

IS INTELLECTUAL PROPERTY “INVESTMENT”? ELI LILLY v. CANADA AND THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM

RUTH L. OKEDIJI*

INTRODUCTION

On September 12, 2013, Eli Lilly filed a Notice of Arbitration against Canada under the North American Free Trade Agreement (NAFTA) arbitration provisions,¹ commencing the first intellectual property investment dispute filed under NAFTA. The dispute was instigated by court rulings invalidating two of Lilly’s pharmaceutical patents based on judicial interpretations of the utility requirements contained in the Canadian patent statute. The so-called “promise of the patent doctrine” requires patent applications to support the claimed inventive promise made by the applicant to satisfy the utility requirement. Lilly claims this standard is inconsistent with the utility standards of other NAFTA signatories and a departure from Canadian law at the time Lilly filed its patent applications.² According to Lilly, the invalidation of the patents amounts to indirect expropriation of its intellectual property rights and contravenes the firm’s legitimate expectations about the treatment of its investments.³ Lilly seeks \$500 million in damages, but observers have noted that compensation is not Lilly’s ultimate goal; rather, 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. Lilly’s chief patent counsel highlighted this ultimate goal stating, “[t]he Parliament could have stepped in and fixed Canada’s patent statutes, . . . [but] [t]o date

* William L. Prosser Professor of Law, University of Minnesota Law School. My appreciation goes to Bethany Mihalik for excellent research assistance, to the Symposium Chair Diepiriye Anga and my co-panelists at the University of Pennsylvania Journal of International Law Journal Symposium held on November 8, 2013.

¹ Eli Lilly v. Can., UNCITRAL, Notice of Arbitration (Sept. 12, 2013), *available at* <http://italaw.com/sites/default/files/case-documents/italaw1582.pdf> [hereinafter Notice of Arbitration Against Canada].

² *Id.* ¶ 9.

³ *Id.* ¶ 4.

they have looked the other way.”⁴

This case represents not only a new frontier in investment arbitration, but more importantly, uncharted territory in the increasingly complex and contested landscape of international intellectual property obligations. Intellectual property has long ceased to be primarily a domestic concern; indeed, some argue that its chief significance lies in setting the terms and conditions of global competition, including facilitating access to technology and public goods. Incorporating intellectual property obligations in bilateral investment treaties (BITs) was intended to provide stronger and more stable protection for firms in developed countries. Instead, the confluence of intellectual property and foreign investment standards in a single legal framework foreshadows a landscape of varying and conflicting obligations for states whose regulatory powers are already under significant strain from expansive obligations flowing from a robust collection of transnational laws.

The inclusion of intellectual property within the investment arbitration realm threatens to turn intellectual property law on its head. National innovation policy is one of the very few areas still largely insulated from the pervasive economic governance that conditions contemporary international economic relations. Intellectual property obligations in the investment context thus pose a new threat to states' traditional lawmaking powers by providing foreign actors a singular opportunity to challenge laws that have been enacted with the domestic public interest in full view, even when they are in conformity with international intellectual property treaties. Subverting a core judicial function—interpretation of a domestic law *already* infused with multilateral obligations—to the oversight of a private international tribunal precariously alters the contours of state power and responsibility for compliant domestic legislation and policy prescriptions.

Lilly's arguments amount to a claim that, in agreeing to an investment treaty, a government takes on an affirmative obligation to constrain the evolution of national legal standards, or to limit the public policy that fuels such evolution to the equilibrium that existed at the time the treaty was signed. Such a backwards-looking approach suggests a rigidity not contemplated in the international

⁴ See Adam Behsudi, *Eli Lilly Sues Canada on Drug Patents*, POLITICO (Sept. 12, 2013, 7:03 PM), available at <http://www.politico.com/story/2013/09/eli-lilly-sues-canada-over-drug-patents-96743.html> (quoting Doug Norman, Eli Lilly's chief patent counsel, in an interview with POLITICO).

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intellectual property framework and that, uncurbed, would undermine the capacity of intellectual property law and policy to respond to dynamic shifts in the national or global technological frontier.

In this essay, I briefly consider some implications for intellectual property protection within the investment landscape in light of the Eli Lilly dispute. Part I highlights the dense network of international intellectual property obligations, focusing on the policy considerations involved with incorporating intellectual property in the definition of "investment." Part II reviews the relationship between the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and investment treaties, emphasizing the relationship between multilateral intellectual property obligations and the domestic policy context. I argue that there is no substantive standard of utility in any international instrument with which Canada or any other country is required to conform,⁵ and that Lilly's claim appears to confuse minimum standards with means of implementation. Under the TRIPS Agreement and existing investor-state arbitration precedent, Canada's only obligation is to apply *its* law. Lilly's arguments seek to undermine the TRIPS Agreement's deliberately crafted "wiggle room," freezing intellectual property policy and subordinating national welfare interests to the private expectations of a single foreign actor. Moreover, the doctrine of reasonable expectations upon which Lilly so heavily relies has already been debunked in the context of the TRIPS Agreement which, under the Vienna Convention on the Law of Treaties, should be deemed a superseding agreement between Canada and the United States.

Finally, in Part III, I point to differences in intellectual property disputes in investment proceedings versus the TRIPS context and suggest approaches that could facilitate a less disruptive role for investor-state disputes involving intellectual property rights. On face value, Eli Lilly's claims could effectively constitute a revision of NAFTA.⁶ If Lilly is successful in its grander objective—a ruling

⁵ Jerome H. Reichman, *Securing Compliance with the TRIPS Agreement After US v. India*, 1 J. INT'L ECON. L. 585, 585, 589 (1998) (noting the absence of strict harmonization in the TRIPS Agreement).

⁶ *Methanex Corp. v. United States*, UNCITRAL, Second Opinion of Professor Sir Robert Jennings, Q.C. (Sept. 6, 2001), available at <http://italaw.com/cases/documents/1273>. Under NAFTA, parties can agree on a binding interpretation of a particular provision. See, e.g., NAFTA Free Trade

that Canada is required to change its current utility standard—the implications for intellectual property multilateralism, and for intellectual property policy in *all* countries, would be stunning indeed.

1. INTELLECTUAL PROPERTY AND THE INTERNATIONAL INVESTMENT LANDSCAPE

Efforts to create an international framework regulating private investment began in the period after World War II in the context of European reconstruction efforts and the assimilation of former colonial states into the world economy. Initial attempts to negotiate multilateral instruments failed, but provided the blueprints for bilateral and regional investment treaties. European countries negotiated the first wave of BITs, starting with a Germany–Pakistan BIT in 1959. The demise of communism and abandonment of command economies ushered in a new period of investment treaty negotiation in the 1980s, as competition for capital inflows outweighed the desires of countries to strictly manage the terms of foreign direct investment. Over the past three decades, BITs and regional trade agreements have grown exponentially; today, it is estimated that there are more than 2750 regional and bilateral investment treaties in force, and cumulative totals of FDI around the globe is estimated at 1.35 to 1.45 trillion dollars annually.⁷

Roughly during the same post-War period, multilateral intellectual property treaty negotiations established minimum substantive standards of protection in every major category of intellectual property, culminating in 1994 with the conclusion of the TRIPS Agreement.⁸ Although the definition of “investment” contained in most investment treaties mention intellectual property, the obligations, expectations, and enforcement aspects of these treaties are largely undeveloped. Moreover, the doctrinal, policy, and structural differences between BITs and the TRIPS Agreement have rarely been meaningfully analyzed, leaving a gap in the international law of intellectual property. That is the gap Eli Lilly now seeks to exploit.

Comm’n, Notes of Interpretation of Certain Chapter 11 Provisions (July 31, 2001), *available* [at](http://www.sice.oas.org/tpd/nafta/Commission/CH11understanding_e.asp) http://www.sice.oas.org/tpd/nafta/Commission/CH11understanding_e.asp.

⁷ U.N. CONF. ON TRADE AND DEV. (UNCTAD), WORLD INVESTMENT REPORT 2013 xii, xix (2013).

⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

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1.1. *Is Intellectual Property an Investment?*

Modern investment treaties typically define covered assets broadly. Various agreements define an "investment" as an asset with "the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk";⁹ "real estate or other property, tangible or intangible";¹⁰ or "any kind of assets and any contribution in cash, in kind or in services, invested or reinvested in any sector of economic activity."¹¹ Investment may also be defined by reference to an illustrative, but non-exhaustive list, which explicitly mentions intellectual property.¹²

Many commentators have taken the inclusion of intellectual property within most "investment" definitions as given because of the importance of intellectual property to the modern information economy. Intellectual property, however, differs considerably from most other covered investment assets in important respects. Intellectual property rights can be held simultaneously in many countries and in some cases, like copyright, without any formalities or other domestic process that would indicate a specific investment purpose. Is merely having authorial works in circulation in a host country sufficient to constitute an "investment in a given country?" Similarly, where patent rights are acquired by mere registration, such as in many least-developed countries, should this alone confer the status of an "investment"? Should requirements of local working conditions that more firmly anchor the patent grant to domestic priorities make a difference in an assessment of a protected investment?

The multilateral intellectual property system has largely evolved around the administrative objective of facilitating ease of acquisition and enforcement of minimum rights in global markets. The prospect that this objective for intellectual property multilater-

⁹ U.S. Model Bilateral Investment Treaty, § A, art. 1 (2012), available at <http://www.ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf> [hereinafter U.S. Model BIT].

¹⁰ Agreement Between Japan and the United Mexican States for the Strengthening of the Economic Partnership, art. 96(i)(GG), Sept. 17, 2004, WT/REG198/1 (not yet in force).

¹¹ Agreement Between the Belgo-Luxembourg Economic Union and the Government of the Republic of India for the Promotion and the Protection of Investments, art. 1(b), Oct. 31, 1997, 2136 U.N.T.S. 121, 124.

¹² See U.S. Model BIT, *supra* note 9, at § A, art. 1 (listing the forms that an investment can take and specifically including IP rights).

alism could now confer status as an “investment” is singularly problematic. At a minimum, a determination that an intellectual property rights owner is also an investor cannot plausibly be based solely on acquiring rights, particularly since member states of the WTO have no choice but to accord such rights, and to do so on the terms set by the TRIPS Agreement. Moreover, all intellectual property rights are to some extent contingent rights only; whether a claimant is a rightful owner, has complied with national eligibility standards for protection, whether there are any applicable subject-matter limits or supervening policy considerations, or whether a granting agency has appropriately granted (or denied) such rights are always subject to question before national courts. To transform such contingent rights into property-like assets gives graver import than contemplated by States to the role of intellectual property treaties.

1.2. Who is an Intellectual Property ‘Investor’?

Whether intellectual property constitutes “investment” requires granular analysis on a case-by-case basis. A few considerations should be important in such an exercise by an arbitration panel. First, empirical evidence on the effect of intellectual property protection for foreigners is mixed; certainly for developing and least-developed countries, uncritical protection of intellectual property rights can exact significant economic costs. For example, rather than constituting an “investment” in the local economy as such, protection of foreign patent rights may serve primarily to preserve export markets for the patent owner, leading to welfare losses for the host country, including dislocating local industries, impeding local innovation, and increasing the costs of access to knowledge goods. Further, host countries must invest significantly in enhancing the domestic legal and business environment to attract sustainable levels of FDI. Indeed, the competitive situation between firms in the host country and a foreign firm seeking to invest in their must be such that protecting an import market is more profitable than selling or licensing intellectual property assets to the local firms. Moreover, host countries typically must offer foreign investors additional incentives such as tax breaks and advantageous regulatory environments in addition to macroeconomic variables such as low input prices, reliable infrastructure, and ac-

cess to distribution networks.¹³ In short, what constitutes an "investment" safeguarded under an investment treaty should not be decided merely by the existence of the intellectual property grant; the real and dynamic costs to the host country must be part of the assessment.

Second, intellectual property protection for foreign holders can actually *limit* the flow of resources and other investments to host countries, thus curtailing the benefits that ordinarily flow from traditional forms of foreign investment. For example, increased market power that flows from the exercise of intellectual property rights may decrease competition in the host country or raise entry barriers for smaller, foreign firms.¹⁴ Such observations have long been the basis for resistance by developing countries to the international intellectual property system, and in particular the international patent system. Simply put, one foreign firm's intellectual property "investment" may be another foreign firm's reason for divesting from the same host country. No determination of intellectual property as an "investment" is per se neutral; both domestic firms and other foreign firms will be affected by any resulting welfare loss. For example, foreign generic pharmaceutical companies that have invested in the Canadian market arguably have benefitted from the very utility doctrine Lilly is contesting. If Canada changes its law to address Lilly's demands, could those firms successfully claim that the new standard amounts to an indirect appropriation since it would alter the competitive equilibrium between them and Lilly?

Any determination about the investment status of intellectual property requires careful consideration of how these rights are acquired, used, and deployed in national markets.¹⁵ The outcome of such analyses will neither be straightforward nor necessarily consistent in all cases and contexts. This is not to say that intellectual

¹³ Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT'L L. 163, 170 (1998).

¹⁴ *Id.* at 172.

¹⁵ See e.g., Constantine V. Vaitsos, *The Revision of the International Patent System: Legal Considerations for a Third World Position*, 4 WORLD DEV. 85, 85-99 (1976) ("Practically all patents granted in developing countries are never worked in their territories. . . . [P]atent protection is not only divorced from innovative but also from investment activity, and can block the use of technology to directly work the patented processes or products."). See also PETER DRAHOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* 79-81 (2002) (arguing that the international patent system did not bring benefits to developing countries, but rather harmed them).

property can *never* constitute foreign investment, but that it cannot automatically or easily be deemed as such.

2. INTELLECTUAL PROPERTY OBLIGATIONS UNDER INVESTMENT TREATIES AND THE TRIPS AGREEMENT

For all WTO member countries, domestic intellectual property laws are required to reflect the robust obligations of the TRIPS Agreement. The TRIPS Agreement reflected a significant upgrade from prior multilateral arrangements in terms of its comprehensive scope and, notably, the opportunity to enforce the new rules.

2.1. TRIPS' Deference to National Frameworks

Article 27.1 of the TRIPS Agreement requires every member country to establish utility or industrial application as a requirement for patentability, but neither TRIPS nor any other international agreement specifies the substantive interpretation of the requirement.¹⁶ The multilateral commitment to minimum standards and not harmonization is clear in TRIPS Art. 1.1, which states “[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”¹⁷ Moreover, the WTO Agreement incorporates by reference The General Agreement on Tariffs and Trade (GATT), which explicitly reserves to member states the right to apply measures “necessary to secure compliance with laws or regulations . . . not inconsistent with the provisions of this Agreement, including . . . the protection of patents, trademarks and copyrights”¹⁸ Further, the WTO Appellate Body confirmed in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* that TRIPS obligations are limited only to the explicitly stated minimum standards, “legitimate expectations of Members and private rights holders” to the contrary. According to the Ap-

¹⁶ Jerome H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 26 (1996) (analyzing the lack of harmonization in crucial doctrinal issues in all areas of IP rights); E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CAN. INTELL. PROP. REV. (forthcoming June 2014).

¹⁷ TRIPS Agreement, *supra* note 8.

¹⁸ General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) (incorporating by reference The General Agreement on Tariffs and Trade of 1947).

pellate Body, "the legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself."¹⁹

Investment treaties, however, have been widely interpreted to require deference to (and compliance with) the legitimate expectations of the investor as part of the "fair and equitable treatment" clauses contained in most BITs and regional investment agreements.²⁰ Arbitration panels have not generally interpreted legitimate expectations to allow investors to freeze legislative or regulatory frameworks,²¹ but the doctrine has been used to limit the policy choices available to countries.²² Nonetheless, the unique role of intellectual property in national public policy, its importance to innovation and global competition, and the overlapping network of intellectual property treaties that restate the same basic obligations (often using the same language in the TRIPS Agreement) make it highly questionable that a doctrine of legitimate expectations should dominate the construction of NAFTA's intellectual property provisions, as Lilly suggests.

There are good reasons it should not. First, the repetition of intellectual property standards in multiple bilateral, investment, and multilateral treaties were not meant to change the substantive meaning of these obligations under domestic law, but rather to entrench accepted criteria in the fabric of international economic relations. Accordingly, an interpretation of NAFTA's provisions must take place in the broader context of this network of treaties.

Second, some investment treaties contain asymmetric provisions in which investor-state dispute provisions accord different treatment to investors from one treaty partner than what applies to investors from another treaty partner in similar circumstances.²³ A recent OECD survey shows there are more than 1,200 different in-

¹⁹ Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶¶ 13, 48, WT/DS50/AB/R (Dec. 19, 1997) [hereinafter *India – Patents*].

²⁰ Michele Potestà, *Legitimate Expectations in Investment Treaty Law: Understanding the Roots and the Limits of a Controversial Concept*, 28 ICSID REV. 88, 91 (2013).

²¹ See *id.* at 98–121 (defining the contours of the legitimate expectations doctrine).

²² See *id.* at 116 (discussing the results of the *Total v. Argentine Republic* arbitration, in which the Tribunal found that Argentina's gas pricing scheme violated the investor's legitimate expectations) (internal citations omitted).

²³ See, e.g., Convention on the Protection of Investments, Fr.-Tunis., June 30, 1972, 848 U.N.T.S. 144; Convention on the Protection of Investments, Fr.-Serb., Mar. 28, 1974, 974 U.N.T.S. 110.

vestor-state dispute settlement (ISDS) clauses in about 1,500 treaties, raising important challenges to the harmonization of investment law, consistency in arbitral awards,²⁴ and equal treatment of all investors. While the survey only found limited instances of such disparate treatment, it is likely that there are much larger instances of de facto discrimination between investors. For example, if successful, Lilly's claimed interpretation of the utility standard would apply to investors from NAFTA countries, but not to other foreigners filing for patents in Canada.²⁵ Arguably, Canada may even exclude *Canadians* from enjoying the lower utility threshold advanced by Lilly. Such disparate treatment of inventors and the resulting unevenness in international intellectual property protection is largely part of what the TRIPS Agreement was intended to correct.²⁶

2.2. Dispute Settlement in the WTO and Investment Treaties

Procedural and substantive differences between dispute settlement under investment treaties and the WTO have particular significance for the construction of states' intellectual property obligations. The WTO procedures are a public law process: only state-to-state disputes are contemplated, panels produce published opinions, and third-party participation is possible, allowing countries to develop coalitions around aggregated interests.²⁷ Investment treaties, on the other hand, may include ISDS clauses that allow investors to invoke compulsory arbitration. The ability of a foreign, private investor to seek redress against a sovereign state is unique to the international investment realm. Investors may bring claims autonomously, without regard to the interests, concerns, or support of their source countries. Investors may also bring claims and receive settlements in entirely confidential proceedings.

²⁴ Joachim Pohl, Kekeletso Mashigo & Alexis Nohen, *Dispute Settlement Provisions in International Investment Agreements: A Large Sample Survey*, (OECD Investment Division, OECD Working Paper on International Investment, No. 2012/2, 2012), available at <http://www.oecd.org/daf/investment/workingpapers>.

²⁵ There is a related, important question of whether Canada could legally offer one utility standard for other NAFTA members and another for Canadians, in other words, a "reverse" national treatment rule in which the host country's citizens are treated worse than foreign applicants.

²⁶ See TRIPS Agreement, *supra* note 8, at pmbl., arts. 1–4 (emphasizing that the agreement is intended to "reduce distortions . . . to international trade").

²⁷ Peter Drahos, *Weaving Webs of Influence: The United States, Free Trade Agreements and Dispute Resolution*, 41 J. WORLD TRADE 191, 201 (2007).

As a general matter, WTO panels determine the scope of international obligations by applying systemic tools of treaty interpretation, including consideration of other public international law regimes and even local conditions.²⁸ The Appellate Body has insisted that WTO Panels must have regard to the broader framework of international law, although Panels do not always adopt the same approach to the issue of coherence between legal regimes. A discernible culture of referencing the Vienna Convention rules is evident in modern investment arbitration decisions, but this trend has yet to yield a generally prevailing theory of interpretation in Tribunal awards, though important principles of interpretation can be gleaned.²⁹ Importantly, it is far less likely that a strong argument can be made for an interpretative approach by investment Tribunals that compels coherence with norms in other legal regimes.³⁰ This is particularly so for investor-state disputes which are often based on a set of facts particular to a single economic transaction or rights explicitly provided for individual investors.³¹ Of course, the fact that Parties to an investment treaty can choose what interpretations of terms will bind them³² may also limit the role of other international law rules of treaty interpretation. This freedom to choose may insulate contracting Parties from competing values, arguably including those in international treaties to

²⁸ For example, see Panel Report, *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009) (considering local conditions of the Chinese copyright economy, criminal enforcement priorities in China, and language in FTAs to determine compliance with TRIPS minimum standards obligations).

²⁹ Ian A. Laird, *Interpretation in International Investment Arbitration – Through the Looking Glass*, in *A LIBER AMICORUM: THOMAS WÄLDE - LAW BEYOND CONVENTIONAL THOUGHT* 151 (Jacques Werner & Arif Hyder Ali eds., 2009).

³⁰ See, e.g., *RosInvestCo. U.K. Ltd. v. Russ. Fed'n*, SCC Case No. V079/2005, Award on Jurisdiction (Oct. 5, 2007) (holding that Article 31(3)(c) of the Vienna Convention applies only in “reference to rules of international law that condition the performance of the specific rights and obligations stipulated in the treaty . . .”, and thus declining the salience of human rights treaties raised by the claimant).

³¹ Laird, *supra* note 28, at 157 (noting the “constant pressure that exists in investor-state arbitration between the fundamentally state-based system” and rights of individual investors under investment treaties).

³² See, e.g., Economic Partnership and Cooperation Agreement Between the European Community and its Member States, of the One Part, and the United Mexican States, of the Other Part, art. 12, Dec. 8, 1997, 2000 O.J. (L 276) (maintaining that the Joint Council is charged with establishing measures to protect IP rights, as well as choosing the appropriate mechanism to resolve disputes and enforce these rights).

which only one of the Parties to the investment treaty is bound.³³

Finally, it is clear that ISDS provisions are meant to facilitate challenge to government policies that harm a *single* investor even if they advance the domestic public interest, or for that matter, provide a benefit to other foreign investors. Today, these provisions have become increasingly controversial, with Germany recently withdrawing formal support for such a provision in the Transatlantic Trade and Investment Partnership Agreement.³⁴

3. CONSTRUCTING A POTENTIAL ROLE FOR INVESTOR-STATE INTELLECTUAL PROPERTY DISPUTES

Like all treaties, intellectual property agreements include deliberate gaps, reflecting areas of non-convergence and the residual sovereignty of states to legislate specific rules. Indeed, because intellectual property rights are intimately connected with how countries achieve a competitive equilibrium in their local economies, and how they promote innovation and assure a “pro-competitive balance of private and public interests,”³⁵ it is well-recognized that domestic implementation of international intellectual property standards will take distinctive twists across countries.³⁶ Rather than define every standard, fill every normative hole, or seek uniform rules, international intellectual property agreements merely create global competitive conditions *between* countries—not within them. This domestic flexibility, key to both the theoretical justifications and the pragmatic, welfare-conscious administration of intel-

³³ See, e.g., *Kardassopoulos v. Georgia*, ICSID Case No. ARB/05/18, Decision on Jurisdiction ¶ 215 (July 6, 2007) (concluding that there is some uncertainty whether the provisional application of the Energy Charter Treaty by one party constituted a rule of international law applicable under the BIT).

³⁴ Shawn Donnan & Stefan Wagstyl, *Transatlantic Trade Talks Hit German Snag*, FINANCIAL TIMES (Mar. 14, 2014, 9:00 PM), <http://www.ft.com/cms/s/0/cc5c4860-ab9d-11e3-90af-00144feab7de.html#axzz2wjXA4r9>.

³⁵ Reichman, *supra* note 5, at 588.

³⁶ Michael P. Van Alstine, *Dynamic Treaty Interpretation*, 146 U. PA. L. REV. 687, 691–92 (1998)

(“[T]he [Supreme] Court has consistently refused to view a treaty as a body of integrated norms . . . capable of generating internal solutions for gaps in its provisions. Instead, when faced with an unsettled question under a treaty, the common approach has been to retreat to otherwise-applicable domestic law, ‘whatever may be the imperfections or difficulties’ this may leave in the fulfillment of the international law project.”) (internal citations omitted).

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lectual property laws, is endangered by Lilly's claims under NAFTA.

3.1. *Legitimate Expectations and Domestic Solicitude*

Intellectual property rights are fundamentally directed at the public good.³⁷ Each sovereign nation may evaluate the intellectual property bargain differently, defining rights, limitations, and exceptions in ways that address its particular domestic welfare calculus. The conception of intellectual property as a tool to advance national welfare has long been part of multilateral intellectual property relations.³⁸ The basis for determining the "legitimate expectations" of an intellectual property "investment" thus must resonate in domestic law.

Intellectual property assets protected by various investment agreements, however, are not always defined solely by reference to domestic law. Unless expressly restricted to the definitions contained in domestic law, the scope of intellectual property rights in an investment agreement may be subjugated to notions of symmetry and international harmonization.³⁹ For example, in *Saipem S.p.A. v. Bangladesh*,⁴⁰ Bangladesh argued that because certain intellectual property rights did not exist under Bangladeshi law, they could not fall within the definition of "investment" in its BIT with Italy. The tribunal, however, rejected this argument, holding that "Bangladesh's approach . . . would lead to a different interpretation and thus a different scope of protection under the BIT depending on the country in which the investment is made."⁴¹ Under the tribunal's reasoning, the scope of protection of a BIT must be

³⁷ Brook K. Baker, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines – Eli Lilly and the TPP* 1, 23 (PIJIP Research Paper Series, Paper No. 36, May 17, 2013), available at <http://digitalcommons.wcl.american.edu/research/36>.

³⁸ See Ruth L. Okediji, *Public Welfare and the International Patent System*, in *PATENT LAW IN GLOBAL PERSPECTIVE* 1 (Ruth L. Okediji & Margo A. Bagley eds., 2014) (observing that IP rights have historically been used to "improve the welfare of citizens at home.") (internal citations omitted).

³⁹ Tania S. Voon, Andrew D. Mitchell & James Munro, *Intellectual Property Rights in International Investment Agreements: Striving for Coherence in National and International Law*, in *INTERNATIONAL ECONOMIC LAW AFTER THE CRISIS: A TALE OF FRAGMENTED DISCIPLINES* 7 (C.L. Lim & Bryan Mercurio eds., forthcoming 2014), available at <http://ssrn.com/abstract=2318955>.

⁴⁰ *Saipem S.p.A. v. People's Republic of Bangl.*, ICSID Case No. ARB/05/07, Decision on Jurisdiction (Mar. 21, 2007).

⁴¹ *Id.* ¶ 124.

symmetrical for parties to the treaty, and therefore an investor may be able to claim an intellectual property right that the host state does not recognize.

Even under a strict reading of the tribunal's reasoning in *Sai-pem*, Eli Lilly would still be advancing a weak claim; the United States and Canada are party to the same intellectual property agreements, and Lilly was not denied protection for any category of intellectual property. Lilly challenges the *interpretation* of patentability requirements and objects to the departure from an alleged regionally harmonized utility standard. Lilly imports this standard from U.S. law, the TRIPS Agreement, and the Patent Cooperation Treaty, arguing that its profit expectations derive from the representations in those agreements. Yet, these agreements explicitly reserve the ability to interpret patentability standards, like utility, to individual countries. As discussed above, multilateral intellectual property treaties do not provide or mandate any substantive interpretation of utility or any other patentability requirement. NAFTA also does not impose a substantive standard of utility; in fact, the only mention of the utility standard in the entire intellectual property chapter is semantic—Art. 1709 provides that “capable of industrial application” is synonymous with “useful,” parroting the language of the TRIPS Agreement.

Ironically, Lilly's reliance on the alleged stable, “low” standard of utility embraced by U.S. courts is misplaced, and its citation to the *In re Brana* decision is misleading.⁴² *In re Brana* is one of a line of cases defining the contours of the U.S. utility standard; the jurisprudence is viewed by some commentators as internally inconsistent and technology specific.⁴³ As leading scholars have noted, patentability standards, like the utility standard at issue in the Lilly case, are fundamentally policy levers.⁴⁴ These standards vary by country precisely because they are used to implement specific patent policy goals. Often, countries calibrate across patentability standards to achieve net policy goals in specific sectors. The ultimate question is whether the inventor has provided enough in exchange for the patent grant. It is the responsibility and prerogative

⁴² Notice of Arbitration Against Canada, *supra* note 1, ¶ 31.

⁴³ *In re Brana* failed to address the earlier *Brenner v. Manson* case which dealt with the exact same technology, steroid chemistry, and which arguably set a higher utility standard. *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995); *Brenner v. Manson*, 383 U.S. 519 (1966).

⁴⁴ Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1644–46 (2003).

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of each country to answer this question within its domestic legal system and practice. And, as the TRIPS Agreement makes clear, the interpretation of multilateral intellectual property standards must necessarily "tak[e] into account differences in national legal systems."⁴⁵

Finally, Lilly's claims conflict with generally accepted interpretations of the legitimate expectations doctrine before investment tribunals: only in rare scenarios have changes in regulatory frameworks through the normal operation of domestic legal process been held to violate "legitimate expectations."⁴⁶ In *Continental Casualty v. Argentine Republic*, the Tribunal held:

it would be unconscionable for a country to promise not to change its legislation as time and needs change, or even more to tie its hands by such a kind of stipulation in case a crisis of any type or origin arose. Such an implication as to stability . . . would be contrary to an effective interpretation of the Treaty; reliance on such an implication by a foreign investor would be misplaced and, indeed, unreasonable.⁴⁷

As an investor, Lilly is obligated to not only accept Canadian patent law as it stood at the time it filed the patent applications, but to anticipate that Canadian courts, like its U.S. counterparts, will apply patentability standards consistent with national law and policy.

3.2. *Conflicting or Consistent Obligations?*

Investment treaty standards may operate in tension with the pragmatic administration of intellectual property protection in several ways. Tribunal decisions may force countries to import standards that reflect insufficient links to relevant domestic policies crucial to a country's innovation framework. Tribunal-driven interpretations may also unravel the ideal of a consistent framework for international intellectual property regulation, introducing

⁴⁵ TRIPS Agreement, *supra* note 8, at pmb1., ¶ C.

⁴⁶ See Potestà, *supra* note 20, at 111 (highlighting the decision in *Total v. Argentine Republic*, where the Tribunal held that "'only exceptionally has the concept of legitimate expectations been the basis of redress when legislative actions by a state was at stake'" (internal citations omitted).

⁴⁷ *Cont'l Cas. Co. v. Argentine Republic*, ICSID Case No. ARB/03/9, Certified Award, ¶ 258 (Aug. 27, 2008).

one set of rules for multinationals and another set of rules for other inventors, creators and owners. Overall, standards for states that are party to investment treaties could be different than those that apply to non-member states, thus disrupting the minimum international baseline upon which the global community has come to rely.

In reality, the intellectual property provisions of NAFTA were negotiated in full view of the TRIPS Agreement and in line with the expected outcome of the Uruguay Round. The patent provisions in the TRIPS Agreement significantly upgraded the Paris Convention, but without changing the standards required of member states. Instead, TRIPS reinforced basic requirements of patentability and preserved flexibility for Member States to apply them within their own legal system.

The decision of the Canadian court is a decision consistent with Canada's obligations under TRIPS and thus must be deemed consistent under NAFTA. It simply cannot be the case that intellectual property obligations mean one thing under investment treaties and a completely different thing under trade agreements. In the long term, rigid constraints on a state's ability to advance its priorities in areas as crucial as innovation, access to knowledge goods, and other inputs basic to economic growth and development may lead to an unraveling of investment treaties, as suggested already by the actions of countries such as Indonesia and South Africa.⁴⁸

3.3. Rethinking Investor-State Intellectual Property Dispute Settlement

Investor-state dispute settlement (ISDS) provisions can sometimes be used as an opportunity for private firms to extract more from host countries than their governments were able to extract during the negotiating process. The political bargains that make a treaty acceptable to the popular will in member states can be substantially unraveled by a single investor whose interests are unlikely to reflect the full policy bargain reflected in the treaty. The Lilly complaint illustrates the dangers of treating intellectual property as "investment" per se, isolated from its appropriate policy domains.

⁴⁸ Ben Bland & Shawn Donnan, *Indonesia to Terminate More than 60 Bilateral Investment Treaties*, FINANCIAL TIMES (Mar. 26, 2014, 3:20 PM), <http://www.ft.com/cms/s/0/3755c1b2-b4e2-11e3-af92-00144feabdc0.html#axzz2yv00FuS5>; *South Africa Begins Withdrawing from EU-Member BITs*, INT'L INST. FOR SUSTAINABLE DEV. (Oct. 30, 2012), available at <http://www.iisd.org/itn/2012/10/30/news-in-brief-9/>.

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Lilly's claims should have no legitimate resonance in light of an international intellectual property system in which technological developments require agility, adaptation, and alignment of competing interests by governments seeking to advance innovation and the public welfare. Despite these challenges related to the use of ISDS to address the intellectual property policies of states party to an investment treaty, there could be a role for such provisions. I briefly offer four approaches:

1. *A Narrowly Tailored ISDS Provision:* A narrowly tailored ISDS provision could be useful for situations where a host country specifically targets the intellectual property right of a particular investor. An example may be the issuance of a compulsory license without complying with the domestic process established to provide legal certainty for an investor pursuant to TRIPS. Because this type of dispute targets a particular action, rather than the interpretation of an intellectual property standard, the policy-making ability of the host state is not threatened, and the dispute would not undo the TRIPS balance or compel potentially inconsistent normative outcomes across countries.

2. *An Institutional Approach:* Another approach is to provide a form of appellate review for investor-state disputes involving intellectual property, such as the type that exists in the WTO system or in national law. Given the carefully crafted policy values built into national and multilateral intellectual property systems, such a review could be an important vehicle for adjusting outcomes that unreasonably undermine the competitive equilibrium between rights holders and second comers that often are at the heart of intellectual property disputes. Ideally, the review process would incorporate the hallmarks of a public law process: published decisions, the ability for third-party input and comment, and the involvement of other affected states or international institutions.

3. *An Investment Test:* A third approach is to require a complainant to establish that its intellectual property rights have had a clear economic benefit to the host country and thus constitutes an "investment." One key factor in such an "investment test" could be requiring the claimant to establish the significance of the intellectual property to the host State's economic development.⁴⁹

⁴⁹ See Emmanuel Gaillard, *Identify or Define? Reflections on the Evolution of the Concept of Investment in ICSID Practice*, in INTERNATIONAL INVESTMENT LAW FOR THE 21ST CENTURY: ESSAYS IN HONOUR OF CHRISTOPH SCHREUER 404 (2009) (delineating the four elements of the *Salini* test for defining the term investment: (1) "contribu-

4. *A Holistic International Approach:* Finally, tribunals could be required to consider and address the construction of intellectual property standards in relation to the network of legal regimes that bear upon innovation policy and the welfare objectives of the intellectual property system. This could include competition policy or human rights considerations. The point simply is to facilitate arbitration outcomes that take into account the competing welfare claims of owners, users, and the public interest as reflected in complementary fields of law.

CONCLUSION

The Eli Lilly complaint illustrates the dangers of treating intellectual property as “investment” per se, and offers an opportunity to reconcile intellectual property protection in BITS with the TRIPS Agreement. By leveraging investor-state dispute provisions, the political bargains that make an investment treaty acceptable to States may be unraveled by a single investor whose interests will not reflect the range of policy tradeoffs animating the treaty. The fact is, as evidenced by Canada’s contested utility standard, the architecture of the multilateral intellectual property system purposefully accommodates some *disharmony* to facilitate national welfare objectives. As such, countries still have legal room to work within national constitutional prerogatives and policies affecting innovation to implement the rights prescribed in intellectual property treaties even in the face of ever-increasing transnational obligations. The role of national intellectual property regimes in establishing a globally competitive market place is vital to the public policy goals that undergird a progressive vision of public welfare in an integrated world economy; the peculiarities of investment treaties should not be leveraged to override this longstanding virtue of the international intellectual property framework.

tions,” (2) “duration of performance of the contract,” (3) “participation in the risks of the transaction,” and (4) “contribution to the economic development of the host State”).