this patent term expires, competitors may replicate the compound.

The TRIPS Agreement has been controversial since its inception. Developing countries opposed its adoption fearing that the introduction of high standards of intellectual property protection would jeopardize access to pharmaceuticals and other technology, and that the agreement would privilege the private economic interests of patent holders vis-à-vis important public

⁶⁶ Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property* 3–4 (N.Y. Univ. Public Law & Legal Theory, Working Paper No. 14-53, 2014).

⁶⁷ Helfer, *supra* note 57, at 314.

⁶⁸ Paris Convention, *supra* note 65, at art. 28.

⁶⁹ Dreyfuss & Frankel, *supra* note 66, at 5.

⁷⁰ TRIPS Agreement Annex 1C.

⁷¹ The TRIPS Agreement has incorporated some of the fundamental principles of the Paris Convention such as the equal treatment of nationals and foreigners among others. *See* TRIPS Agreement art. 3; *see also id.* art. 2.1 (stating that “Members shall comply with Articles 1 through 12, and Article 19 of the Paris Convention.”).

⁷² For a detailed commentary, *see* CARLOS CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS — A COMMENTARY ON THE TRIPS AGREEMENT* (2007); DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* (4th ed., 2012).

⁷³ TRIPS Agreement at art. 27 (introducing pharmaceuticals as a patentable subject matter and 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.”).

⁷⁴ *Id.* at art. 33 (stating that “[t]he term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

policies furthering public health and developmental objectives.⁷⁵ Some scholars also doubted intellectual property's link to trade, given its effect of restricting the market.⁷⁶ Not by chance, the General Agreement on Tariffs and Trade (GATT)⁷⁷ listed intellectual property among the general exceptions to the general commitment to free trade and lower tariffs.⁷⁸ Nevertheless, through intense negotiation and 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 came into force in January 1995.⁷⁹ As the outcome of intense cross-sectorial negotiations, the signing of the TRIPS Agreement does not mean that it provides an optimal equilibrium between the private and public interests. Rather, countries accepted its high standards of IP protection potentially reducing their regulatory autonomy in the pharmaceutical sector in light of the overall perceived benefits of the entire WTO package. By conceptualizing IP as a commodity,⁸⁰ the TRIPS Agreement severely constrained the regulatory autonomy of states in the pharmaceutical sector.

⁷⁵ 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, 441–43 (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).

⁷⁶ Michael Spence, *Which Intellectual Property Rights are Trade-Related?*, in ENVIRONMENT, HUMAN RIGHTS AND INTERNATIONAL TRADE 263–85 (Francesco Francioni and Tullio Scovazzi eds., 2001).

⁷⁷ General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].

⁷⁸ *Id.* at art. 20(d) (“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, trade marks and copyrights, and the prevention of deceptive practices . . .”).

⁷⁹ José E. Alvarez, *The WTO as Linkage Machine*, 96 AM. J. INT'L L. 146, 147 (2002) (noting “[t]he 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.”).

⁸⁰ Dreyfuss & Frankel, *supra* note 66, at 3, 32 (noting that 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 suggesting that the system may be “inclined to interpret proprietary rights broadly while construing user interests narrowly.”). On the different, albeit related, phenomenon of the propertization of intangible assets, see Valentina Vadi, *Trademark Protection, Public Health and International Investment Law: Strains and*

The TRIPS Agreement provides minimum standards for intellectual property protection, below which the member states cannot fall.⁸¹ WTO Members have the right to provide for more extensive protection that is not required by the TRIPS Agreement, as long as they follow the general principles of the most-favoured-nation clause and national treatment.⁸² Therefore, any intellectual property agreement negotiated subsequent to TRIPS by WTO members can only create similar or higher standards for IP protection (commonly known as *TRIPS-plus*).⁸³ Members can enforce the provisions of the TRIPS Agreement through the WTO Dispute Settlement Mechanism (DSM), which has compulsory jurisdiction over TRIPS-related disputes.⁸⁴

International investment law, the last wave of IP rights protection, considers IP as a form of investment.⁸⁵ As investment treaties broadly define the notion of investment, a potential tension exists when a state adopts measures governing pharmaceutical patents that interfere with foreign investments. This is because such regulation may be considered a violation of investment treaty provisions protecting the patent rights of foreign companies. Moreover, because investment treaties provide foreign investors with direct access to investment arbitration, foreign investors can directly challenge national measures and can seek compensation for the impact of such regulation on their business. Indeed, a number of investor-state arbitrations have dealt with pharmaceutical regulation, and the time is ripe for a comprehensive analysis and critical assessment,

Paradoxes, 20 EUR. J. INT'L L. 773, 775 (2009) (“The propertization of intangible goods has become a common trend in international standard setting. Propertization can be defined as the process of putting emphasis on proprietary aspects of given intangible rights or the characterization of modern knowledge governance as moving towards a property-based regime.”).

⁸¹ TRIPS Agreement art. 1.1 (“Members shall give effect to the provisions of this Agreement.”)

⁸² *Id.* (“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.”).

⁸³ 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).

⁸⁴ TRIPS Agreement art. 64. See generally Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VAND. J. INT'L L. 275, 282 (1997).

⁸⁵ Boie, *supra* note 2, at 4 (noting that “[international investment agreements] usually protect intellectual property by including it in the definition of investment.”).

especially concerning their potential effect of emphasizing private property at the expense of the public interest.⁸⁶

C. *Pharmaceuticals and International Health Law*

In contrast with IP protection, another component of the regime governing pharmaceuticals, international health law, has developed slowly.⁸⁷ The internationalization of public health law is not a new phenomenon. The shift from national to international governance began in the mid-19th century,⁸⁸ when states adopted a discrete number of binding international conventions dealing with various aspects of public health.⁸⁹ The cholera epidemics through Europe in the first half of the 19th century catalyzed intense international health diplomacy and cooperation.⁹⁰ Not only did the cholera epidemics show the failure of national quarantine systems to prevent the spread of the disease, but they also created discontent among merchants, whose trade had been affected by the quarantine measures.⁹¹ The merchants urged their governments to take international action.⁹² The first International Sanitary Conference was organized in 1851 “to discuss cooperation on cholera, plague, and yellow fever,”⁹³ and established the principle that “health protection was a proper subject for

⁸⁶ Dreyfuss & Frankel, *supra* note 66, at 3.

⁸⁷ Jennifer Prah Ruger, *Normative Foundations of Global Health Law*, 96 GEO. L. J. 423, 424 (2007–2008) (describing international health law as “a relatively new academic field”); 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 AND PHILOS. 245, 245 (2009) (noting that “neither the WHO ... nor international law ... have yet played their necessary part in promoting ‘health for all.’”); *see generally* DAVID P. FIDLER, INTERNATIONAL LAW AND PUBLIC HEALTH: MATERIAL ON AND ANALYSIS OF GLOBAL HEALTH JURISPRUDENCE (2000).

⁸⁸ David P. Fidler, *International Law and Global Public Health*, 48 U. KAN. L. REV. 1, 2 (1999–2000) [hereinafter Fidler, *Int’l Law and Global Public Health*] (highlighting “states’ extensive use in the late part of the nineteenth century and first half of the twentieth century of international law in dealing with public health problems.”).

⁸⁹ The First International Sanitary Convention focused on cholera. *See* BOB REINALDA, ROUTLEDGE HISTORY OF INTERNATIONAL ORGANIZATIONS: FROM 1815 TO THE PRESENT DAY 172 (2009). The Convention was adopted at the seventh International Sanitary Conference held in Venice in 1892. *See* AGINAM OBJIOFOR, GLOBAL HEALTH GOVERNANCE: INTERNATIONAL LAW AND PUBLIC HEALTH IN A DIVIDED WORLD 51 (2005).

⁹⁰ David P. Fidler, *The Globalization of Public Health: The First 100 Years of International Health Diplomacy*, 79 BULL. WORLD HEALTH ORG. 842, 843 (2001).

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

international consultations.”⁹⁴ Other international conferences followed, “focusing exclusively on the containment of epidemics.”⁹⁵

Despite these early adoptions of binding international health law instruments, since the inception of the World Health Organization (WHO) in 1946,⁹⁶ international health law has taken a less ambitious path. In fact, the WHO has favored non-legal, medical-technical approaches to health issues.⁹⁷ The WHO, mainly composed of health specialists,⁹⁸ has principally, if not exclusively, adopted 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.”⁹⁹ Instruments such as declarations and recommendations adopted by the WHO have been described as “limited in scope and application”¹⁰⁰ as well as “historically, politically and structurally inadequate to do what is needed.”¹⁰¹ Such instruments “are being developed ... in an uncoordinated ... manner” and “pale in comparison to that of other international [organizations]”¹⁰² International health law has not been an effective system, due to its mainly non-legal approach, lack of enforcement mechanisms and states’ consequent failure to comply with its rules.¹⁰³ The WHO adopted its first binding convention only a decade ago.¹⁰⁴ The organization “rarely participate[s] in trade negotiations or the resolution of trade disputes, even when such are linked to public health.”¹⁰⁵ Only in 2015 has it,

⁹⁴ WHO, *THE WORLD HEALTH REPORT 2007: A SAFER FUTURE: GLOBAL PUBLIC HEALTH SECURITY IN THE 21ST CENTURY* 7 (2007).

⁹⁵ *Id.*

⁹⁶ Constitution of the World Health Organization, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185.

⁹⁷ Fidler, *Int’l and Global Public Health*, *supra* note 88, at 22 (noting “the historical penchant [of the WHO] for dealing with public health problems within a narrow ‘medical-technical’ approach.”).

⁹⁸ *Id.* at 22 (“WHO has historically been staffed predominantly by physicians, medical scientists, and public health experts.”).

⁹⁹ David P. Fidler, *The Future of the World Health Organization: What Role for International Law?* 31 VAND. J. TRANSNAT’L L. 1079, 1099 (1998).

¹⁰⁰ Harmon, *supra* note 87, at 251.

¹⁰¹ *Id.* (internal citation omitted).

¹⁰² *Id.*

¹⁰³ Jennifer Prah Ruger, *Normative Foundations of Global Health Law*, 96 GEO. L.J. 423, 438 (2007–2008) (noting that “international health law has been viewed as ‘ineffective’”).

¹⁰⁴ WHO, *FRAMEWORK CONVENTION ON TOBACCO CONTROL* 6 (2003), http://www.who.int/tobacco/framework/WHO_FCTC_english.pdf.

¹⁰⁵ Harmon, *supra* note 87, at 251.

cautiously, started intervening in investment treaty arbitration as *amicus curiae*.¹⁰⁶

In the absence of a well-articulated international health law regime, public health protection has remained a fundamental prerogative of the states.¹⁰⁷ States have a right and a duty to protect public health, and the power to adopt measures to protect their population: one of the conditions of their very existence.¹⁰⁸ Each state has a social contract with its citizens, which prompt it to assume these public-health related burdens.¹⁰⁹

Given the interconnectedness of health with other global issues, including trade and foreign investments,¹¹⁰ and the asymmetrical development of international health law and other fields of international law, many elements of public health governance have been affected by the actions of international bodies whose primary objectives do not concern health.¹¹¹ For instance, international investment law and arbitration has increasingly governed or impacted international public health policy. 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.

¹⁰⁶ Jarrod Hepburn, Clovis Trevino & Luke Eric Peterson, *World Health Organization is Given Green-Light by Arbitrators to Intervene in Philip Morris v. Uruguay Arbitration*, 8 INV. ARB. REP. 1, 31 (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. 93–130 (2012).

¹⁰⁷ Lawrence O. Gostin, *Public Health Law in a New Century* 283 JAMA. 2837, 2837 (2000) (highlighting that “the government has the primary responsibility to advance the public’s health because it acts on behalf of the people” and noting, at 2838, that “theories of democracy” explain “the primacy of government in matters of public health.”).

¹⁰⁸ VADI, *supra* note 54, at 30; Montevideo Convention on the Rights and Duties of States art. 1., Dec. 26, 1933, 49 Stat. 3097, 165 L.N.T.S. 19 (stating that a population is one of the three elements required for statehood, together with territory and government).

¹⁰⁹ Harmon, *supra* note 87, at 247.

¹¹⁰ Allyn Taylor, *Global Governance, International Health Law and WHO: Looking Towards the Future*, 80 BULL. WORLD HEALTH ORG. 975, 975–76 (2002), [http://www.who.int/docstore/bulletin/pdf/2002/bul-12-E-2002/80\(12\)975-980.pdf](http://www.who.int/docstore/bulletin/pdf/2002/bul-12-E-2002/80(12)975-980.pdf).

¹¹¹ *Id.* at 251.

II

INTERNATIONAL INVESTMENT LAW AND ARBITRATION

International investment law constitutes an important part of international law governing foreign direct investment (FDI).¹¹² As there is still no single comprehensive global treaty, investor rights are mainly defined by almost 3,000 international investment agreements (IIAs), which encompass both bilateral investment treaties (BITs) and multilateral instruments, that are signed by participating states and are governed by public international law.¹¹³ Under these agreements, state parties concede to provide a certain degree of protection to investors who are nationals of contracting states. These concessions include compensation in the case of expropriation, fair and equitable treatment, most favoured nation treatment, and full protection and security, among others.

As IIAs are “the most important instruments for the protection of foreign investment,”¹¹⁴ there is a general expectation that the conclusion of such agreements will encourage FDI among the contracting nations.¹¹⁵ Host

¹¹² JOSÉ E. ALVAREZ, *THE PUBLIC INTERNATIONAL LAW REGIME GOVERNING INTERNATIONAL INVESTMENT* 14–15 (2011). For a historical overview, see ANDREAS LOWENFELD, *INTERNATIONAL ECONOMIC LAW* 469–494 (2d ed. 2008); JESWALD W. SALACUSE, *THE LAW OF INVESTMENT TREATIES* (2010); M. SORNARAJAH, *THE INTERNATIONAL LAW ON FOREIGN INVESTMENT* 19–28 (3d ed. 2010); ANDREW NEWCOMBE & LUIS PARADELL, *LAW AND PRACTICE OF INVESTMENT TREATIES* 3–57 (2009).

¹¹³ United Nations Conference on Trade and Development [UNCTAD], *World Investment Report 2011*, 100, U.N. Doc. UNCTAD/WIR/2011 (July 26, 2011).

¹¹⁴ United Nations Conference on Trade and Development [UNCTAD], *Bilateral Investment Treaties: 1959–1999*, 1, U.N. Doc. UNCTAD/ITE/IIA2 (Dec. 14, 2000).

¹¹⁵ Some authors are skeptical about whether BITs actually attract investment. See Jason W. Yackee, *Do BITs Really Work? Revisiting the Empirical Link between Investment Treaties and Foreign Direct Investment*, in *THE EFFECT OF TREATIES ON FOREIGN DIRECT INVESTMENT: BILATERAL INVESTMENT TREATIES, DOUBLE TAXATION TREATIES, AND INVESTMENT FLOWS* (Sauvant & Sachs eds. 2009); Jason W. Yackee, *Bilateral Investment Treaties, Credible Commitment, and the Rule of (International) Law: Do BITs Promote Foreign Direct Investment*, 42 *LAW & SOC’Y REV.* 805, 807 (2008). See generally M. Hallward-Driemeier, *Do Bilateral Investment Treaties Attract Foreign Direct Investment? Only a Bit... And They Could Bite* (Policy Research, Working Paper No. 3121, 2003). However, other authors have identified a positive impact. See generally Jeswald Salacuse & N. P. Sullivan, *Do BITs Really Work? An Evaluation of Bilateral Investment Treaties and Their Grand Bargain*, 46 *HARV. INT’L. L.J.* 67 (2005); E. Neumayer & L. Spess, *Do Bilateral Investment Treaties Increase Foreign Direct Investment to Developing Countries?*, 33 *WORLD DEV.* 1567 (2005); A. Bénassy-Quéré, M. Coupet & T. Mayer, *Institutional Determinants of Foreign Direct Investment*, 30 *WORLD ECONOMY* 764 (2007); P. Egger & V. Merlo, *The Impact of Bilateral Investment Treaties on FDI Dynamics*, 30 *WORLD ECONOMY* 1536 (2007); P. Egger & M Pfaffermayr, *The Impact of Bilateral Investment Treaties on Foreign Direct Investment*, 32 *J. OF COMPARATIVE ECON.* 788 (2004); J. Tobin & S. Rose-Ackerman, *Foreign Direct Investment and the Business Environment in Developing*

countries, generally developing and least developed countries but now increasingly developed countries,¹¹⁶ assume obligations for the protection of foreign investments in order to attract foreign investments. Countries also adhere to these dealings to protect the economic interests of their nationals investing overseas. For both of these reasons, such agreements have come to play a major role in the growing competition to attract and export FDI.

At the procedural level, IIAs can grant foreign investors holding patents direct access to investment treaty arbitration.¹¹⁷ In doing so, they create a set of procedural rights for the direct benefit of investors.¹¹⁸ This is a novelty in international law, as customary international law does not provide such a diagonal mechanism for settling disputes between foreign investors and host states.¹¹⁹ 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 to protect foreign investors.¹²⁰ Arbitration is also used because of perceived advantages in confidentiality and effectiveness.¹²¹

Countries: The Impact of Bilateral Investment Treaties (Yale Law and Econ. Working Paper No. 293, 2005).

¹¹⁶ See generally Valentina Vadi, *Converging Divergences: The Rise of Chinese Outward Foreign Investment and Its Implications for International (Investment) Law*, 2011–2012 Y.B. INT'L INV. L. 705 (2013) (noting that the traditional distinction between capital importers and capital exporters has become blurred and investment treaties have increasingly been signed not only among industrialized countries on the one side and developing countries on the other side, but also among LDCs and emerging economies).

¹¹⁷ Lahra Liberti, *Intellectual Property Rights in International Investment Agreements: An Overview* 1, 3 (OECD Working Papers on Int'l Inv., 2010/01, 2010), http://www.oecd-ilibrary.org/finance-and-investment/intellectual-property-rights-in-international-investment-agreements_5kmfq1njzl35-en (noting the “possibility for an IPR holder to bring a claim against a state under the investor-state dispute settlement mechanism.”).

¹¹⁸ Jan Paulsson, *Arbitration Without Privity* 10 ICSID REV. FOR INV. L. J. 232, 239 (1995).

¹¹⁹ David R. Sedlak, *ICSID's Resurgence in International Investment Arbitration: Can the Momentum Hold?*, 23 PENN. ST. INT'L L. REV. 147, 147–49 (2004) (noting that investor-state arbitration has become a standard feature in international investment treaties since the 1980s).

¹²⁰ See Andrew Newcombe & Lluís Paradell, *LAW AND PRACTICE OF INVESTMENT TREATIES* 24 (2009).

¹²¹ See Ibrahim F.I. Shihata, *The Settlement of Disputes Regarding Foreign Investment: The Role of the World Bank, with Particular Reference to ICSID and MIGA*, 1 AM. U. J. INT'L L. & POL'Y 97, 103 (1986) (noting that “The main features of th[e] ICSID System] include its voluntary character, its flexibility, and its effectiveness.”).

Investor-state arbitration is procedurally similar to international commercial arbitration between private parties.¹²² The parties choose the arbitrators among law scholars and practitioners.¹²³ Although arbitrators are expected to be both independent of the party appointing them and impartial,¹²⁴ they may permissibly share the political, economic, or legal ideals of the party that nominated them. From the offset, such appointees may be presumed sympathetic to the nominating party's contentions and positions.¹²⁵

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.¹²⁶ Final awards may or may not be published, depending upon the parties' will. Names of the parties can remain undisclosed, as do the details of the dispute, albeit to a lesser degree.

Although confidentiality is well suited to private commercial disputes, 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.¹²⁷ Because investment disputes are settled using a variety of

¹²² 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).

¹²³ JOHN COLLIER & VAUGHAN LOWE, THE SETTLEMENT OF DISPUTES IN INTERNATIONAL LAW 69 (1999) ("The parties choose an uneven number of arbitrators, three in the absence of agreement, and the persons to act as arbitrators."); J.A. Fontoura Costa, *Comparing WTO Panelists and ICSID Arbitrators: The Creation of International Legal Fields*, 1 ONATI SOCIO-LEGAL SERIES 1, 14 (2011) ("Virtually all ICSID arbitrators and ad hoc committee members have some legal background, since only 0.4% of the whole population is composed of individuals who had not at least studied law. On the other hand, WTO figures are very different: 45% of panelists and 10% of AB members have no links to any legal background or professional activity.").

¹²⁴ Jeswald W. Salacuse, *The Emerging Global Regime for Investment*, 51 HARV. INT'L L. J. 427, 466 (2010).

¹²⁵ Alan S. Rau, *Integrity in Private Judging*, 38 S. TEX. L. REV. 485, 507 (1997).

¹²⁶ Some hearings have been broadcast in special viewing rooms at the ICSID headquarters in Washington, but were not webcast. 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*, 6 INV. ARB. REP. 1, 5 (2013).

¹²⁷ While 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,

arbitral rules,¹²⁸ some of which do not even disclose the existence of arbitration claims, there can be no accurate accounting of all such disputes.¹²⁹ This should be a matter of concern given the public policy implications of such disputes.

In recent years, efforts to make investment arbitration more transparent have been undertaken in various *fora*. In response to calls from civil society groups, the three parties to the North American Free Trade Agreement (NAFTA), Canada, the United States, and Mexico, have pledged to disclose all NAFTA arbitrations and open future arbitration hearings to the public.¹³⁰ Similarly, the International Centre for Settlement of Investment Disputes (ICSID) requires public disclosure of dispute proceedings under its auspices,¹³¹ 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 or to access the arbitral process.¹³²

However, these important developments in transparency appear in only a limited number of investment disputes. The vast majority of existing IIAs do not mandate such transparency, which means that most of the proceedings are still 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”),¹³³ by which Parties to IIAs have

subject to any redactions of confidential commercial information. A previously released copy 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*, 6 INV. ARB. REP. 1, 3–4 (2013).

¹²⁸ States usually offer investors a variety of rules to choose from, which may include the UNCITRAL Arbitration Rules, the Rules of Procedure for Arbitration of the International Centre for Settlement of Investment Disputes (ICSID), the arbitration rules of the International Chamber of Commerce (ICC) or other arbitration rules such as the arbitration rules of the Stockholm Chamber of Commerce (SCC).

¹²⁹ Luke Eric Peterson, Int’l Inst. for Sustainable Dev. [IISD], *Bilateral Investment Treaties and Development Policy-Making*, 15 (2004).

¹³⁰ NAFTA Free Trade Commission, *Statement of the Free Trade Commission on Non-Disputing Party Participation*, at 7 (Oct. 7, 2003), <http://www.state.gov/documents/organization/38791.pdf>.

¹³¹ ICSID, *Administrative and Financial Regulations, Reg. 22: Publication*, at 66, ICSID Doc. ICSID/15 (April 2006), [hereinafter ICSID, *Admin. and Financial Regs.*], https://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/CRR_English-final.pdf.

¹³² ICSID, *Rules of Procedure for Arbitration Proceedings, Rule 37: Visits and Inquires; Submissions of Non-Disputing Parties*, at 117, ICSID Doc. ICSID/15 (April 2006), https://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/CRR_English-final.pdf.

¹³³ United Nations Convention on Transparency in Treaty-based Investor-State Arbitration (the “Mauritius Convention on Transparency”), Dec. 10, 2014, A/RES/69/116.

expressed their consent to apply the United Nations Commission on International Trade Law (UNCITRAL) Rules on Transparency in agreement-based investor-state arbitrations, may increase the transparency of such disputes.

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,¹³⁴ and Washington Conventions.¹³⁵ In arbitrations under the ICSID Convention, awards are only subject to an internal annulment process, enforced as a local court judgment, and exempt from the supervision of local courts.¹³⁶ 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.¹³⁷ Thus, if the arbitration is sited in a country other than the host state, there may be no capacity whatsoever for the host government to challenge the award in its own legal system.

Given these characteristics of the arbitral process, significant issues arise in the context of disputes involving pharmaceuticals. Arbitration structurally constitutes a private model of adjudication, but arbitral awards ultimately shape the relationship between the state and private individuals.¹³⁸ Arbitrators weigh in on vital policy 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.¹³⁹ In cases involving public health, one may wonder whether investment arbitration provides an adequate forum to address important non-economic concerns. Furthermore, the mere possibility of a dispute with a

The Convention will enter into force six months after the deposit of the third instrument of ratification. 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.

¹³⁴ New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards, Jun. 10, 1958, 330 U.N.T.S. 38 [hereinafter NY Convention].

¹³⁵ Convention on the Settlement of Investment Disputes between States and Nationals of other States, Mar. 18, 1965, 17 U.S.T. 1270 [hereinafter ICSID Convention].

¹³⁶ *Id.* at art. 52.

¹³⁷ NY Convention, *supra* note 134, at art. 5.

¹³⁸ GUS VAN HARTEN, INVESTMENT TREATY ARBITRATION AND PUBLIC LAW 70 (Vaughan Lowe ed., 2007).

¹³⁹ M. Sornarajah, *The Clash of Globalizations and the International Law on Foreign Investment* 12 CAN. FOR. POL'Y. 2, 2–10 (2003).

powerful investor can exert a chilling effect on governments' actions to regulate in the public interest.¹⁴⁰

III THE RISE OF INVESTOR-STATE ARBITRATIONS CONCERNING PHARMACEUTICAL PATENTS

Despite the economic importance of pharmaceutical patents, and the flourishing of arbitrations concerning them among private parties, known patent investment disputes have been rare.¹⁴¹ Only recently has this situation started to change.¹⁴² The few known pharmaceutical patent arbitrations have been high profile disputes that raise a number of important questions. How much does investment arbitration limit the regulatory autonomy of states? What is the interplay between investment arbitration and the parallel WTO DSM? Does investment arbitration allow adjudicators to strike an optimal equilibrium between private and public interests characterizing pharmaceutical patents? This part examines the reasons for the traditional paucity of cases and the recent rise of investor-state arbitrations concerning pharmaceuticals. Part IV explores the substantive issues raised by such arbitrations, highlighting the emergence of a new dialectics between the public and private interests embedded in intellectual property rights.

Several factors may have accounted for the relative paucity of patent-related investor-state arbitrations. Firstly, the available data could represent just the tip of the iceberg, given the investment arbitration's limited transparency. While ICSID makes the existence of all proceedings public and generally

¹⁴⁰ See generally Kyla Tienhaara, *Regulatory Chill and the Threat of Arbitration: A View from Political Science*, in *EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION* 607 (Chester Brown & Kate Miles eds., 2011); Stuart G. Gross, *Inordinate Chill: BITS, Non-NAFTA MITS, and Host-state Regulatory Freedom: An Indonesian Case Study*, 24 *MICH. J. INT'L L.* 893, 960 (2003) (examining a case where Indonesia repealed a regulation protecting forests after the threat of an investment treaty arbitration). *But see* Jeremy Caddel & Nathan M. Jensen, *Which Host Country Government Actors are Most Involved in Disputes with Foreign Investors?*, in *COLUMBIA FDI PERSPECTIVES* No. 120 at 1, 2 (Karl P. Sauvant & Shawn Lim eds., 2014) ("Given the low rate of disputes involving legislative branch activity, arguments that investor-state arbitration may encroach on the legitimate prerogatives of domestic governments appear to be overstated. Instead, democratic legislatures should embrace investor state arbitration as an additional check on executive branch misbehavior.").

¹⁴¹ LUKAS VANHONNAEKER, *INTELLECTUAL PROPERTY RIGHTS AS FOREIGN DIRECT INVESTMENTS: FROM COLLISION TO COLLABORATION* VII (2015) (noting "a relative paucity of cases").

¹⁴² For a comprehensive analysis of the pharmaceutical patent-related arbitrations see *infra* Part IV.

encourages the publication of awards,¹⁴³ other arbitral institutions do not necessarily disclose their dockets, and even when they do so, they do not publish the awards unless the parties so agree.¹⁴⁴ Moreover, the existence of *ad hoc* arbitrations could remain unknown.

Secondly, it takes time for parties to switch to this new forum. Although the first BIT providing for investor-state arbitration was signed in 1959,¹⁴⁵ only during the 1990's did investment arbitration clearly emerge as an international mechanism of adjudicative review.¹⁴⁶ The first investment treaty arbitration was registered in 1987.¹⁴⁷ Since then, the flow of investment treaty claims has increased remarkably,¹⁴⁸ totaling 608 as of the year 2015.¹⁴⁹ Traditionally, parties preferred other *fora* for claims concerning pharmaceutical patents. National courts are always an option to foreign investors.¹⁵⁰ As pharmaceutical patents are territorial in nature, they are subject to the national laws of each individual country.¹⁵¹ At the regional level, the Court of Justice of the European Union (CJEU) has adjudicated several cases dealing with IP in general and pharmaceutical patents in particular. Even human rights courts can and have adjudicated IP-related cases. For instance, the European Commission of Human

¹⁴³ ICSID Convention, *supra* note 135, at art. 48(5) (“The Centre shall not publish the award without the consent of the parties.”); ICSID, *Admin. and Financial Regs.*, *supra* note 131, at 66, (“The Secretary-General shall appropriately publish information about the operation of the Centre, including the registration of all requests for conciliation or arbitration and in due course an indication of the date and method of the termination of each proceeding. If both parties to a proceeding consent to the publication of . . . arbitral awards; or the minutes and other records of proceedings, the Secretary-General shall arrange for the publication thereof, in an appropriate form with a view to furthering the development of international law in relation to investments.”).

¹⁴⁴ See, e.g., The Arbitration Inst. of the Stockholm Chamber of Commerce, *Rules of the Arbitration Institute of the Stockholm Chamber of Commerce*, art. 46, (Jan. 2010), http://www.sccinstitute.se/filearchive/1/13207/1999_web_a4_vanliga_2004_eng_rev_2005.pdf.

¹⁴⁵ Treaty for the Promotion and Protection of Investments, Ger.-Pak., Nov. 25, 1959, 457 U.N.T.S. 24.

¹⁴⁶ Gus Van Harten and Martin Loughlin, *Investment Treaty Arbitration as a Species of Global Administrative Law*, 17 EUROPEAN JOURNAL OF INTERNATIONAL LAW 121, 124 (2006).

¹⁴⁷ Asian Agricultural Products Ltd v. Democratic Socialist Republic of Sri Lanka, ICSID Case No. ARB/87/3, Award, at 527 (June 27 1990).

¹⁴⁸ LUCY REED, JAN PAULSSON & NIGEL BLACKABY, *GUIDE TO ICSID ARBITRATION* 7 (2d ed. 2011).

¹⁴⁹ U.N. Conference on Trade & Dev. [UNCTAD], *World Investment Report 2007: Transnational Corporations, Extractive Industries and Development*, xi, U.N. Doc. UNCTAD/WIR/2007 (July 2007).

¹⁵⁰ VADI, *supra* note 54, at 51.

¹⁵¹ Helfer, *supra* note 57, at 314 (“National patent laws are exclusively territorial in scope.”).

Rights (ECoHR) has deemed that IP is a form of property and thus protected under Article 1 of the first Protocol of the Convention.¹⁵² Finally, at the international level, the WTO has an additional DSM for cases in which a state violates its commitments under the TRIPS Agreement.¹⁵³

Thirdly, investment disputes take many years to complete and are extremely expensive—often more expensive than dispute resolutions at national and regional *fora*.¹⁵⁴ Thus, initiating an investment dispute may prove to be a suitable option only for large corporate actors that have the resources to fund multi-year, multi-million dollar disputes.

Finally, investment lawyers may lack sufficient knowledge about intellectual property.¹⁵⁵ For a long time, investment disputes focused mainly on tangible assets,¹⁵⁶ while intellectual property was considered to be “a highly technical subject.”¹⁵⁷ Conversely, IP lawyers may lack sufficient knowledge about international investment law. The lack of knowledge and familiarity on

¹⁵² See, e.g., *Anheuser Busch Inc. v. Portugal*, 2007-II Eur. Ct. H.R. (holding that intellectual property undeniably attracts the protection of Art. 1 of Protocol No. 1). 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 (Christopher Geiger ed., 2014).

¹⁵³ See generally Pauwelyn, *supra* note 25.

¹⁵⁴ Although alternative dispute mechanisms such as arbitration and mediation have been traditionally described as cheaper than litigation, this is not always the case, especially with regard to investment disputes, where legal fees and expenses are extremely high. See Matthew Hodgson, *Counting the Costs of Investment Treaty Arbitration*, 9 GLOBAL ARB. REV. 2 (2014) (“[T]he average party costs were quite similar, at \$4,437,000 for claimants and \$4,559,000 for respondents.”); Tamara L. Slater, *Investor-State Arbitration and Domestic Environmental Protection*, 14 WASH. U. GLOBAL STUD. L. REV. 131, 147 (2015) (noting that “[i]n international arbitration, the monetary cost is often millions of dollars.”). The cost variation depends on jurisdiction. See generally International Bar Association, Intellectual Property and Entertainment Law Committee, *International Survey of Specialised Intellectual Property Courts and Tribunals* (Sep. 2007) (determining, country by country, the level of effectiveness of the judicial system in its ability to settle IP disputes).

¹⁵⁵ Valentina Vadi, *Mapping Uncharted Waters: Intellectual Property Disputes with Public Health Elements in Investor-State Arbitration*, 2 TRANSN'L DISP. MGMT. 1, 6 (2009) [hereinafter Vadi, *Mapping Uncharted Waters*].

¹⁵⁶ See, e.g., *AHS Niger and Menzies Middle East and Africa S.A. v. Republic of Niger*, ICSID Case No. ARB/11/11, Award, at 15 (July 2013) (where Niger was found liable for expropriation of airport services concession, but no damages due for subsequent “misuse” of intellectual property).

¹⁵⁷ See Vadi, *Mapping Uncharted Waters*, *supra* note 155 (referring to David Vaver, *Does the Public Understand Intellectual Property? Do Lawyers?* (Univ. of Oxford Faculty of Law & Legal Studies Research Paper Series, Working Paper No. 23/2006, 2006)).

the part of investment and IP lawyers may disincentivize them from advising their clients to pursue investment disputes for their IP rights.

However, patent holders have started filing investment treaty arbitrations to protect their rights. There are several reasons for this change. First, investment treaty arbitration allows the investor to file a claim against the host state directly without the home state's intervention.¹⁵⁸ The private party can control the litigation strategy,¹⁵⁹ and obtain compensation for the host state's past wrongs.¹⁶⁰ In contrast to the mechanism afforded by investor-state arbitration, the ICJ and the WTO dispute settlement systems are inter-state dispute resolution mechanisms.¹⁶¹ Recourse to these dispute settlement mechanisms is exercised at the discretion of the home state of the private party and requires the exercise of diplomatic protection.¹⁶² However, diplomatic protection constitutes a prerogative and not a duty for states, and they may

¹⁵⁸ HEGE ELISABETH KJOS, *APPLICABLE LAW IN INVESTOR-STATE ARBITRATION: THE INTERPLAY BETWEEN NATIONAL AND INTERNATIONAL LAW* 225 (2013) (noting that "the sanctioning of the host state behaviour no longer depends on the discretionary intervention by the investor's home state.").

¹⁵⁹ BARTON LEGUM, *Investment Treaty Arbitration: An Option Not to Be Overlooked*, in *INTERNATIONAL LITIGATION STRATEGIES AND PRACTICE* 189, 190 (Barton Legum ed., 2005) (stressing that "in a significant innovation, [investment treaties] allowed the foreign investor to initiate and control prosecution of the arbitration, without having to rely on its state to bring the treaty case for it.").

¹⁶⁰ Arbitral tribunals have held states liable to compensate investors for breaches of treaty standards that result in injury, relying on a case involving a Chorzów, Poland factory. *See, e.g.,* MTD Equity Sdn. Bhd & MTD Chile S.A. v. Republic of Chile, ICSID Case No. ARB/01/7, Award, ¶ 238 (May 24, 2004). The Chorzów Factory case involved the German government seeking damages for harm sustained by two German companies caused by acts of the Polish government. *Case Concerning the Factory at Chorzów*, 1928 P.C.I.J. (ser. A) No. 17, at 47 (Sep. 13) (judgment on the merits) (holding that "reparation must, as far as possible, wipe out all the consequences of the illegal act and re-establish the situation which would in all probability, have existed if that act had not been committed.").

¹⁶¹ Statute of the International Court of Justice art. 34(1), Jun. 26, 1946, 8 U.N.T.S. 993 ("Only state[s] may be parties in cases before the [International] Court [of Justice]."); *see also* Understanding on Rules and Procedures Governing the Settlement of Disputes art. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU]; COLLIER & LOWE, *supra* note 123, at 132–69 (describing the nature and scope of ICJ jurisdiction); Robert O. Keohane, Andrew Moravcsik & Anne-Marie Slaughter, *Legalized Dispute Resolution: Interstate and Transnational*, 54 INT'L ORG. 457, 463 (2000) (referring to "the GATT and WTO panels" and the ICJ as "interstate tribunals . . . in which only member states may file suit against one another.").

¹⁶² *Barcelona Traction, Light and Power Company, Limited (Belgium v. Spain)*, 1970 I.C.J. 3 (Feb. 5). In a more recent case, the Court has recognized the residual nature of the exercise of diplomatic protection and recourse to the Court in case of investment disputes. *Case Concerning Ahmadou Sadio Diallo (Guinea v. Dem. Rep. Congo)*, 2007 I.C.J. 582, ¶ 88–91 (May 24) (Preliminary Objections).

exercise it at their will.¹⁶³ While companies lobby their governments to file disputes before the WTO DSM, it is up to the states to decide whether to bring a claim.¹⁶⁴ The home state may be reluctant to initiate a trade dispute because of political and diplomatic considerations, especially when the alleged IP violation is limited in scope.¹⁶⁵ Even when the home state does bring an ICJ or WTO claim, governments are generally more wary in promoting interpretations of international law that could limit their own regulatory freedom in the future.¹⁶⁶ An investor would exercise limited, if any, control over the dispute settlement strategy. Moreover, under an ICJ or WTO dispute, the state would be under no obligation to pay any reparation to the IP owners who were actually injured.¹⁶⁷ Remedies under the WTO DSM¹⁶⁸ have only a prospective character.¹⁶⁹

¹⁶³ MALCOLM N. SHAW, *INTERNATIONAL LAW* 589 (7th ed. 2014) (“There is under international law no obligation for states to provide diplomatic protection for their nationals abroad.”).

¹⁶⁴ See generally Petros C. Mavroidis et al., Panel Discussion, *Is the WTO Dispute Settlement Mechanism Responsive to the Needs of the Traders? Would a System of Direct Action by Private Parties Yield Better Results?*, 32 *J. WORLD TRADE* 14 (1998) 147–165 (discussing the questions whether the WTO DSM is responsive to the traders’ economic interests and whether a system of direct action would better serve those interests); Joel P. Trachtman & P.M. Moremen, *Costs and Benefits of Private Participation in WTO Dispute Settlement: Whose Right is it Anyway?*, 44 *HARV. INT’L L.J.* 221 (2003) (analyzing the role of private actors in the WTO DSM); A. Catbagan, *Rights of Action for Private Non-State Actors in the WTO Disputes Settlement System*, 37 *DENV. J. INT’L L. & POL’Y* 279, 302 (2008) (proposing the institutionalization of direct action by private parties).

¹⁶⁵ CHRISTINA L DAVIS, *SETTING THE NEGOTIATION TABLE* 21 (2005) (“Low-profile issues that do not have a strong interest group on either side ... are unlikely to rise to the level of adjudication. A government will be reluctant to initiate the formal adjudication process if there is not a strong interest group with sufficient political and economic interests to gather the backing for a formal dispute complaint. Government officials rely on interest groups to provide the background information to help select and prepare trade dispute cases.”).

¹⁶⁶ Sean Flynn, *How the Leaked TPP ISDS Chapter Threatens Intellectual Property Limitations and Exceptions*, *INTELLECTUALPROPERTYWATCH.ORG*, (Mar. 26, 2015), <http://www.ip-watch.org/2015/03/26/how-the-leaked-tpp-isds-chapter-threatens-intellectual-property-limitations-and-exceptions/>.

¹⁶⁷ MARTIN DIXON, ROBERT MCCORQUODALE & SARAH WILLIAMS, *CASES AND MATERIALS ON INTERNATIONAL LAW* 423 (5th ed. 2011) (noting that “[b]ecause a State brings an international claim for its own injury, it is neither under an obligation to exercise diplomatic protection nor to pay any reparation (including compensation) received by it to the national actually injured.”).

¹⁶⁸ See generally DSU.

¹⁶⁹ Geraldo Vidigal, *Re-Assessing WTO Remedies: The Prospective and the Retrospective*, 16 *J. INT’L ECON. L.* 505, 505 (2013) (noting the “World Trade Organization (WTO) system of ‘prospective’ or ‘forward-looking’ remedies” and highlighting “their different functions when contrasted to reparation: inducing compliance *ex post*, rather than discouraging it *ex ante*.”).

Inversely proportional to the decrease of patent disputes at the DSM,¹⁷⁰ the number of patent investor-state arbitrations has arisen.¹⁷¹ While the effectiveness of the DSM is under dispute,¹⁷² the recent rise of IP-related investment disputes may indicate a shift of forum.¹⁷³

Second, investment arbitration may be a suitable choice when the host state's judiciary does not seem to ensure fair trials or impartiality. In such circumstances, the foreign investor may immediately refer the dispute to arbitration.¹⁷⁴ Alternatively, the investor-state arbitration 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 for reasons such as perceived discrimination and denial of justice.¹⁷⁵

Third, the dispute settlement chapters of a number of Free Trade Agreements provide for the option of filing non-violation complaints for IP rights,¹⁷⁶ which is not currently possible under the TRIPS Agreement. Non-

¹⁷⁰ Yoshifumi Fukunaga, *Enforcing TRIPS: Challenges of Adjudicating Minimum Standards Agreements*, 23 BERKELEY TECH. L.J. 868, 879 (2008) (noting that “the use of the WTO DSM to resolve TRIPS disputes has fallen, while its use to resolve general trade disputes continues unabated.”).

¹⁷¹ *But see* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (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); Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997).

¹⁷² Fukunaga, *supra* note 170 (noting “there remain questions regarding the effectiveness of the WTO DSM in the TRIPS context.”).

¹⁷³ States have increasingly settled potential IP-related disputes. *Id.* at 888–889 (noting that “more than half of the disputes concerning TRIPS were settled within the consultation process through a mutually agreed solution.”). The TRIPS Council may have helped in reducing the number of IP-related disputes. *Id.* at 894, 897 (noting that “[t]he Council’s effectiveness as a monitoring body might be working to preempt potential disputes well before they would reach the DSM.”). In fact, discussion of given issues before the Council allows member states to explain, discuss and eventually adjust their regulatory measures.

¹⁷⁴ However, in case of denial of justice claims, the exhaustion of local remedies is needed.

¹⁷⁵ *See generally* Michael Goldhaber, *The Rise of Arbitral Power Over Domestic Courts*, 1 STAN. J. OF COMPLEX LITIG. 373, 375 (2013) (tracing the doctrinal evolution of the denial of justice doctrine and discussing the rise of arbitral power over domestic courts more generally.).

¹⁷⁶ GATT, *supra* note 77, at art. 23(1)(b), (c) (“If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of . . . (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or (c) the existence of any other situation, the contracting party may, with a view to the satisfactory adjustment of the matter, make written

violation complaints are geared toward state measures that do not appear to directly violate treaty provisions but are nevertheless sufficiently disadvantageous to the investor's IP. The aim of the provision is to maintain the balance of benefits struck during negotiations and transfer from the treaty-negotiating parties to arbitral panels the authority to decide when the investor has suffered enough disadvantage. There are indications that non-violation complaints have already been raised before investment tribunals.¹⁷⁷ Non-violation complaints about IP regulation were controversial during the TRIPS negotiations and remain so.¹⁷⁸ While the TRIPS Agreement provides for such remedies,¹⁷⁹ WTO Members have adopted a moratorium and agreed not to use non-violation complaints.¹⁸⁰ This is because non-violation complaints were historically used in GATT to address situations that were not specifically covered by the vague obligations of the agreement.¹⁸¹ Therefore, they were not needed in the TRIPS context, in which member states' obligations had been more clearly detailed in international conventions including the TRIPS Agreement and the Paris Convention.¹⁸²

representations or proposals to the other contracting party or parties which it considers to be concerned. Any contracting party thus approached shall give sympathetic consideration to the representations or proposals made to it.”). See generally Susy Frankel, *Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes*, 12 J. INT'L ECON. L. 1023 (2009).

¹⁷⁷ 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).

¹⁷⁸ Haochen Sun, *TRIPS and Non-Violation Complaints From a Public Health Perspective*, CTR. FOR INT'L DEV. AT HARV. UNIV. 5 (2002), <http://www.cid.harvard.edu/cidtrade/Papers/Sun-TRIPS.pdf> (“During the TRIPS negotiations in particular, there was significant disagreement regarding the inclusion of a provision on non-violation in the context of intellectual property disputes,” and that “[t]he potential application of the non-violation remedy to the TRIPS Agreement remains controversial.”).

¹⁷⁹ TRIPS Agreement art. 64.2.

¹⁸⁰ The 9th WTO Ministerial Conference held in Bali, Indonesia (3–7 December 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. Press Release, WTO, Intellectual Property Meeting Mulls Irish Tobacco Plan, Drug Tariffs, Sport, Non-Violation (Oct. 10, 2013), https://www.wto.org/english/news_e/news13_e/trip_10oct13_e.htm#nonviolation.

¹⁸¹ ROBERT E. HUDEC, ENFORCING INTERNATIONAL TRADE LAW: THE EVOLUTION OF THE MODERN GATT LEGAL SYSTEM, 7 (1993) 7 (noting that the non-violation procedure allows, to a certain extent, “the closing-up of a loophole in substantive law, offering the possibility of maintaining the balance of interests even in cases where the substantive law dose not cover the issues at hand”).

¹⁸² Paris Convention, *supra* note 65.

Finally, the increasing use of investment arbitration for settling patent-related disputes may reflect the growing importance of “intellectual capital” as a source of wealth generation vis-à-vis other forms of capital investment in industries such as the extractive industries, and manufacturing. Ideas play a vital role in modern economies.¹⁸³ Science, technology, and creativity generate economic value and increase the significance of intellectual property¹⁸⁴ as useful tools to incentivize creativity and technological development on as well as enhance access to technology.¹⁸⁵

IV

TOWARDS A NEW DIALECTICS: PHARMACEUTICAL PATENTS, PUBLIC HEALTH AND FOREIGN DIRECT INVESTMENTS

In recent years, a growing number of investor-state arbitrations have concerned the way host states govern the pharmaceutical sector. Arbitrations have been filed against both industrialized and developing countries in different continents, indicating that the phenomenon has a truly global scale.¹⁸⁶ The rise of patent-related investment arbitrations highlights the emergence of a new battlefield between the public and private interests. Investment arbitrations provide a new place of dialectical interaction between the private interests of the patent holders and the public interest of the host states in preserving access to medicines and ensuring the safety and effectiveness of given pharmaceutical products.

Some of these arbitrations are related to states’ regulatory measures in the patent system.¹⁸⁷ For instance, the first known investment arbitration dealing with pharmaceutical patents, *Signa S.A. v. Canada*,¹⁸⁸ challenged Canada’s patent regulations. Signa, a Mexican generic pharmaceutical company, contended that the regulations governing the authorization process violated the

¹⁸³ Christopher S. Gibson, *Latent Grounds in Investor-State Arbitration: Do International Investment Agreements Provide New Means to Enforce Intellectual Property Rights?*, Y.B. ON INT’L INV. LAW & POL’Y 397, 398 (2010) [hereinafter Gibson, *Latent Grounds in Investor-State Arbitration*] (noting that modern economies have become “predominantly ‘conceptual,’ reflecting the vital role of ideas in ... products and services.”).

¹⁸⁴ *Id.* at 398.

¹⁸⁵ *Id.* at 412.

¹⁸⁶ These arbitrations are showcased in the subsections below, which distinguish and categorize them on the basis of the claims articulated by the claimants.

¹⁸⁷ See, e.g., *Eli Lilly and Co. v. The Government of Canada*, ICSID Case No. UNCT/14/2, <http://www.italaw.com/cases/1625>.

¹⁸⁸ *Signa S.A. v. Government of Canada*, Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement (Mar. 4, 1996), <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/signa-01.pdf>.

fair and equitable treatment standard under Article 1105 of the NAFTA.¹⁸⁹ Signa established a joint venture with the Canadian company Apotex, Inc. for the production of a generic version of Bayer's top-selling ciprofloxacin hydrochloride, an antibiotic that treats a number of bacterial infections.¹⁹⁰ In order to sell the pharmaceutical in Canada, an authorization was required by the relevant authorities.¹⁹¹ According to the claimant, the relevant regulations provided that "by merely purporting to have a relevant patent, a person c[ould] obtain a mandatory prohibition against a generic competitor for a period of about 3 years."¹⁹² Because Bayer, the patent holder company, prevented Apotex and Signa from making ciprofloxacin hydrochloride for a period of about three years, Signa claimed loss of revenues and market share.¹⁹³ As the parties quickly settled this case, there is no publicly available information on the dispute and whether the filing of the Notice of Intent to Arbitrate had any strategic or other impact is not known. Nonetheless, the case is significant because it shows that foreign investors can challenge patent regulation governing the duration of patent protection and even the authorization processes.

Other arbitration disputes relate to various issues, ranging from the regulation of competition law to the implementation of harmonization measures in the pharmaceutical sector required by the European Union. For instance, Uruguay is reportedly facing an arbitration claim over a recent decree that limits the concentration of ownership in Uruguay's pharmacy sector.¹⁹⁴ A U.S. investment fund has filed Notices of Dispute pursuant to the Spain–Uruguay and U.S.–Uruguay BITs respectively, alleging that the decree harms the company's recent investment in a chain of local pharmacies.¹⁹⁵ In parallel, the *Servier v. Poland* case arose because of regulatory measures adopted by Poland to implement EU law harmonizing pharmaceutical regulations.¹⁹⁶

By including IP within their ambit, IIAs restrict the regulatory autonomy of states in the pharmaceutical sector, potentially affecting fundamental public

¹⁸⁹ *Id.* ¶¶ 4, 12.

¹⁹⁰ *Id.* ¶¶ 1–3.

¹⁹¹ *Id.* ¶ 4.

¹⁹² *Id.* ¶ 6.

¹⁹³ *Id.* ¶ 9.

¹⁹⁴ Luke Eric Peterson, *Uruguay Threatened over Decree Affecting Ownership of Pharmacies*, INVESTMENT ARBITRATION REPORTER (May 13, 2014), <http://www.iareporter.com/articles/round-up-water-concessionaire-warns-estonia-under-dutch-treaty-uruguay-threatened-over-decree-affecting-ownership-of-pharmacies/>.

¹⁹⁵ *Id.*

¹⁹⁶ Luke Eric Peterson, *France's Second Largest Pharmaceutical Company Quietly Pursues Arbitration Against Republic of Poland*, INVESTMENT ARBITRATION REPORTER (Aug. 19, 2011), <http://www.iareporter.com/articles/frances-second-largest-pharmaceutical-company-quietly-pursues-arbitration-against-republic-of-poland/>.

interests. These disputes give rise to both jurisdictional and substantive issues. First, some disputes will center on the jurisdictional issue of which economic activities amount to an investment, giving rise to an arbitral tribunal's jurisdiction over the dispute.¹⁹⁷ Second, some investment disputes are concerned with whether or not a certain state action constitutes an unlawful expropriation of the patent right.¹⁹⁸ Third, if an expropriation has occurred, claims may concern the adequacy of the amount or form of compensation.¹⁹⁹ Fourth, the patent owner may also allege violation of the fair and equitable treatment standard.²⁰⁰ Finally, some claims may concern alleged discrimination suffered by the foreign investor in violation of national treatment and most favoured nation treatment.²⁰¹ This article examines each of these claims.

While it is too early to predict how relevant arbitral tribunals will adjudicate these cases, such disputes highlight the emergence of an additional litigation venue, *i.e.* investment treaty arbitration, for resolving pharmaceutical patent-related disputes. International investment agreements enable private companies to file claims against the host states directly without the intervention of the home state and to recover damages and loss of profits; they internationalize a given dispute, isolating it from the oversight of the domestic courts of the host state.

At the same time, these new dialectics require the elaboration of new procedural, substantive and interpretive legal tools for recalibrating the expectations, entitlements and powers of the litigating parties. In fact, at the procedural level, investment treaty arbitration may not be adequate to enable arbitrators to strike an optimal equilibrium between public and private interests. As IP disputes can affect important public values, these arbitrations and the relevant awards should be disclosed to the public. Moreover, at the substantive level, arbitrators may not have in-depth expertise of IP law and the underlying policy considerations. The risk is that an inadequate appreciation of the policies underlying IP rights by adjudicators may lead to an overemphasis of the private interests and an under-emphasis of the public interests. The propertization of patents, *i.e.* conceiving them as mere assets, may lead interpreters to forget that they are based on a compromise between public and private interests.²⁰² As the substantive interplay between IP and international investment law remains

¹⁹⁷ See *infra* Section IV. A.

¹⁹⁸ See *infra* Section IV. B.

¹⁹⁹ See *infra* Section IV. B.

²⁰⁰ See *infra* Section IV. D.

²⁰¹ See *infra* Section IV. E.

²⁰² See Dreyfuss & Frankel, *supra* note 66, at 3–4 (pinpointing the reconceptualization of IP by international law).

uncharted,²⁰³ and the functioning of investment treaty obligations with regard to IP, the parties' expectations, and enforcement aspects of these treaties are largely unexplored.²⁰⁴ Interpretation is crucial to striking an appropriate balance between private and public interests. The next subsections provide an overview of the existing patent-related investment disputes and are organized by issues that may arise in arbitration.

A. *The Notion of Investment*

International investment agreements are “agreements concluded between states for the promotion and protection of reciprocal investments.”²⁰⁵ Addressing the question as to whether certain economic activities relating to pharmaceutical products amount to an investment is crucial to establishing an arbitral tribunal's subject matter jurisdiction. A patent holder is entitled to the substantive and procedural protections afforded by the treaty only if the treaty classifies her as an “investor” or her economic activity as an “investment”. If a given economic activity—*in casu*, a pharmaceutical patent—constitutes a protected investment, the patent holder will benefit from the substantive protections of the applicable IIA.

In order to ascertain whether pharmaceutical patents constitute a form of protected investment under a given IIA, one has to look at the specific text of the applicable treaty. If the parties have opted for resolving their dispute at the ICSID, the ICSID Convention will be also applicable, which extends jurisdiction “to any legal dispute arising directly out of an investment.”²⁰⁶ In this situation, the adjudicators will have to determine whether a given economic activity constitutes an investment under both the ICSID Convention and the applicable IIA. Patents are usually considered a form of investment under the ICSID Convention and most IIAs.

²⁰³ 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 L. 163 (1998).

²⁰⁴ Ruth L. Okediji, *Is Intellectual Property “Investment”?* *Eli Lilly v. Canada and the International Intellectual Property System*, 35 U. PA. J. INT'L L. 1121, 1124 (2014) [hereinafter Okediji, *Is Intellectual Property “Investment”?*] (noting that “[a]lthough the definition of ‘investment’ contained in most investment treaties mention intellectual property, the obligations, expectations, and enforcement aspects of these treaties are largely undeveloped.”).

²⁰⁵ Boie, *supra* note 2, at 4 (defining IIAs – a term encompassing both “bilateral investment treaties (BITs) and FTAs or Regional Trade Agreements (RTAs) with investment chapters” – as “agreements concluded between states for the promotion and protection of reciprocal investments.”).

²⁰⁶ ICSID Convention, *supra* note 135, at art. 25(1).

The ICSID Convention does not provide a definition of investment.²⁰⁷ Rather, it stipulates that ICSID jurisdiction extends “to any legal dispute arising directly out of an investment.”²⁰⁸ In practice this has meant that commentators and arbitral tribunals have elaborated a number of criteria for defining the term.²⁰⁹ Most notably, the leading test was articulated by *Salini v. Morocco*, which involves 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.²¹⁰ In general terms, tribunals allow the consideration of pharmaceutical patents as a form of investment. First, pharmaceutical patents are assets of economic value, with a duration of twenty years. Second, creating a medicine involves an element of risk, as it may take years of research and development. Finally, the availability of pharmaceutical products—which goes hand in hand with the protection of pharmaceutical patents—can improve the public health of a given country, and albeit indirectly, to its economic development. These requirements embody a balance between the private interests of foreign companies and the public interest of the host state, because they ensure that economic activities are protected as long as they contribute to the economic development of the host state.

However, given the vagueness of the ICSID Convention, the definition of investment provided by the applicable IIA will often be decisive for ascertaining whether a given activity constitutes an investment, because the

²⁰⁷ Alex Grabowski, *The Definition of Investment Under the ICSID Convention: A Defense of Salini*, 15 CHI. J. INT’L L. 287, 293 (2014) (noting that “[t]he signatories to the [ICSID] convention purposefully left the term ‘investment’ undefined when granting the body jurisdiction over matters of international investment.”).

²⁰⁸ ICSID Convention, *supra* note 135, at art. 25(1).

²⁰⁹ Grabowski, *supra* note 207, at 293 (noting that “[a] variety of tribunals have applied a plethora of different tests . . .”).

²¹⁰ *Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco*, ICSID Case No. ARB/00/4, Decision on Jurisdiction, (July 23, 2001). The need for the last element, the contribution to the economic development of the host state, is sometimes put in doubt. See *L.E.S.I.–DIPENTA v. République Algérienne Démocratique et Populaire*, Decision on Jurisdiction, (July 12, 2006); *Apotex Holdings Inc. v. United States (Apotex III)*, ICSID Case No. ARB(AF)/12/1, Award, ¶ 7.62 (Aug. 25, 2014) (holding that it did not seem necessary that the investment contribute to the economic development of the country; according to the Tribunal, the contribution to economic development was difficult to establish, and was implicitly covered by the other three elements of an investment); *Quiborax 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).

specific languages of the IIAs are frequently given deference.²¹¹ In *Servier v. Poland*,²¹² a dispute concerning the commercialization of pharmaceuticals in Poland, the Tribunal upheld its jurisdiction notwithstanding Poland's opposition.²¹³ According to Poland, the presence of Servier subsidiaries in Poland did not entitle Servier to recover,²¹⁴ as the claimants did not have any investments in the host state itself under Polish law.²¹⁵ Servier counter-argued that "it [wa]s the Treaty, not Polish law, that [wa]s relevant in assessing whether Servier's assets [we]re protected investments."²¹⁶ The Tribunal held that it possessed jurisdiction, acknowledging that the companies were incorporated in France, thus being foreign investors, and therefore it had jurisdiction *ratione personae*.²¹⁷

It usually requires a case-by-case analysis to determine whether IP constitutes an investment²¹⁸ because different IIAs provide different definitions of investment. BITs do not include detailed regulation of pharmaceutical patents. Rather, they briefly mention IP rights as a form of protected investment.²¹⁹ Some IIAs incorporate a broad definition of investment that generally covers both tangible and intangible property.²²⁰ Other IIAs either

²¹¹ Malaysian Historical Salvors SDN BHD v. The Government of Malaysia, ICSID Case No. ARB/05/10, Decision on the Application for Annulment (Apr. 16, 2009).

²¹² Les Laboratoires Servier, S.A.S., Biofarma, S.A.S., Arts et Techniques du Progrès v. Republic of Poland, Award, ¶¶ 515, 532 (Feb. 14, 2012).

²¹³ *Id.* ¶ 190 (noting that Servier did not plead that the marketing authorizations were a protected investment).

²¹⁴ *Id.* ¶ 206.

²¹⁵ *Id.* ¶ 222.

²¹⁶ *Id.*

²¹⁷ *Id.* ¶ 510, 518.

²¹⁸ Okediji, *Is Intellectual Property "Investment"?*, *supra* note 204, at 1126.

²¹⁹ *Id.* (noting that "[s]uch agreements usually protect intellectual property by including it in the definition of investment."). Conversely, FTAs often include a distinct chapter for governing intellectual property. *See id.* (highlighting that "[t]he fact in RTAs, that several subject matters, including both investment and IP, are covered in one single agreement may have significant consequences for the interplay of these provisions"). IP chapters providing for higher standards of IP protection than those provided by the TRIPS Agreement are known as 'TRIPS-plus.' *See* Beatrice Lindstrom, *Scaling Back TRIPS-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific*, NYU J. OF INT'L L. AND POL. 917, 919 (2010) (noting that "[o]ver the past ten years, a new trend has developed in which bilateral trade agreements mandate changes to domestic intellectual property laws, resulting in laws that exceed the standards agreed to at the WTO. These agreements are referred to as 'TRIPS-plus.'") A complete analysis of the interactions between the investment and IP chapters of FTAs is outside the scope of this article.

²²⁰ For instance, Article 1139(g) of the North American Free Trade Agreement (NAFTA) states "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."

generally refer to IP rights, or explicitly indicate the types of IP covered, such as copyright, patents, industrial designs, trade secrets, trademarks and others.²²¹

A question that often arises is whether patent applications are covered investments under the relevant investment treaty. Although registered patents are covered in most investment treaties, it remains an open question as to whether patent applications should be deemed a form of protected investment even if they are not entitled to the same protections as a patent itself.²²² Certain IIAs expressly exclude the possibility that patent applications constitute protected investments.²²³ Other investment treaty provisions protecting “rights with respect to [IP]”²²⁴ or “patentable inventions” leave much uncertainty.²²⁵ For instance, the U.S.–Jamaica BIT covers patentable inventions and therefore should cover patent applications as investments.²²⁶ Other IIAs protect

North American Free Trade Agreement, signed on 17 December 1992, in force on 1 January 1994, 32 ILM 289, 605 (1993).

²²¹ See, e.g., the Agreement between the Swiss Confederation and the Dominican Republic on the Promotion and Protection of Investments (CH-Cuba BIT), art. 1.2(d) (stating that “[t]he 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”). The first BIT, signed between West Germany and Pakistan in 1959, included “patents and technical knowledge” in the definition of “investment.” Treaty for the Promotion and Protection of Investments, Ger.-Pak., art. 8(1)(a), Nov. 25, 1959, 457 U.N.T.S. 24 (affirming that “[t]he term ‘investment’ shall comprise capital brought into the territory of the other Party for investment in various forms in the shape of assets such as foreign exchange, goods, property rights, patents and technical knowledge.”).

²²² Liberti, *supra* note 117, at 8 (“A first issue regarding the scope of the definition of investment is whether patent applications, though not an IPR, would qualify as an intangible property.”).

²²³ See, e.g., 2009 ASEAN Comprehensive Investment Agreement, art. 4(c) (limiting an “investment” to “intellectual property rights which are conferred pursuant to the laws and regulations of each Member State.”).

²²⁴ Agreement Between the Government of Hong Kong and the Government of Australia for the Promotion and Protection of Investment, Austl.-H.K., art 1(e)(iv), Sep. 15, 1993, 1748 U.N.T.S. 385; Agreement Between the Government of Canada and the Government of the Republic of Argentina for the Promotion and Protection of Investment, Arg.-Can., art. 1(a)(iv), May 11, 1991, 2467 U.N.T.S. 97.

²²⁵ Treaty Between the United States of America and Jamaica Concerning the Reciprocal Encouragement and Protection Investment, Jam.-U.S., art. I.1(a)(iv), Feb. 2, 1994, S. TREATY DOC. NO. 103–35.

²²⁶ *Id.* (stating that “[f]or the purposes of this Treaty, (a) ‘investment’ means every kind of investment in the territory of one Party owned or controlled directly or indirectly by nationals or companies of the other Party, such as equity, debt, and service and investment contracts; and includes without limitation: ... (iv) intellectual property which includes, inter alia, rights relating to: literary and artistic works, including sound recordings, patentable inventions,

“intangible property” and arguably this generic notion can include patent applications.²²⁷ As patent applications can be sold and assigned to third parties,²²⁸ the argument goes that they are a form of “intangible property,” even though they do not constitute “intellectual” property.²²⁹ The European Court of Human Rights held that both registered trademarks and applications to register trademarks were “property rights” within the meaning of Article 1 of Protocol No. 1 of the European Convention on Human Rights.²³⁰ The fact, however, that most investment treaties provide protection to both investors and their investments only after the establishment of an investment suggests that a case-by-case analysis is needed.

Recently in *Apotex Holdings Inc. v. United States (Apotex III)*, a Tribunal held that patent applications were not investments under NAFTA Chapter 11.²³¹ The claimants sought over \$1 billion in damages from the United States²³² after the U.S. Food and Drug Administration (FDA) imposed an Import Alert on certain generic medicines that were produced in Canada by Apotex Inc., exported to the U.S. and sold in that market by a U.S.-based Apotex subsidiary.²³³ According to the respondent, the FDA issued the alert after its inspections of Apotex facilities in Canada found “significant violations of U.S. laws and regulations.”²³⁴ The United States emphasized that Apotex produced all of its products in Canada,²³⁵ and argued that the cross-border trade of pharmaceuticals did not constitute an investment.²³⁶ The claimants argued that

industrial designs, semiconductor mask works, trade secrets and confidential business information, and trademarks, service marks, and trade names.”).

²²⁷ See generally Liberti, *supra* note 117.

²²⁸ Bryan Mercurio, *Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements*, 15 J. OF INT’L ECON. L. 871, 878 (2012) (“For instance, the value of the expected IPRs (and hence the expected profit to be derived from the IPRs) can be vast and easily quantifiable as, for instance, applications for a patent (and in some jurisdictions, applications for trademark) can be sold and assigned to third parties.”).

²²⁹ Patents can only be acquired through registration.

²³⁰ *Anheuser-Busch Inc. v. Portugal*, 45 Eur. Ct. H.R. 36 (2007).

²³¹ *Apotex Holdings Inc. v. United States (Apotex III)*, ICSID Case No. ARB(AF)/12/1, Award, ¶ 7.62 (Aug. 25, 2014).

²³² *Id.* ¶ 2.34.

²³³ *Id.* ¶ 2.24.

²³⁴ *Id.* ¶ 2.40.

²³⁵ *Id.* ¶ 2.51 (“The Respondent submits that Apotex Inc. does not claim to manufacture or even test any drugs in the USA; nor does it assert the existence of any offices or employees in the USA; nor does it assert the existence of any offices or employees in the USA; it pays no taxes in the USA on its supposed investments (including its ANDA-related activities)”).

²³⁶ *Id.* ¶ 2.37 (contending that “the Tribunal has no jurisdiction to decide the Parties’ dispute under NAFTA”; that “the Claimants’ complaint is in fact directed at a trade measure”; and that “the Claimants are seeking improperly in these proceedings to convert a

they had the following investments in the U.S.: 1) certain intellectual property rights, that is, abbreviated new drug applications (ANDAs), directly held by Apotex Inc. and indirectly held by Apotex Holdings;²³⁷ and 2) Apotex Corp., a U.S.-based subsidiary of Apotex Holdings, that markets pharmaceuticals produced in Canada.²³⁸

The Tribunal held that ANDAs were not “investments” in the United States.²³⁹ In this regard, the Tribunal followed previous awards (*Apotex I* and *II*) which rejected claims that applications for the sale of medicines into a host state could be considered investments.²⁴⁰ 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.²⁴¹ Therefore, the only investment was the subsidiary Apotex Corp. Commentators criticized the award on this latter point, submitting that it “blurs the line between trade and investment disputes,” and that companies might use their subsidiaries as a kind of “Trojan horse” for obtaining protection under the relevant BIT.²⁴²

The mere sale of pharmaceutical products does not amount to an investment. Mere sales of goods do not have the prerequisites of a certain duration, risk and contribution to the economic development of the host state which characterize investments. Rather, 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.²⁴³ As mentioned, IIAs reflect a bargain where the state restricts some of its sovereign rights to attract foreign investments. When the private party is not holding up her end of the bargain by taking risks and making a real contribution to the host state’s economy, such sales are not investments and are not entitled to the substantive protection of the IIA.

possible trade-related claim between NAFTA Contracting States (under NAFTA Chapter Twenty) into an investment claim by a foreign entity (under NAFTA Chapter Eleven).”).

²³⁷ *Id.* ¶ 2.28.

²³⁸ *Id.* ¶ 2.27.

²³⁹ *Id.* ¶ 7.62.

²⁴⁰ *Apotex Inc. v. United States*, UNCITRAL, Award on Jurisdiction and Admissibility (June 14, 2013).

²⁴¹ *Apotex III*, ¶ 7.62. One of the three arbitrators dissented from the Tribunal’s conclusion. He suggested that approved ANDAs can be bought and sold and are in other ways treated as property under U.S. law. *Id.* ¶ 7.66.

²⁴² Lise Johnson, *New Weaknesses: Despite a Major Win, Arbitration Decisions in 2014 Increase the US’s Future Exposure to Litigation and Liability* 4 (2015), <http://ccsi.columbia.edu/files/2014/03/Brief-on-US-cases-Jan-14.pdf>.

²⁴³ Okediji, *Is Intellectual Property “Investment”?*, *supra* note 204, at 1126.

An arbitral tribunal recently clarified that the mere sale of medicines does not amount to an investment in *Italy v. Cuba*.²⁴⁴ Italy initiated this investment treaty arbitration arguing that the contractual agreement between Menarini, an Italian pharmaceutical company, and Medicuba, an entity affiliated with the Cuban Ministry of Health, was an investment protected under the Italy-Cuba BIT.²⁴⁵ According to the claimant, the agreement did not relate merely to the supply of medicines, but also included the research and development of new pharmaceutical products.²⁴⁶ 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.²⁴⁷ The respondent counter-argued that Menarini was not an “investor” as it merely sold its products to Medicuba and had no subsidiary in Cuba.²⁴⁸ 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.²⁴⁹ Cuba concluded that it had reached an agreement with the company, according to which Cuba would have paid its invoices, while the company would have started its commercial operations with Medicuba again.²⁵⁰ After reaching the mentioned agreement with Cuba, Menarini ceased to invoke diplomatic protection.²⁵¹ In light of this circumstance, Italy withdrew its diplomatic protection.²⁵² However, it did not withdraw the claim in its own name.²⁵³

²⁴⁴ *La Republique d’Italie v. La Republique de Cuba*, UNCITRAL, Arbitrage ad hoc, Sentence Finale, ¶ 219 (Jan. 15, 2008). Italy espoused the claims of sixteen investors operating in different fields and raised claims in its own name for breach of the Italy-Cuba BIT. *Id.* at ¶ 46. 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. *Id.* ¶ 96(1)(e)(6).

²⁴⁵ See, e.g., Enrico Milano, *The Investment Arbitration between Italy and Cuba: The Application of Customary International Law under Scrutiny*, 11 L. & PRACTICE OF INT’L CTS AND TRIBUNALS 424, 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).

²⁴⁶ *La Republique d’Italie v. La Republique de Cuba*, UNCITRAL, Arbitrage ad hoc, Sentence Finale, ¶ 219 (Jan. 15, 2008).

²⁴⁷ *Id.* ¶ 90.

²⁴⁸ *Id.* ¶ 134.

²⁴⁹ *Id.*

²⁵⁰ *Id.* ¶ 136.

²⁵¹ *Id.* ¶ 39.

²⁵² *Id.* ¶ 39, n.1.

²⁵³ *Id.* ¶ 93. In fact, Italy did still have standing to sue in its own name.

The Tribunal found Menarini's activities not an investment, and dismissed Italy's claims due to lack of subject matter jurisdiction. In its reasoning, 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, for a certain duration and involving commercial risks.²⁵⁴ After examining the contract between Menarini and Medicuba, tellingly entitled "Contrato de Compra-Venta" which translates to "Contract of Sale,"²⁵⁵ the Tribunal held that the given commercial activity was not an investment but a sale of pharmaceuticals. As there was neither contribution of resources into Cuba nor assumption of risk beyond the mere risk of nonpayment, the Tribunal held that such sale of medicines did not constitute an investment protected under the Italy–Cuba BIT.²⁵⁶ 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.²⁵⁷

To summarize, the question as to whether intellectual property constitutes an "investment" requires a case-by-case assessment. Mere sales of pharmaceuticals do not amount to investments. IIAs reflect a bargain—where the state gives up some of its sovereign rights in exchange for a better chance of attracting foreign investments. Arbitral tribunals have taken this bright-line rule that when it is mere sale of goods, the state is not gaining enough from the bargain and the investor is not contributing enough by taking risks or contributing to the economic development of the state.²⁵⁸ Patent applications create a mere expectation of obtaining a patent but do not constitute patents.

²⁵⁴ *La Republique d'Italie v. La Republique de Cuba*, UNCITRAL, Arbitrage ad hoc, Sentence Finale, ¶ 81 (Jan. 15, 2008) ("sauf 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.").

²⁵⁵ *Id.* ¶ 215.

²⁵⁶ *Id.*

²⁵⁷ *Id.* ¶ 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.").

²⁵⁸ For instance, the sale of cattle was deemed not to constitute an investment in the *Canadian Cattlemen* case. In 2003, when the United States closed the U.S.–Canadian border to beef and cattle after a case of mad cow disease was discovered in Canada, a group of Canadian cattlemen brought a NAFTA Chapter 11 suit alleging that the U.S. discriminated against Canadian operators, because it allowed U.S. cattlemen who owned Canadian cattle to keep it, while stopping Canadian cattle (of Canadian operators) at the border. Thus, Canadian cattlemen requested damages for losses incurred during the border closure. The case was dismissed on jurisdictional grounds. *Canadian Cattlemen for Fair Trade v. United States*, UNCITRAL, Award on Jurisdiction (28 Jan. 2008).

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 IIA.²⁵⁹ Because the specific language of the treaty reflects the voluntary consent of the state involved, it can be presumed that the states have already taken the public interest into account when accepting to protect patent applications as forms of investments.

Any determination of intellectual property as an “investment” in international investment law and arbitration has far-reaching policy implications. Firstly, the IIA language reflects a delicate balance between private and public interests. States can shape this balance when defining investment in their IIAs—a fine balance that is also intrinsic in the protection of pharmaceutical patents. Secondly, when arbitral tribunals determine whether an economic activity constitutes an investment, such determination can affect both foreign and domestic pharmaceutical companies.²⁶⁰ In fact, the tribunals’ awards could have effects reverberating beyond the parties to the given disputes. Although the rule of *stare decisis*, or binding precedent, does not apply to international arbitration and awards are binding only between the parties,²⁶¹ previous arbitral awards have influenced, if not shaped, much of contemporary investment law.²⁶²

For example, if a patent application is considered to be a protected investment, private interests may receive a higher level of protection than they otherwise would be and the state regulatory autonomy will be restricted according to the relevant investment treaty provisions. By contrast, if a patent application is not considered to be a protected investment, private interests will receive a lower level of protection than they otherwise would, but the host state will preserve its regulatory autonomy. Therefore, it is crucial that when treating intellectual property as an “investment,” arbitrators should consider the precise wording of the applicable investment treaty and the underlying policy implications,²⁶³ taking into account both private and public interests. The determination whether a certain economic activity constitutes an investment can

²⁵⁹ Gibson, *Latent Grounds in Investor-State Arbitration*, *supra* note 183, at 433.

²⁶⁰ Okediji, *Is Intellectual Property “Investment”?*, *supra* note 204, at 1127 (noting that both investor and state “will be affected by any resulting welfare loss.”).

²⁶¹ See ICSID Convention, *supra* note 135, at art. 53 (stating that “The award shall be binding on the parties . . .”); see also NAFTA, *supra* note 16, at art. 1136(1) (providing that “an award made by a Tribunal shall have no binding force except between the disputing parties and in respect of the particular case.”).

²⁶² Gabrielle Kaufmann-Kohler, *Arbitral Precedent: Dream, Necessity or Excuse?*, 23 *ARB. INT’L* 357 (2007).

²⁶³ *Id.* at 1136 (illustrating “the dangers of treating intellectual property as ‘investment’ per se, isolated from its appropriate policy domains.”).

affect the ability of the host state to calibrate national policies to local conditions and needs.

B. Expropriation

International investment treaties provide, *inter alia*, for protection against unlawful expropriation.²⁶⁴ This raises two questions: whether a state action constitutes expropriation, and if it does, whether or not the expropriation is lawful. Several arbitrations have been concerned with the issues of what acts of the state amount to an expropriation. Treaty provisions lack a precise definition of expropriation, and their languages encompass a potentially wide variety of state activities that may interfere with pharmaceutical patents.²⁶⁵ Usually IIAs 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.²⁶⁶ Failure to satisfy any of these requirements will imply that the expropriation is unlawful and thus requires compensation.

Expropriation includes both direct and indirect expropriation. Direct expropriation of intellectual property is usually done through formal transfer of title or outright seizure of the same.²⁶⁷ This has happened in the past.²⁶⁸ For

²⁶⁴ See Germany-Burundi BIT, *supra* note 3, at art. 2(4) (“Investment by nationals or companies of either Contracting Party shall not be expropriated, nationalized or subjected to any other measure the effects of which would be tantamount to expropriation or nationalization in the territory of the other Contracting Party except for the public benefit and against compensation... The legality of any such expropriation, nationalization, or comparable measure and the amount of compensation shall be subject to review by due process of law.”); Fr.-Pol., art. 5(2), Feb. 14, 1989 (“The Contracting Parties shall not take any expropriation or nationalization measures or any other measures which would have the effect of divesting investors of the other Party, either directly or indirectly, of investments belonging to them in its territory or maritime areas, except for reasons of public necessity and on condition that these measures are not discriminatory or contrary to a specific undertaking. Any divestment measures that may be taken shall give rise to the payment of prompt and adequate compensation, the amount of which shall correspond to the real value of the investments in question on the day before the measures are taken or made known to the public”).

²⁶⁵ Wena Hotels Ltd. v. Arab Republic of Egypt, ICSID Case ARB/98/4, Award, at ¶ 98 (Dec. 8, 2000) (noting that “expropriation is not limited to tangible property rights.”).

²⁶⁶ See NAFTA, *supra* note 16, at art. 1110.1.

²⁶⁷ United Nations Conference on Trade and Development, 2012, *Expropriation: UNCTAD Series on Issues in International Investment Agreements II*, 6, UNCTAD/DIAE/IA/2011/7 (“Direct expropriation means a mandatory legal transfer of the title to the property or its outright physical seizure. Normally, the expropriation benefits the State itself or a State-mandated third party.”).

²⁶⁸ For instance, during the First World War, the German-owned Bayer trademark for aspirin was assigned to an unrelated US company. See Allen Z. Hertz, *Shaping the Trident:*

instance, 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, expropriated not only the Chorzów factory, but also certain patents.²⁶⁹ More recently, in *Shell Brand International AG v. Nicaragua*,²⁷⁰ two Shell subsidiaries filed a claim against the Government of Nicaragua for breach of the Netherlands–Nicaragua BIT in response to an alleged direct expropriation of their logo and brand name.²⁷¹ According to the claimants, Nicaragua seized their trademarks in an effort to enforce a judgment of a Nicaraguan court.²⁷²

Even without direct expropriation, a state action could nonetheless amount to indirect expropriation of a patent. Indirect expropriation indicates measures that do not directly take investment property but interfere with its use, depriving the owner of its economic benefit.²⁷³ For instance, 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 without the consent of the patent owner—can amount to an expropriation of pharmaceutical patents.²⁷⁴ Although the TRIPS Agreement permits compulsory licenses and parallel imports,²⁷⁵ the issue remains open as to whether they constitute indirect expropriation under

Intellectual Property Under NAFTA, Investment Protection Agreements and at the World Trade Organization, 23 CANADA–U.S. L.J. 261, 276 (1997).

²⁶⁹ The Factory at Chorzów (Germany v. Poland), Judgment, PCIJ Rep, Series A No. 7, at 44 (May 25, 1926).

²⁷⁰ Shell Brands International AG & Shell Nicaragua S.A. v. The Republic of Nicaragua, ICSID Case No. ARB/06/14, Request for Arbitration (May 17, 2006).

²⁷¹ Damon Vis-Dunbar, *Shell Launches Claim against Nicaragua over Seizure of Intellectual Property*, INVESTMENT TREATY NEWS (Oct. 13, 2006) (noting that according 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.* That judgment was in favour of Nicaraguan citizens who claimed to have been affected by a pesticide, which was manufactured for use on banana plantations in the 1960s and 70s. As the case was withdrawn, very little information is available about the dispute.).

²⁷² *Id.*

²⁷³ Brigitte Stern, *In Search of the Frontiers of Indirect Expropriation*, in CONTEMPORARY ISSUES IN INTERNATIONAL ARBITRATION AND MEDIATION 35 (Arthur Rovine ed., 2008).

²⁷⁴ For an examination of the question as to whether compulsory licenses can amount to an indirect expropriation, see VADI, *supra* note 54, at 52–53, 76–80, 88–90; Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT'L L. REV. 25 357 (2010); Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT'L L. 331 (2004).

²⁷⁵ TRIPS Agreement arts. 6, 31.

investment agreements. So far no claims have been brought concerning these specific issues.²⁷⁶

In *Servier v. Poland*, the Tribunal held Poland liable for expropriation of pharmaceutical marketing authorization in breach of the France–Poland BIT.²⁷⁷ As part of Poland’s accession to the European Union (EU), the country revised its pharmaceutical laws to harmonize them with EU law.²⁷⁸ Under one of these harmonization measures, medicines to be sold in Poland required a renewal of their marketing authorization.²⁷⁹ In late 2008, Polish health authorities did not renew the authorization for two medicines produced by the claimants,²⁸⁰ the precise reasons for which remain confidential.²⁸¹ Around the same time, authorization was granted to Polish companies to produce market alternatives of these medicines.²⁸² Against this background, the claimants, three French pharmaceutical companies, commenced arbitration under the France–Poland BIT, contending that the denial of authorizations amounted to a substantial deprivation of value, and thus a direct or indirect expropriation of their pharmaceutical patents.²⁸³

Poland argued that its decisions not to renew marketing authorizations were adopted in the “normal course of [its] duties as pharmaceutical regulator, and based on the drugs’ failure to comply with EU law requirements,”²⁸⁴ and thus did not amount to an expropriation. 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 its EU membership.²⁸⁵ 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.”²⁸⁶ According to Poland, 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,²⁸⁷ and therefore it

²⁷⁶ For discussion of an investment treaty arbitration concerning compulsory licensing, see VADI, *supra* note 54, at 78.

²⁷⁷ *Les Laboratoires Servier, S.A.S. v. Republic of Poland*, UNCITRAL, Final Award, ¶¶ 574–76 (Feb. 14, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw3005.pdf>.

²⁷⁸ *Id.* ¶ 40.

²⁷⁹ *Id.* ¶¶ 57–58.

²⁸⁰ *Id.* ¶¶ 80, 89.

²⁸¹ *Id.* ¶ 48 (redacting the reason for denial).

²⁸² *Id.* ¶¶ 108–110 and 124.

²⁸³ *Id.* ¶ 215.

²⁸⁴ *Id.* ¶ 190.

²⁸⁵ *Id.* ¶¶ 271, 274.

²⁸⁶ *Id.* ¶ 264.

²⁸⁷ *Id.* ¶ 265.

would be “inappropriate to find that the regulatory requirements to which both parties agreed could give rise to an obligation of compensation.”²⁸⁸ Poland further contended that in denying marketing authorizations to certain medicines, it exercised its police powers²⁸⁹ in a way that was proportionate to the public interest to promote public health and adopted in good faith,²⁹⁰ and hence the arbitrators should show deference to state regulatory choices.²⁹¹ Poland concluded that it had an obligation to adopt the regulatory measures because EU law would not have allowed other regulatory choices.²⁹²

Servier contended that the state measures were discriminatory, disproportionate and unreasonable. According to Servier, the state measures were discriminatory because the state granted authorizations to local producers but rejected Servier’s applications,²⁹³ even though no regulations required Poland to reject foreign applications over local.²⁹⁴ Servier contended that “Poland viewed the harmonization process as a means to promote the local pharmaceutical industry, in particular through the registration of low-cost local generic products.”²⁹⁵ On proportionality, Servier 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.²⁹⁶ Finally, the claimant alleged that no reasonable serious public health reason justified the nonrenewal of their syrup product²⁹⁷ while authorizing the same product in tablet form.²⁹⁸

The Tribunal found that the denial of marketing authorizations amounted to an indirect expropriation, implicating a State’s substantial interference with

²⁸⁸ *Id.* ¶ 265.

²⁸⁹ *Id.* ¶ 276.

²⁹⁰ *Id.* ¶ 403.

²⁹¹ *Id.* ¶ 280 (stressing that “in 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.”) *and* ¶ 282 (arguing that “A deferential standard of review must be employed by the Tribunal when it comes to regulatory decisions based around science and national regulation.”).

²⁹² *Id.* ¶ 336.

²⁹³ *Id.* ¶ 310.

²⁹⁴ *Id.* ¶ 264 (noting 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.”).

²⁹⁵ *Id.* ¶ 267.

²⁹⁶ *Id.* ¶ 332.

²⁹⁷ *Id.* ¶ 352.

²⁹⁸ *Id.*

the investor's rights.²⁹⁹ The Tribunal held that such indirect expropriation was discriminatory and "not a matter of public necessity"³⁰⁰ and awarded compensation to the foreign investor. As the award is extensively redacted, the legal test that the Tribunal adopted remains opaque; it also remains unclear whether the Tribunal upheld Servier's argument that the indirect expropriation was unlawful.³⁰¹ But the award does show that the Arbitral Tribunal has looked closely to the language of the applicable IIA that provided that "any divestment" (whether lawful or unlawful) would give rise to prompt and adequate compensation at the "real value" of the investment.³⁰²

In another recent dispute, the U.S.-based pharmaceutical company Eli Lilly filed a Notice of Intent against the Government of Canada under NAFTA Chapter 11,³⁰³ claiming that the invalidation of some of its patents by Canadian courts for "inutility"³⁰⁴ amounted to unlawful expropriation³⁰⁵ and sought \$500 million in damages.³⁰⁶ Although this case is still pending, an examination of the parties' arguments on the central issue of expropriation sheds light on the private and public considerations in the evolving dialectics.

Eli Lilly contended that by invalidating its patent, the Canadian court adopted a standard of utility that was contrary to Canada's international treaty obligations.³⁰⁷ It required not only that a given invention have some "scintilla" of usefulness, but also that the patent holder prove the invention has lived up to the usefulness "promised" by the patent holder at the time of seeking the patent.³⁰⁸ If the patented invention is found not to meet this promise, the patent can be invalidated. According to the claimant, this promise doctrine of utility diverged from patent law in other countries, and had had the effect of invalidating a large number of patents in recent years.³⁰⁹ Eli Lilly argued that not

²⁹⁹ *Id.* ¶ 576.

³⁰⁰ *Id.* ¶ 575.

³⁰¹ *Id.* ¶ 426 ("Servier advance[d] a theory of 'full reparation in the event of unlawful expropriation,' supported by principles of international law").

³⁰² *Id.* ¶ 643.

³⁰³ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Intent (7 Nov. 2012) <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

³⁰⁴ *Id.* ¶ 90.

³⁰⁵ *Id.* ¶¶ 89–97.

³⁰⁶ See Okediji, *Is Intellectual Property Investment?*, *supra* note 204, 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.").

³⁰⁷ *Id.* at 94.

³⁰⁸ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Intent, ¶ 37.

³⁰⁹ *Id.*

only would the promise doctrine unduly impede research and development,³¹⁰ but it would also breach Canada's obligations under several IP conventions³¹¹ "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."³¹² Thus, Eli Lilly argued, it constituted either a direct expropriation because it deprived Eli Lilly of its exclusive rights to prevent third parties from making, using, or selling its patented products during the patent term,³¹³ or alternatively, an indirect expropriation because it had the effect of nullifying the value associated with the patent.³¹⁴

In its Statement of Defense, Canada countered that a direct expropriation only occurs when rights are taken by the state,³¹⁵ but not when a court invalidates a patent, because this "does not amount to a 'taking', but rather, constitutes juridical determination of the existence and scope of rights at law."³¹⁶ In other words, according to Canada, the company cannot claim its investments were expropriated because there were no investments; its "patents" did not even exist under Canadian law.³¹⁷ Canada also argued that the protection against expropriation under NAFTA Article 1110 "does not apply to the procedurally fair invalidation of a patent by a domestic court"³¹⁸ because this

³¹⁰ *Id.* ¶ 16.

³¹¹ *Id.* ¶ 6 (referring to Article 27 of the TRIPS Agreement, NAFTA Chapter 17 and the Patent Cooperation Treaty.)

³¹² *Id.* ¶ 42.

³¹³ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Arbitration, ¶ 75 (Sep. 12, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1582.pdf>.

³¹⁴ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Intent, ¶ 91 (7 Nov. 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

³¹⁵ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Government of Canada Statement of Defence, ¶ 117 (June 30, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf>.

³¹⁶ *Id.* ¶ 108.

³¹⁷ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, 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 "If 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.").

³¹⁸ *Id.*

happens each year by courts in all major jurisdictions.³¹⁹ Additionally, Canada argued that its actions cannot give rise to expropriation under Article 1110(7) of NAFTA,³²⁰ because they were consistent with NAFTA Chapter Seventeen,³²¹ which grants the inventor 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.³²²

Turning to the indirect expropriation claim, Canada argued that the patent invalidation did not constitute a substantial deprivation of the economic value of the claimant's investments.³²³ Rather, according to Canada, the invalidated patents were just one component of Eli Lilly's overall business in Canada.³²⁴ In fact, the company continues to grow and sells a number of products.³²⁵ With regard to the character of the invalidation, Canada emphasized that "it was a legitimate and good faith exercise of the judicial authority of the state."³²⁶ 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."³²⁷ 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 as domestic courts refused jurisdiction to its claim seeking a declaratory judgment of noninfringement.³²⁸ The Federal Food, Drug and Cosmetic Act and subsequent amendments provide for an ANDA that enables generic

³¹⁹ Eli Lilly and Company v. The Government of Canada, ICSID Case No. UNCT/14/2, Statement of Defence, ¶ 106 (Jun. 30, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf>.

³²⁰ Eli Lilly and Company v. Government of Canada, ICSID Case No. UNCT/14/2, Counter Memorial, ¶ 344 (Jan. 27, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf>.

³²¹ *Id.* (invalidating patents cannot give rise to expropriation claims under Chapter Eleven if those measures are consistent with Chapter Seventeen).

³²² *Id.* ¶ 7 (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.").

³²³ *Id.* ¶¶ 409, 411.

³²⁴ *Id.* ¶ 411.

³²⁵ *Id.*

³²⁶ *Id.* ¶ 415.

³²⁷ *Id.* ¶ 414.

³²⁸ *Apotex Inc. v. U.S.*, ICSID Case No. ARB(AF)/12/1, Notice of Arbitration, ¶ 7 (Dec. 10, 2008), <http://www.state.gov/documents/organization/115447.pdf>.

manufacturers to obtain regulatory approval of lower-priced generic versions of previously approved medicines on an expedited basis, thereby benefitting the U.S. healthcare system and American consumers.³²⁹ In 2003, Apotex filed an application with the FDA to obtain the approval of a generic version of an antidepressant before the expiration of the relevant patent.³³⁰ When the patent holder Pfizer declined to file an infringement suit, Apotex filed for a declaratory judgment that it was not infringing on the patent, which Apotex claimed to be a common legal tactic in patent litigation.³³¹ However, the Southern District of New York dismissed Apotex's suit as the claimant lacked a "reasonable apprehension" that Pfizer would launch a suit for patent infringement.³³² The Federal Circuit affirmed the district court's decision, and the petition for *certiorari* was denied.³³³

Against this background, Apotex filed a notice of arbitration, contending that the United States' conduct amounted to an unlawful expropriation in violation of NAFTA Article 1110.³³⁴ The claimant argued that "under international law, expropriation occurs where government action unreasonably interferes with an alien's effective use or enjoyment of property."³³⁵ According to the Apotex, the U.S. interfered with its property rights in the ANDA "by unlawfully preventing [it] from obtaining a federal court decision" assessing the validity of the relevant patent, and "substantially depriving [it] of the benefits of its investment."³³⁶ The claimant also argued that the defendant "ha[d] no 'public purpose' for interfering with Apotex property rights,"³³⁷ and it "failed to provide the company with due process of law."³³⁸ Finally, Apotex claimed that it did not receive compensation for the damages it alleged to have suffered.³³⁹

A parallel dispute,³⁴⁰ which was joined to the former and heard by the same Arbitral Tribunal,³⁴¹ involved the submission of an ANDA seeking

³²⁹ *Id.* ¶ 29.

³³⁰ *Id.* ¶ 14.

³³¹ *Id.* ¶ 19.

³³² *Id.* ¶ 20.

³³³ *Id.*

³³⁴ *Id.* ¶¶ 65–71.

³³⁵ *Id.* ¶ 65.

³³⁶ *Id.* ¶ 64.

³³⁷ *Id.* ¶ 68.

³³⁸ *Id.* ¶ 69.

³³⁹ *Id.* ¶ 70.

³⁴⁰ Apotex Inc. v. The Government of the United States of America, ICSID Case No. ARB(AF)/12/1, Notice of Arbitration, ¶ 32 (June 4, 2009), <http://www.italaw.com/sites/default/files/case-documents/italaw1229.pdf>.

³⁴¹ Although there were two different statements of claims and the US Department of State maintained two different web pages for the documents relating to the respective claims,

approval for a generic version of a heart medication.³⁴² In order to obtain approval of its application, Apotex had sued the patent owner, Bristol Myers Squibb (BMS), to make sure that it would not face a patent infringement claim after it launches the Apotex medicines on the market.³⁴³ In response, BMS moved to dismiss the claim for lack of subject matter jurisdiction on the ground that it had no intention of suing Apotex for infringement.³⁴⁴ The Court granted BMS' motion to dismiss.³⁴⁵ Apotex argued in the arbitration that the administrative decision of the FDA and the opinion of the courts each violate both U.S. statutory law³⁴⁶ and NAFTA.³⁴⁷ In particular, Apotex alleged that the state action interfered with its property rights in its medicine application, thus amounting to an unlawful expropriation in breach of NAFTA Article 1110.³⁴⁸ Apotex further claimed that because the United States had no "public purpose" for interfering with its property rights and did not provide compensation,³⁴⁹ the company was entitled to compensatory damages. The Arbitral Tribunal dismissed both claims on jurisdiction because of the failure to exhaust local remedies,³⁵⁰ time limits,³⁵¹ and lack of investment.³⁵² It also ordered Apotex to pay the United States' legal fees and arbitral expenses.³⁵³ Although the holding does not touch upon the claim of expropriation, the case shows that claims of judicial expropriation have been brought by pharmaceutical companies.

In conclusion, there is no mechanical formula for determining whether state conduct amounts to a direct or indirect expropriation. Generally,

the jurisdiction/admissibility phase in each arbitration was held concurrently, albeit not consolidated. Therefore there was only one award dealing with the two different claims. *Apotex Inc. v. the Government of the United States of America*, ICSID Case No. ARB(AF)/12/1, Award on Jurisdiction and Admissibility, ¶ 4 (June 14, 2013), <http://www.italaw.com/sites/default/files/case-documents/italaw1550.pdf>.

³⁴² *Apotex Inc. v. the Government of the United States of America*, ICSID Case No. ARB(AF)/12/1, Award on Jurisdiction and Admissibility, ¶ 105 (June 14, 2013), <http://www.italaw.com/sites/default/files/case-documents/italaw1550.pdf>.

³⁴³ *Id.* ¶ 114.

³⁴⁴ *Id.* ¶ 115.

³⁴⁵ *Id.* ¶ 116.

³⁴⁶ *Apotex Inc. v. The Government of the United States of America*, ICSID Case No. ARB(AF)/12/1, Notice of Arbitration, ¶ 66 (June 4, 2009), <http://www.italaw.com/sites/default/files/case-documents/italaw1229.pdf>.

³⁴⁷ *Id.* ¶ 32.

³⁴⁸ *Id.* ¶ 76.

³⁴⁹ *Id.* ¶¶ 78–80.

³⁵⁰ *Apotex Inc. v. the Government of the United States of America*, ICSID Case No. ARB(AF)/12/1, Award on Jurisdiction and Admissibility, ¶ 298 (*Apotex I and II*) (June 14, 2013), <http://www.italaw.com/sites/default/files/case-documents/italaw1550.pdf>.

³⁵¹ *Id.* ¶ 335.

³⁵² *Id.* ¶ 336.

³⁵³ *See generally id.*

expropriation requires that there be an investment in the first place. Depending on the language of the applicable IIA, patent applications may not constitute investments. Expropriation requires that there be a substantial deprivation to the investor.³⁵⁴ The invalidation of a patent can affect the economic interests of the patent holder and can constitute an indirect expropriation of its rights.³⁵⁵ However, the act of governing patents can constitute a form of legitimate regulatory activity.³⁵⁶ 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's police power or an indirect expropriation.³⁵⁷ The burden of proving that the state conduct is inconsistent with a legitimate exercise of its police powers falls upon the claimant.³⁵⁸

C. Determining Compensation

Another area where the fine-tuning of private and public interest takes place is the determination of compensation to be paid after an expropriation has taken place. IIAs' expropriation provisions may be more beneficial to the patent owner than both domestic and international patent law.³⁵⁹ Customary compensation rules, uniformly enshrined in investment protection treaties, do not differentiate between the various public purposes of expropriations, but instead pose a single standard:³⁶⁰ in the case of expropriation, investors must be

³⁵⁴ Les Laboratoires Servier, S.A.S. v. Republic of Poland, UNCITRAL, Final Award, ¶ 576 (Feb. 14, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw3005.pdf> (finding that the denial of marketing authorizations amounted to an indirect expropriation, implicating a State's substantial interference with the investor's rights.)

³⁵⁵ *Id.* (noting that "indirect expropriation, at issue in this case, implicates a State's substantial interference with an investor's rights. Such interference must be significant, even if not complete, in the sense of depriving the investor of its ability to benefit from the relevant asset").

³⁵⁶ Gibson, *Latent Grounds in Investor-State Arbitration*, *supra* note 183, at 454.

³⁵⁷ Les Laboratoires Servier, S.A.S. v. Republic of Poland, UNCITRAL, Final Award, ¶ 568 (Feb. 14, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw3005.pdf> (holding that, while it "must accord due deference to the decisions of specialized Polish administrators interpreting and applying laws and regulations governing their area of competence", it "will also consider the manner in which those decisions were taken and their effect on the Claimants' investments.").

³⁵⁸ *Id.* ¶ 584 (stating that "the burden then falls onto the Claimants to show that Poland's regulatory actions were inconsistent with a legitimate exercise of Poland's police powers.").

³⁵⁹ Carlos M. Correa, *Bilateral Investment Agreements: Agents of New Global Standards for the Protection of Intellectual Property Rights?*, GRAIN.ORG 15 (Aug. 3, 2004), <https://www.grain.org/fr/article/entries/125-bilateral-investment-agreements-agents-of-new-global-standards-for-the-protection-of-intellectual-property-rights> (last visited Oct. 15, 2015).

³⁶⁰ *Compañía del Desarrollo de Santa Elena v. Costa Rica*, Award, Case No. ARB/96/1, Final Award, ¶ 72 (Feb. 17, 2000) (holding that "[e]xpropriatory environmental measures—no matter how laudable and beneficial to society as a whole—are, in this respect, similar to

fully compensated.³⁶¹ Several investment treaties further require compensation to be prompt, adequate and effective, according to the so-called Hull formula.³⁶²

In *Servier 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.³⁶³ Therefore, the Tribunal held that this compensation standard was to be applied, regardless of whether the expropriation was lawful or unlawful.³⁶⁴ While the Tribunal had “discretion to impose additional sanctions to punish Treaty violations of particular seriousness,”³⁶⁵ it found that Poland had “not engaged in bad faith behaviour ... that would require damages beyond the Treaty standard.”³⁶⁶ Instead, the Tribunal awarded the real value of the investment plus interests, calculated “on the basis of the appropriate rate of interest in force at the time of divestment” as required by the France-Poland BIT.³⁶⁷

D. Fair and Equitable Treatment

Fair and equitable treatment (FET) has become the most often invoked provision in investment treaty arbitration.³⁶⁸ Due to its deliberate vagueness, it constitutes a catch-all provision covering the situations where there is no finding of expropriation or any other breach of other investment treaty standards.³⁶⁹ The FET standard is an absolute standard of treatment, designed to

any other expropriatory measures that a state may take in order to implement its policies: where property is expropriated, even for environmental purposes, whether domestic or international, the state's obligation to pay compensation remains.”).

³⁶¹ See, e.g., *CME Czech Republic B.V. v. Czech Republic*, UNCITRAL, Final Award, ¶ 497 (Mar. 14, 2003).

³⁶² 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.

³⁶³ *Les Laboratoires Servier, S.A.S. v. Republic of Poland*, UNCITRAL, Final Award, ¶ 37 (Feb. 14, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw3005.pdf>.

³⁶⁴ *Id.* ¶ 644.

³⁶⁵ *Id.* ¶ 645.

³⁶⁶ *Id.* ¶ 642.

³⁶⁷ *Id.* ¶ 663.

³⁶⁸ See Sergey Ripinsky, *Russia*, in COMMENTARIES ON SELECTED MODEL INVESTMENT TREATIES 605 (Chester Brown ed., 2013) (noting that “this obligation is the one most often invoked by claimants in investment disputes—it is present practically in every case.”); see also Rudolf Dolzer, *Fair and Equitable Treatment: Today's Contours*, 12 SANTA CLARA J. INT'L L. 7, 10 (2014) (pinpointing that “FET may be considered to be at the heart of investment arbitration.”).

³⁶⁹ *Sempra Energy Int'l v. Argentine Republic*, ICSID Case No. ARB/02/16, Award, ¶¶ 300–01 (Sept. 28, 2007).

provide a basic safeguard upon which the investor can rely at any time, as opposed to the “relative” standards embodied in both the “national treatment” and “most favored nation” principles, which, in contrast, define the required treatment by reference to the treatment accorded to other investments.³⁷⁰

In an attempt to delimit the perimeters of the standard, the NAFTA Free Trade Commission issued an interpretation of the provision,³⁷¹ which is binding on all NAFTA tribunals.³⁷² The Commission clarified that the FET provision under NAFTA Article 1105 prescribes the customary international law’s minimum standard of treatment and does not require any standard of treatment that goes beyond that.³⁷³ Traditionally, the minimum standard of treatment protected investors only in instances of “egregious and shocking” conduct or “manifestly unfair or inequitable conduct.”³⁷⁴ Therefore, in the NAFTA context, arbitral tribunals still consider the FET standard to be the customary international law minimum standard of treatment.³⁷⁵

³⁷⁰ See generally CATHERINE YANNACA SMALL, INTERNATIONAL INVESTMENT LAW: A CHANGING LANDSCAPE 74 (2005) (highlighting that fair and equitable treatment is “an ‘absolute’, ‘non-contingent’ standard of treatment, *i.e.* a standard that states the treatment to be accorded in terms whose exact meaning has to be determined, by reference to specific circumstances of application, as opposed to the “relative” standards embodied in “national treatment” and “most-favoured-nation” principles which define the required treatment by reference to the treatment accorded to other investment.”).

³⁷¹ See generally NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter 11 Provisions, (Jul. 31, 2001), http://www.sice.oas.org/tpd/nafta/Commission/CH11understanding_e.asp.

³⁷² NAFTA, *supra* note 16, at art. 1131 (providing that “[a]n interpretation by the [FTC] of a provision of this Agreement shall be binding on a Tribunal established under this Section.”).

³⁷³ NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter 11 Provisions, *supra* note 371, at B.2 (affirming that “[t]he concepts of ‘fair and equitable treatment’ and ‘full protection and security’ do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens.”).

³⁷⁴ See *L. F. H. Neer and Pauline Neer (U.S.A.) v. United Mexican States*, 4 REP. INT’L ARB. AWARDS, 60, 60–62 (1926). In *Neer*, the widow and daughter of a murdered US citizen sued the Mexican government for “lack of diligence” or “lack of intelligent investigation” in prosecuting the murderers. *Id.* at 61. The US-Mexico Claims Commission held that Mexico was not liable although it acknowledged that “better methods might have been used” for the investigations and the prosecution. *Id.* at 62. The Commission held that “the treatment of an alien, in order to constitute an international delinquency, should amount to an outrage, to bad faith, to wilful [sic] neglect of duty, or to an insufficiency of governmental action so far short of international standards that every reasonable and impartial man would readily recognize its insufficiency.”).

³⁷⁵ For instance, the *Glamis Gold* Tribunal held that “the customary international law minimum standard remains as apparently articulated in the 1926 *Neer* award: to violate the

For instance, in *Apotex Holdings Inc, Apotex Inc. v. United States (Apotex III)*,³⁷⁶ which concerned the import ban on certain pharmaceuticals produced in Canada, the claimant contended that the U.S. breached the minimum standard of treatment due to a perceived lack of due process in providing the issue alert and the delays experienced in re-inspecting the facilities.³⁷⁷ Although Apotex contended that the FET standard is an evolving standard which has gone beyond the customary minimum standard of treatment, the Tribunal sided with the United States and affirmed that in the NAFTA context, FET means the customary minimum standard of treatment.³⁷⁸ The Tribunal found that the Claimants had not presented sufficient evidence of state practice or *opinio juris* indicating an expansion of the customary minimum standard of treatment.³⁷⁹ After noting 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,”³⁸⁰ the Tribunal did not find any breach of the FET provision.

In *Eli Lilly v. Canada*, the pending case relating to the invalidation of patents for failure to meet the utility requirement, 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,”³⁸¹ and in breach of NAFTA Article 1105.³⁸²

customary international law minimum standard of treatment codified in Article 1105 of the NAFTA, an act must be sufficiently egregious and shocking – a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons – so as to fall below accepted international standards” *Glamis Gold, Ltd. v. The United States of America*, UNCITRAL, Award, ¶ 22 (June 8 2009) <http://www.italaw.com/sites/default/files/case-documents/ita0378.pdf>.

³⁷⁶ *Apotex Holdings Inc, Apotex Inc. v. United States of America (Apotex III)*, ICSID Case No. ARB(AF)/12/1, Award (Aug. 25, 2014).

³⁷⁷ *Id.* ¶¶ 2.30, 2.64.

³⁷⁸ *Id.* ¶ 9.3 (recalling the FTC Note of interpretation), ¶ 9.4 (accepting the binding effect of this Note of Interpretation).

³⁷⁹ *Id.* ¶ 9.17.

³⁸⁰ *Id.* ¶ 9.39 (quoting *S.D. Myers Inc. v. The Government of Canada*, UNCITRAL, Partial Award, ¶ 261 (Nov. 13, 2000)). *See also id.* ¶ 9.37 (recalling “the need for international tribunals to recognise the special roles and responsibilities of regulatory bodies charged with protecting public health and other important public interests. These are of course not binding on this Tribunal, which must make its own determinations regarding the facts and the law relevant to this case Nevertheless ... other decisions indicate the need for international tribunals to exercise caution in cases involving a state regulator’s exercise of discretion, particularly in sensitive areas involving protection of public health and the well-being of patients.”).

³⁸¹ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Intent, ¶ 95 (Nov. 7, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

The company argues that it could not have anticipated at the time of its investment that the requirement for utility would be altered by the adoption of the “promise of the patent” doctrine into Canadian law and practice.³⁸³ In its Statement of Defence,³⁸⁴ the Government of Canada counter-argued that the claimant received due process before Canadian courts and simply being disappointed with the outcome of two patent trials does not amount to a breach of the relevant obligations.³⁸⁵ 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.³⁸⁶ Canada highlights that the FET standard does not prevent the evolution of a State’s legal framework,³⁸⁷ 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.”³⁸⁸ 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.³⁸⁹ According to Canada, “a violation of Article 1105(1) will not be found unless there is evidence of serious malfeasance, manifestly arbitrary behaviour or denial of justice by the respondent NAFTA Party.”³⁹⁰ Therefore, Canada argues that a mere frustration 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.³⁹¹

Although the FET standard has not presented much of a viable claim in the NAFTA context, it can have a concrete impact outside the NAFTA milieu, where arbitral tribunals have broadened the notion of fair and equitable treatment significantly. The standard has exceeded the customary minimum standard of treatment and comprises various additional requirements, such as transparency, due process, and others.³⁹² Under this broader conceptualization,

³⁸² *Id.* ¶¶ 98, 104.

³⁸³ *Id.* ¶ 101.

³⁸⁴ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Statement of Defence, (Jun. 30, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf>.

³⁸⁵ *Id.* ¶ 90.

³⁸⁶ *Id.* ¶ 99.

³⁸⁷ *Id.* ¶ 104.

³⁸⁸ *Id.*

³⁸⁹ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Counter Memorial, ¶ 15 (Jan. 27, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf>.

³⁹⁰ *Id.* ¶ 227.

³⁹¹ *Id.* ¶ 266.

³⁹² Christoph Schreuer, *Fair and Equitable Treatment in Arbitral Practice*, 6 J. WORLD INV. & TRADE, 357, 360, 364 (2005).

the FET standard has figured prominently in a number of patent-related investment arbitrations.

IP-related FET claims, both within and beyond the NAFTA context, 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?³⁹³ Can an investor rely upon international IP norms as a source of legitimate expectations?³⁹⁴ Does investment treaty arbitration provide a new means to enforce international IP agreements?³⁹⁵ What is the relationship between denial of justice and indirect expropriation claims? The next subsections address these questions.

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

The concept of “legitimate expectations” allows a foreign investor to claim compensation in situations where “the conduct of a host state creates a reasonable expectation ... that [the investor] may rely on that conduct, such that a subsequent failure by the host state to honour those expectations causes the investor to suffer damages”.³⁹⁶ Legitimate expectations are not an independent cause of action. Whether or not the fair and equitable standard protects the legitimate expectations of foreign investors has been answered in various ways.³⁹⁷ The divergence concerning the content of the FET standard, and the

³⁹³ Henning Grosse Ruse-Khan, *Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation* 13 (University of Cambridge Faculty of Law Legal Studies, Working Paper No. 52/2014, 2014), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711.

³⁹⁴ *Id.*

³⁹⁵ Gibson, *Latent Grounds in Investor-State Arbitration*, *supra* note 183, at 397.

³⁹⁶ Chris Yost, *A Case Review and Analysis of the Legitimate Expectations Principle as it Applies Within the Fair and Equitable Treatment Standard* 6 (Mar. 8, 2007) (unpublished thesis, Australian National University), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1364996.

³⁹⁷ *See, e.g.,* *Azurix Corp. v. Argentine Republic*, ICSID Case No. ARB/01/02, Award, ¶ 372 (July 14, 2006) (holding that the fair and equitable treatment standard now protects legitimate investor expectations even in the absence of bad faith or egregious conduct by the host state); *see also* Vaughan Lowe, *The Changing Dimensions of International Investment Law* 98 (University of Oxford Faculty of Law Legal Studies Research Paper Series, Working Paper No. 4/2007, 2007) (arguing “there is an emerging consensus that transparency and legitimate expectations are matters that it is proper to consider in the context of fair and equitable treatment.”); *cf.* Michele Podestà, *Legitimate Expectations in Investment Treaty Law: Understanding the Roots and the Limits of a Controversial Concept* 1–2 (Soc’y of Int’l Econ. Law, 3rd Biennial Global Conference, Working Paper, 2012), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2102771## (noting that “Arbitral tribunals ... have typically taken for granted the idea that a breach of the investor’s expectations may be relevant in deciding upon a violation of an investment treaty especially of the fair and equitable treatment standard.”) (internal parenthetical omitted).

protection of the legitimate expectations of the investor, is really about the level of protection that should be granted to foreign investors and their investments. While investors want stronger investment protections, host states favor weaker restrictions on the exercise of their sovereign powers.³⁹⁸ The variance also expresses the preference of NAFTA states for striking a balance between public and private interests at the legislative (domestic) level, rather than empowering arbitral tribunals to find that balance between such interests at the adjudicative (international) level.

Translating this general discussion in the specific context of IP protection, one wonders what type of expectations, if any, patents can give rise to. Patents are a type of IP, governed by both national statutes and international instruments such as the Paris Convention and the TRIPS Agreement. Can investors legitimately expect that these domestic and international instruments will not be violated by the host state? Can investors legitimately expect an absolute protection of their economic interests?

Patent law is characterized by the concept of the “patent bargain” or granting the right of exclusive exploitation of a given invention in exchange for the disclosure of a novel invention.³⁹⁹ It expresses a fundamental and intrinsic balance of public and private interests. Patents do not confer absolute rights, nor do they create any legitimate expectation that the exclusivity they confer is absolute and will remain without interference from accepted checks and balances inherent in the IP system.⁴⁰⁰ Not only does the international IP framework provide for commonly used regulatory controls on the utilization and exploitation of patents,⁴⁰¹ but patents are territorial in nature. Patents exist by virtue of legal recognition from the state. 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. Moreover, IP rights do not confer positive rights for rights holders to make or use the protected invention; rather they are negative rights, which allow rights holders to exclude competitors from exploiting a given invention for a limited time. They cannot prevent states from

³⁹⁸ See Tai-Heng Cheng, Remarks as Chairman for Panel Discussion at 2007 International Law Weekend: Is the Fair and Equitable Treatment Standard Fair and Equitable? (Oct. 27, 2006), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1259939 at 5 (“[T]he disagreements about the content of the fair and equitable treatment standard are really about investors wanting stronger investment protections, and host states favoring weaker restrictions on the exercise of their sovereign powers.”).

³⁹⁹ E.g., Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 90–93 (2004) (describing a patent as a bargain between the inventor and society).

⁴⁰⁰ Grosse Ruse-Khan, *supra* note 393, at 13.

⁴⁰¹ *Id.* at 13–14 (referring to the WTO panel report in *EC–Geographical Indications*).

regulating the use of such rights in the pursuit of legitimate public policy objectives.⁴⁰² Conversely, if a host state grants specific assurances to an investor 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.⁴⁰³

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

In several investment arbitrations, investors have claimed that measures adopted by the host state and affecting their investments are illegal under a number of international IP agreements and therefore violate the FET standard. According to this line of argument, if the host state is party to international intellectual property agreements such as the TRIPS Agreement, the Paris Convention and the Patent Cooperation Treaty, an investor is justified in having a legitimate expectation that the state will not violate such agreements.⁴⁰⁴ This argument assumes that if the state has acted in a way that deviates from the investor's legitimate expectations, it violates the FET.

In *Eli Lilly v. Canada*, the pending case relating to the invalidation of patents on grounds of inutility, the claimant contends that the adoption by the Canadian courts of a new, stricter approach to patent invalidation is contrary to the company's "reasonable investment-backed expectations,"⁴⁰⁵ and in breach of NAFTA Article 1105.⁴⁰⁶ The claimant contends that by violating a number of international law instruments governing patentability requirements, the Canadian measures are in breach of the FET standard.⁴⁰⁷ The company stresses its legitimate expectations that Canada complies with international IP treaties,⁴⁰⁸ including the TRIPS Agreement, the Patent Cooperation Treaty and NAFTA Chapter 17.

⁴⁰² Panel Report, *European Communities–Protection of Trademarks and Geographical Indications For Agricultural Products and Foodstuffs*, ¶ 7.210 WTO Doc. WT/DS/174R (Mar. 15, 2015) (holding that "the [TRIPS A]greement 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.").

⁴⁰³ Grosse Ruse-Khan, *supra* note 393, at 14.

⁴⁰⁴ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2. Notice of Intent, ¶¶ 95, 96 (7 Nov. 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

⁴⁰⁵ *Id.* ¶ 95.

⁴⁰⁶ *Id.* ¶¶ 98–104.

⁴⁰⁷ *Id.* ¶ 5–86.

⁴⁰⁸ *Id.* ¶ 96.

Canada maintains that the Tribunal lacks jurisdiction over the alleged breaches of Canada's international treaty obligations⁴⁰⁹ under TRIPS, PCT or NAFTA Chapter Seventeen, and that enforcement of obligations under these other international IP agreements may only be brought before their own respective venues.⁴¹⁰

Canada also maintains that it is not breaching the investor's legitimate expectations because it is complying with the substantive provisions of the TRIPS Agreement, NAFTA Chapter 17 and the PCT. First, according to Canada, the TRIPS Agreement "did not attempt to create a uniform or deeply harmonized patent regime," rather, it "left ample room for national variations and approaches to substantive patent issues."⁴¹¹ In fact during the TRIPS negotiations, "broad terms were used due to the lack of consensus on substantive law and the desire to maintain flexibility."⁴¹² Second, Canada stresses that NAFTA Article 1709(1), whose language was drawn upon the TRIPS negotiations,⁴¹³ includes the criteria "new," "result[ing] from an inventive step," and "capable of industrial application" as criteria for patentability of a given medicine, but 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."⁴¹⁴ This indicates that the parties could not agree on a common terminology for patentability requirements and their substantive content. Third, Canada notes the irrelevance of the PCT to the case. In fact, according to the state, such treaty "does not govern either substantive conditions of patentability or the invalidation of patents. It simply facilitates the international filing of patent applications"⁴¹⁵ In fact, Canada stresses that "[f]iling in accordance with the PCT is no

⁴⁰⁹ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Government of Canada Statement of Defence, ¶ 83 (June 30, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf> (pinpointing that "[t]he Tribunal's jurisdiction in this matter relates only to alleged breaches of NAFTA Chapter Eleven obligations.").

⁴¹⁰ *Id.* ¶ 84 (noting that "[d]isputes 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.").

⁴¹¹ *Id.* ¶ 91.

⁴¹² *Id.* ¶ 87.

⁴¹³ *Id.*

⁴¹⁴ *Id.*

⁴¹⁵ *Id.* ¶ 94.

guarantee that a patent application will result in a successful patent grant, or that any grant of a patent will withstand judicial scrutiny.”⁴¹⁶

The argument that a state’s adhesion to other treaties gives rise to legitimate expectations that the state will not breach such treaties relies on an expansive and evolving interpretation of the FET standard. Under NAFTA, it seems that such a claim lacks merits, as NAFTA tribunals have adopted a restrictive approach to the interpretation of the standard, analogizing it to the minimum standard of treatment under customary law. Beyond the NAFTA context, some tribunals have considered that the protection of legitimate expectations constitutes part of the FET standard. However, it remains to be seen whether arbitral tribunals will consider that legitimate expectations include an expectation that the host state will not breach its international law commitments. The argument, if adopted, would impose a powerful constraint on states for which the state did not bargain for in the negotiation of IIAs.

Even if arbitral tribunals accepted such an expansive interpretation of the FET standard, the fact remains that international IP treaties provide very vague terms, and therefore have traditionally left much room for maneuver to the states. In general terms, international IP treaties “include deliberate gaps, reflecting areas of non-convergence and the residual sovereignty of states to legislate specific rules.”⁴¹⁷ Such treaties do not define the concepts of utility, novelty and nonobviousness because “there is no consensus on how to apply these doctrines.”⁴¹⁸ Rather the content of these “open-ended” standards evolves over time,⁴¹⁹ and states shape patentability standards “to achieve net policy goals in specific sectors.”⁴²⁰

The national implementation of international IP standards varies across countries.⁴²¹ As the current international IP regime is “rooted in the disparate practices ... of different nations,” “non-uniformity pervades [its] very fabric.”⁴²² For instance, the TRIPS Agreement clarifies that “[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”⁴²³ Moreover, the Rules and Procedures Governing the Settlement of Disputes (DSU) provides that

⁴¹⁶ *Id.*

⁴¹⁷ Okediji, *Is Intellectual Property Investment?*, *supra* note 204, at 1132.

⁴¹⁸ Jerome Reichman, Panelist Presentation, Investment Chapters in Trade Agreements: IP Rights as Protected Investments (Apr. 11, 2014).

⁴¹⁹ *Id.*

⁴²⁰ Okediji, *Is Intellectual Property Investment?*, *supra* note 204, at 1134.

⁴²¹ *Id.* at 1132.

⁴²² Alan M. Anderson et al., *The Globalization of Intellectual Property Rights: TRIPS, BITs, and the Search for Uniform Protection*, 38 GA. J. INT’L & COMP. L. 265, 289 (2010).

⁴²³ TRIPS Agreement art. 1.1.

WTO panels and the Appellate Body (AB) “cannot add to or diminish the rights and obligations provided for in the covered agreements.”⁴²⁴ WTO jurisprudence has confirmed this “space reserved for state sovereignty.”⁴²⁵ In conclusion, how countries achieve a competitive balance between public and private interests remains a national prerogative, provided that they comply with their international obligations.

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

Can investment treaty arbitration constitute a new tool to enforce international IP 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 DSM and investment treaty arbitral tribunals respectively, will arbitral tribunals, WTO panels and the AB show any deference to the other venues?

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.⁴²⁶ For instance, a Canadian investor filed an investment treaty claim against Barbados, arguing that the alleged failure to enforce its own environmental law implementing international obligations violates FET under the Canada-Barbados BIT.⁴²⁷ The formulation of this claim illustrates a novel form of interplay between international investment law and other branches of international law.

When adjudicating IP investment disputes, the question arises as to whether arbitral tribunals can take into account other bodies of law in addition to international investment law. A breach of the TRIPS Agreement cannot provide a basis for an independent claim in investment treaty arbitration. Investment treaty arbitral tribunals cannot adjudicate on a violation of international IP law, unless the relevant investment treaty requires them to do so.

⁴²⁴ DSU art. 19.2.

⁴²⁵ Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶¶ 47–48, WTO Doc. WT/DS/50/AB/R (Dec. 19, 1997).

⁴²⁶ VALENTINA VADI, *CULTURAL HERITAGE IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION* 129–31 (2014).

⁴²⁷ Peter A. Allard v. Barbados, UNCITRAL, Notice of Dispute, ¶ 16 (Sept. 8, 2009), <http://graemehall.com/legal/papers/BIT-Complaint.pdf> (asserting 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).

If an international investment agreement does not refer to other treaty obligations, it appears difficult to assume that the IIA parties wished to interpret the FET standard in such a wide-ranging manner.⁴²⁸ In fact, had the IIA parties wished to expand the scope of protection to cover violations of other treaties, they could have included explicit reference to these other treaties. In addition, the DSM has exclusive jurisdiction in settling disputes over breaches of WTO law.⁴²⁹ This seems to preclude arbitral tribunals to adopt such an expansive interpretation of the FET standard.

For instance, in *Grand River Enterprises Six Nations v. United States*, the Tribunal held that the FET standard in NAFTA Chapter 11 “does not incorporate other legal protections that may be provided investors or classes of investors under other sources of [international] law” otherwise the standard would become “a vehicle for generally litigating claims based on alleged infractions of domestic and international law.”⁴³⁰ In another case, the Tribunal held that the applicable law “does not incorporate the universe of international law into the BITs or into disputes arising under the BITs.”⁴³¹

Yet, when interpreting a treaty, a 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 Law of Treaties (VCLT).⁴³² Article 31.3(c) of the VCLT provides that there shall be taken into account, together with the context, “[a]ny relevant rules of international law applicable in the relations between the parties.” Therefore, the host state’s obligation under other international IP treaties can come into consideration of the disputes before arbitral tribunals. The TRIPS Agreement, for example, can thus provide “interpretive background” to inform investment treaty standards.⁴³³

Arbitral tribunals risk overlooking important aspects of IP policy and being detached from local communities and their concerns. This is all the more likely considering the fact that their appointment usually requires expertise in international investment law, not IP law. They contribute to an investment law culture with its own language and way of speaking, expressing ideas, as well as

⁴²⁸ Grosse Ruse-Khan, *supra* note 393, at 295.

⁴²⁹ DSU art. 23.

⁴³⁰ *Grand River Enterprises Six Nations, Ltd. v. United States*, Award, ¶ 219 (Jan. 12, 2011), <http://www.state.gov/documents/organization/156820.pdf>.

⁴³¹ *Bernhard von Pezold v. Republic of Zimbabwe* (ICSID Case No. ARB/10/15) and *Border Timbers Ltd. v. Republic of Zimbabwe* (ICSID Case No. ARB/10/25), Procedural Ord. No. 2, ¶ 57 (June 26, 2012), <http://www.italaw.com/sites/default/files/case-documents/ita1044.pdf>.

⁴³² Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331.

⁴³³ Gibson, *Latent Grounds in Investor-State Arbitration*, *supra* note 183, at 402.

defining problems and solutions.⁴³⁴ Furthermore, due to the emergence of a *jurisprudence constante* in international investment law, there is a risk that arbitral tribunals will conform to these *de facto* precedents without necessarily considering analogous IP cases adjudicated before other international courts and tribunals. Although consistency in decision-making is desirable because it can enhance the coherence and predictability of the awards and contribute to the legitimacy of arbitral tribunals as a legal institution, arbitrators should be cautious of precedents that place strong emphases on the investors' economic interests at the detriment of the public interest pursued by the host state.

Have arbitral tribunals paid any attention to the specificities of IP? Are they imposing standards of good IP governance, by adopting general administrative law principles, such as proportionality, due process, and reasonableness? These questions present a fertile field of inquiry, which may help in detecting common patterns and lead to a balance between the protection of investors' economic interests and public welfare. While international investment law should not be used to enforce other IP treaties, arbitral tribunals still have to consider these other treaties in the arbitrations.⁴³⁵

4. Denial of Justice Claims

One particular form of FET violations,⁴³⁶ denial of justice, is one of the oldest principles of customary international law,⁴³⁷ and "lies at the heart of the

⁴³⁴ For an analogous argument with regard to the WTO law, see Fiona Smith, *Power, Rules and the WTO*, 54 B.C.L. REV. 1063, 1082 (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' . . .").

⁴³⁵ 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).

⁴³⁶ IIAs require fair and equitable treatment consistent with customary international law, including "the obligation not to deny justice in criminal, civil, or administrative adjudicatory proceedings in accordance with the principle of due process embodied in the principal legal systems of the world." See, e.g., Treaty Concerning the Encouragement and Reciprocal Protection of Investment, U.S.-Rwanda, art. 6(5), Feb. 19, 2008, S. TREATY DOC. No. 110-23. Therefore, the FET standard is considered to include denial of justice claims. See UNCTAD, *Fair and Equitable Treatment*, at xvi-xvii (2012).

development of international law on the treatment of aliens and of foreign investment.”⁴³⁸ Denial of justice imposes liability on the state for serious failures of its system of justice.⁴³⁹ Since denial of justice involves a system failure, exhaustion of local remedies is a prerequisite for claiming it.⁴⁴⁰ While denials of justice claims were traditionally discussed in inter-state disputes, nowadays, foreign investors can challenge denial of justice directly before arbitral tribunals.⁴⁴¹

A successful invocation of denial of justice is mutually exclusive with a finding of a judicial expropriation,⁴⁴² but investors often make both claims as a matter of strategy. This parallel invocation of the denial of justice claim and the indirect expropriation claim enables the foreign investor to fully exploit the

⁴³⁷ Francesco Francioni, *Access to Justice, Denial of Justice and International Investment Law*, 20 EUR. J. INT’L L. 729, 730–31 (2009) (“[T]he principle of the ‘minimum standard of justice’ to be reserved to aliens and their economic interests under customary international law . . . presupposes that the individual who has suffered an injury in a foreign country at the hands of public authorities or of private entities must be afforded the opportunity to obtain redress before a court of law or appropriate administrative agency. Only when ‘justice’ is not delivered, either because judicial remedies are not available or the administration of justice is so inadequate, deficient, or deceptively manipulated as to deprive the injured alien of effective remedial process, can the alien invoke ‘denial of justice’: a wrongful act for which international responsibility may arise.”).

⁴³⁸ *Id.* at 729.

⁴³⁹ JAN PAULSSON, DENIAL OF JUSTICE IN INTERNATIONAL LAW 4, 36 (2005) (“[A] state incurs responsibility if it administers justice to aliens in a fundamentally unfair manner” and “[I]nternational responsibility arises as a result of the failure of a national legal system to provide due process.”).

⁴⁴⁰ *Loewen v. United States*, ICSID Case No. ARB(AF)/98/3, Award, ¶ 154 (June 26, 2003), <http://www.italaw.com/sites/default/files/case-documents/ita0470.pdf> (“No instance has been drawn to our attention in which an international tribunal has held a State responsible for a breach of international law constituted by a lower court decision when there was available an effective and adequate appeal within the State’s legal system.”).

⁴⁴¹ Roger P. Alford, *Ancillary Discovery to Prove Denial of Justice*, 53 VA. J. INT’L L. 127, 131–132 (2012) (“Until recent decades, the denial of justice was frequently a wrong without a remedy . . .” that “the diplomatic espousal of claims pursuant to a friendship, commerce, and navigation treaty (FCN) or similar treaties — w[as a] cumbersome and rare event[] . . .” but that the rise of BITs has “altered this course of events . . .”).

⁴⁴² *See, e.g., Saipem S.p.A. v. People’s Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award (June, 30 2009), <http://www.italaw.com/sites/default/files/case-documents/ita0734.pdf> (finding the host state responsible for expropriation resulting from the judicial intervention in arbitral proceedings instituted by an investor in pursuit of its contractual right.).

scope of the protection afforded under IIAs.⁴⁴³ This section examines how these claims have been articulated.

Denial of justice is very difficult to prove. Rarely has such a claim been successful. It is not a denial of justice 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. 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 international arbitral tribunal.⁴⁴⁴

For instance, in *Apotex v. United States (Apotex I and II)*, concerning the approval for generic versions of given antidepressant and anti-cholesterol medicines, the claimant made parallel claims that the courts' judgments were "unjust" and amounted to an expropriation of its investment, and that they constituted a "substantive 'denial of justice'" in violation of NAFTA Article 1105.⁴⁴⁵ In particular, the claimant contended that it was denied justice when U.S. courts allegedly "rendered manifestly unjust decisions" by misapplying domestic law.⁴⁴⁶

Both parties agreed that, in order to eventually establish a denial of justice, "judicial finality must first be reached in the host State's domestic courts ... unless such recourse is 'obviously futile'."⁴⁴⁷ However, they disagreed on the meaning of "obviously futile."⁴⁴⁸ The United States pointed out that with respect to one of its medicines, Apotex had not pursued all available avenues before the domestic courts. In particular, it had not sought U.S. Supreme Court review of the lower court decisions.⁴⁴⁹ Apotex submitted that "it [wa]s 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

⁴⁴³ See generally Mavluda Sattorova, *Denial of Justice Disguised?: Investment Arbitration and the Protection of Foreign Investors from Judicial Misconduct*, 61 INT'L COMP. L. Q. 223–46 (2012); Mavluda Sattorova, *Judicial Expropriation or Denial of Justice?: A Note on Saipem v Bangladesh*, 13 INT'L ARB. L. REV. 35 (2010). On denial of justice, see generally PAULSSON, *supra* note 439.

⁴⁴⁴ PAULSSON, *supra* note 439, at 130.

⁴⁴⁵ *Apotex Inc. v. U.S.*, ICSID Case No. ARB(AF)/12/1, Notice of Arbitration, ¶¶ 61–62 (Dec. 10, 2008), <http://www.state.gov/documents/organization/115447.pdf>.

⁴⁴⁶ *Id.* ¶ 63.

⁴⁴⁷ *Apotex Inc. v. U.S.*, ICSID Case No. ARB(AF)/12/1, Award on Jurisdiction and Admissibility, ¶ 257 (June 14, 2013), <http://www.italaw.com/sites/default/files/case-documents/italaw1550.pdf> (footnote omitted).

⁴⁴⁸ *Id.*

⁴⁴⁹ *Id.* ¶ 250.

favour ... Any efforts to achieve such a result would have been “objectively futile.”⁴⁵⁰

The Arbitral Tribunal upheld all preliminary objections raised by the United States, including dismissing the denial of justice claim, on the grounds that the claimant had failed to exhaust local remedies.⁴⁵¹ The Tribunal reasoned that the judicial acts of the lower courts lacked sufficient finality to form the basis of claims under NAFTA Chapter 11.⁴⁵² While the Tribunal appreciated that “petitioning the U.S. Supreme Court was unlikely to secure the desired relief,”⁴⁵³ 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.”⁴⁵⁴ The Tribunal explained that the national court system must be given a chance to correct errors before its perceived failings can constitute an international wrong.⁴⁵⁵

By contrast, claims of judicial expropriation have not required exhaustion of local remedies.⁴⁵⁶ 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 judicial expropriation. 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. Therefore, the claim of judicial expropriation can be easier to substantiate and can be more investor-friendly in terms of eventual compensation. As a result, denial of justice claims seem to favour the state autonomy over the protection of private economic interests. Conversely, judicial expropriation claims may be more favorable to investors than denial of justice claims and can affect the state judiciary autonomy in the pharmaceutical sector.

⁴⁵⁰ *Id.* ¶ 274.

⁴⁵¹ *Id.* ¶ 135.

⁴⁵² *Id.* ¶ 267.

⁴⁵³ *Id.* ¶ 276.

⁴⁵⁴ *Id.*

⁴⁵⁵ *Id.* ¶¶ 281–282.

⁴⁵⁶ See generally Sattorova, *Judicial Expropriation or Denial of Justice?: A Note on Saipem v Bangladesh*, *supra* note 443; Sattorova, *Denial of Justice Disguised?: Investment Arbitration and the Protection of Foreign Investors from Judicial Misconduct*, *supra* note 443.

E. Non-Discrimination

The non-discrimination principle is a cornerstone of international investment law.⁴⁵⁷ It is typically reflected in two investment treaty provisions:⁴⁵⁸ the principles of national treatment (NT)⁴⁵⁹ and most-favored-nation (MFN) treatment.⁴⁶⁰ The basic purpose of the NT and MFN 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,”⁴⁶¹ one should first consider whether they are in the same sector and whether those competitors 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 a given state measure in the particular field.⁴⁶²

Certain apparently neutral regulations may substantively discriminate against foreign companies and their investments.⁴⁶³ In *Eli Lilly v. Canada*, the pending case relating to the invalidation of patents, the claimant alleges that Canada denied the company national treatment.⁴⁶⁴ 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.⁴⁶⁵ Yet, this form of extraterritorial analogy is highly unusual in national treatment

⁴⁵⁷ Grosse Ruse-Khan, *supra* note 393, at 31.

⁴⁵⁸ The principle of non-discrimination also constitutes one of the prongs for establishing the lawfulness of expropriation and the unfairness of a given state’s conduct. *See supra* Sections IV. B. , IV. D. respectively.

⁴⁵⁹ *See, e.g.*, US Model BIT (“1. Each Party shall accord to investors of the other Party treatment no less favorable than that it accords, in like circumstances, to its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments in its territory. 2. Each Party shall accord to covered investments treatment no less favorable than that it accords, in like circumstances, to investments in its territory of its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.”).

⁴⁶⁰ *Id.*

⁴⁶¹ *Id.*

⁴⁶² Grosse Ruse-Khan, *supra* note 393, at 34.

⁴⁶³ *See Les Laboratoires Servier, S.A.S. v. Republic of Poland*, UNCITRAL, Final Award (Feb. 14, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw3005.pdf>.

⁴⁶⁴ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Intent, ¶¶ 105–07 (Nov. 7, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

⁴⁶⁵ *Id.* ¶ 106.

claims before arbitral tribunals, given the regulatory diversity of IP laws across the globe, and is likely not going to be accepted by the Arbitral Tribunal.⁴⁶⁶ Second, the company argues that domestic generic pharmaceutical companies received more favourable treatment as they have benefited from the invalidation of Eli Lilly's patent.⁴⁶⁷ Third, the claimant highlights that only pharmaceutical companies bear the burden of the promise doctrine, rather than patent holders in other economic sectors.⁴⁶⁸ According to the claimants, the judicial decisions amount to a *de facto* discrimination against pharmaceutical patents, contrary to the state's obligation not to discriminate among different fields of technology under NAFTA Article 1709(7).⁴⁶⁹ While the case is still pending, it can have a significant impact on access to medicines. In fact, if the Arbitral Tribunal upholds the investor's claim, it would be more difficult for generic pharmaceutical companies to enter into the relevant market.

In *Apotex v. United States (Apotex I and II)*,⁴⁷⁰ concerning the approval for generic versions of antidepressant and anti-cholesterol medicines,⁴⁷¹ the claimant contended *inter alia* that the host state violated the non-discrimination provision by "failing to treat Apotex in the same fashion as U.S. investors."⁴⁷² As the case was dismissed on jurisdiction, the discrimination claim became moot.⁴⁷³

There is a fine line between discrimination and legitimate distinctions based on public policy reasons. This line is difficult to identify, because "discrimination" and "non-discrimination" are not polar opposites in a static

⁴⁶⁶ Luke Eric Peterson, *Newly Discovered Document Shows that Pharma Corp Hopes to Construe Alleged Non-Compliance with Patent Treaties as a Breach of Investment Treaty*, 5 INV. ARB. REP. 15, 17 (Dec. 10, 2012) ("This unusual form of extra-territorial comparison is not commonly seen in National Treatment claims under investment treaties.").

⁴⁶⁷ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Intent, ¶ 107 (Nov. 7, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf>.

⁴⁶⁸ *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Arbitration, ¶ 12 (Sept. 12, 2003).

⁴⁶⁹ *Id.*

⁴⁷⁰ *Apotex Holdings Inc, Apotex Inc. v. United States of America (Apotex III)*, ICSID Case No. ARB(AF)/12/1, Award on Jurisdiction and Admissibility, ¶ 257 (June 14, 2013), <http://www.state.gov/documents/organization/115447.pdf>.

⁴⁷¹ *Apotex Holdings Inc, Apotex Inc. v. United States of America (Apotex III)*, ICSID Case No. ARB(AF)/12/1, Notice of Arbitration, ¶¶ 58–60 (Dec. 10, 2008), <http://www.italaw.com/sites/default/files/case-documents/italaw1323.pdf>.

⁴⁷² *Id.* ¶ 60(f).

⁴⁷³ *Apotex Holdings Inc, Apotex Inc. v. United States of America (Apotex III)*, ICSID Case No. ARB(AF)/12/1, Award on Jurisdiction and Admissibility, ¶ 358(a)–(c) (June 14, 2013), <http://www.state.gov/documents/organization/115447.pdf>.

system.”⁴⁷⁴ In *Apotex III*, which concerned 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. Under the NT claim, Apotex argued that it had been treated less favourably than other comparable domestic investors.⁴⁷⁵ The U.S. countered that manufacturers in the U.S. are subject to even more regular inspections and enforcement due to their location.⁴⁷⁶ The Tribunal held that there was no violation of NT as the claimant and the domestic competitors were not in “like circumstances.”⁴⁷⁷ Under the MFN claim, Apotex contended the FDA inspected a competitor’s facilities in Israel and found many violations,⁴⁷⁸ but did not issue an import alert against the Israeli manufacturer.⁴⁷⁹ Although the Tribunal held that the U.S. had treated Apotex less favourably than the Israeli manufacturer,⁴⁸⁰ and thus had *de facto* discriminated against Apotex, it still concluded that there was no discrimination because the U.S. had established legitimate reasons for the different treatment.⁴⁸¹ The United States submitted that “the FDA is required necessarily to exercise a difficult regulatory discretion lying at the heart of its important mandate on public health; and that this discretion as to enforcement actions is never a binary choice, but depends on many factors particular to the specific situation.”⁴⁸² The Tribunal concluded that, *in casu*, the FDA actions were “materially influenced by the FDA’s genuine concerns over shortages of essential drugs manufactured” by the Israeli manufacturer,⁴⁸³ and had established a legitimate reason for the different treatment.⁴⁸⁴

Not only can discrimination claims substantiate breaches of NT and MFN treatment, they can also evidence the unlawfulness of a given expropriation or the unfairness of a given state conduct. While in some arbitrations, arbitral tribunals can uphold such claims as a distinct violation of the MFN or NT

⁴⁷⁴ Konrad von Moltke, *Discrimination and Non-Discrimination in Foreign Direct Investment: Mining Issues*, Conference on Foreign Direct Investment and the Environment, at 7 (Feb. 8, 2002), <http://www.oecd.org/env/1819921.pdf>.

⁴⁷⁵ *Apotex Holdings Inc. v. United States*, ICSID Case No. ARB(AF)12/1, Award, (*Apotex III*), ¶ 2.31 (Aug. 25, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw3324.pdf>.

⁴⁷⁶ *Id.* ¶¶ 8.31, 8.48.

⁴⁷⁷ *Id.* ¶ 8.57.

⁴⁷⁸ *Id.* ¶ 3.120.

⁴⁷⁹ *Id.* ¶ 3.153.

⁴⁸⁰ *Id.* ¶ 8.62.

⁴⁸¹ *Id.* ¶ 8.65.

⁴⁸² *Id.* ¶ 8.69.

⁴⁸³ *Id.* ¶¶ 8.71, 8.73.

⁴⁸⁴ *Id.* ¶ 8.78.

provisions in the relevant BIT,⁴⁸⁵ in other cases discrimination can constitute evidence of the breach of the FET standard,⁴⁸⁶ or be one of the relevant factors of unlawful expropriation.⁴⁸⁷ For instance, in *Servier v. Poland*, Servier asserted that “under customary international law, the expropriation of an investment can only take place for a public purpose, in a non-discriminatory manner, and against compensation.”⁴⁸⁸ After holding that “notions of unfairness and discrimination may insert themselves into a discussion of what constitutes divestment of property,”⁴⁸⁹ the Arbitral Tribunal concluded that “[n]ot only was the refusal of authorisation discriminatory, but the regulatory measures were disproportionate in nature and ... not a matter of public necessity,”⁴⁹⁰ thus amounting to an indirect expropriation.⁴⁹¹

Discrimination claims play an important role in investment treaty arbitration. A first issue that arbitral tribunals must ascertain is the existence of like circumstances. In the absence of like circumstances, differential treatment does not constitute discrimination but a legitimate distinction between different

⁴⁸⁵ See, e.g., *id.* ¶ 8.65.

⁴⁸⁶ Kenneth Vandeveld, *A Unified Theory of Fair and Equitable Treatment*, 43 N.Y.U. INT’L L. & POL. 43, 53 (2010) (“The fair and equitable treatment standard in BITs has been interpreted as requiring that covered investment or investors receive treatment that is reasonable, consistent, non-discriminatory, transparent, and in accordance with due process.”). See also *Les Laboratoires Servier, S.A.S. v. Republic of Poland*, UNCITRAL, Final Award, ¶ 410 (Feb. 14, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw3005.pdf>, (“Servier’s position is that Poland has breached its obligation to provide fair and equitable treatment to Servier’s investments and has treated Servier’s investments in an unjustified and discriminatory manner.” (footnote omitted)).

⁴⁸⁷ United Nations Conference on Trade and Development, 2012, *Expropriation: UNCTAD Series on Issues in International Investment Agreements II*, 3, UNCTAD/DIAE/IA/2011/7 (reviewing “the conditions for an expropriation to be lawful, namely public purpose, non-discrimination, due process and payment of compensation.”).

⁴⁸⁸ See *Les Laboratoires Servier, S.A.S. v. Republic of Poland*, UNCITRAL, Final Award, ¶ 217 (Feb. 14, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw3005.pdf>.

⁴⁸⁹ *Id.* ¶ 524.

⁴⁹⁰ *Id.* ¶ 575.

⁴⁹¹ *Id.* ¶ 570 (“[T]he Respondent’s denial of marketing authorisations would divest the Claimants of their property, giving rise to a requirement of compensation under the BIT, if Poland exercised its administrative and regulatory powers in bad faith, for some non-public purpose, or in a fashion that was either discriminatory or lacking in proportionality between the public purpose and the actions taken.”).

issues.⁴⁹² Certain distinctions may be legitimate and thus do not constitute discrimination in breach of the relevant investment treaty standards.⁴⁹³

In conclusion, non-discrimination is a key element for striking an appropriate balance between the public and private interests.⁴⁹⁴ It helps to ensure that the private interests are not unduly constrained for unspecified illegitimate reasons. A measure allegedly pursuing a public purpose but in fact serving other private domestic interests can constitute a disguised discrimination in breach of relevant investment treaty standards. By reviewing state measures and checking that they are not discriminatory, arbitral tribunals can foster an appropriate balance between genuinely public and private interests.

V

CRITICAL ASSESSMENT

States have an inherent right to regulate,⁴⁹⁵ particularly with regard to pharmaceuticals, because the regulation of medicines is crucial to public health.⁴⁹⁶ Public health is central to the very existence of the state, and the duty to protect it arises from both domestic law and the social contract that underlies most governments.⁴⁹⁷ Moreover, from a practical standpoint, national authorities are better placed to appreciate local societies' needs.⁴⁹⁸ Therefore, international conventions protecting various aspects of IP acknowledge the state's right and duty to protect public health.⁴⁹⁹

⁴⁹² *Apotex Inc. v. U.S.*, ICSID Case No. ARB(AF)/12/1, Award, ¶ 8.57 (Aug. 25, 2014), <http://www.state.gov/documents/organization/233043.pdf> (stressing that domestic pharmaceutical companies and foreign companies were not in like circumstances).

⁴⁹³ *Id.* ¶ 8.78.

⁴⁹⁴ Konrad von Moltke, *Discrimination and Non-Discrimination in Foreign Direct Investment: Mining Issues*, Conference on Foreign Direct Investment and the Environment, at 6 (Feb. 8, 2002), <http://www.oecd.org/env/1819921.pdf> (“[N]on-discrimination in relation to foreign direct investment means that the interests of a foreign investor and the public interest in an investment will be weighed in a manner that is legitimate, transparent, and accountable, and in accordance with same rules, criteria and procedures that apply to domestic [and other foreign] investors.”).

⁴⁹⁵ 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’”).

⁴⁹⁶ *See, e.g.*, the summary of the Respondent’s case in *Apotex III*, ¶ 2.38 (contending that “for more than a century, the Respondent has established laws and regulations to prevent the importation of adulterated drugs in order to protect public health in the USA. The FDA’s policy on import alerts has been in effect since at least the 1970s. The Respondent did not relinquish this authority and responsibility when it concluded NAFTA.”).

⁴⁹⁷ VADI, *supra* note 54, at 30.

⁴⁹⁸ *Id.*

⁴⁹⁹ *See, e.g.*, TRIPS Agreement art. 8.

Regulations governing patent rights are based on a delicate equilibrium between public and private interests.⁵⁰⁰ States balance public and private interest in such areas depending on their developmental and public health needs. In fact, the protection of public health necessarily requires constraining a wide range of private activities.⁵⁰¹ For example, states can constrain the rights of pharmaceutical companies so as to prevent nuisance and protect public health.⁵⁰²

Patent owners have increasingly used investor-state arbitration to challenge regulatory measures adopted by the host states, and these arbitrations have significant impact on the state regulatory autonomy. Arbitral tribunals assess the state's compliance with investment treaty provisions. This scrutiny may promote good pharmaceutical governance, incentivizing states to pursue the regulation of public health objectives in a transparent, reasonable and non-discriminatory manner, while preserving a state's legitimate interest to regulate for its domestic public policy.

Given the recent rise in the incidence of arbitrations,⁵⁰³ it is of utmost importance to reflect on this emerging jurisprudence and its possible impact on the public health policies of host states. Pharmaceutical patent investment arbitrations constitute a paradigmatic case study of the interplay between the public and private interests in international investment law and arbitration.⁵⁰⁴ They show that private actors are increasingly playing a prominent role in transnational governance of IP, and there are ongoing attempts of shifting enforcement of IP rights from interstate *fora* to international investment arbitration. Investment arbitration constitutes an avenue for the dialectical

⁵⁰⁰ See *Apotex Holdings Inc, Apotex Inc. v. United States of America (Apotex III)*, ICSID Case No. ARB(AF)/12/1, Award on Jurisdiction and Admissibility, ¶ 210 (June 14, 2013), <http://www.state.gov/documents/organization/115447.pdf>; *Apotex Inc. v. U.S.*, ICSID Case No. ARB(AF)/12/1, Award, ¶ 7.44 (Aug. 25, 2014), <http://www.state.gov/documents/organization/233043.pdf> (with regard to grant of patents and the ANDAs); *Eli Lilly and Company v. The Government of Canada*, ICSID Case No. UNCT/14/2, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven, ¶ 35 (Nov. 7, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf> (with regard to the revocation of patents).

⁵⁰¹ VADI, *supra* note 54, at 31.

⁵⁰² *Id.* (noting that “[w]hile the industry often asserts that economic principles militate against state interference, public health law has historically constrained the rights of individuals and businesses so as to prevent nuisance.”).

⁵⁰³ See *supra* Part IV.

⁵⁰⁴ Other studies have examined the clash between private and public interests in investment law and arbitration. See Julie A. Maupin, *Public and Private in International Investment Law: An Integrated Systems Approach*, 54 VA. J. INT'L L. 367 (2013–2014); Alex Mills, *Antinomies of Public and Private at the Foundations of International Investment Law and Arbitration*, 14 J. INT'L ECON. L. 469 (2011).

interaction between the economic interests of the patent holders and the state interest in public health protection.

VI

LEGISLATIVE AND INTERPRETIVE APPROACHES TO THE EMERGING DIALECTICS BETWEEN PRIVATE AND PUBLIC INTERESTS IN IP-RELATED INVESTMENT DISPUTES

In the emerging dialectics between patent protection and public health in international investment law and arbitration, treaty making and interpretation can play a crucial role to address the tension between, and eventually reconcile, public and private interests. This section proposes some legislative and interpretive approaches to better accommodate the dialectics between private and public interests in international investment law and arbitration.

At the legislative level, treaty negotiators can introduce some carve-outs, clarifications and flexibilities in the text of investment treaties. Negotiators could consider carving out litigation on pharmaceutical patents from the jurisdiction of investment arbitral tribunals. 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,⁵⁰⁵ and that compliance with the TRIPS Agreement provisions may preclude any expropriation claim.⁵⁰⁶ For instance, Article 6(5) of the U.S. Model BIT of 2012 states that “This Article does not apply 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.”⁵⁰⁷

Yet, the creation, limitation, and revocation of IP rights are regulated only in very broad brushes by the TRIPS Agreement. For instance, the TRIPS Agreement only requires that patents should be granted for new, inventive and useful inventions,⁵⁰⁸ but it does not define these terms.⁵⁰⁹ The question of what

⁵⁰⁵ See, e.g., US Model BIT art. 6(5) (“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.”).

⁵⁰⁶ Mercurio, *supra* note 228, at 905.

⁵⁰⁷ US Model BIT art. 6(5).

⁵⁰⁸ TRIPS Agreement art. 27(1) (“Subject to the provisions of paragraphs 2 and 3, patents shall be available 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.”).

deserves to be patented is left for countries to determine in light of their own needs. Countries can exclude some fields, such as plants, animals and surgical methods, from patentability to protect public order.⁵¹⁰ The TRIPS Agreement also allows for member states to provide for limited exceptions and other uses of the patent without the patent owner's consent, leaving states with the flexibility to implement regulatory measures for the purpose of domestic policy.⁵¹¹ With regard to revocation, the TRIPS Agreement does not address the grounds for forfeiture; it only requires member states to provide judicial review for every decision to revoke a patent.⁵¹²

Therefore, not only can arbitrations pioneer the interpretation and application of relevant IP provisions and pave the way to subsequent arbitral awards, but they can also serve as indirect enforcement tools of WTO law and influence the development of the same. WTO law has its own enforcement tools. The WTO DSM has been defined as the "jewel in the crown" of this organization,⁵¹³ and it has exclusive jurisdiction to settle disputes under the covered agreements.⁵¹⁴ However, only a limited number of IP disputes have been brought before the WTO,⁵¹⁵ and TRIPS consistency is tested in proceedings outside the DSM.⁵¹⁶ There is a certain "convergence" between

⁵⁰⁹ For instance, deciding whether a new formulation (producing a pill version of a medicine that formerly came as a powder) 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 is a prerogative of states and is not determined by the TRIPS Agreement.

⁵¹⁰ TRIPS Agreement art. 27(2) ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.").

⁵¹¹ *Id.* at art. 30 ("Exceptions to Rights Conferred") and art. 31 ("Other Use Without Authorization of the Right Holder").

⁵¹² *Id.* at art. 32 (providing that "[a]n opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.").

⁵¹³ AMRITA NARLIKAR, *THE WORLD TRADE ORGANIZATION: A VERY SHORT INTRODUCTION* 85 (2005).

⁵¹⁴ DSU art. 23 (providing that "When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding.").

⁵¹⁵ *Id.* at 20. See generally Joost Pauwelyn, *The Dog That Barked But Didn't Bite: Fifteen Years of Intellectual Property Disputes at the WTO*, 1 J. OF INT'L DISP. SETTLEMENT 389 (2010).

⁵¹⁶ Grosse Ruse-Khan, *supra* note 393, at 19, 36 (highlighting the risk that "the interpretative result may well be different from the result achieved in a 'pure' WTO setting.").

international investment law and international trade law,⁵¹⁷ and the interpretation of the TRIPS Agreement by arbitral tribunals is one of the areas of contact between the two areas of international law.⁵¹⁸

In interpreting the TRIPS Agreement, arbitrators should be aware of the balance between private and public interests intrinsic to the regulation of pharmaceutical patents. The TRIPS Agreement expressly presents clauses taking public health under consideration in construing IP rights. 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 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.”⁵¹⁹

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.”⁵²⁰ When interpreting the TRIPS Agreement, arbitrators must take into account Articles 7 and 8, which set forth fundamental principles of IP governance,⁵²¹ and provide space for reconciliation between private and public interests in IP regulation.

The Doha Declaration on the TRIPS Agreement and Public Health⁵²² has further reinforced state regulatory space to adopt public health measures,⁵²³ recognizing the WTO members’ right to protect public health⁵²⁴ and to use the

⁵¹⁷ *Id.*

⁵¹⁸ See VALENTINA VADI, ANALOGIES IN INTERNATIONAL INVESTMENT LAW AND ARBITRATION 148 (forthcoming 2016) (on file with author) (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.).

⁵¹⁹ TRIPS Agreement art. 7.

⁵²⁰ TRIPS Agreement art. 8(1).

⁵²¹ Articles 7 and 8 of the TRIPS Agreement are entitled “Objectives” and “Principles”, respectively.

⁵²² World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

⁵²³ 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 (2002).

⁵²⁴ Doha Declaration ¶ 4 (“We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while

flexibilities provided by the TRIPS Agreement.⁵²⁵ Where clear reference is made to the TRIPS Agreement, international investment agreements incorporate the TRIPS Agreement, including its objectives and principles as stated in Articles 7 and 8, as well as the relevant interpretative background provided by the Doha Declaration.⁵²⁶ Such provisions then become applicable and may provide guidance in the context of investment disputes.

Arbitrators must be mindful of the need of preserving a suitable balance between the public and private interests intrinsic in patent protection even in those cases in which the investment chapters of FTAs refer to its own IP chapters instead of TRIPS as a safeguard against expropriation claims.⁵²⁷ 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 17.⁵²⁸ NAFTA Chapter 17 contains “TRIPS-plus” provisions on IP rights, which strengthen the IP regimes of NAFTA countries beyond the global standards established by the TRIPS Agreement. For instance, NAFTA Chapter 17 does not include provisions analogous to Articles 7 and 8 of the TRIPS Agreement. Still, arbitrators can take into account public interest considerations under a number of flexibilities embodied in NAFTA Chapter 17.⁵²⁹ For instance, states can exclude certain inventions from patentability,⁵³⁰ introduce limited exceptions,⁵³¹ and compulsory licenses,⁵³² as well as revoke the patents.⁵³³

Striking an appropriate balance between the private and public interests in investment arbitration should be easier where states have appended declarations to their FTAs clarifying the interplay between the expropriation provision

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.”).

⁵²⁵ *Id.* (“In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”).

⁵²⁶ For instance, the EU has referred to the provisions of the Doha Declaration as an overarching principle in its bilateral trade agreements with Korea, Colombia and Peru, and Central America. *See Access to Medicines*, EUROPEAN COMMISSION, <http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/access-to-medicines/> (last visited Oct. 16, 2015).

⁵²⁷ Grosse Ruse-Khan, *supra* note 393, at 36–7.

⁵²⁸ NAFTA, *supra* note 16, at art. 1110(7).

⁵²⁹ *Id.* at art. 1709.

⁵³⁰ *Id.* at art. 1706(2).

⁵³¹ *Id.* at art. 1706(6).

⁵³² *Id.* at art. 1706(10).

⁵³³ *Id.* at art. 1706(8).

(included in the investment chapter) and IP provisions (included in the relevant chapter). For instance, in the Canada–EU Comprehensive Economic and Trade Agreement (CETA),⁵³⁴ a declaration appended to the expropriation provision of Chapter X, which governs foreign direct investment,⁵³⁵ 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.”⁵³⁶ This means that arbitration tribunals should be deferential to the decisions of domestic courts and tribunals regarding the existence and validity of patents. The mere fact that a company is disappointed with the outcome of a patent trial does not amount to a breach of the relevant treaty provisions. CETA reasserts “each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement regarding intellectual property within their own legal system and practice.”⁵³⁷ The possibility to issue binding interpretations at a later stage is also reserved.⁵³⁸ Moreover, Article 3 of Chapter 22, which governs intellectual property, refers to the Doha Declaration, thus incorporating its interpretative guidelines on balancing IP rights and public health.⁵³⁹

In most cases, however, IIAs make no reference to the TRIPS Agreement. In the absence of an express reference, it would be a radical departure from the text of the IIA, as well as the DSU,⁵⁴⁰ to provide investors with the possibility of asserting violations of the TRIPS Agreement against host states. Therefore, in the absence of a reference to the TRIPS Agreement, the argument that an investor can assert a claim for a violation of the state’s TRIPS obligation in an investor-state arbitration proves too much.

⁵³⁴ Comprehensive Economic and Trade Agreement, Can.-E.U., Sep. 26, 2014, European Comm’n, <http://ec.europa.eu/trade/policy/in-focus/ceta/>.

⁵³⁵ *Id.* at art. X.11, ¶ 6.

⁵³⁶ *Id.*

⁵³⁷ *Id.*

⁵³⁸ *Id.*

⁵³⁹ *Id.* at ch. 22, art. 3 (recognizing “the importance of the Doha Declaration on the TRIPS Agreement and Public Health” and providing that “[i]n interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with this Declaration” and that “[t]he 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.”).

⁵⁴⁰ DSU art. 3.

However, this does not mean that the TRIPS Agreement is irrelevant. The TRIPS Agreement can provide interpretive guidance and context.⁵⁴¹ If the applicable law is national law, as is the case for IP, which is territorial by 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.

Treaty interpretation can also provide the adjudicators with interpretive tools to reconcile the public and private interests emerging in the new dialectics between patent protection and public health in international investment law and arbitration. When adjudicating investment disputes, arbitrators must identify the applicable rules, clarify their meaning and relate them to the specific facts of the case. When the arbitrators have limited expertise on IP and its policy implications, experts should be consulted to facilitate sound decision-making and ensure the arbitrators take into account the two equilibria that characterize patent regulation.

The intrinsic equilibrium between private and public interest concerns the very structure or architecture of patents. It is evident in the conceptual matrix of patent regime. The “patent bargain” indicates the *quid pro quo* between the private and public interests that are intrinsic to the patent regime. For instance, compulsory licenses, limited exceptions and even the grant and revocation of patents provide means to limit the private interests under certain circumstances and give a margin of deference to policymakers and adjudicators to determine whether a patent should be granted, or revoked, or limited.

In parallel, the extrinsic equilibrium between patent rights and other values appears in the interplay between the IP regime and other fields of law. If one adopts an instrumentalist view of IP, the international IP system should function for the good of all. The notion that the IP regime serves such a social function is widely accepted in international law,⁵⁴² as expressly indicated by Articles 7 and 8 of the TRIPS Agreement.⁵⁴³ In scrutinizing the regime complex that governs IP, it appears that IP is never an absolute right.⁵⁴⁴ Rather, IP rights

⁵⁴¹ Gaetan Verhoosel, *The Use of Investor-State Arbitration under Bilateral Investment Treaties to Seek Relief for Breaches of WTO Law*, 6 J. INT’L ECON. L. 493, 503–6 (2003).

⁵⁴² See generally Christophe Geiger, *The Social Function of Intellectual Property Rights, or How Ethics can Influence the Shape and Use of IP Law* (Max Planck Institute for Intellectual Property and Competition Law, Working Paper No. 13-06, 2013).

⁵⁴³ TRIPS Agreement arts. 7, 8.

⁵⁴⁴ Geiger, *supra* note 542, at 5 (stressing that “there cannot be an ‘absolute’ right that can be exercised in a totally selfish manner with no consideration for the consequences that this

must be put into perspective as they are part of a broader legal system,⁵⁴⁵ and must always be harmonized with other rights of equally significant value and with the interests of the community.⁵⁴⁶ This is particularly the case with regard to pharmaceuticals, which have deep implications in public health.

Finally, 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. Pursuant to Article 31(3)(c) of the VCLT, adjudicators should take into account “[a]ny relevant rules of international law applicable in the relations between the parties.”⁵⁴⁷ 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.”⁵⁴⁸ A number of international organizations play an active role in the governance of pharmaceutical patents, creating a sort of institutional density or regime complex. As all these organizations receive almost worldwide consensus, a broader perspective of the legal environment that surrounds a given dispute should be adopted in investor-state arbitration.

CONCLUSION

This article highlights the emergence of international investment law and arbitration as a new battlefield, where the dialectical interaction between private and public interest is taking place. The clash between the economic interests of the patent owner and the pursuit of public policies is not a new phenomenon; what is new is the use of investment treaty law and arbitration as a place of confrontation between these private and public interests. International investment law is a vital area of international law that has furthered the protection of patents, considering them as a form of investment and providing patent owners access to investor-state arbitration. By including intellectual property within their ambit, investment treaties restrict the regulatory autonomy of states in the pharmaceutical sector, potentially affecting fundamental public

exercise involves, but only rights that are ‘relativized’ by the rights of others and the well-being of the community.”).

⁵⁴⁵ *Id.* at 4.

⁵⁴⁶ *Id.* See also Jakob Cornides, *Human Rights and Intellectual Property: Conflict or Convergence?*, 7 J. WORLD INTELL. PROP. 135, 143 (2004) (pointing out that “property is not an end in itself. Obviously, it must be used in a way that contributes to the realization of the higher objectives of human society.”); 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.”).

⁵⁴⁷ Vienna Convention art. 31(3)(c).

⁵⁴⁸ IAN SINCLAIR, *THE VIENNA CONVENTION ON THE LAW OF TREATIES* 139 (1984).

interests. Patent owners have increasingly used investment treaty arbitration to challenge alleged infringements of patent rights by governments, giving rise to an increasingly complex and contested interplay between pharmaceutical patent protection and public health.

This article examines the growing number of investment treaty arbitrations relating to pharmaceutical patents and critically assesses how the emerging dialectics between public and private interests is taking place in investment treaty arbitration. These arbitrations give rise to both jurisdictional and substantive issues. First, some disputes will center on the question as to which economic activities amount to an investment, giving rise to the arbitral tribunal's jurisdiction over the dispute.⁵⁴⁹ Second, although it may be very difficult to prove, an affected patent owner may claim that an unlawful expropriation has taken place.⁵⁵⁰ Third, if an expropriation has occurred, claims may concern the adequacy of the amount, or mode, of compensation.⁵⁵¹ Fourth, the patent owner may also allege a violation of the FET standard.⁵⁵² Finally, some claims may concern alleged discrimination suffered by the foreign investor.⁵⁵³

This article argues that international investment law and arbitration should contribute to the construction of public international law as a unitary whole, which aims at furthering public policy interests internationally. To the extent that investment treaty arbitration has failed to do so, either by de-emphasizing public policies or leaving them out entirely, it would be problematic to move forward with globally important policy issues through the vehicle of public international law.

Against the critical examination of the legal norms that are developing in the field, this article proposes some legislative and interpretive approaches to better accommodate the dialectics between private and public interests in pharmaceutical patent-related investment disputes. Treaty-making and interpretation can play a crucial role to address the tension between, and eventually reconcile, public and private interests.

At the normative level, treaty negotiators can introduce some clarifications, flexibilities or carve-outs in the text of investment treaties. Treaty drafting can improve the language of international investment agreements to include reference to other international instruments, such as the Doha

⁵⁴⁹ *See supra* Section IV. A.

⁵⁵⁰ *See supra* Section IV. B.

⁵⁵¹ *See supra* Section IV. C.

⁵⁵² *See supra* Section IV. D.

⁵⁵³ *See supra* Section IV. E.

Declaration on the TRIPS Agreement and Public Health. Although these other instruments are not necessarily promoting a better balance between the public and private interests, reference to such international law instruments can still help international arbitrators to obtain useful information on how other instruments are coping with the interaction between private and public interests, as well as achieve mutual support and harmonization across instruments. Negotiators could consider carving out litigation on pharmaceutical patents from the jurisdiction of investment arbitral tribunals.

Interpretation can help arbitrators reach a suitable balance between the protection of patent rights *qua* foreign investments and other non-economic values in public health-related investment disputes. Arbitrators should focus on the nature and purpose of the right that 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, depending on the specific circumstances of the case, might be viewed as an intrinsic limit to the patent right. Foreign investments protection, when applied to pharmaceutical patents, should be considered not as an end in itself but as one of the available tools to promote human welfare. Moreover, as required by customary rules of treaty interpretation, arbitrators should embrace their roles as cartographers of international law and adopt a holistic approach to treaty interpretation, which takes into account other international law instruments that are binding upon the parties.