

12-2016

A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings

Cynthia M. Ho
cho@luc.edu

Follow this and additional works at: <https://scholarship.law.uci.edu/ucilr>

Recommended Citation

Cynthia M. Ho, *A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings*, 6 U.C. IRVINE L. REV. 395 (2016).
Available at: <https://scholarship.law.uci.edu/ucilr/vol6/iss3/6>

This Article is brought to you for free and open access by UCI Law Scholarly Commons. It has been accepted for inclusion in UC Irvine Law Review by an authorized editor of UCI Law Scholarly Commons.

A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings

Cynthia M. Ho*

This Article discusses an important, yet understudied threat to patent, as well as other intellectual property sovereignty under TRIPS: pending and potential challenges by companies under international agreements protecting investments. Although such agreements have existed for decades, Philip Morris and Eli Lilly are blazing a new path for companies to sue countries they claim interfere with their intellectual property rights through so-called investor-state arbitrations. These suits seek hundreds of millions in compensation and even injunctive relief for alleged violations of internationally agreed intellectual property norms. The suits fundamentally challenge TRIPS flexibilities at the very time the Declaration on Patent Protection and Regulatory Sovereignty under TRIPS, as well as the UN High Level Panel Report seek to encourage countries to utilize them. These disputes may have a chilling effect on countries that would otherwise consider following policy recommendations to better utilize TRIPS flexibilities. Given the importance of this threat to TRIPS and domestic sovereignty, this Article analyzes the pending disputes and offers some proposals for how to promote TRIPS flexibilities and sovereignty.

Introduction	396
I. Background.....	400
A. Intellectual Property Law and Policy.....	400
B. Investment Agreements (Permitting Investor-State Arbitration) ..	403
1. Background.....	404
2. Criticism of Investment Claims	408
3. Addressing Criticisms?	413
C. The Under-Recognized Current Conflict.....	415
1. Limited Recognition of Overlap, Let Alone Conflict	416

* Clifford E. Vickrey Research Professor and Director, Intellectual Property Program, Loyola University Chicago School of Law. The Author thanks Professor Dan Burk and the UC Irvine Symposium for the opportunity to consider this topic. The Author is grateful to comments from participants at the UC Irvine Symposium, as well Sergio Puig and Peter Yu. In addition, the Author thanks Christian Morgan and Hattie Strange for their excellent research assistance.

2. Prominent Defenses of Investor-State Disputes Do Not Recognize Conflict	421
a. ISDS Promotes Sovereignty Concerns and Regulatory Chill Are Overstated	422
b. Investment Claims Promote Investment and Economic Development.....	426
c. Investor-State Disputes as a Fair Process with Procedural Protection	429
II. The Current Collision Course.....	431
A. Initial Investment Cases Challenging TRIPS	431
1. Philip Morris.....	431
a. Factual Context	432
b. Investment Claims	435
i. Vulnerability to Expropriation Claims	435
ii. FET Claims Can Prevail Against Tobacco Regulation	437
2. Eli Lilly.....	440
a. Factual Context	441
b. Investment Claims	443
i. Expropriation	444
ii. Fair and Equitable Treatment	450
B. Potential Problems	453
1. Patentability Standards	453
2. Denial of Permanent/Preliminary Injunction	454
3. No Data Exclusivity	455
III. Addressing Current Conflict	457
A. Narrow Scope	457
1. Limit the Scope of Covered Investments.....	458
2. Narrow Investment Claims	459
3. Expropriation	460
4. FET	460
B. Modify Dispute Settlement	461
C. Increase Transparency and Access.....	465
Conclusion.....	467

INTRODUCTION

Although the areas of intellectual property rights and protection of foreign investments have coexisted peacefully for decades, they are now on a collision course. Phillip Morris and Eli Lilly have claimed that alleged violations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) compromise their “investments” of intellectual property, such that they should be

financially compensated by countries where they obtained these investments.¹ These assertions are not made in the World Trade Organization (WTO) forum. Rather, they are made under international agreements that permit foreign investors to bring unique claims against a country before a tribunal of three typically private attorneys, in a so-called “investor-state” arbitration proceeding.² Investor-state claims can exist without regard to compliance with other international agreements, such as TRIPS, and may exist in agreements that do not have any intellectual property norms.³ These claims are a creative way for companies to directly challenge TRIPS despite the fact that they cannot do so at the WTO.⁴ Moreover, companies can obtain substantial financial compensation that would not typically be available at the WTO.⁵

These investment claims may create havoc concerning TRIPS flexibilities. Notably, TRIPS only requires countries to provide *minimum*, but not uniform standards of protection.⁶ Because of this, TRIPS is often considered to have built-in flexibilities that permit compliance with TRIPS while also recognizing domestic priorities.⁷ Indeed, policy makers have repeatedly recommended countries take

1. See *Eli Lilly & Co. v. Can.*, International Centre for Settlement of Investment Disputes [ICSID] Case No. UNCT/14/2, Notice of Arbitration (Sept. 12, 2013) [hereinafter *Eli Lilly*, Notice of Arbitration], <http://www.italaw.com/cases/1625> [<https://perma.cc/J9AS-CLQ6>]; *Philip Morris Asia Ltd. v. Austl.*, Permanent Court of Arbitration [PCA] Case Repository No. 2012-12, Notice of Arbitration (Nov. 21, 2011) [hereinafter *P.M. v. Austl.*, Notice of Arbitration], <http://www.italaw.com/cases/851> [<https://perma.cc/5NYB-39BB>]; *Philip Morris Brands Sàrl v. Uru.*, ICSID Case No. ARB/10/7, Request for Arbitration, ¶ 1 (Feb. 19, 2010) [hereinafter *P.M. v. Uru.*, Request for Arbitration], <http://www.italaw.com/documents/PMI-UruguayNoA.pdf> [<https://perma.cc/9U7H-4RXM>].

2. This is alternatively called investor-state dispute settlement (ISDS), or less frequently, Foreign Direct Investment Arbitration.

3. For example, the Philip Morris dispute against Australia was initiated under a Bilateral Investment Treaty. See Agreement for the Promotion and Protection of Investments, Austl.-H.K., Sept. 15, 1993, 1770 U.N.T.S. 386. Even when investment claims exist in an agreement with IP rules, they are typically in different parts of a free trade agreement, such as under NAFTA.

4. See Understanding on Rules and Procedures Governing the Settlement of Disputes art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU] (referring to contracting parties, i.e. countries, as the only ones that can initiate a dispute).

5. The routine remedy in a WTO case is to come into compliance with WTO requirements. See *id.* art. 19.1 This may require amending a law. In addition, although a prevailing country could occasionally obtain financial recourse, that is only if a country fails to bring its laws into compliance. See *id.* Moreover, even if this were the case, any monetary compensation would be provided only to the prevailing country. See *id.*

6. See, e.g., Agreement on Trade-Related Aspects of Intellectual Property Rights art. 1.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

7. See, e.g., Carlos M. Correa, *Patent Rights*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189, 198–201 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998) [hereinafter *Correa, Patent Rights*]; CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES 70–97 (2009); Joseph Straus, *Implications of the TRIPS Agreement in the Field of Patent Law*, in FROM GATT TO TRIPS: THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 160, 187 (Friedrich-Karl Beier & Gerhard

advantage of these flexibilities in the decades since TRIPS was concluded.⁸ The Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS, written by forty academics, aims to clarify these flexibilities,⁹ and the recent UN High Level Panel on Access to Medicines reiterates that these flexibilities should be adopted.¹⁰ However, the pending investor-state cases may make states reluctant to take advantage of these flexibilities. After all, an investment tribunal could require a nation to pay millions in compensation for an alleged violation of investment agreement. This possibility could have a substantial chilling effect.

In addition to having a chilling effect on TRIPS flexibilities, investment claims premised on alleged violations of TRIPS could result in conflicts with the WTO/TRIPS regime. This seems particularly likely since investor-state tribunals frequently issue decisions that are criticized as surprising and inconsistent.¹¹ There would be a direct conflict if a WTO panel and an investment tribunal interpreted the identical TRIPS provision differently, which is possible since neither system presently precludes simultaneous or even subsequent litigation. Even if a WTO panel adjudicated a similar factual situation first, an investor-state tribunal would not be bound to the WTO decision.¹² Notably, although WTO rulings tend to be

Schricker eds., 1996); World Health Org. et al., Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade 13, 57, 71–73 (2012).

8. See e.g., Chamber of Deputies Ctr. for Strategic Studies & Debates, BRAZIL'S PATENT REFORM: INNOVATION TOWARDS NATIONAL COMPETITIVENESS 57, 79 (2013) [hereinafter BRAZIL'S PATENT REFORM]; CHAN PARK ET AL., UNITED NATIONS DEV. PROGRAMME, USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA: AN ANALYSIS OF PATENT, COMPETITION AND MEDICINES LAW, 15–16, 22 (2013); U.N. CONFERENCE ON TRADE & DEV.-INT'L CONFERENCE ON SCI. & TECH. FOR SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 367 (2005); *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, § 2.6.1 (Sept. 14, 2016) [hereinafter UN 2016 High Level Panel Report]; Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 26 (WHO-ICTSD-UNCTAD Working Paper, 2007); World Health Org. et al., *supra* note 7, at 209–19.

9. Matthias Lamping et al., *Declaration on Patent Protection - Regulatory Sovereignty under TRIPS*, 45 IIC - INT'L REV. INTELL. PROP. & COMPETITION L. 679 (2014) [hereinafter *Declaration on Patent Protection*].

10. UN 2016 High Level Panel Report, *supra* note 8, § 2.6.1.

11. See, e.g., August Reinisch, *The Issues Raised by Parallel Proceeds and Possible Solutions*, in BACKLASH AGAINST INVESTOR ARBITRATION: PERCEPTIONS AND REALITY, 113, 115–117 (Michael Waibel et al. eds., 2010); Anne van Aaken, *Fragmentation of International Law: The Case of International Investment Law*, 17 FINNISH Y.B. INT'L L. 91, 99 (2006) [hereinafter van Aaken, *Fragmentation of International Law*]; Susan D. Franck, *The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law Through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521 (2005) [hereinafter Franck, *Legitimacy Crisis*]; Federico Ortino, *Legal Reasoning of International Investment Tribunals: A Typology of Egregious Failures*, 3 J. INT'L DISPUTE SETTLEMENT 31 (2012); see also discussion of inconsistency *infra* pp. 116–17.

12. Not only are the two systems entirely distinct such that a decision in one system is not binding in another, but investor-state tribunals are not obligated to follow past tribunal rulings. See, e.g., Christoph Schreuer & Matthew Weiniger, *A Doctrine of Precedent?*, in THE OXFORD HANDBOOK OF INTERNATIONAL INVESTMENT LAW 1188 (Peter Muchlinski et al. eds., 2008).

consistent with prior decisions,¹³ and uniformity is promoted through a standing Appellate Body,¹⁴ there is currently no similar system in place to lend uniformity to all investor-state disputes.¹⁵

The investment cases challenging TRIPS come at a time when there is not only an explosion of investment cases¹⁶ but also significant criticism of investment claims.¹⁷ These investment claims involving IP are arguably expected given that companies increasingly consider IP a valuable type of investment. However, the potential for conflict between these two systems seems largely overlooked. Importantly, even those who vigorously defend investment claims fail to recognize the collision course between TRIPS and investment claims. This Article aims to address this gap and show why existing defenses of investment claims fail to address the unique problems with challenging international IP norms in investment cases.

This Article proceeds in three Parts. Part I provides fundamental background to the initial investment disputes by explaining the relevant law and policy of intellectual property, as well as investment state arbitration. It also documents the current under-recognition of the inherent problems of challenging international IP norms through investment arbitration. Part II discusses the facts and claims of the initial disputes impacting TRIPS, including policy problems. It also discusses possible future cases that may arise. Part III then explores possible ways to minimize the present collision course between IP agreements and investment agreements.

13. E.g., Raj Bhala, *The Precedent Setters: De Facto Stare Decisis in WTO Adjudication (Part Two of A Trilogy)*, 9 J. TRANSNAT'L L. & POL'Y 1 (1999) (WTO tends to operate with *de facto stare decisis*).

14. DSU, *supra* note 4, art. 17.

15. See *infra* note 78 and accompanying text. However, in two recent agreements, there is an appeals tribunal. See Proposal for a Council Decision on the Conclusion of the Comprehensive Economic and Trade Agreement, Can.-EU, art. 8.28, COM (2016) 0443 (July 5, 2016) [hereinafter CETA]; EU-Vietnam Free Trade Agreement: Agreed Text as of January 2016, art. 13 (Feb. 1, 2016) [hereinafter EU-Vietnam FTA], <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1437> [<https://perma.cc/U34F-FTLF>]. Although this is a notable change, it is still different than the WTO system in that the appeals would only be for that single agreement and would not result in uniformity amongst all investment agreements.

16. Whereas the first investment treaty arbitration was only in 1987, from 2012–2014, between forty and sixty claims were filed each year, with over 600 claims currently pending in over fifty countries. See U.N. Conference on Trade and Development, *Recent Trends in IIAS and ISDS*, at 5, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2015/1 (Feb. 2015) [hereinafter UNCTAD, *Recent Trends*]; U.N. Conference on Trade and Development, *Recent Developments in Investor-State Dispute Settlement (ISDS): Updated for the Multilateral Dialogue on Investment*, at 2–3, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/3/REV (2013); see also Burghard Ilge, *Both Ends, To Change a BIT is Not Enough: On the Need to Create Sound Policy Frameworks for Investment* 6 (2015) (only nineteen known cases in 1997, but at least one new case every week in 2015), <http://www.s2bnetwork.org/to-change-a-bit-is-not-enough/> [<https://perma.cc/RCG8-3CFE>]. The number of claims continues to grow. In 2016, nearly 1000 new cases were filed involving 3000 parties from over 1000 countries. ICC Reveals Record Number of New Arbitration Cases Filed in 2016, INT'L CHAMBER COM. (Jan. 18, 2017), <http://www.iccwbo.be/icc-reveals-record-number-of-new-arbitration-cases-filed-in-2016> [<https://perma.cc/GGY7-6LVX>].

17. See *infra* Part I.B.3.

I. BACKGROUND

This Part lays the groundwork to understand the initial landmark cases challenging TRIPS issues through investment arbitration. Part A explains intellectual property law and policy, including the current international landscape. Part B explains international agreements permitting investor-state claims. Understanding their genesis, including underlying policy reasons, is critical to illuminate the present conflict. Section B explains not only investment law, but some basics of key claims that are at issue in both cases, including “expropriation” of investments, as well as when a company has purportedly been denied “fair and equitable treatment.”¹⁸ Section C then addresses the largely unrecognized conflict for TRIPS flexibilities in investment arbitration.

A. Intellectual Property Law and Policy

Traditionally, the existence and scope of intellectual property rights were solely a function of domestic policy concerning which interests a nation wanted to foster. Intellectual property rights were understood to impose a social cost in that such rights generally result in higher priced goods. Some countries viewed some goods, such as drugs, to be an area where the social cost of patent protection should be viewed skeptically in light of an interest in ensuring that drugs are not priced beyond reach.¹⁹

Today, however, most countries do not have the luxury of designing intellectual property laws solely based on domestic policy. This is because over 160 countries are members of the WTO, which requires compliance with the “minimum” levels of intellectual property rights under TRIPS.²⁰ TRIPS is considered a landmark agreement that for the first time requires countries to provide patent rights. Under TRIPS, all member countries (except Least Developed Countries) must now provide patent protection regardless of their policy preferences.²¹

Although it is well known that TRIPS requires “minimum,” but not uniform standards,²² the “minimum” standards have been hotly contested. This is partly a

18. These are unique claims to investment suits. *See infra* notes 48–52 and accompanying text.

19. *See, e.g.,* Correa, *Patent Rights*, *supra* note 7, at 192 (over 50 countries did not provide patents on drugs prior to TRIPS).

20. *Understanding the WTO: The Organization, Members and Observers*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm [<https://perma.cc/AJZ4-U4SZ>] (last visited Mar. 23, 2016).

21. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/73 (Nov. 6, 2015); TRIPS, *supra* note 6, art. 27.

22. The fact that TRIPS only requires minimum standards is underscored by the fact that subsequent to TRIPS, parties attempted, but failed, to adopt an international agreement requiring uniform standards that would not have been necessary if TRIPS had such standards already. *E.g.,* Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 89–90 (2007).

function of the fact that TRIPS does not define key aspects of the minimum standards. For example, although TRIPS states that members must grant patents for “inventions” if they meet certain criteria such as being “new,” having an “inventive step,” and being “capable of industrial application,” TRIPS leaves these key terms undefined.²³ Before TRIPS, countries often defined these terms differently and because TRIPS requires minimum instead of uniform standards, continued flexibility seems to have been contemplated.²⁴ Accordingly, scholars, as well as policy makers, believe that countries retain substantial discretion in deciding these terms.²⁵

Importantly, although WTO countries are now required to provide intellectual property rights, this does not indicate that all WTO countries believe this is good domestic policy. Some countries, such as India, resisted incorporating intellectual property rights into the WTO/TRIPS framework and also tried to minimize the scope of obligations.²⁶ There are a variety of theories on why developing countries agreed to TRIPS, but not one of them suggests that such countries were agreeing that it was good *policy* to adopt stronger intellectual property rights. Rather, the theories range from ignorance of the impact of TRIPS, to the fact that TRIPS should be considered a treaty of adhesion.²⁷

On the other hand, the existence of TRIPS does reflect the fact that *some* countries, and especially some industries (such as pharmaceutical companies), were desirous of stronger global protection that led to TRIPS. Until TRIPS, there was no multilateral international agreement mandating any type of intellectual property protection exist. Previously, multilateral agreements primarily aimed to help inventors more easily obtain global protection *if* a country elected to provide it.²⁸

23. TRIPS, *supra* note 6, art. 27.

24. Notably, not only were there different definitions of these terms, but TRIPS even permits slightly different key terms, stating, for example, that a country can require an invention to be “useful” or have “industrial application” even though these terms are not interchangeable. *See* TRIPS, *supra* note 6, art. 27.

25. *E.g.*, E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30:1 CAN. INTELL. PROP. REV. 35 (2014); Correa, *Patent Rights*, *supra* note 7, at 198–00; Reichman & Dreyfuss, *supra* note 22, at 89; PARK, *supra* note 8, at 39; UNITED NATIONS DEV. PROGRAMME, *supra* note 8, at 57; UN 2016 High Level Panel Report, *supra* note 8, at 22.

26. *E.g.*, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods, *Communication from Argentina, Brazil, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay*, art. III, MTN.GNG/NG11/W/71 (May 14, 1990), https://www.wto.org/gatt_docs/English/SULPDF/92100147.pdf [<https://perma.cc/5HUC-SVFJ>] (proposing limiting scope of IP in WTO); *see also* A.V. Ganesan, *Negotiating for India, in THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS* 211, 213–14 (Jayashree Watal & Antony Taubman eds., 2015) (noting that India resisted including IP as not adequately trade related and concerned about the impact on affordable medicine).

27. *E.g.*, Peter K. Yu, *TRIPS and its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 373 (2006); Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L L. 681, 691 (2014).

28. *E.g.*, Paris Convention for the Protection of Industrial Property arts. 3–4, Mar. 20, 1883, as last revised at the Stockholm Revision Conference, July 14, 1967, arts. 2–3 21 U.S.T. 1583, 828 U.N.T.S. 305 (last amended Sept. 28, 1979) (showing that if a nation provided patents, it could not treat

But now, although many countries and some scholars consider TRIPS to require too much IP protection, some developed countries such as the United States have sought and continue to seek international agreements requiring even more protection.²⁹ These “TRIPS-plus” agreements are often bilateral agreements with developing countries that may sign agreements to gain desired market access without fully understanding the implications of the intellectual property provisions.³⁰ Scholars consider these TRIPS-plus agreements savvy forum shifting by countries that did not obtain optimal levels of protection under TRIPS³¹ and also note how TRIPS-plus agreements reduce TRIPS flexibilities.³² In a similar fashion, the companies now bringing landmark investment claims may be shifting to the investment tribunal forum to seek remedies that they cannot obtain in the WTO directly or even by lobbying their governments which often exercise substantial discretion in deciding what claims to challenge at the WTO.³³

Against the upward ratcheting of IP standards, some counter-movements promote the use of TRIPS flexibilities. The Doha Public Health Declaration, for

its nationals better than foreign applicants); Patent Cooperation Treaty June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 (Oct. 3, 2001) (providing a mechanism to help inventors more easily obtain patents in multiple countries with a single application if countries provided patents).

29. *E.g.*, RUTH MAYNE, HUMAN DEV. REPORT OFFICE, UNDP, REGIONALISM, BILATERALISM AND THE TRIPS PLUS AGREEMENTS: THE THREAT TO DEVELOPING COUNTRIES 1 (2005), http://hdr.undp.org/sites/default/files/hdr2005_mayne_ruth_18.pdf [<https://perma.cc/N832-KKZW>]; Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 866–69 (2007); DEERE, *supra* note 7, at 113–42.

30. *E.g.*, MAYNE, *supra* note 29, at 6–8.

31. *See, e.g.*, Susan Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP*, 18 J. INTEL. PROP. L. 447, 454 (2011) [hereinafter Sell, *TRIPS Was Never Enough*]. Of course, this is not the first instance of forum shifting. Incorporating IP standards in the WTO framework is generally considered a landmark forum shift that was orchestrated not just by countries, but also by a few powerful industries that successfully lobbied their governments. *E.g.*, SUSAN SELL, PRIVATE POWER, PUBLIC LAW (2003).

32. *E.g.*, CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 223–51 (2011) [hereinafter HO, ACCESS TO MEDICINE] (providing an overview of TRIPS-plus standards and how they limit TRIPS flexibilities); Henning Grosse Ruse-Khan, *Protecting Intellectual Property Rights Under BITs, FTAs and TRIPS: Conflicting Regimes or Mutual Coherence*, in EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION 485, 490–93 (Chester Brown & Kate Miles eds. 2011) [hereinafter Ruse-Khan, *Protecting Intellectual Property Rights*]; Sell, *TRIPS Was Never Enough*, *supra* note 31, at 454.

33. *See, e.g.*, James Gathii & Cynthia Ho, *Regime Shifting of IP Law Making and Enforcement from the WTO to the International Investment Regime*, 18 MINN. J.L. SCI. & TECH. (forthcoming 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2914650 [<https://perma.cc/YNF4-3K42>]; *see also* Valentina S. Vadi, *Towards a New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investments*, 5 N.Y.U. J. INTEL. PROP. & ENT. L. 113, 142 (2015) [hereinafter Vadi, *Towards a New Dialectics*] (noting that as TRIPS disputes have declined, there are now IP-related investment disputes). In fact, some have specifically noted how investment-state arbitrations can be considered TRIPS Plus. *E.g.*, LUKAS VANHONNAEKER, INTELLECTUAL PROPERTY RIGHTS AS FOREIGN DIRECT INVESTMENTS: FROM COLLISION TO COLLABORATION 177–86 (2015). *But see* Bertram Boie, *The Protection of Intellectual Property Rights Through Bilateral Investment Treaties: Is there a TRIPS-Plus Dimension?* 40–44 (NCCR Trade, Working Paper No. 2010/19, 2010) (noting that although BITs may require more than TRIPS, they arguably address different subject matter, such that they are not TRIPS-plus, so much as incongruent).

example, affirmed that members have flexibility in implementing TRIPS in a way that protects public health.³⁴ Since then, some countries have adopted or considered adopting national laws to better incorporate TRIPS flexibilities.³⁵ The need to incorporate TRIPS flexibilities was recently underscored by the September 2016 Report of the United Nations (UN) Secretary General's High Level Panel on Access to Medicine, which it issued after public hearings worldwide.³⁶ However, the use of these flexibilities may be threatened by the pending disputes premised on alleged TRIPS violations. Indeed, although the initial investment disputes involve only three countries, they seem designed to influence the laws of other countries that are not formal members of these disputes.³⁷

B. Investment Agreements (Permitting Investor-State Arbitration)

There are currently over 3,000 international agreements that provide “foreign” investors to a particular country with certain rights concerning their investments, as well as a mechanism to enforce these rights before a tribunal of private arbitrators.³⁸ The vast majority of these agreements are bilateral investment agreements.³⁹ However, recent trade agreements include a chapter on investment agreements, as well as chapters on other topics such as intellectual property rights.⁴⁰ This Section

34. World Trade Organization [WTO], Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) (“we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to . . . promote access to medicines for all.”).

35. India, Argentina and the Philippines have already adopted some TRIPS flexibilities. *E.g.*, The Patents (Amendment) Act, No. 15 of 2005, India Code (2005) [hereinafter India Patents (Amendment) Act]; Republic of the Philippines, Congress of the Philippines, Republic Act No. 9502 (June 6, 2008), http://www.lawphil.net/statutes/repacts/ra2008/ra_9502_2008.html [<https://perma.cc/3LTT-7J3H>]; *Non-patentable Subject Matter according to the New Guidelines of the Argentine PTO*, MOELLER IP ADVISORS, (June 24, 2013), <http://www.moellerip.com/non-patentable-subject-matter-according-to-the-new-guidelines-of-the-argentine> [<https://perma.cc/HD9A-Z4KZ>]; see also Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295 (2014-2015). Countries that are contemplating following suit include Brazil and South Africa. See, e.g., Draft National Policy on Intellectual Property (Sept. 2013) (S. Afr.), <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf> [<https://perma.cc/4LRY-Y6Q6>]; Catherine Tomlinson et al., *Reforming South Africa's Procedures for Granting Patents to Improve Medicine Access*, 105 S. AF. MED. J. 741 (2015); BRAZIL'S PATENT REFORM, *supra* note 8.

36. See UN 2016 High Level Panel Report, *supra* note 8, at 22.

37. *E.g.*, Ruth Okediji, *Is Intellectual Property “Investment”?* *Eli Lilly v. Canada and the International Intellectual Property System*, 35 U. PA. J. INT'L L. 1121, 1121-22 (2014); see also Gathii & Ho, *supra* note 33 (arguing that these initial disputes indicate an intent to shift from the WTO/TRIPS regime to the use of investment disputes to effectuate policy changes in domestic and global laws).

38. *E.g.*, U.N. CONF. ON TRADE AND DEV., INVESTOR-STATE DISPUTES: PREVENTION AND ALTERNATIVES TO ARBITRATION, at 3, U.N. Doc. UNCTAD/DIAE/IA/2009/11, U.N. Sales No. E.10.II.D.11 (2010) [hereinafter UNCTAD, INVESTOR STATE DISPUTES].

39. *E.g.*, U.N. CONF. ON TRADE & DEV., *Investment Policy Hub: International Investment Agreements Navigator* (2013), <http://investmentpolicyhub.unctad.org/IIA> [<https://perma.cc/GTR8-FYBK>] (showing that there are over 2,900 bilateral investment treaties, but fewer than 400 other types of agreements).

40. *E.g.*, North American Free Trade Agreement, Can.-Mex.-U.S., Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA]; *Trans-Pacific Partnership*, OFF. U.S. TRADE

explains the unique claims, and how they are enforced, followed by criticisms of this system. This Section primarily focuses on the similarities among the majority of existing agreements, including criticisms of such agreements, although modifications in a few recent agreements are also addressed at the end of the Section.

1. Background

Agreements permitting investor-state arbitrations have been introduced since 1959 to promote foreign direct investment in countries.⁴¹ They were largely introduced in agreements by newly independent countries desirous of encouraging foreign investments.⁴² The new rights and mechanism for enforcement were intended to address a myriad of prior problems that often discouraged investments. For example, foreign investors might be loath to purchase property in a state when they know they could be the target of unlawful state action (i.e., taking their purchase without compensation), and not have recourse. Lack of recourse might exist because the nation did not have a robust rule of law, because the government had sovereign immunity, or because the judgment was not enforceable. Investors often had to seek intervention by their governments, which usually took the form of military interventions, often referred to as “gunboat diplomacy.”⁴³ Against this backdrop, new claims specific to foreign investors, as well as a method to enforce them, were created to mitigate risks and induce foreign investment.⁴⁴

Investment agreements generally provide the same basic set of enforceable substantive rights to investors intended to contribute to a stable investment climate.⁴⁵ Some of the rights clearly aim to put foreign investors on a level playing field with domestic ones. For example, there is usually a guarantee that foreign

REPRESENTATIVE (last visited Nov. 7, 2016) [hereinafter TPP], <https://ustr.gov/tpp/> [<https://perma.cc/9NLT-EBSB>].

41. See generally U.N. CONF. ON TRADE AND DEV., BILATERAL INVESTMENT TREATIES IN THE MID 1990S, U.N. Doc UNCTAD/ITE/IIT/7, U.N. Sales No. E.98.II.D.8, 8–10 (1998) (showing that Germany and Pakistan signed the first such agreement in 1959); see also Rudolf Dolzer & Christoph Schreuer, *Principles of International Investment Law* (2d ed. 2012) (showing that although international agreements to promote investments date back to the late 1700s, they were limited in scope to expropriation and importantly lacked arbitration-type remedies common in modern agreements).

42. E.g., UNCTAD, INVESTOR-STATE DISPUTES, *supra* note 38, at 3–4; LORENZO COTULA, INT’L INST. FOR ENV’T & DEV., INVESTMENT TREATIES AND SUSTAINABLE DEVELOPMENT: INVESTMENT LIBERALISATION 1 (2014).

43. E.g., KENNETH VANDEVALDE, UNITED STATES INVESTMENT TREATIES: POLICY AND PRACTICE 7 (1992); see also Anthea Roberts, *State-to-State Investment Treaty Arbitration: A Hybrid Theory of Interdependent Rights and Shared Interpretive Authority*, 55 HARV. INT’L L.J. 1, 15–17 (2014) (discussing gunboat diplomacy as well as broader historical context). Alternatively, investors sometimes sought to have their home country make a claim on their behalf at the International Court of Justice, but that resulted in only a small number of successful claims and even those that were successful did not result in any compensation to the investor and were not truly enforceable without enactment of a Security Council Resolution. See, e.g., Franck, *Legitimacy Crisis*, *supra* note 11, at 1536–37.

44. E.g., VANDEVALDE, *supra* note 43, at 7.

45. E.g., JESWALD W. SALACUSE, THE LAW OF INVESTMENT TREATIES 146–51 (2d ed. 2015).

investors will not be treated less favorably than domestic ones and that they will be free from unreasonable or discriminatory measures; this is referred to as “national treatment.”⁴⁶ Similarly, most agreements require that investors be provided the most favored nation treatment such that foreign investors under one agreement are provided no less favorable treatment than foreign investors under a different agreement.⁴⁷

However, there are two other core obligations in most agreements that may provide investors with *more* rights than domestic ones and are of particular issue concerning intellectual property claims.⁴⁸ First, states are prohibited from expropriating investments without compensation.⁴⁹ Although somewhat analogous to domestic takings laws in most countries, the interpretation is often broader than under domestic laws.⁵⁰ Second, states are required to provide minimum standards of treatment to foreign investments, which is often referred to as “fair and equitable treatment” (FET).⁵¹ Although some aspects of what could constitute an FET claim might have parallels in domestic law such as denial of due process and undue discrimination, such claims generally have no true parallel to the extent that they focus on protecting alleged “legitimate expectations” of investors.⁵²

FET claims deserve special discussion not only since investors tend to prevail on these, but also because they are more likely to create problems with IP norms given their broad scope. The concept of “legitimate expectations” was first

46. *E.g., id.* at 149; U.S. Dep’t of State, 2012 U.S. Model Bilateral Investment Treaty art. 3 (2012) [hereinafter 2012 U.S. Model BIT].

47. *E.g.,* 2012 U.S. Model BIT, *supra* note 46, art.4; SALACUSE, *supra* note 45, at 149. *E.g.,* Claudia Salomon & Sandra Friedrich, *How Most Favoured Nation Clauses in Bilateral Investment Treaties Affect Arbitration*, PRACTICAL LAW ARBITRATION, 3–4 (2013), <https://m.lw.com/thoughtLeadership/favoured-nation-clauses-arbitration> [https://perma.cc/WL4U-9QRW] (showing that although the original intent would seem reasonable, it has been used creatively to expand protection).

48. Nations that promote such rights, however, often misrepresent this issue. *See, e.g., Investor-State Dispute Settlement (ISDS), Fact Sheet*, OFF. U.S. TRADE REPRESENTATIVE (Mar. 2015) [hereinafter *ISDS Fact Sheet*], <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2015/march/investor-state-dispute-settlement-isds> [https://perma.cc/JB7N-RATQ] (alleging that claims under investment agreements simply “mirror” U.S. rights and are “designed to provide no greater substantive rights to foreign investors than are afforded under . . . U.S. law.”).

49. *See, e.g.,* 2012 U.S. Model BIT, *supra* note 46, art. 6; NAFTA, *supra* note 40, art. 1110.

50. *E.g.,* Vicki Been & Joel Beauvais, *The Global Fifth Amendment? NAFTA’s Investment Protections and the Misguided Quest for an International “Regulatory Takings” Doctrine*, 78 N.Y.U. L. Rev. 30, 37 (2003); LISE JOHNSON ET. AL., COLUM. CTR. ON SUSTAINABLE INV., INVESTOR-STATE DISPUTE SETTLEMENT, PUBLIC INTEREST AND US DOMESTIC LAW, 1, 7 (May 2015), <http://ccsi.columbia.edu/files/2015/05/Investor-State-Dispute-Settlement-Public-Interest-and-U.S.-Domestic-Law-FINAL-May-19-8.pdf> [https://perma.cc/9KX6-PZEL].

51. *E.g.,* NAFTA, *supra* note 40, art. 1105; TPP, *supra* note 40, art. 9.6; SALACUSE, *supra* note 45, at 241 (noting that this is a requirement of “virtually all investment treaties” even though formulations differ).

52. *E.g.,* Lise Johnson & Oleksandr Volkov, *Investor-State Contracts, Host-State “Commitments” and the Myth of Stability in International Law*, 24 AM. REV. INT’L ARB. 361, 381–82 (2013) (noting that protection of expectations, versus actual rights, provides investors more protection against regulatory change than under U.S. domestic law).

mentioned by a tribunal in 2003 and is now considered “so general a provision [that it] is likely to be almost sufficient to cover all conceivable cases.”⁵³ In addition, even though tribunals have stated that defeat of legitimate expectations alone is not an automatic breach of FET, it nonetheless can be given significant weight, arguably disproportionately, in ultimately finding a violation of an FET claim.⁵⁴ Recent expansive interpretations of FET claims have resulted in a proliferation of claims; this stands in stark contrast to previous decades where the standard was rarely invoked because it was considered only applicable where action was egregious and shocking.⁵⁵

An important aspect of modern investment claims is the process for addressing these claims, including how it is dramatically different than most adjudications. Investment claims are a unique aspect of international law that permit private companies to assert a claim against a state.⁵⁶ The ability of a company to sue a host state directly is considered an unprecedented “revolutionary innovation” in international law that usually involves only state-to-state interactions.⁵⁷ In addition, *how* the claims are adjudicated is also notable. Investment claims are decided by a tribunal of three individuals that lacks the independence of most domestic and international courts.⁵⁸ There is also a high level of confidentiality regarding not only hearings, but also written submissions; this means that generally only parties to the

53. Técnicas Medioambientales Tecmed S.A. v. United Mexican States, ICSID Case No. ARB (AF)/00/2, Award, ¶ 154 (May 29, 2003), 19 ICSID Rev. 158 (2004); F. A. Mann, *British Treaties for the Protection and Promotion of Investments*, 52 BRIT. Y.B. INT'L L. 241, 243 (1981).

54. E.g., Bonniticha, *Substantive Protection Under Investment Treaties: A Legal and Economic Analysis* 167–68 (2014); Clayton v. Canada, PCA Case No. 2009-04, Award on Jurisdiction and Liability, ¶ 572 (Mar. 17, 2015); see also LISE JOHNSON & LISA SACHS, COLUM. CTR. ON SUSTAINABLE INV., THE TPP'S INVESTMENT CHAPTER: ENTRENCHING, RATHER THAN REFORMING, A FLAWED SYSTEM 5 (2015), <http://ccsi.columbia.edu/2015/11/18/the-tpps-investment-chapter-entrenching-rather-than-reforming-a-flawed-system> [<https://perma.cc/5YUX-UNR7>].

55. E.g., Bryan Mercurio *Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements*, 15 J. INT'L ECON. L. 871, 894 (2012) [hereinafter Mercurio, *Awakening*]; see also Barnali Choudhury, *Evolution or Devolution? Defining Fair and Equitable Treatment in International Investment Law*, 6 J. WORLD INV. & TRADE 297, 298 (2005). The standard dates back to a 1926 case concerning international standards in which a tribunal held that to violate international standards, treatment of an alien should amount to “an outrage, to bad faith, to willful neglect of duty, or to an insufficiency of governmental action so far short of international standards that every reasonable and impartial man would recognize its insufficiency.” *Neer v. United Mexican States*, 4 R.I.A.A. 60, 61–62 (Mex.-U.S.A. Gen. Cl. Comm'n 1926); see also Elettronica Sicula S.p.A. (ELSI) (U.S. v. It.), 1989 I.C.J. 15, ¶ 128 (July 20) (noting that state arbitrariness would require “willful disregard of due process of law, an act which shocks, or at least surprises a sense of judicial propriety”).

56. E.g., Gus Van Harten, *Perceived Bias in Investment Treaty Arbitration*, in THE BACKLASH AGAINST INVESTMENT ARBITRATION: PERCEPTIONS AND REALITY 433, 434–35 (Waibel et al. eds., 2010) [hereinafter Van Harten, *Perceived Bias*].

57. BG Grp. PLC v. Republic of Argentina, Final Award, ¶ 145 (UNCITRAL Arb. Trib. Dec. 24, 2007) (“profound transformation of international investment law”); Jan Paulsson, *Arbitration Without Privity*, 10 ICSID REV. 232, 256 (1995) (“dramatically different from anything previously known in the international sphere”).

58. E.g., Sergio Puig, *Social Capital in the Arbitration Market*, 25 EUR. J. INT'L L. 387, 397 (2014); Alan Scott Rau, *Integrity in Private Judging*, 38 S. TEX. L. REV. 485, 521–22 (1997); Van Harten, *Perceived Bias*, *supra* note 56, at 439.

dispute have full access to all the information.⁵⁹ Under the vast majority of agreements, the tribunal is also not required to permit interested third parties to participate.⁶⁰ Finally, there is currently no possibility of appeal in all but two of over 3000 agreements.⁶¹ Awards can theoretically be annulled,⁶² but the conditions are very limited.⁶³ Although these features are radically different than most adjudicatory systems, they are based on earlier international commercial arbitration between private parties for whom confidentiality was considered essential.⁶⁴ However, as will be discussed in the next section, investment claims inherently involve public matters, such that the model for private parties may be a poor fit.

59. *E.g.*, Franck, *Legitimacy Crisis*, *supra* note 11, at 1544–45.

60. *E.g.*, Jeffery Atik, *Legitimacy, Transparency and NGO Participation in the NAFTA Chapter 11 Process*, in *NAFTA INVESTMENT LAW AND ARBITRATION: PAST ISSUES, CURRENT PRACTICE, FUTURE PROSPECTS* 135, 147 (Todd Weiler ed., 2004). The trend in recently concluded and pending agreements is toward more transparency and participation. However, that has no retroactive impact on older agreements.

61. The EU has included an appeal process in its agreement with Vietnam, as well as with Canada, and the proposed agreement with the US. *See* EU-Vietnam FTA, *supra* note 15; CETA, *supra* note 15, art. 8.27–28; Press Release, Eur. Comm’n, EU Finalises Proposal for Investment Protection and Court System for TTIP (Nov. 12, 2015). In addition, although its success is uncertain, the EU has proposed a multilateral investment court. Appeals could be introduced in other agreements. *See* The Multilateral Investment Court Project, EUR. COMM’N (Dec 21, 2016), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1608> [<https://perma.cc/7QVT-FX6S>].

62. *E.g.*, Letter from Payam Akhavan, Associate Professor, McGill University, et al., to Harry Reid, U.S. S. Minority Leader, et al. (Apr. 7, 2015), <http://www.mcgill.ca/fortier-chair/isds-open-letter> [<https://perma.cc/J6PY-RSU9>] [hereinafter April 2015 Letter] (stating that “[a]wards are subject to review either in national courts or by ad hoc annulment committees composed of representatives drawn from rosters created by states”).

63. International Convention for the Settlement of Investment Disputes between States and Nationals of Other States, art. 52, Mar. 18, 1965, 17 U.S.T. 1270, 575 UNTS. 159 [hereinafter ICSID Convention] (permitting annulment if the tribunal was not properly constituted, the tribunal manifestly exceeded its powers, there was corruption by a member, there was a serious departure from a fundamental rule of procedure, or the award failed to state the reasons on which it was based); U.N. Comm’n on Int’l Trade Law, UNCITRAL Model Law on International Commercial Arbitration, art. 34 (1985 with amendments as adopted in 2006), http://www.uncitral.org/pdf/english/texts/arbitration/ml-arb/07-86998_Ebook.pdf [<https://perma.cc/ZW2W-FV7E>] (limited grounds for setting aside an award). Moreover, attempts to annul are generally unsuccessful. *E.g.*, UNCTAD, *Recent Trends*, *supra* note 16, at 8 (noting that all five applications for annulment in 2014 were entirely rejected). *But see* Promod Nair & Claudia Ludwig, *ICSID Annulment Awards: Time for Reform?* 5 GLOBAL ARB. REV. 18, 19–20 (2010) (suggesting that in some cases, annulment proceedings have been more akin to appellate review despite lack of support from language of ICSID). The lack of review of such awards was recently reinforced when the U.S. Supreme Court held that domestic courts must not review their merits. *BC Grp., PLC v. Republic of Arg.*, 134 S. Ct. 1198, 1212 (2014).

64. *E.g.*, Frank Garcia et al, *Reforming the International Investment Regime: Lessons from International Trade Law*, 18 J. INT’L ECON. L. 861 (2015).

2. Criticism of Investment Claims

Although investment claims and the investor-state system were originally applauded for promoting investment flows,⁶⁵ they are now highly controversial.⁶⁶ There are several key criticisms that will be explained in this section. A major issue is that investment claims are often expansively interpreted in favor of investors. Moreover, investment claims can be interpreted inconsistently. This results in a serious chilling effect—especially given the increasing number of claims and significant awards. A related issue is the lack of democratic accountability by tribunals. After discussing each of these criticisms, recent initiatives aimed at addressing criticisms will be explained, including why these fail to fully address problems relating to TRIPS issues.

A major issue with investment claims is their expansive interpretation. Although most agreements have similar protections, they tend to leave key terms undefined.⁶⁷ Even newer generation agreements that provide factors to *consider* for either expropriation or FET claims, still leave much discretion in the hands of tribunals since they provide no guidance on how to weigh and balance broad factors.⁶⁸ Moreover, since investment claims primarily exist in bilateral investment agreements that focus on investments, undefined terms, as well as ambiguities, may be resolved in favor of investors because of the lack of competing language in the

65. E.g., David P. Riesenber, Note, *Fee Shifting in Investor-State Arbitration: Doctrine and Policy Justifying Application of the English Rule*, 60 DUKE L.J. 977, 985 (2011).

66. E.g., Simon Lester, *The ISDS Controversy: How We Got Here and Where Next*, INT'L CTR. FOR TRADE & SUSTAINABLE DEV.: OPINION (June 1, 2016), <http://www.ictsd.org/opinion/the-isds-controversy-how-we-got-here-and-where-next> [https://perma.cc/F5EQ-ZSV9]; Elizabeth Warren, Opinion, *The Trans-Pacific Partnership Clause Everyone Should Oppose*, WASH. POST (Feb. 25, 2015), https://www.washingtonpost.com/opinions/kill-the-dispute-settlement-language-in-the-trans-pacific-partnership/2015/02/25/ec7705a2-bd1e-11e4-b274-e5209a3bc9a9_story.html [https://perma.cc/G2JF-5KGV]; *The Arbitration Game: Governments are Souring on Treaties to Protect Foreign Investors*, ECONOMIST (Oct. 11, 2014), <http://www.economist.com/news/finance-and-economics/21623756-governments-are-souring-treaties-protect-foreign-investors-arbitration> [https://perma.cc/P336-GJSE]. For example, the E.U. initiated a public consultation to address concern about whether to include an investment chapter in its pending agreement with the U.S. European Commission Press Release IP/14/56, Commission to Consult European Public on Provisions in EU-US Trade Deal on Investment and Investor-State Dispute Settlement (Jan. 21, 2014).

67. For example, most agreements provide for FET claims without any reference point by which to determine the standard. E.g., Bryan Mercurio, *Safeguarding Public Welfare?—Intellectual Property Rights, Health and the Evolution of Treaty Drafting in International Investment Agreements*, 6 J. INT'L DISPUTE SETTLEMENT 252, 265 (2015) [hereinafter Mercurio, *Safeguarding*]. Accordingly, there remains significant uncertainty concerning the scope of such claims, as well as the potential for them to be interpreted expansively. E.g., Lee M. Caplan & Jeremy K. Sharpe, *United States, in COMMENTARIES ON SELECTED MODEL INVESTMENT TREATIES* 755, 756 (Chester Brown ed., 2013); LAUGE N. SKOVGAARD POULSEN ET AL., LSE ENTERPRISE, COSTS AND BENEFITS OF AN EU-USA INVESTMENT PROTECTION TREATY 29 (2013), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/260380/bis-13-1284-costs-and-benefits-of-an-eu-usa-investment-protection-treaty.pdf [https://perma.cc/2QYG-89FN].

68. E.g., 2012 U.S. Model BIT, *supra* note 46, Annex B.4(a); CETA, *supra* note 15, art. 8.10(1)–(4); *see also* Mercurio, *Safeguarding*, *supra* note 67, at 259–60.

treaty to promote public interest goals.⁶⁹ In addition, tribunals sometimes interpret agreements in favor of investors without textual support. For example, even though FET claims under the North American Free Trade Agreement (NAFTA) are expressly linked to violations of international law, which should require general and consistent practice of states,⁷⁰ some NAFTA tribunals have found FET violations without considering international law.⁷¹ Critics of investment claims often express concern about investor-friendly rulings.⁷² Not only critics but also some defenders have noted investment agreements have become an economic bill of rights solely for foreign investors since corporations generally have rights, but no duties, whereas host states have duties, but no rights.⁷³ Even some arbitrators have themselves

69. *E.g.*, *SGS Société Générale de Surveillance S.A. v. Republic of the Phil.*, ICSID Case No. ARB/02/6, Objections to Jurisdiction, ¶ 116 (Jan. 29, 2004) (“It is legitimate to resolve uncertainties in its interpretation so as to favour the protection of covered investments.”); *Siemens A.G. v. Argentine Republic*, ICSID Case No. ARB/02/8, Decision on Jurisdiction, ¶ 81 (Aug. 3, 2004) (referring to treaty purpose as “to protect” and “to promote” investments).

70. NAFTA, *supra* note 40, art. 1105(1).

71. For example, in *Metalclad*, a tribunal found Mexico in violation of FET under NAFTA, which requires such claims to be tied to minimum standards of treatment under customary international law, which in turn means a general and consistent practice of all states, without actually examining customary international law. *Metalclad Corp. v. United Mexican States*, ICSID Case No. ARB (AF)/97/1, Award, paras. 74–101 (Aug. 30, 2000) (discussing expropriation, but never actually addressing what constitutes customary international law before finding a violation). Similarly, in *Railroad Development Corporation*, the NAFTA tribunal arguably failed to consider customary international law when it found that customary international law can be a developing standard. *R.R. Dev. Corp. v. Republic of Guatemala*, ICSID Case No. ARB/07/23, Award, para. 218 (June 29, 2012) (not evaluating customary international law and instead alleging it can be a developing standard); *see also* UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, FAIR AND EQUITABLE TREATMENT: UNCTAD SERIES ON ISSUES IN INTERNATIONAL INVESTMENT AGREEMENTS II: A SEQUEL, at xv, 11 (2012); Matthew C. Porterfield, *A Distinction Without a Difference? The Interpretation of Fair and Equitable Treatment under Customary International Law by Investment Tribunals*, INVESTMENT TREATY NEWS (Mar. 22, 2013), <http://www.iisd.org/itn/2013/03/22/a-distinction-without-a-difference-the-interpretation-of-fair-and-equitable-treatment-under-customary-international-law-by-investment-tribunals/> [https://perma.cc/FV3G-55KR]. Indeed, by 2001 after several NAFTA panels interpreted this requirement to go beyond customary international law, NAFTA parties issued an interpretative note attempting to cabin the scope of this standard. NAFTA Free Trade Comm’n, *Notes of Interpretation of Certain Chapter 11 Provisions* (July 31, 2001), <http://www.state.gov/documents/organization/38790.pdf> [https://perma.cc/23PZ-MCYZ]. However, this has not completely solved the problem. *E.g.*, *Saluka Inv. B.V. v. Czech Republic*, Partial Award, ¶ 309 (BIT/UNCITRAL Arb. Trib. Mar. 17, 2006), <http://www.italaw.com/sites/default/files/case-documents/ita0740.pdf> [https://perma.cc/8DRQ-CCHY] (considering FET unmoored to customary international law).

72. *E.g.*, Gus Van Harten, et al., *Public Statement on the International Investment Regime* (Aug. 31, 2010), [hereinafter Van Harten, *Public Statement*] <http://www.osgoode.yorku.ca/public-statement-international-investment-regime-31-august-2010/> [https://perma.cc/NW53-N9RA] (public statement of academics criticizing pro-investor interpretations); A. Claire Cutler, *New Constitutionalism, Democracy and the Future of Global Governance*, in CRITICAL PERSPECTIVES ON THE CRISIS OF GLOBAL GOVERNANCE: REIMAGINING THE FUTURE 89, 103–04 (Stephen Gill ed., 2015); *see also* van Aaken, *Fragmentation of International Law*, *supra* note 11, at 126 (“it seems fair to say that tribunals have been on the whole rather investor friendly” although noting that a few recent decisions or minority opinions have taken a different approach).

73. *E.g.*, THE SEATTLE TO BRUSSELS NETWORK ET AL., A TRANSATLANTIC CORPORATE BILL OF RIGHTS: INVESTOR PRIVILEGES IN EU-US TRADE DEAL THREATEN PUBLIC INTEREST

expressed concern in recent years concerning expansive interpretations.⁷⁴ In addition to expansive interpretations of investment claims, many have criticized tribunals for expansively interpreting who is considered a foreign investor; tribunals are criticized for blessing “nationality shopping,” which refers to a phenomenon whereby companies re-incorporate or incorporate subsidiaries to take advantage of investment agreements, such as in the *Philip Morris* case.⁷⁵

A related issue to expansive investor-friendly rulings is that they are often inconsistent. On one level, inconsistency should be expected since agreements have different language. However, tribunals have interpreted identical wording in different ways.⁷⁶ The UN Conference on Trade and Development has recently noted that contradictions between awards is a major concern, especially in light of a proliferation of cases.⁷⁷ The inconsistency is exacerbated by the lack of any

AND DEMOCRACY (2013), <http://corporateurope.org/sites/default/files/attachments/transatlantic-corporate-bill-of-rights-oct13.pdf> [<https://perma.cc/3NCD-MQ3X>]; Susan D. Franck, *Empirically Evaluating Claims About Investment Treaty Arbitration*, 86 N.C. L. REV. 1, 9 (2007).

74. E.g., Fauwaz Abdul Aziz, *Investor-state Arbitration System Needs ‘Complete Overhaul’*, BILATERALS.ORG, (May 12, 2014), <http://www.bilaterals.org/?investor-state-arbitration-system> [<https://perma.cc/P2GK-L2X2>] (noting prominent lawyer who has served as counsel in several investment cases expressed problem in keynote address to annual Investment Treaty Arbitration Conference).

75. Jane Kelsey & Lori Wallach, “*Investor-State Disputes in Trade Pact Threaten Fundamental Principles of National Judicial Systems*,” PUB. CITIZEN 3 (Apr. 2012), <http://www.citizen.org/documents/isds-domestic-legal-process-background-brief.pdf> [<https://perma.cc/YEH7-9G6Z>]; Rachel Thorn & Jennifer Doucleff, *Disregarding the Corporate Veil and Denial of Benefits Clauses: Testing Treaty Language and the Concept of “Investor”*, in THE BACKLASH AGAINST INVESTMENT ARBITRATION 3 (Michael Waibel et al. eds., 2010); see also Anne van Aaken, *Perils of Success? The Case of International Investment Protection*, 9 EUR. BUS. ORG. L. REV. 1, 20 (2008) (noting extreme case in Tokios Tokeles v. Ukraine in which Ukrainian investors incorporated in Lithuania and then used that to invest back in Ukraine). Some suggest that these broad interpretations are a function of the fact that arbitrators are paid by the hour such that they have an incentive for suits to continue. E.g., Gus Van Harten, *A Report on the Flawed Proposals for Investor-State Dispute Settlement (ISDS) in TTIP and CETA* 3 (Osgoode Hall L. Sch., Research Paper No. 16, 2015) [hereinafter Van Harten, *Flawed Proposals*] (noting that salaries are a function of whether a case continues). Although the Australian panel properly rejected this attempt, future tribunals of course need not follow that approach. Philip Morris v. Austl., Case No. 2012-12, Award on Jurisdiction and Admissibility (Perm. Ct. Arb. 2015) [hereinafter P.M. v. Austl., Award], http://www.italaw.com/sites/default/files/case-documents/italaw7303_0.pdf [<https://perma.cc/6VUN-W4M4>].

76. For example, several cases against Argentina were decided by tribunals with the same President, but used different interpretations and reached differing conclusions regarding the same basic facts. E.g., Leon E. Trakman, *The ICSID Under Siege*, 45 CORNELL INT’L L.J. 603, 642–43 (2012); see also Schreuer & Weiniger, *supra* note 12, at 1196–98 (identical wording interpreted differently); Stephanie Bijlmakers, *Effects of Foreign Direct Investment Arbitration on a State’s Regulatory Autonomy Involving the Public Interest*, 23 AM. REV. INT’L ARB. 245, 253 (2012) (noting divergent interpretation of comparable factual and legal cases in *Lauder v. Czech Republic* and *CME v. Czech Republic*).

77. U.N. Conference on Trade and Development, *Reform of Investor-State Dispute Settlement: In Search of a Roadmap*, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/4 (May 24, 2013).

appellate body under virtually all agreements.⁷⁸ In fact, even defenders of the current system have acknowledged this problem.⁷⁹

The expansive and inconsistent rulings lead to the most significant criticism of investment claims—that they have a chilling effect on legitimate domestic action. Notably, companies might be inclined to file claims that have a limited chance of success in hopes of encouraging governments to settle, which usually favors companies.⁸⁰ However, chilling effects are not solely a result of actual claims; legitimate action can also be suppressed because of specific threats, or even the possibility of action. For example, some countries declined to enact plain-package tobacco laws after specific threats, whereas other countries, such as New Zealand, delayed enacting contemplated legislation even though not specifically threatened.⁸¹ Even more concerning, countries might fail to even begin to take legitimate regulatory or legislative action for fear of potential claims. Some of these chilling effects can be hard to document and there are admittedly often multiple variables that impact domestic action.⁸² However, there is adequate evidence such that

78. *E.g., id.* at 8–9. Of course, there is an appeal possible under two current agreements. *See, e.g., supra* note 61.

79. *E.g., Franck, Legitimacy Crisis, supra* note 11, at 1617–25; Schreuer & Weiniger, *supra* note 12, at 1201–03. However other defenders of investment agreements may not view this as problematic. *E.g., Stephen Schwebel, In Defense of Bilateral Investment Treaties*, 135 COLUMBIA FDI PERSPECTIVES, Nov. 24, 2014, at 2, <http://ccsi.columbia.edu/files/2013/10/No-135-Schwebel-FINAL.pdf> [<https://perma.cc/M3LV-7LTU>] (comparing inconsistency to conflicts between state and federal courts in the United States); José E. Alvarez, *The Emerging Foreign Direct Investment Regime*, 99 AM. SOC'Y INT'L L. PROC. 94, 97 (2005) (noting that inconsistent rulings are inherent to the existing structure of the dispute settlement and differing treaty texts).

80. *E.g., POULSEN ET AL., supra* note 67, at 28, 30.

81. Sabrina Tavernise, *Tobacco Industry Tactics Limit Poorer Nations' Smoking Laws*, N.Y. TIMES, Dec. 13, 2013, at A1; *see also* John Muchangi, *Why MPs Should Pass Tobacco Regulations*, STAR (Mar. 30, 2015, 9:00 AM), http://www.the-star.co.ke/news/2015/03/30/why-mps-should-pass-tobacco-regulations_c1109267 [<https://perma.cc/9HWW-D64Y>] (detailing the efforts of tobacco companies to derail efforts to enact regulations in Kenya); Rachel Rose Jackson, *Tobacco Industry Accused of 'Intimidation and Interference' in Kenya*, THE GUARDIAN (Mar. 2, 2015), <http://www.theguardian.com/sustainable-business/2015/mar/02/tobacco-industry-accused-intimidation-interference-kenya> [<https://perma.cc/8UJE-Y92P>]; Cancer Action Network, *TPP Fact Sheet*, May 2015; Tobacco Institute of South Africa, *Submission on Draft Regulations in Terms of Section 37(3) of the Namibian Tobacco Products Control Act, 2010* (2011), <http://www.fairwarning.org/2012/11/as-nations-try-to-snuff-out-smoking-cigarette-makers-use-trade-treaties-to-fire-up-legal-challenges/4tisanamibia2011-dec-14/> [<https://perma.cc/Q6Y5-JGNV>].

82. *E.g., Kyla Tienhaara, Regulatory Chill and the Threat of Arbitration: A View from Political Science*, in EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION 606, 609 (Chester Brown & Kate Miles eds., 2011) (“[R]egulatory chill does not lend itself to statistical analysis.”).

scholars and policy makers have expressed concern.⁸³ In addition, the concern has become part of mainstream public discussions.⁸⁴

Another major issue of concern is the inherently public-private nature of disputes that lacks democratic accountability under most existing agreements. Investor-state disputes inherently involve disputes of public policy and domestic regulation, yet are generally decided by tribunals that lack the hallmarks of a democratic process to protect public interest.⁸⁵ Under most agreements, the arbitrators are not independent and lack job security common to most courts; an arbitrator in one case can also serve as an attorney for a party in another case, which would never happen in a traditional judicial setting.⁸⁶ Notably, although the model of decision making is borrowed from traditional commercial arbitration, there are some key differences. First, investor claims are more likely to raise public policy issues than disputes between private parties; whereas confidentiality in commercial

83. Rep. of the High Comm'r for Human Rights, Comm. on Human Rights, U.N. Doc. E/CN.4/Sub.2/2003/9, ¶ 35 (July 2, 2003) (warning that investor-state arbitrations could have a chilling effect on efforts to promote human rights and a healthy environment); *see also* Rep. of the Indep. Expert on the Promotion of a Democratic and Equitable Int'l Order Alfred-Maurice de Zayas, Human Rights Council, U.N. Doc. A/HRC/30/44 (July 14, 2015); Peter Muchlinski, *Trends in International Investments: Balancing Investor Rights and the Right to Regulate: the Issue of National Security*, in YEARBOOK ON INTERNATIONAL INVESTMENT LAW & POLICY 2008–2009, 35, 39–40 (Karl P. Sauvant ed., 2009); U.N. Conference on Trade and Development, *World Investment Report 2003: FDI Policies for Development: National and International Perspectives* 111 (2003); Letter from Erwin Chemerinsky, Dean of the Univ. of Cal., Irvine School of Law, et al., to Harry Reid, U.S. S. Minority Leader, et al. (Mar. 11, 2015), <http://www.afj.org/wp-content/uploads/2015/03/ISDS-Letter-3.11.pdf> [<https://perma.cc/SRM9-VG59>] [hereinafter March 2015 Letter] (noting that investor challenges threaten domestic sovereignty); Van Harten, *Flawed Proposals*, *supra* note 75, at 7–11 (2015).

84. Claire Provost & Matt Kennard, *The Obscure Legal System that Lets Corporations Sue Countries*, THE GUARDIAN (June 10, 2015, 1:00 AM), <http://www.theguardian.com/business/2015/jun/10/obscure-legal-system-lets-corporations-sue-states-ttip-icsid> [<https://perma.cc/DF33-D65E>]; Glyn Moody, *Corporate Sovereignty's Chilling Effects*, TECHDIRT (Nov. 25, 2014, 1:03 AM), <https://www.techdirt.com/articles/20141121/07460329216/corporate-sovereignty-chilling-effects.shtml> [<https://perma.cc/AW66-TCCL>]; Danielle Kurtzleben, *Why Elizabeth Warren is Declaring War on an Obscure Trade Policy*, VOX (last updated Feb. 28, 2015, 12:30 PM), <http://www.vox.com/2015/2/28/8124057/investor-state-dispute-settlement-elizabeth-warren> [<https://perma.cc/B54X-PXA8>].

85. *E.g.*, Barnali Choudhury, *Democratic Implications Arising from the Intersection of Investment Arbitration and Human Rights*, 46 ALBERTA L. REV. 983 (2009); Julie A. Maupin, *Public and Private in International Investment Law: An Integrated Systems Approach*, 54 VA. J. INT'L L. 367, 385–93 (2014).

86. NATHALIE BERNASCONI-OSTERWALDER ET AL., INT'L INST. FOR SUSTAINABLE DEV., ARBITRATOR INDEPENDENCE AND IMPARTIALITY: EXAMINING THE DUAL ROLE OF ARBITRATOR AND COUNSEL (2010), http://www.iisd.org/pdf/2011/dci_2010_arbitrator_independence.pdf [<https://perma.cc/E2EH-HB2S>]; *see also* David Gaukrodger & Kathryn Gordon, *Investor-State Dispute Settlement: A Scoping Paper for the Investment Policy Community* 44 (OECD Working Papers on International Investment, Working Paper No. 2012/3, 2012), http://www.oecd.org/daf/inv/investment-policy/WP-2012_3.pdf [<https://perma.cc/QP9A-4EMC>] (stating that a majority of arbitrators have served as counsel for investors in other cases whereas about 10% of arbitrators have acted as counsel for states in other cases).

arbitration is not controversial, it is for disputes involving wider policy issues.⁸⁷ Second, unlike commercial arbitration claims between private parties that only arise because of an explicit consent in an agreement to the dispute, no such consent is generally required for an investor-state claim since the agreement itself is considered consent for all disputes that arise after the conclusion of the agreement.⁸⁸ This general consent for future investor-state claims has been considered to be a “blank cheque which may be cashed for an unknown amount at a future, and as yet unknown date,” transforming “investor-state arbitration from a modified form of commercial arbitration into a system to control the state’s exercise of regulatory authority.”⁸⁹ There is serious concern that general consent to permit a tribunal of private individuals to decide investment claims undermines democratic principles.⁹⁰ In addition, the lack of transparency and inability for interested parties to participate have also been cited as major problems.⁹¹

3. Addressing Criticisms?

In light of these concerns, the recently concluded Transpacific Partnership (TPP), a trade agreement that covers the United States and Pacific Rim countries,⁹² Comprehensive Economic and Trade Agreement (CETA) between Canada and the

87. See, e.g., Kate Miles, *Reconceptualizing International Investment Law: Bringing the Public Interest into Private Business*, in INTERNATIONAL ECONOMIC LAW AND NATIONAL AUTONOMY, 295, 295 (Meredith Kolsky Lewis & Susy Frankel eds., 2010) (noting that the public interest is inherently involved in investor-state disputes).

88. This is true for agreements since the 1990s. E.g., GUS VAN HARTEN, INVESTMENT TREATY ARBITRATION AND PUBLIC LAW 24–26, 30 (2007); see also, e.g., TPP, *supra* note 40, art. 9.19. This consent resulted in a substantial increase in claims. VAN HARTEN, *supra*, at 30.

89. Gus Van Harten, *Private Authority and Transnational Governance: The Contours of the International System of Investor Protection*, 12 REV. INT’L POL. ECON. 600, 607–08 (2005) (quoting ALAN REDFERN & MARTIN HUNTER, LAW AND PRACTICE OF INTERNATIONAL COMMERCIAL ARBITRATION 21–22 (1999)).

90. E.g., Barnali Choudhury, *Recapturing Public Power: Is Investment Arbitration’s Engagement of the Public Interest Contributing to the Democratic Deficit?*, 41 VAND. J. TRANSNAT’L L. 775, 779 (2008).

91. E.g., Daniel Barstow Magraw Jr. & Niranjali Manel Amerasinghe, *Transparency and Public Participation in Investor-State Arbitration*, 15 ILSA J. INT’L & COMP. L. 337, 337 (2009); Valentina S. Vadi, *Trade Mark Protection, Public Health and International Investment Law: Strains & Paradoxes*, 20 EUR. J. INT’L L. 773, 779–80 (2009) [hereinafter Vadi, *Trade Mark Protection*].

92. The TPP was concluded on October 5, 2015. Jackie Calmes, *11 Pacific Nations and U.S. Endorse Giant Trade Pact*, N.Y. TIMES, Oct. 6, 2015, at A1. Countries signed the agreement on February 4, 2016. E.g., Press Release, US Trade Representative, TPP Minister’s Statement (Feb. 4, 2016), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/February/TPP-Ministers-Statement> [https://perma.cc/7PDP-VLD7]; *Trans Pacific Partnership Trade Deal Signed in Auckland*, BBC NEWS (Feb 4, 2016), <http://www.bbc.com/news/business-35480600> [https://perma.cc/H7WD-5T5V]. Of course, the status of the TPP is questionable since the recent U.S. withdrawal from the agreement would seem to preclude possibility of ratification. See TPP, *supra* note 40, art. 30.5 (requiring ratification by at least 6 countries that represent 85% of the TPP’s combined GDP); see also Joshua Berlinger, *TPP Unravels: Where the 11 Other Countries Go From Here*, CNN (Jan. 24, 2017), <http://www.cnn.com/2017/01/24/asia/tpp-other-11-countries-what-next/> [https://perma.cc/2MGU-NLEV] (explaining that both the US and Japan need to ratify the agreement for it to be effective).

EU,⁹³ as well as the proposed Transatlantic Trade and Investment Partnership (TTIP) between the United States and European Union (EU) have proposed some changes to traditional investment claims. Although the TPP and TTIP may not be ratified, they are still relevant to consider as a comparison to older investment agreements and whether its language addresses recognized problems.⁹⁴ Under the TPP and TTIP there are listed factors to consider for what constitutes indirect expropriation.⁹⁵ Although defenders claim this protects the domestic right to regulate,⁹⁶ the language still clearly contemplates that in some unspecified “rare” instances, nondiscriminatory regulatory action that is designed to protect legitimate public welfare, such as health, could be considered expropriation.⁹⁷ Similarly, these agreements attempt to cabin FET claims; for example, the TPP clarifies that violation of a separate international agreement does not necessarily establish a breach;⁹⁸ however, even though alleged violation of a separate international agreement, such as TRIPS, is not an automatic breach, there is nothing to preclude a tribunal from considering this relevant.⁹⁹ CETA, on the other hand, focuses instead on denial of justice, such that violation of TRIPS should not alone be considered a breach.¹⁰⁰

Since 2015, the EU has introduced a major innovation to recent and pending agreements. Notably, its proposal to the TTIP includes the first-ever appointed investment tribunal court and an appellate body; in addition, it would prevent arbitrators from also serving as lawyers in other investment cases.¹⁰¹ The initial reaction to this proposal by the U.S. Trade Representative was fairly negative,¹⁰² and

93. CETA, *supra* note 15.

94. *E.g.*, Kavaljit Singh, *The TPP IS Dead. What Happens Next?*, GLOBAL RESEARCH (Dec. 7, 2016), <http://www.globalresearch.ca/the-tpp-is-dead-what-happens-next/5560781> [https://perma.cc/24BH-UVTQ].

95. Both TPP and CETA list specific factors relevant to assessing indirect expropriation. TPP, *supra* note 40, Annex 9-B, para. 3(a) (including character of government action, the extent to which it interferes with distinct and reasonable investment-backed expectations, and the economic impact of the government action); Transatlantic Trade and Investment Partnership, Ch. II, Annex I, arts. 2–3 (proposed July 31, 2015) [hereinafter TTIP], http://trade.ec.europa.eu/doclib/docs/2015/september/tradoc_153807.pdf [https://perma.cc/S32C-CCUE] (character of government measure, duration of the measure, and economic impact of measure are relevant). However, CETA does not include comparable clarifications. *See generally* CETA, *supra* note 15, art. 8.12 (expropriation).

96. *E.g.*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, UPGRADING AND IMPROVING INVESTOR-STATE DISPUTE SETTLEMENT, <https://ustr.gov/sites/default/files/TPP-Upgrading-and-Improving-Investor-State-Dispute-Settlement-Fact-Sheet.pdf> [https://perma.cc/Q4NG-W2QB] (“We would never negotiate away our right to do so, and we don’t ask other countries to do so either.”). There is even some proposed language that aims to protect domestic regulation. *E.g.*, TTIP, *supra* note 95, art. 2 (“The provisions of this section shall not affect the right of the Parties to regulate within their territories through measures necessary to achieve legitimate policy objectives . . .”).

97. *E.g.*, TTIP, *supra* note 95, art. 3; TPP, *supra* note 40, Annex 9-B, para. 3(b).

98. TPP, *supra* note 40, art. 9.6(2)–(3); CETA, *supra* note 15, art. 8.10(2) (limited situations).

99. TPP, *supra* note 40, art. 9.6(3).

100. CETA, *supra* note 15, art. 8.10(2).

101. TTIP, *supra* note 95, arts. 9–11.

102. *E.g.*, Krista Hughes & Philip Blenkinsop, *U.S. Wary of EU Proposal for Investment Court in Trade Pact*, REUTERS, Oct. 29, 2015, <http://www.reuters.com/article/us-trade->

it is especially unclear whether the TTIP will move forward under the current U.S. administration.¹⁰³ However, since announcing this, the EU added this same unique process in the EU-Vietnam agreement, and even in CETA despite the fact that CETA was officially concluded two years earlier.¹⁰⁴ Moreover, as will be discussed, even this significant proposal will not address the unique conflict investment claims have with TRIPS flexibilities. Accordingly, although these proposals can be considered an attempt to address previous criticisms, they ultimately fail to address the conflict with TRIPS flexibilities that is the focus of this Article.

C. *The Under-Recognized Current Conflict*

The lack of recognition of the impending conflict is best appreciated in light of two issues that will be explained in this Section. First, there are few who even recognize the potential for the disciplines to overlap. Even when there is recognition that IP issues could be central to investment claims, there is generally no acknowledgement that IP norms could be threatened. Second, the defenders of the present system have repeatedly asserted certain defenses that fail to recognize IP conflicts. Since these defenses are so widely reported, they likely overshadow the limited recognition of mere overlap.

ttp-idUSKCN0SN2LH20151029 [https://perma.cc/4HJM-8BBG]; see also BROMUND ET AL., *The U.S. Should Reject the European Commission's Proposed Investment Court* (Heritage Foundation Issue Brief No. 4485, Nov. 13, 2015), <http://www.heritage.org/research/reports/2015/11/the-us-should-reject-the-european-commissions-proposed-investment-court> [https://perma.cc/358T-MCKD].

103. E.g., Alex Lawson, *Trump's Election Puts TTIP In the Freezer: EU Trade Boss*, LAW 360 (Jan. 24, 2017), <https://www.law360.com/articles/884136/trump-s-election-puts-ttip-in-the-freezer-eu-trade-boss> [https://perma.cc/GJS7-5KMQ]; Sean O'Grady, *By Scrapping TPP and TTIP, Trump Has Boosted American Jobs in the Short Term—and Destroyed Them in the Long Term*, INDEP. (Jan. 24, 2017), <http://www.independent.co.uk/voices/donald-trump-trade-deals-tpp-ttip-american-business-workers-boost-short-term-destroy-long-term-a7543706.html> [https://perma.cc/CWM5-XP2N]; Tereza Novotna, *Will Donald Trump Shoot Down TTIP or Rebrand It as the Trump Trade and Investment Partnership?*, LSE U.S. CENTRE BLOG (Jan. 19, 2017), <http://blogs.lse.ac.uk/usappblog/2017/01/19/will-donald-trump-shoot-down-ttip-or-rebrand-it-as-the-trump-trade-and-investment-partnership/> [https://perma.cc/U5Q9-8DN5].

104. EU-Vietnam FTA, *supra* note 15; CETA, *supra* note 15, art. 8.27–28. Technically, the EU was simply scrubbing the document, but it added substantial changes, including a permanent investment tribunal, as well as an appellate tribunal. E.g., Stephen Drymer, *CETA Under New Management: Why is Trudeau Changing the Game?*, CENTRE FOR INTERNATIONAL GOVERNANCE INNOVATION (May 12, 2016), <https://www.cigionline.org/publications/ceta-under-new-management-why-trudeau-changing-game> [https://perma.cc/887S-GRH8]; Wolfgang Alschner & Dmitriy Skougarevskiy, *Legal Scrubbing or Renegotiation? A Text-As-Data Analysis of How the EU Smuggled an Investment Court Into Its Trade Agreement with Canada*, THE PLOT (Mar. 24, 2016), <http://www.the-plot.org/2016/03/24/legal-scrubbing-or-renegotiation/> [https://perma.cc/YBS7-53KQ].

1. Limited Recognition of Overlap, Let Alone Conflict

The first issue is the limited recognition of overlap by attorneys,¹⁰⁵ scholars, and policy makers.¹⁰⁶ Of course, the *Philip Morris* and *Eli Lilly* investment cases reflect corporate recognition of the overlap and although these cases are recent, there is evidence that the tobacco industry was aware of the overlap two decades ago.¹⁰⁷ However, it is notable that despite widespread criticism of investment claims, until recently there were relatively few that had noted the potential for IP to intersect with investment agreements, let alone result in a collision of norms.¹⁰⁸ For example,

105. In 2009, when a publication aimed at international investment attorneys published a special issue on how intellectual property could be protected under investment agreements, it was noted that the literature concerning this overlap was in its infancy. Markus Perkams & James M. Hosking, *The Protection of Intellectual Property Rights Through International Investment Agreements: Only a Romance or True Love?*, TRANSNAT'L DISP. MGMT., Aug. 2009, at 2, 2 nn.6–7.

106. Although some public interest groups seem well aware of the threat to TRIPS flexibilities based on informal discussions, they do not necessarily expressly mention TRIPS flexibilities in documents aimed at the public at large. *E.g.*, U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada's Medicine Patent Policy, Demand \$100 Million for Denial of a Patent, PUB. CITIZEN (Jan. 2013), <http://infojustice.org/wp-content/uploads/2013/02/PC-factsheet-on-Eli-Lilly-ISDS.pdf> [<https://perma.cc/EPW3-NWJX>] (noting that, if successful, Eli Lilly's suit would permit corporate enforcement litigation of WTO rights even though corporations have no such rights in at the WTO, although not focusing on threat to TRIPS flexibilities). However, groups do note the issue in other situations. *E.g.*, Ante Wessels, *ISDS Threatens Privacy and Reform of Copyright and Patent Law*, FOUNDATION FOR A FREE INFORMATION INFRASTRUCTURE, Apr. 30, 2014, at 17, http://people.ffii.org/~ante/ISDS/FFII_NL_ISDS-threatens-privacy.pdf [<https://perma.cc/YF4W-K42F>] (Foundation for a Free Information Infrastructure comment to Dutch Parliament noting that Canada's "minor adjustment" to patent law prompted Eli Lilly's \$500 million claim and that bigger reforms will "seriously endanger" a major overhaul of patent and copyright laws). Similarly, representatives of Public Citizen, Health Gap, and MSF, together with other intellectual property law professors, requested permission to file an amicus brief in the *Eli Lilly v. Canada* case. Letter from Burcu Kilic, Legal & Policy Dir., Glob. Access to Meds. Program, Pub. Citizen, & Brook K. Baker, Senior Policy Analyst, Healthgap, to Int'l Ctr. for Settlement of Inv. Disputes (Feb. 12, 2016), <http://www.italaw.com/sites/default/files/case-documents/italaw7111.pdf> [<https://perma.cc/EBV8-GHBZ>]. *But see* Peter K. Yu, *Investment Related Aspects of Intellectual Property Rights*, TEXAS A&M U. SCH. L. 2016, at 5–10 (arguing that there has long been an overlap of IP and investment agreements and that the only new development is the actual initiation of investor-state suits).

107. The tobacco industry actually first suggested that plain package legislation could result in investment claims when Canada contemplated enacting legislation in 1994. *E.g.*, Letter from RJR to Standing Committee on Health, May 4, 1994, Memo from Carla Hill to RJR Reynolds and Philip Morris, May 3, 1994, at 18, 21; Letter to Jean Chretien, Prime Minister of Canada, Mar. 25, 1994, at 5 (suggesting violation of NAFTA's investment chapter). In addition, it initiated an investor-state claim in 2001, alleging expropriation, when Canada proposed bans of the terms "light" and "mild" on tobacco products, although the case settled. The actual notice of arbitration is not publicly available, but there is evidence that the case was filed. *E.g.*, *Plain Packaging of Tobacco Products Dispute*, <http://www.italaw.com/cases/1282> [<https://perma.cc/7G5T-9Z2K>]; *see also* PHYSICIANS FOR A SMOKE-FREE CANADA, THE PLOT AGAINST PLAIN PACKAGING: HOW MULTINATIONAL TOBACCO COMPANIES COLLUDED TO USE TRADE ARGUMENTS THEY KNEW WERE PHONEY TO OPPOSE PLAIN PACKAGING 25–27 (2008), http://www.smoke-free.ca/pdf_1/plotagainstplainpackaging-apr1.pdf [<https://perma.cc/X3WE-DCK4>].

108. The 2015 debate between different groups of academics for and against investor-state dispute settlement did not address this topic. *See* April 2015 Letter, *supra* note 62; March 2015 Letter, *supra* note 83; *see also* Mercurio, *Awakening*, *supra* note 55, at 871–72 (noting that the lack of literature

even though the *Philip Morris* case against Australia has prompted significant attention, attention tends to focus on a general threat to regulatory, but not intellectual property, sovereignty.¹⁰⁹ In addition, although the *Eli Lilly* case against Canada could have dramatically changed the notion of TRIPS flexibilities for patents, this case received little attention from scholars as well as the popular media, especially compared to the *Philip Morris* cases.¹¹⁰ Strikingly, the Declaration on Patent Sovereignty drafted by prominent patent scholars does not acknowledge that TRIPS flexibilities could quickly evaporate if challenged by an investor-state dispute; rather, the underlying assumption would seem to be that these are not threatened.¹¹¹ Similarly, although the 2016 UN High Level Panel Report cited the

analyzing the use of investment claims to enforce intellectual property is “striking”). In light of Eli Lilly’s dispute, Canada is obviously aware of this issue and did in fact seek to limit the scope of investor-state disputes in its trade agreement with the EU. *E.g.*, Schewel, *EU, Canada Fail to Close CETA; Stuck Over Issue Related to Eli Lilly Case*, Inside US Trade, Sept. 12, 2013. However, Canada did not prevail. This seems to be changing, however. For example, a recent issue of the Journal of International Economic Law contained a special issue on IP and international investment law. Henning Grosse Ruse-Khan, *The Protection of Intellectual Property and International Investment Law*, 19 J. INT’L ECON. L. (2016).

109. *E.g.*, Lukasz Gruszczynski, *Australian Plain Packaging Law, International Litigations and Regulatory Chilling Effect*, 2 EUR. J. RISK REG. 242 (2014); Deborah Sy, *Warning: Investment Agreements are Dangerous to Your Health*, 43 GEO. WASH. INT’L L. REV. 625 (2011); *ISDS Fact Sheet*, *supra* note 48.

110. There are only a few academic articles. *E.g.*, Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH L.J. (2015); Okediji, *supra* note 37; Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines—Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement*, 23 J. INTELL. PROP. L. 1 (2015). Although there are some articles in the popular press concerning the *Eli Lilly* case, they generally fail to recognize the implication for TRIPS flexibilities, and instead focus on the fact that it represents an opportunity for corporations to utilize investor-state disputes. *E.g.*, BAKER DONELSON BEARMAN CALDWELL & BERKOWITZ PC, *The TPP Battle Begins*, LEXOLOGY (Dec. 2, 2015), <http://www.lexology.com/library/detail.aspx?g=cca98a76-30fc-49bc-b312-842ebb76e429> [<https://perma.cc/YQ2J-BYWN>] (mentioning the *Eli Lilly* dispute as an example of a foreign company that can attack an adverse court or agency action, without mention of TRIPS implication); MICHAEL GEIST, *The Trouble With the TPP, Day 43: Eli Lilly is What Happens When ISDS Rules Go Wrong* (Mar. 3, 2016), <http://www.michaelgeist.ca/2016/03/the-trouble-with-the-tpp-day-43-eli-lilly-is-what-happens-when-isds-rules-go-wrong/> [<https://perma.cc/CR8B-WJXC>] (no mention of TRIPS at all); Yuki Noguchi, *Trans-Pacific Partnership Provision on Trade Disputes Draws Criticism*, NPR: ALL THINGS CONSIDERED (Oct. 27, 2015, 4:17 PM), <http://www.npr.org/2015/10/28/452608600/trans-pacific-partnership-provision-on-trade-disputes-draws-criticism> [<https://perma.cc/G99K-GXAH>] (mentioning the *Eli Lilly* investor-state dispute as a way to get around domestic law, with no mention of TRIPS implications); Ed Silverman, *Eli Lilly v. Canada: The Patent War Moves to Washington*, WALL ST. J., (Apr. 14, 2014, 4:00 PM), <http://blogs.wsj.com/corporate-intelligence/2014/04/14/eli-lilly-vs-canada-the-patent-war-moves-to-washington/> [<https://perma.cc/MC59-2ZQ7>] (noting Eli Lilly alleges violation of TRIPS, but focusing more on corporate efforts against Canada through investor-state arbitration and Special 301).

111. To be fair, the Declaration on Patent Sovereignty was drafted as part of a TRIPS anniversary. However, one of the key drafters remarked at the Irvine symposium that he appreciated learning about investor-state cases and thought they should be addressed in the next version of the Declaration. This view is likely typical of IP policymakers since there are other recommendations for countries to use TRIPS flexibilities since both the *Philip Morris* and *Eli Lilly* investment cases were filed that do not acknowledge this issue. *E.g.*, CHAN PARK ET AL., *supra* note 8. Indeed, the 2016 discussion by the UN continues to recommend using TRIPS flexibilities. U.N. General

Eli Lilly investment dispute in two footnotes,¹¹² the Report overall does not recognize how this dispute could have fundamentally compromised its overall suggestion that states embrace more TRIPS flexibilities.¹¹³ Even those that realize that investment disputes could impact TRIPS tend to focus on how TRIPS *should* be interpreted to avoid conflict, without considering whether this is likely given past practice of tribunals, such as the fact that decisions tend to favor investors and not consistently rely on standard interpretive principles for international law.¹¹⁴

This is not entirely surprising since the investment and IP regimes not only developed independently of one another, but did not seem to overlap until recently. For example, although investment agreements have existed for decades, it was only relatively recently that investment agreements consistently listed IP as a type of

Assembly, Human Rights Council, *Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, 32d Sess., U.N. Doc. A/HRC/32/L.23, ¶¶ 3–4 (June 28, 2016) (calling upon states to implement TRIPS flexibilities); see also Office of the United Nations High Commissioner for Human Rights [OHCHR], Human Rights Council Suspends Thirty-Second Session After Adopting 33 Resolutions and One Decision (July 1, 2016), <http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20226&LangID=E> [<https://perma.cc/XUG2-RAC9>] (noting adoption of proposal); Knowledge Ecology International, *Human Rights Council Adopts Watershed Resolution on Access to Medicines* (July 1, 2016), <http://keionline.org/node/2605> [<https://perma.cc/YZD5-V5QN>].

112. UN 2016 High Level Panel Report, *supra* note 8, at 19 (citing *Eli Lilly* dispute as an example of how trade agreements should not interfere with health policies, without clear recognition that it is investment chapters of trade agreements that are problematic); *Id.* at 25 (citing *Eli Lilly* investment dispute as an example of “undue political and economic pressure” against government action to protect public health).

113. The initial charge of the panel did not formally include investor-state disputes. *Id.* at 3 (noting charge to review and assess proposals and recommend solutions regarding policy incoherence among inventors, international human rights law, trade rules and public health, but not mentioning international investment laws). However, the report is nonetheless conscious of them. In particular, it does note that for pending and future agreements including investment provisions, governments should ensure that there are no provisions that “interfere” with the obligation to fulfill the right to health. *Id.* at 28. However, this seems to fundamentally fail to realize the serious impact that many existing agreements with investor provisions have on the realistic use of TRIPS flexibilities.

114. See, e.g., Henning Grosse Ruse-Khan, *Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation* (University of Cambridge Faculty of Law Legal Studies Research Paper No. 52/2014, 2014) [hereinafter Ruse-Khan, *Litigating Intellectual Property Rights*], http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711 [<https://perma.cc/SS8W-6TQU>] (suggesting that only the exception to indirect expropriation requires TRIPS interpretation); Susy Frankel, *Interpreting the Overlap of International Investment and Intellectual Property Law*, 19 J. INT’L ECON. L. 121 (2016) (arguing that if tribunals properly apply Vienna convention, they should reject *Eli Lilly*’s claims); Kathleen Liddell & Michael Waibel, *Fair and Equitable Treatment and Judicial Patent Decisions*, J. INT’L ECON. L. (2016) (arguing that investment tribunals should defer to domestic court decisions concerning patent laws and that investors have no legitimate expectation that patent law will remain static over time, such that there should not be a FET breach); Ruse-Khan, *Protecting Intellectual Property Rights*, *supra* note 32 (assuming the only conflict is that a state elects not to use TRIPS flexibility, rather than that TRIPS flexibilities may be directly challenged by investment actions and concluding that pending investment claims are unlikely to succeed); Okediji, *supra* note 37, at 1135–36 (noting that investment claims may be “in tension” with IP norms but suggesting that they should be interpreted identically for parties to the WTO).

investment explicitly covered.¹¹⁵ Similarly, although the WTO Dispute Settlement Forum was designed to be the sole forum to adjudicate non-compliance of agreement such as TRIPS,¹¹⁶ it is completely silent about investor-state suits.¹¹⁷ Considering that the potential for such suits existed decades before the WTO, this suggests that in the early 1990s when the WTO was negotiated, there was no serious contemplation of a conflict. This could partially be due to the fact that although agreements existed, few cases were brought.¹¹⁸ Even in the years since the IP investment claims have been brought, they are still not widely known or understood.¹¹⁹

In addition, both the investment and IP arenas are fairly specialized with most individuals in one not traditionally familiar with the other. For example, investment agreements have traditionally focused on tangible assets, and although IP has been considered a valuable asset for decades, it has long been considered a “highly technical subject,” such that investment lawyers may not have focused on it.¹²⁰ Similarly, IP lawyers recognize that IP is a commercial asset, but do not generally focus on domestic or international commercial law, such that they do not focus on investment law.

Of particular note, the few who see an overlap do not necessarily see, or focus on, the impending conflict. To companies and those that support corporations, or at least investment claims, the intersection of the two systems is generally viewed as

115. For example, NAFTA, which was concluded in the mid-1990s, did not include intellectual property as a listed investment. *E.g.*, NAFTA, *supra* note 40, art. 1139. Of course, explicitly listing intellectual property is not required since the *Eli Lilly* case is in fact brought under NAFTA. However, it is notable that this is the first IP case under NAFTA, even though companies could have asserted such claims earlier, thus suggesting that the utility of investment claims for IP was not contemplated earlier.

116. *E.g.*, PETER VAN DEN BOSSCHE & WERNER ZDOUC, *THE LAW AND POLICY OF THE WORLD TRADE ORGANIZATION* 161 (3d ed. 2013).

117. *See generally* DSU, *supra* note 4, art. 23 (noting that WTO members seeking redress of violation of WTO agreements, such as TRIPS, should comply with the DSU and not make their own determinations).

118. Before TRIPS was concluded in 1994, there were only a few known cases filed, but since its conclusion, cases have increased exponentially. *See* Van Harten, *Public Statement*, *supra* note 72.

119. For example, after I wrote a 2015 blog post on the *Eli Lilly* case and the potential for impacting TRIPS flexibilities, I received a number of emails from attorneys and academics who were previously unaware of the issue. *See* Cynthia M. Ho, *Million Dollar Mistake? The Cost of Limiting or Canceling IP Rights*, PATENTLYO (Mar. 29, 2015), <http://patentlyo.com/patent/2015/03/million-limiting-canceling.html> [<https://perma.cc/7SSB-E2R3>].

120. *E.g.*, Vadi, *Towards a New Dialectics*, *supra* note 33, at 27.

a positive,¹²¹ with little concern for interference with the WTO system.¹²² Some scholars who initially recognized the overlap may not have seriously considered this possibility,¹²³ or assumed that an investment tribunal would necessarily apply WTO norms to avoid a conflict.¹²⁴ One scholar of international economic law recognized that investment tribunals could interpret TRIPS provisions, but seemed to assume that arbitrators will apply TRIPS norms even when investment agreements do not have any language to support such an approach.¹²⁵ A few early scholars who initially recognized a potential problem for TRIPS flexibilities mentioned it in passing without actual discussion of the depth of the problem, or how to address it.¹²⁶

121. E.g., Christopher S. Gibson, *Latent Grounds in Investor-State Arbitration: Do International Investment Agreements Provide New Means to Enforce Intellectual Property Rights?*, in YEARBOOK ON INTERNATIONAL INVESTMENT LAW & POLICY 2009–10 397, 423 (Karl P. Sauvant ed., 2010) (noting that investment claims provide benefits to companies over the WTO context); Peter B. Rutledge, *TRIPS and BITs: An Essay on Compulsory Licenses, Expropriation, and International Arbitration*, 13 N.C.J. L. & TECH. ONLINE 149, 152 (2012) (suggesting that arbitration could be used to address compulsory licenses); Baiju S. Vasani et. al, *Treaty Protection for Global Patents: A Response to a Growing Problem for Multinational Pharmaceutical Companies*, JONES DAY (Oct. 2012), http://www.jonesday.com/treaty_protection/ [<https://perma.cc/6TSV-K4C9>] (suggesting that alleged violation of TRIPS standards could be challenged through investment agreements and that this is preferable to the WTO system for pharmaceutical patents “under assault” in the developing world).

122. For example, Gibson’s article notes the competing legal regimes but solely from the perspective of what an investor will prefer. He acknowledges that some suggest this is a radical departure from the WTO system but quickly dismisses this. In particular, he argues that each system has distinct claims and that the WTO rules could be relevant “context” for the investment claims, such that there is not necessarily a conflict. See Gibson, *supra* note 121, at 465–72. However, one scholar with familiarity of not only investment claims, but also the WTO system has expressed concern. See Mercurio, *Awakening*, *supra* note 55, at 899–00 (noting that it would be “dangerous” for an investment tribunal to interpret TRIPS given the limited record of tribunals attempting to interpret WTO law).

123. E.g., Lahra Liberti, *International Property Rights in International Investment Agreements: An Overview* 13 (OECD Working Papers on International Investment, Working Paper No. 2010/1, 2010), https://www.oecd.org/daf/inv/investment-policy/WP-2010_1.pdf [<https://perma.cc/4WHR-P2ZT>] (stating “one might wonder whether the ‘fair and equitable’ standard can be invoked in order to challenge national IPR laws consistent with the TRIPS agreement” without further exploring the possibility).

124. E.g., Carlos M. Correa, *Bilateral Investment Agreements: Agents of New Global Standards for the Protection of Intellectual Property Rights?*, GRAIN (Aug. 2004), <https://www.grain.org/article/entries/125-bilateral-investment-agreements-agents-of-new-global-standards-for-the-protection-of-intellectual-property-rights> [<https://perma.cc/6LAS-34EW>] (suggesting that the WTO principle of differentiation versus discrimination is relevant to FET and also that the NAFTA exception for compulsory licenses should provide protection against indirect expropriation claims).

125. See Vadi, *Towards a New Dialectics*, *supra* note 33 at 179–81; see also Vadi, *Trade Mark Protection*, *supra* note 91, at 796–800 (arguing that investment tribunals do consider prior arbitral awards as well as the other international courts).

126. See, e.g., Carlos M. Correa, *Investment Agreements: A New Threat to Health and TRIPS Flexibilities?*, BILATERALS.ORG (June 27, 2013), <http://www.bilaterals.org/?investment-agreements-a-new-threat> [<https://perma.cc/3R56-8QLY>] (stating that “systemic implications” of the *Eli Lilly* case for TRIPS flexibilities are very significant and that countries should be circumspect about signing more international agreements without providing other solutions); Mercurio, *Awakening*, *supra* note 55, at 914 (lacking any details on the danger or how to address it despite noting potential danger); van Aaken, *Fragmentation of International Law*, *supra* note 11, at 115–17 (noting accurately that although the Doha Public Health Declaration considers relevant human rights law, there is no equivalent found in

This may be changing. In 2014, one essay recognized that Eli Lilly's claim could have major implications for TRIPS flexibilities and although primarily arguing that the claims should be rejected, briefly considered possible reforms.¹²⁷ A 2016 article recognized that FET claims could impact TRIPS flexibilities and argued that there should be great deference to judicial decisions, such as Canada's interpretation of the patentability requirement of utility.¹²⁸ Similarly, another article argued that tribunals should either have no jurisdiction to hear disputes that implicate TRIPS, or at least follow Vienna Convention rules to interpret TRIPS to avoid conflicts.¹²⁹ However, it remains unclear whether a tribunal of commercial lawyers will accept these arguments given not only a narrow view of intellectual property rights that do not consider public policy, but also a general trend towards viewing intellectual property as solely an asset divorced from its policy foundations.¹³⁰ Moreover, even the limited recognition of overlap between IP and investment agreements is far overshadowed by prominent defenses that dominate in both academic and mainstream discussions discussed in the next section.

2. *Prominent Defenses of Investor-State Disputes Do Not Recognize Conflict*

An important issue is that those who most robustly and frequently defend investor-state disputes fail to recognize any overlap, and their defenses do not address the pending collision course. Granted, some of these defenses could reflect mere rhetoric or positions that have since changed—especially since some recently concluded agreements or proposed agreements could arguably address some conflict with domestic regulatory space. However, even though drafters of recent agreements may recognize the need to modify investment disputes going forward, proposals thus far do not entirely eliminate TRIPS conflicts, as discussed in Part II. Moreover, they do not address conflicts under the majority of existing agreements. Accordingly, this Section focuses on three defenses that are often articulated in support of investment claims and its dispute system.¹³¹ This Section begins with sovereignty concerns. Then, the Section addresses the arguments that investment claims promote foreign direct investment and economically benefit the host country. Finally, the argument that investment-state disputes provide a fair process will be addressed. As will be explained, each of the “defenses” is questionable and even if generally true, inadequately addresses current and forthcoming IP conflicts.

investment law, but only focusing on the TRIPS conflict for compulsory licensing). *See generally* VANHONNAEKER, *supra* note 33 (noting that investment claims can be read coherently with TRIPS by giving TRIPS priority, without noting that this is unlikely).

127. Okediji, *supra* note 37.

128. *See* Liddell & Waibel, *supra* note 114, *passim*.

129. Frankel, *supra* note 114, at 1132–38.

130. *E.g.*, Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law Is Reconceptualizing Intellectual Property*, 36 MICH. J. INT'L L. 557 (2015); Yu, *supra* note 106.

131. Although there are other defenses raised, these seem most relevant to the IP collision clash and how the defenses are not applicable.

a. ISDS Promotes Sovereignty Concerns and Regulatory Chill Are Overstated

A central defense of investment claims that has great relevance to TRIPS flexibilities focuses on domestic sovereignty. There are two aspects to the sovereignty defense that will be addressed in this Section. First, defenders of investment claims assert that the ISDS system in fact *promotes* sovereignty and the rule of law—in direct opposition to the concern raised by critics that domestic regulatory authority is unduly impeded. Second, even when defenders acknowledge that the system might limit traditional domestic sovereignty, they either raise irrelevant issues or claim these concerns are overstated. As this Section will explain, neither of these related defenses of ISDS are well supported and, even if accurate, would fail to address the problem with TRIPS flexibilities.

Some defenders of investment claims assert that agreements promote the rule of law by ensuring that U.S.-like legal protections exist in other countries as well. For example, the USTR has alleged that investment rules are designed to provide “no greater substantive rights to foreign investors than are afforded under the Constitution and U.S. law.”¹³² Similarly, a number of international law scholars have argued that these agreements provide rights similar to the U.S. Constitution.¹³³ Although there are similarities, the problem is that the investment claims actually go beyond domestic law, but without the usual democratic accountability. As explained earlier, investment tribunals often interpret claims more expansively than U.S. law. In addition, although never mentioned by defenders of investment claims, the rule of law typically requires clear rules that are equally enforced and *independently adjudicated*.¹³⁴ Investment claims seem to lack these fundamental qualities since the investment “rules” giving rise to claims generally only apply to states, not investors, are inherently unclear, and adjudicated by private individuals with no job security.

Even when defenders of investment claims attempt to address concerns about domestic sovereignty, they tend to raise issues that do not actually address domestic sovereignty, as will be explained.¹³⁵ For example, some allege that states often win,¹³⁶ that the United States has never “lost” a case,¹³⁷ or that most challenged actions are not legislative.¹³⁸ However, these facts do not mean that there is no

132. See *ISDS Fact Sheet*, *supra* note 48.

133. April 2015 Letter, *supra* note 62, at 1 (alleging rights similar to those guaranteed in the Constitution).

134. *E.g.*, Cutler, *supra* note 72, at 92–93.

135. Some even suggest that international agreements are intended to limit domestic action in exchange for some benefit. *E.g.*, Schwebel, *supra* note 79, at 1–2.

136. *E.g.*, April 2015 Letter, *supra* note 62 (claiming that states win more often than investors).

137. *E.g.*, *ISDS Fact Sheet*, *supra* note 48 (“Despite having 50 ISDS agreements in place, the United States has never lost a case and nothing in our agreements has inhibited our response.”).

138. See CHRISTIAN TIETJE ET AL., THE IMPACT OF INVESTOR-STATE-DISPUTE SETTLEMENT (ISDS) IN THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP 92–93 (2014) (noting mostly administrative decisions impacting single investors); Jeremy Caddel & Nathan M. Jensen, *Which Host Country Government Actors are Most Involved in Disputes with Foreign Investors* (Columbia FDI Perspectives, Paper No. 120, 2014), <http://ccsi.columbia.edu/files/2013/10/No-120-Caddel-and-Jensen-FINAL-WEBSITE-version.pdf> [<https://perma.cc/LKN4-9QLQ>].

impact on domestic decision making; roughly a third of filed investment claims result in settlements that typically favor investors and intrude on domestic sovereignty.¹³⁹ In addition, domestic sovereignty includes far more than legislative activity; permitting private corporations to second-guess executive or even judicial decisions still raises concerns. The United States has also attempted to defend investment claims as consistent with regulatory autonomy because its agreements do not permit tribunals to overturn U.S. law and instead can only award monetary compensation.¹⁴⁰ Although this is technically true,¹⁴¹ it does not actually address how nations are constrained: some international agreements permit investment tribunals to order injunctive relief that could in fact overturn domestic laws.¹⁴² Limiting remedies to “only” monetary compensation is of little solace to countries when remedies can be tens or hundreds of millions of dollars and the average defense of even a successful suit costs almost \$5 million,¹⁴³ but has been up to \$40 million to simply assess jurisdiction.¹⁴⁴ Given that the average loss is a significant sum of \$16.6 million,¹⁴⁵ with awards as high as \$50 billion,¹⁴⁶ a state may consider legitimate action to be too much of a gamble. This is of particular concern for developing countries that have been ordered to pay hundreds of millions or even over a billion dollars in damages.¹⁴⁷

139. E.g., UNCTAD, *Recent Trends*, *supra* note 16, at 1.

140. See *ISDS Fact Sheet*, *supra* note 48.

141. E.g., 2012 U.S. Model BIT, *supra* note 46, art. 34; TPP, *supra* note 40, art. 9.28.

142. For example, one tribunal ordered Ecuador to halt enforcement of an Ecuadorian appellate ruling that had previously ordered Chevron to pay for its contamination even before a final panel decision. E.g., *Chevron Corp. v. Republic of Ecuador*, PCA Case No. 2009-23, First Interim Award on Interim Measures (UNCITRAL Arb. Trib. Jan. 25, 2012), <http://www.italaw.com/sites/default/files/case-documents/ita0173.pdf> [<https://perma.cc/LKT3-JRYS>]; Ian Laird et al., *International Investment Law and Arbitration: 2012 in Review*, in *YEARBOOK ON INTERNATIONAL INVESTMENT LAW AND POLICY 2012–2013*, at 203 (Andrea K. Bjorklund ed., 2014); see also Ankita Ritwik, *Tobacco Packaging Arbitration and the State’s Ability to Legislate*, 54 *HARV. INT’L L.J.* 523, 528–32 (2013) (noting that Philip Morris’ attempt to enjoin Australia’s plain package law would be broader than most injunctive relief previously ordered by tribunals). Of course, even though not all agreements would permit injunctive relief, this possibility still poses a threat under some agreements.

143. E.g., Matthew Hodgson, *Counting the Costs of Investment Treaty Arbitration*, *GLOBAL ARBITRATION REVIEW* (Mar. 24, 2014), http://www.allenoverly.com/SiteCollectionDocuments/Counting_the_costs_of_investment_treaty.pdf [<https://perma.cc/FLE6-66TJ>].

144. E.g., OECD, *GOVERNMENT PERSPECTIVES ON INVESTOR-STATE DISPUTE SETTLEMENT: A PROGRESS REPORT 8* (2012), <http://www.oecd.org/daf/inv/investment-policy/ISDSprogressreport.pdf> [<https://perma.cc/28YG-UUQL>].

145. E.g., Susan D. Franck & Lindsey E. Wylie, *Demystifying Investment Treaty Arbitration 4* (2015) (unpublished manuscript) (on file with the author).

146. See Glen Moody, *Corporate Sovereignty Tribunal Makes \$50 Billion Award Against Russia*, *TECHDIRT* (Aug. 5, 2014, 12:37 AM), <https://www.techdirt.com/articles/20140801/05242228082/corporate-sovereignty-tribunal-makes-50-billion-award-against-russia.shtml> [<https://perma.cc/JAX6-8VMV>].

147. E.g., Pia Eberhardt, *Investment Protection at a Crossroads: The TTIP and the Future of International Investment Law*, 2014 *FRIEDRICH EBERT STIFTUNG INT’L POL’Y ANALYSIS* 7 (noting 2012 award of \$2.4 billion against Ecuador that is about three percent of the country’s GDP and roughly equal to its annual health budget); see also Claire Provost & Matt Kennard, *The Obscure Legal System That Lets Corporations Sue Countries*, *THE GUARDIAN* (June 10, 2015, 1:00 AM),

Even when defenders of investment claims actually recognize that traditional domestic decisions could be impacted by investment claims, they argue that there is no cause for concern. These defenses focus on a few different issues. First, some assert that “bona fide” government acts will not result in liability.¹⁴⁸ However, what one nation considers “bona fide” may not be to an investor; otherwise, there would be no outpouring of concern regarding investment claims. In addition, although most defenders of investment claims seem to recognize that the challenges to tobacco packaging laws are challenges to domestic sovereignty, they have asserted that because these cases are not “representative” of investment claims in general, there is no actual threat to sovereignty.¹⁴⁹

Defenders of investment claims tend to assume that there are no sovereignty concerns because of supposed lack of evidence of a chilling effect.¹⁵⁰ For example, the United States claims this is true because of an alleged increase in public interest regulation after investment agreements.¹⁵¹ However, it does not mean that governments have not been hesitant to enact *more* regulation because of the existence of investment claims. Although it can be difficult to fully catalog chilling effects where there are likely nonpublic negotiations, there are nonetheless some examples.¹⁵² Countries have limited enforcement of environmental laws due to actual or threatened investment claims.¹⁵³ In addition, countries have been hesitant

<http://www.theguardian.com/business/2015/jun/10/obscure-legal-system-lets-corporations-sue-states-ttip-icsid> [<https://perma.cc/YHR9-ENC4>] (noting substantial awards against Ecuador and El Salvador).

148. See, e.g., April 2015 Letter, *supra* note 62, at 2 (“[B]ona fide government acts will pass muster.”); *ISDS Fact Sheet*, *supra* note 48. One article makes a similar claim based on a selective case study of published environmental decisions; by focusing solely on environmental decisions, it completely omitted discussion of the pending *Philip Morris* case. See The Honorable Charles N. Brower & Sadie Blanchard, *What’s in a Meme? The Truth About Investor-State Arbitration: Why It Need Not, and Must Not Be Repossessed by States*, 52 COLUM. J. TRANSNAT’L L. 689, 689–99 (2014). Moreover, even focusing just in the environmental area, there now seems to be a contrary decision in which one of the arbitrators himself noted that the majority decision was an “intrusion into the environmental policy of the state.” *Bilcon of Del., Inc. v. Canada*, Dissenting Opinion of Professor Donald McRae, Case NO. 2009-04, ¶ 49 (Perm. Ct. Arb. 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4213.pdf> [<https://perma.cc/T5LS-4ZWH>].

149. E.g., April 2015 Letter, *supra* note 62.

150. Along somewhat similar lines, some scholars have suggested that domestic regulatory concerns are not supported based on an empirical evaluation of renegotiated and terminated investment agreements, although their evaluation notably excludes the most recent time period when such issues have been hotly contested. Tomer Broude et al., *Legitimation Through Negotiation: Do States Seek More Regulatory Space In their BITs?*, HEBREW U. OF JERUSALEM (Sept. 29, 2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2845297 [<https://perma.cc/ED6Y-MVUQ>].

151. *ISDS Fact Sheet*, *supra* note 48.

152. Some commentators have noted that investors have used the ability to sue in ISDS as a lobbying tool, but that it is difficult to assess the full impact of the threat to sue since there may be no documented public record. Van Harten, *Flawed Proposals*, *supra* note 75, at 9–10; Poulsen, *supra* note 67, at 29–31.

153. For example, Indonesia has withdrawn a prior regulation on mining and granted an exception to one particular investor. Ryan Suda, *The Effect of Bilateral Investment Treaties on Human Rights Enforcement and Realization*, in TRANSNATIONAL CORPORATIONS AND HUMAN RIGHTS 73,

to enact plain package tobacco laws due to the threat of investor-state arbitration.¹⁵⁴ Well-developed countries are not immune either. For example, Canada has a history of acting cautiously in light of threat of suit for a range of regulatory activities, with one official asserting that many regulations “never saw the light of day.”¹⁵⁵ In addition, Paraguay failed to enforce its own laws, citing a potential expropriation claim under an agreement with Germany, including one instance where the Inter-American Court of Human Rights found Paraguay’s lack of action to violate human rights.¹⁵⁶

The arguments made in defense of investment claims as not unduly impinging on domestic sovereignty are particularly inapplicable to the conflict with TRIPS. The intersection of investment claims with IP involves not only domestic sovereignty, but the sanctity of an entirely separate international agreement and process. Even if the goal of every international agreement is to constrain domestic sovereignty, it is generally *not* a goal to constrain other international agreements.¹⁵⁷ There are a number of interpretive principles in international law that aim to minimize conflict between agreements by interpreting them to avoid

100 (Olivier de Schutter ed., 2006); Ilge, *supra* note 16, at 11. Also, Peru has declined to enforce its environmental regulations against Renco even though the company had agreed to comply with the regulations when Renco bought its metal smelter, and Peru had already granted multiple extensions to comply. *E.g.*, *Renco Uses U.S.-Peru FTA to Evade Justice for La Oroya Pollution*, PUB. CITIZEN (Dec. 2012), <https://www.citizen.org/documents/renco-la-oroya-memo.pdf> [<https://perma.cc/U5KD-3SBA>]; Lori Wallach, *Brewing Storm Over ISDR Clouds: Trans-Pacific Partnership Talks—Part II*, KLUWER ARBITRATION BLOG (Jan. 14, 2013), <http://kluwerarbitrationblog.com/2013/01/14/brewing-storm-over-isdr-clouds-trans-pacific-partnership-talks-part-ii/> [<https://perma.cc/5CG4-B7GN>]; *see also* Provost & Kennard, *supra* note 84 (regarding Guatemala’s decision not to challenge mining company Goldcorp for fear that it would result in an investment claim despite domestic protests and a recommendation from the Inter-American Commission on Human Rights). *But see* TIETJE ET AL., *supra* note 138, at 43–48 (suggesting that investor claims alone should not be considered the sole reason for domestic actions, and fear of domestic court actions, which can enjoin laws, may sometimes be more significant).

154. *E.g.*, Muchangi, *supra* note 81; Tavernise, *supra* note 81.

155. William Greider, *The Right and US Trade Law: Invalidating the 20th Century*, NATION (Nov. 17, 2001), <http://www.thenation.com/article/right-and-us-trade-law-invalidating-20th-century/> [<https://perma.cc/9F7B-G983>] (quoting former Canadian government official); *see also* Letter from Elizabeth May, Member of Parliament for Saanich-Gulf Islands to Trade Agreements and NAFTA Secretariat (Jan. 29, 2013), <http://elizabethmaymp.ca/submission-environmental-assessment-tp> [<https://perma.cc/Q8EZ-37A4>] (noting that as a result of investment cases, the Canadian government has failed to regulate or ban toxic substances it would have before investment suits were permissible); Barrie McKenna, *Ottawa Could Face Lawsuits for Strict Corruption Rules*, GLOBE & MAIL (Nov. 24, 2014), <http://www.theglobeandmail.com/report-on-business/international-business/ottawa-could-face-lawsuits-for-strict-trade-corruption-rules-report/article21739211/> [<https://perma.cc/2LZW-7GFZ>] (Canadian Council of Chief Executive warning that new anti-corruption rules could prompt investor-state action if Canada proceeded.) In addition, New Zealand has delayed proceeding with plain packaging of tobacco.

156. *E.g.*, *Sawhoyamaya Indigenous Cmty. v. Paraguay, Merits, Reparations and Costs*, Judgment, Inter-Am. Ct. H.R. (ser. C) No. 146, ¶ 248 (Mar. 29, 2006); Ilge, *supra* note 16, at 12.

157. *See generally* Stephen M. Schwebel, *In Defense of Bilateral Investment Treaties*, 31 ARB. INT’L 181, 189 (2015) (noting that states can “specify their rights to regulate within their borders” without any mention of attempting to modify other international agreements).

inconsistency.¹⁵⁸ However, these principles are of little help here. The conflict between investment agreements and TRIPS is unusual in that there is technically not a direct conflict with respect to whether nations can comply with both agreements, but there could be a conflict with how each system interprets TRIPS, as well as a conflict with the TRIPS flexibilities.

b. Investment Claims Promote Investment and Economic Development

Another common defense is that investment agreements are beneficial to countries in promoting foreign direct investment as well as economic development more generally.¹⁵⁹ As noted earlier, such agreements originally were intended to promote these goals.¹⁶⁰ However, how well they serve that function today, and whether any such benefits offset current concerns with broad interpretations that impact sovereignty, is a major issue.

Defenders of the ISDS process contend that it promotes foreign direct investment (FDI) and economic development, such that it outweighs potential impingement on domestic discretion. For example, the Business and Industry Advisory Committee to the Organization for Economic Co-Operation and Development (OECD) considers the ISDS process “indispensable” to protect investments and promote FDI,¹⁶¹ while the Center for Strategic and International Studies contends that such agreements facilitate economic growth and job creation.¹⁶² In fact, ISDS defenders often point to surveys indicating that some companies consider ISDS valuable,¹⁶³ and to certain studies that suggest a correlation between investment agreements and FDI.¹⁶⁴ Yet, these studies only find a weak correlation between ISDS and FDI.¹⁶⁵ In addition, correlation is not

158. *E.g.*, RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW § 332 cmt. f (A.L.I. 1987) (“[A]greements should be interpreted to avoid inconsistency if fairly possible. Agreements may not in fact be incompatible if the earlier can be given effect as regards a limited subject matter while the later agreement may be interpreted to govern other matters within its general scope.”); 74 AM. JUR. 2D *Treaties* § 21 (2016) (“To the fullest extent possible, the language of a treaty is to be interpreted so as to avoid inconsistency.”).

159. *E.g.*, Brower & Blanchard, *supra* note 148, at 701–09.

160. *See supra* Part I.B.1.

161. Business & Industry Advisory Committee to the OECD [BIAC], *Investor-State Dispute Settlement: An Indispensable Element of Investment Protection*, ORG. FOR ECON. CO-OPERATION & DEV. 4 (2015).

162. Scott Miller & Gregory Hicks, *Investor-State Dispute Settlement: A Reality Check*, CTR. FOR STRATEGIC & INT’L STUD. 3 (2015), <http://csis.org/publication/investor-state-dispute-settlement> [<https://perma.cc/59ZS-4KWS>].

163. *E.g.*, Brower & Blanchard, *supra* note 148, at 704–05.

164. *E.g.*, *id.* at 706–08; U.N. Conference on Trade and Development, *The Impact of International Investment Agreements on Foreign Direct Investment: An Overview of Empirical Studies 1998-2014*, at 4 [hereinafter UNCTAD, FDI Overview] (Working Paper, Sept. 2014), <http://investmentpolicyhub.unctad.org/Upload/Documents/unctad-web-diae-pcb-2014-Sep%2016.pdf> [<https://perma.cc/5YHG-ZQ9C>].

165. *E.g.*, Emma Aisbett, *Bilateral Investment Treaties and Foreign Direct Investment: Correlation Versus Causation* (Munich Personal RePEc Archive Paper No. 2255, 2007), <https://mpra.ub.uni->

causation. For example, the correlation could reflect that countries that already had strong FDI sign agreements.¹⁶⁶ In addition, other studies find little or no effect on FDI,¹⁶⁷ or that investment claims are only relevant to some investors or some industries.¹⁶⁸ Thus, the evidence is quite mixed.¹⁶⁹ Some countries seem to recognize that any theoretical benefits are far outweighed by potential financial liability as well as sovereignty concerns. Specifically, countries have taken action to terminate investment agreements of which they were signatories or have indicated a lack of support for existing or potential agreements that permit investor-state suits.¹⁷⁰

Even if there were a strong correlation between the existence of an investment agreement and improved economic outcomes, such an argument is tenuous and mirrors a similar fallacy in the IP context. In the IP context, there are those who argue that, since stronger IP rights correlate with foreign direct investment, stronger IP rights should be encouraged.¹⁷¹ However, both arguments ignore the fundamental fact in any statistical analysis that correlation does not establish *causation*. In either context, there are always a wealth of factors that impact whether a foreign company will invest in any given country;¹⁷² this is something the United Nations Conference on Trade and Development (UNCTAD) has recently underscored in noting that investment agreements play a complementary role

muenchen.de/2255/1/MPRA_paper_2255.pdf [https://perma.cc/7U4U-4V8Z] (finding lack of strong correlation between investment treaties and investment flows and noting that evidence is mixed).

166. UNCTAD, FDI Overview, *supra* note 164, at 5.

167. *Id.* at 5–6; *see also* Jason Webb Yackee, *Do Bilateral Investment Treaties Promote Foreign Direct Investment? Some Hints from Alternative Evidence*, 51 VA. J. INT'L L. 397 (2011) (suggesting no meaningful correlation).

168. Roderick Abbott et al., *Demystifying Investor-State Dispute Settlement (ISDS)*, (CEIPE Occasional Paper No. 5/2014, 2014).

169. *See generally* THE EFFECT OF TREATIES ON FOREIGN DIRECT INVESTMENT: BILATERAL INVESTMENT TREATIES, DOUBLE TAXATION TREATIES, AND INVESTMENT FLOWS (Karl P. Sauvant & Lisa E. Sachs eds., 2009) (providing differing views on this issue); Todd Allee & Clint Peinhardt, *Contingent Credibility: The Impact of Investment Treaty Violations on Foreign Direct Investment*, 65 INT'L ORG. 401 (2011) (noting that foreign direct investment only increases in countries where there are no investment claims).

170. *E.g.*, U.N. Conference on Trade and Development, *International Investment Policy Making in Transition: Challenges and Opportunities of Treaty Renewal*, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/9 (June 2013); U.N. Conference on Trade and Development, *Denunciation of the ICSID Convention and BITS: Impact on Investor-State Claims*, U.N. Doc. UNCTAD/WEB/DIAE/IA/2010/6 (Dec. 2010).

171. *E.g.*, Owen Lippert, *One Trip to the Dentist is Enough: Reasons to Strengthen Intellectual Property Rights Through the Free Trade Area of the Americas*, 9 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 241, 248–49 (1998); *see also* Kenneth J. Vandeveld, *The Political Economy of a Bilateral Investment Treaty*, 92 AM. J. INT'L L. 621, 638 n.163 (1998) (stating that “[i]n general, strong intellectual property protection is correlated with the attraction of foreign direct investment.”).

172. Studies indicate other factors such as tax incentives, infrastructure, and skill are more relevant. *E.g.*, 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); Claudio R. Frischtak, *Harmonization Versus Differentiation in Intellectual Property Rights Regime*, in GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 68, 103–05 (Wallerstein et al. eds., 1993); Jeong-Yeon Lee & Edwin Mansfield, *Intellectual Property Protection and U.S. Foreign Direct Investment*, 78 REV. ECON. & STAT. 181, 181–85 (1996).

among a number of determinants and that there are many data limitations.¹⁷³ Thus, not every causative relationship has been (and perhaps never will be) explored and exhausted, and in fact, there are strong counter-examples in both the investment and IP contexts. For example, Brazil enjoys strong foreign direct investment despite the fact that it thus far has not agreed to investor-state arbitration.¹⁷⁴ Similarly, Brazil and India enjoy strong foreign investments even though their IP laws have been noted as inadequate.¹⁷⁵

The claim that investment agreements are beneficial in promoting investment seems particularly unsupported in the IP context. After all, “investment” in creating IP is different from tangible investments such as real property that were traditionally envisioned by such agreements. Whereas tangible investments clearly benefit the host states, stronger IP more likely benefits the foreign private company, but results in higher prices in the host state.¹⁷⁶ Importantly, even if investment agreements theoretically promoted investment, that does not address the conflict with IP flexibility under TRIPS. Moreover, the pending conflict is particularly problematic given that investment claims that impact TRIPS are considered in a process that lacks the type of protections available in the WTO, even though defenders of the system assert the system is fair.¹⁷⁷

173. UNCTAD, FDI Overview, *supra* note 164, at 4, 6, 8.

174. E.g., Fabio Morosini & Michelle Raton Sanchez Badin, *The Brazilian Agreement on Cooperation and Facilitation of Investments (ACFI): A New Formula for International Investment Agreements?*, INT'L INST. FOR SUSTAINABLE DEV. (Aug. 4, 2015), <https://www.iisd.org/itn/2015/08/04/the-brazilian-agreement-on-cooperation-and-facilitation-of-investments-acfi-a-new-formula-for-international-investment-agreements/> [<https://perma.cc/BSV7-TEYY>]; see also Pedro Martini, *Brazil's New Investment Treaties: Outside Looking . . . Out?*, KLUWER ARB. BLOG (June 16, 2015), <http://klowerarbitrationblog.com/2015/06/16/brazils-new-investment-treaties-outside-looking-out-2/> [<https://perma.cc/Z8PC-6Q7Q>].

175. For example, India had \$1 billion in foreign direct investment in three months in 2013 despite controversial patent laws. *India Receives Highest FDI Worth \$1 Billion in Pharma in April-June*, ECON. TIMES (Sept. 1, 2013, 12:15 PM), http://articles.economictimes.indiatimes.com/2013-09-01/news/41663407_1_pharmaceuticals-sector-highest-fdi-fdi-policy [<https://perma.cc/BB8X-LS6E>]. Similarly, Brazil and Thailand received substantial investment in the 1970s and 1980s despite relatively low levels of protection. Compare Edwin Mansfield, Int'l Fin. Corp., *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer* 10 (1994), <http://documents.worldbank.org/curated/en/888591468739296453/pdf/multi-page.pdf> [<https://perma.cc/HUU8-ZX8Q>] (discussing perceived weak intellectual property protections in Brazil and Thailand), with Lawrence Bouton & Mariusz Sumlinski, Int'l Fin. Corp., *Trends in Private Investment in Developing Countries: Statistics for 1970–1998*, at 8 (Working Paper No. 41, 2000), <https://openknowledge.worldbank.org/bitstream/handle/10986/13986/multi0page.pdf?sequence=1&isAllowed=y> [<https://perma.cc/4ZVG-TU4D>] (providing comprehensive statistics of private investment in Brazil and Thailand).

176. For example, when an investor purchases a plant, that usually involves hiring local employees, thus benefitting the host country. By contrast, when an investor has IP in a host country, such as a patent or a trademark, there may be little actual investment in the host country besides purchasing advertising. Moreover, IP is known to raise costs.

177. For example, there is an appellate body at the WTO. See DSU, *supra* note 4, art. 17.

c. Investor-State Disputes as a Fair Process with Procedural Protection

The final major defense of investment claims is that they should not pose any serious concern since the process has procedural protections.¹⁷⁸ Defenders suggest that investment proceedings mimic traditional U.S. litigation where there is legal representation with multiple rounds of briefs and hearings, as well as the right to review and even annul awards.¹⁷⁹ However, once again, the opportunity to “review” awards is typically based on narrow grounds with no appellate review. Also, the multiple rounds of briefs and hearings need not be publicly disclosed and interested parties may not be able to participate in direct contravention of U.S. litigation.¹⁸⁰ Moreover, although defenders have asserted that there is no concern about arbitrator bias since there is process to challenge bias, arbitrators in the current system inherently lack independence of an actual judiciary with procedural protections.¹⁸¹

Most importantly, this purported defense is irrelevant to investment claims premised on IP issues that arguably violate TRIPS. There is already a fair and independent process to address such issues before the WTO.¹⁸² Unlike the situation with investor-arbitration claims, there is no criticism of WTO adjudication as being partial; in fact, a recent study suggests that the WTO system of adjudication results in better results than the traditional investor-state disputes before private arbitrators appointed by parties.¹⁸³ In addition, although investment claims were created to

178. See e.g., April 2015 Letter, *supra* note 62.

179. *Id.*

180. In response to criticisms, transparency has increased. For example, The United Nations Commission on International Trade Law (UNCITRAL) ratified rules to promote transparency for treaties using UNCITRAL arbitration after 2014. See Comm’n on Int’l Trade Law, UNCITRAL Rules on Transparency in Treaty-based Investor-State Arbitration, at 5, U.N. Doc. A/68/17 (2013). However, these rules do not automatically apply to more than 3000 existing agreements. To this end, the UN General Assembly ratified the Convention on Transparency in Treaty-Based Investor-State Arbitration to allow parties that entered into agreements before 2014 to more easily opt into these rules. See Comm’n on Int’l Trade Law, UNCITRAL Convention on Transparency in Treaty-based Investor-State Arbitration, at 5, U.N. Doc. A/69/496 (2014). But, parties that entered into agreements after 2014 can opt out of the default transparency. See *id.* at art. 1; see also LISE JOHNSON & NATHALIE BERNASCONI-OSTERWALDER, NEW UNCITRAL ARBITRATION RULES ON TRANSPARENCY: APPLICATION, CONTENT AND NEXT STEPS 26 (2013), http://ccsi.columbia.edu/files/2014/04/UNCITRAL_Rules_on_Transparency_commentary_FINAL1.pdf [<https://perma.cc/FX7S-JNPQ>].

181. See March 2015 Letter, *supra* note 83.

182. The stability of the WTO process is underscored by the recent proposal for an investment court and appellate body based on the WTO system. See *Commission Concept Paper on Investment in TTIP and Beyond—The Path for Reform* 9 (May 5, 2015), http://trade.ec.europa.eu/doclib/docs/2015/may/tradoc_153408.PDF [<https://perma.cc/SZF4-CVUW>]; see also Joost Pauwelyn, *Why the US Should Support the EU Proposal for an “Investment Court System,”* LINKEDIN (Nov. 16, 2015), <https://www.linkedin.com/pulse/why-us-should-support-eu-proposal-investment-court-system-pauwelyn?forceNoSplash=true> [<https://perma.cc/65BL-RXMI>].

183. See generally Joost Pauwelyn, *The Rule of Law Without the Rule of Lawyers? Why Investment Arbitrators are from Mars and Trade Adjudicators are from Venus* (Oct. 1, 2015), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2549050 (discussing the differences between WTO and

avoid domestic volatility and gunboat diplomacy,¹⁸⁴ given the lack of any investment cases involving IP until recent years, the “need” for investment claims to protect IP seems particularly unfounded.

Recently concluded or proposed agreements that aim to improve procedural protections still fail to adequately address TRIPS conflicts. For example, even recent agreements with a more independent initial investment tribunal and appellate review still fail to address the conflicts with TRIPS norms. In particular, while these measures might promote independence, they do not ensure TRIPS norms will be safeguarded. In addition, although both the TPP and EU proposal for the TTIP aim to prevent forum shopping,¹⁸⁵ they would not completely address a conflict with TRIPS. The EU proposes to bar investment claims that have already been submitted to another international tribunal, but only if it is concerning the “same treatment.”¹⁸⁶ Since investment claims provide different relief than TRIPS, this may be inadequate to prevent simultaneous adjudication in the WTO and investment arenas. Moreover, even if “same treatment” were interpreted to be simply same fundamental facts, the EU Proposal would not prevent a WTO case being litigated after the investment one and resulting in conflicting interpretations of TRIPS. The TPP does require investors to waive the right to initiate or proceed with another dispute settlement procedure regarding the same issue.¹⁸⁷ So, this would theoretically prevent a subsequent WTO panel coming to a conflicting interpretation of TRIPS. However, this does nothing to stop a tribunal from interpreting TRIPS provisions in the first instance, let alone inconsistently with prior WTO decisions and/or accepted norms, even if not embodied in an actual WTO panel decision. CETA also aims to address conflicts by noting that an investment tribunal shall stay its proceedings, but again does not address possible TRIPS issues. After all, it only requires the investment tribunal to stay its proceedings where there is potential for overlapping compensation—which is never the goal of a WTO claim, or another international claim that could have a significant impact on the investment dispute.¹⁸⁸ This provision would still not have stopped the *Eli Lilly* dispute where there is no parallel proceeding in the WTO and does nothing to prevent inconsistency with WTO norms.

ICSID adjudicators as the basis in fact for disparate outcomes between WTO and ICSID adjudication systems).

184. See *supra* Part I.B.1.

185. E.g., European Commission Press Release IP/15/5651, Commission Proposes New Investment Court System for TTIP and Other EU Trade and Investment Negotiations (Sept 16, 2015); *European Commission: Fact Sheet on Investment Protection in the TTIP*, http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153018.5%20Inv%20Prot%20and%20SDS.pdf [https://perma.cc/M28J-ZJ75].

186. See TTIP, *supra* note 95, art. 14, ¶¶ 2–3.

187. TPP, *supra* note 40, art. 9.20(2)(b).

188. CETA, *supra* note 15, art. 8.24.

II. THE CURRENT COLLISION COURSE

This Part aims to explain how investor-state disputes based on IP issues governed by other agreements raise unique conflicts that are not adequately recognized. This Part begins by discussing the first investor-state cases involving alleged violations of TRIPS. Then, this Part provides an overview of potential situations in which investor-state cases could present serious challenges to TRIPS flexibilities.

A. Initial Investment Cases Challenging TRIPS

This Section addresses the first investment cases that directly challenge intellectual property norms under TRIPS. Notably, these cases involve not only TRIPS patent rights, but also trademark rights. Although the Declaration of Patent Sovereignty focuses on patents, domestic discretion that may impinge on trademarks is consistent with the idea of TRIPS flexibilities. As this Section explains, although a direct collision of TRIPS flexibilities has thus far been averted with regard to domestic regulations on tobacco that impact trademark rights, a future collision is possible. Although Part III discusses how to minimize collisions and recognizes that some recent agreements have promising language to do so, these initial cases are likely more representative of likely collisions under the vast majority of investment agreements that lack the new language.

1. Philip Morris

Philip Morris¹⁸⁹ brought investment disputes regarding tobacco regulation against Uruguay¹⁹⁰ and Australia.¹⁹¹ Although both countries have regulated tobacco for decades, they have also been on the forefront of implementing the 2003 World Health Organization's Framework Convention on Tobacco Control.¹⁹² The

189. For the purposes of this section, any reference to the multinational company Philip Morris includes all related entities in the case.

190. P.M. v. Uru., Request for Arbitration, *supra* note 1.

191. See P.M. v. Austl., Notice of Arbitration, *supra* note 1, ¶ 1.1.

192. WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, WORLD HEALTH ORGANIZATION (WHO) (2003) [hereinafter WHO FCTC]. See generally Josef Ostransky, *Tobacco Investment Disputes—Public Policy, Fragmentation of International Law and Echoes of the Calvo Doctrine*, 3 CZECH Y.B. INT'L L. 161, 164–65 (2012), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2164726 (noting that Uruguay and Australia are pioneers at combatting tobacco consumption and Uruguay was one of the first countries to ratify the FCTC). In addition, some have suggested that Philip Morris intentionally chose Uruguay because it is a country with reasonable damages, yet limited resources, to defend against an investment claim. See Todd Weiler, *Philip Morris v. Uruguay: An Analysis of Tobacco Control Measures in the Context of International Investment Law* 17 nn. 54, 36 (Physicians for a Smoke-Free Can., Report #1, 2010), http://www.smoke-free.ca/eng_home/2010/pmivsuruguay/opinion-pmi-uruguay.pdf [<https://perma.cc/34HS-JXXL>] (noting that while the market in Mauritius was too small for damages to be worthwhile, the market in Mexico was larger and established enough to better respond to investment claims such that Uruguay is chosen to “make an example”). Notably, Philip Morris is seeking \$25 million in damages against Uruguay, a country that has a domestic GDP that is roughly half of Philip Morris' annual revenue. See Duff Wilson, *Cigarette Giants in Global Fight on Tigher Rules*,

Framework Convention does not expressly require any bars to trademarks, although the guidelines for implementation do suggest limiting trademarks.¹⁹³ These investment disputes were brought after failed attempts to enjoin the laws domestically.¹⁹⁴

a. Factual Context

Although both Uruguay and Australia regulated tobacco packaging in a manner that impacted trademark rights, their regulations differed. Uruguay's regulations were less onerous on trademark rights; it only required that each brand have a single variation and required health warnings on 80% of the package.¹⁹⁵ Australia, on the other hand, required cigarettes to be packaged in "drab dark brown" and severely restricted the use of trademarks to essentially just the brand name with no trademarked logos.¹⁹⁶ In both cases, Philip Morris claimed that its trademarks were expropriated and that it was denied fair and equitable treatment, with the FET claim based in part on alleged failure to comply with international obligations, under TRIPS and the Paris Convention.¹⁹⁷ The TRIPS claims were contrary to the views of most academics, as well as the World Intellectual Property

N.Y. TIMES, Nov. 13, 2010, at A1; Jim Armitage, *Big Tobacco Puts Companies on Trial*, INDEPENDENT, (Oct. 21, 2014), <http://www.independent.co.uk/news/business/analysis-and-features/big-tobacco-puts-countries-on-trial-as-concerns-over-ttip-deals-mount-9807478.html> [<https://perma.cc/2B8S-QGHU>].

193. See WHO Framework Convention on Tobacco Control, *Elaboration of Guidelines for Implementation of Article 13 of the Convention*, ¶¶ 15, 16, FCTC/COP/3/9 (Sept. 2, 2008); WHO Framework Convention on Tobacco Control, *Elaboration of Guidelines for Implementation of Article 11 of the Convention*, ¶ 46, FCTC/COP/3/7 (Aug. 21, 2008); WHO FCTC, *supra* note 192.

194. See, e.g., *British Am. Tobacco Australasia Ltd. v Commonwealth*, Order, [2012] HCA 43, ¶ 3 (Austl.), <http://eresources.hcourt.gov.au/downloadPdf/2012/HCA/43> [<https://perma.cc/56CA-KE3S>] (entering judgment on behalf of Australia that its tobacco packaging law did not deprive company investment); *JT Int'l SA v Commonwealth*, Order, [2012] HCA 43, ¶ 3 (Austl.), <http://eresources.hcourt.gov.au/downloadPdf/2012/HCA/43> [<https://perma.cc/BS8Z-K66C>] (entering judgment on behalf of Australia that its tobacco packaging law did not deprive company investment); P.M. v. Uru., Request for Arbitration, *supra* note 1, ¶¶ 30–31. Technically, Philip Morris was the intervener in the Australia case. See *British Am. Tobacco Australasia Ltd v Commonwealth*, Philip Morris Ltd's Submissions (Intervening), (2011) HCA 43, ¶ 2, http://www.hcourt.gov.au/assets/cases/s389-2012/BAT_Phillip.pdf [<https://perma.cc/6BKH-NPRJ>] (entering as an intervener).

195. Uruguay only mandated that each brand of tobacco products has a single presentation to prohibit labeling cigarettes as "light" or "ultralight" and required health warnings on 80% of the package. P.M. v. Uru., Request for Arbitration, *supra* note 1, ¶¶ 24–25.

196. See *Tobacco Plain Packaging Act 2011* (Cth) ss 19–20 (Austl.). This law prohibits trademarks from appearing on the package other than as permitted in Article 20(3), which only allows the brand name for the tobacco products. See *id.* s 20.

197. See P.M. v. Austl., Notice of Arbitration, *supra* note 1, ¶¶ 6.6–6.12 (alleging Australia's breach of international agreements), ¶ 7.2(a)–(b) (alleging P.M.'s deprivation of investment in Australia), ¶ 7.7 (referring to violation of international law for FET claim); P.M. v. Uru., Request for Arbitration, *supra* note 1, para 85. While Philip Morris also made other allegations, only these claims have been highlighted to allow for comparison with the *Eli Lilly* case.

Office.¹⁹⁸

After the 2011 investment claim against Australia was initiated, Ukraine, likely acting in conjunction with Philip Morris, initiated a WTO dispute against Australia regarding the same plain package tobacco laws that allegedly violate TRIPS.¹⁹⁹ Other countries, including Indonesia, Cuba, Honduras, and the Dominican Republic subsequently joined the consultation, and the WTO set up a panel to hear a consolidated case.²⁰⁰ This was a high profile WTO case with many third party observers that seemed on a direct collision course with an investment tribunal interpretation of the same TRIPS provisions.²⁰¹

A complete collision is presently averted since the Australian tribunal dismissed the investment case on jurisdictional grounds²⁰² and a majority of the Uruguay tribunal found in favor of Uruguay.²⁰³ The Australian tribunal agreed to

198. *E.g.*, PHYSICIANS FOR A SMOKE-FREE CANADA, *supra* note 107, at 16–19 (WIPO Comments); Mark Davison & Patrick Emerton, *Rights, Privileges, Legitimate Interests, and Justifiability: Art 20 of TRIPS and Plain Packaging of Tobacco*, AM. U. INT'L L. REV. 505 (2014); *see also infra* notes 234, 241 and accompanying text (providing views of additional academics on proper interpretation of TRIPS article 15 and article 20). *But see* Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46 VAND. J. TRANSNAT'L L. 1149 (2013). Intellectual Property attorneys, however, were more sympathetic. *E.g.*, Carmela R. Zocco, *Plain Packaging: A Growing Threat to Trademark Rights*, LES NOUVELLES, June 2013, at 140, 141 (noting that numerous intellectual property rights groups have condemned plain packaging as an “unjustified attack” on rights); Stephen Stern & Olivia Draudins, *Generic Packaging: A Bridge (Over the Bodies of IP Rights) Too Far?*, AUSTL. INTELL. PROP. L. BULL. 146, 149 (2011) (arguing that TRIPS article 20 bars total ban on trademark use even if not explicitly stated).

199. Request for Consultations by Ukraine, *Australia—Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS434/1 (March 15, 2012). Indeed, Philip Morris is financing legal costs of two countries in the WTO challenge. *E.g.*, Stephanie Nebehay, *Australia Says Big Tobacco Aiding WTO Challenges*, REUTERS (May 23, 2012), <http://www.reuters.com/article/2012/05/23/us-trade-tobacco-idUSBRE84M0IO20120523> [<https://perma.cc/VV4K-2JAM>]; Myron Levin, *As Nations Try to Snuff Out Smoking, Cigarette Makers Use Trade Treaties to Fire UP Legal Challenges*, FAIR WARNING (Nov. 29, 2012), <http://www.fairwarning.org/2012/11/as-nations-try-to-snuff-out-smoking-cigarette-makers-use-trade-treaties-to-fire-up-legal-challenges/> [<https://perma.cc/4VHL-834R>].

200. Dispute Settlement, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS458/16 (May 5, 2014); *see also* Brief: Panel Appointed for WTO Mega-Case on Australia Tobacco Packaging, IP-WATCH (May 6, 2014), <http://www.ip-watch.org/2014/05/06/panel-appointed-for-wto-mega-case-on-australia-tobacco-packaging/> [<https://perma.cc/5J7X-L5QR>].

201. *E.g.*, Dispute Settlement, *Australia—Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Other Packaging*, WTO Doc. WT/DS434/13 (May 5, 2014) [hereinafter WTO, Australia Dispute Settlement].

202. P.M. v. Austl., Award, *supra* note 75; *see also* Jarrod Hepburn & Luke Eric Peterson, *Australia Prevails in Arbitration with Philip Morris over Tobacco Plain Packaging Dispute*, INV. ARB. REP. (Dec. 17, 2015), <https://www.iareporter.com/articles/breaking-australia-prevails-in-arbitration-with-philip-morris-over-tobacco-plain-packaging-dispute/> [<https://perma.cc/6HLA-C7JT>]. However, the tobacco industry could easily bring another dispute since it has aggressively fought tobacco restrictions. *E.g.*, Sergio Puig, *Tobacco Litigation in International Courts*, 57 HARV. INT'L L.J. 384 (2016).

203. Philip Morris v. Uru., ICSID Case No. ARB/10/7, Award (July 8, 2016) [hereinafter P.M. v. Uru., Award].

dismiss the Philip Morris claim after finding that the company had improperly restructured itself to become a “foreign” corporation after Australia announced its plans to enact plain packaging, such that there was no jurisdiction.²⁰⁴ However, the tribunal’s failure to address Australia’s other challenge to jurisdiction leaves open an important question for future collisions. In particular, Australia had argued that the investment tribunal had no jurisdiction to decide any issues under TRIPS given the existence of a separate dispute settlement mechanism for such claims with which the investment tribunal ruling could potentially conflict.²⁰⁵ Uruguay did not raise this issue, even though it was facing an alleged violation of TRIPS and challenged jurisdiction on other grounds.²⁰⁶ Accordingly, it remains to be seen whether collisions in the future can be averted based on the defense that there is no jurisdiction at all.

Although the WTO panel is reported to have ruled in favor of Australia on the plain package case as this article goes to press, the panel report is not expected until July and investment claims against countries that enact similar packaging rules are possible.²⁰⁷ Countries have shown clear interest in such laws and some have been enacting them even before the conclusion of the investment cases, let alone the WTO panel ruling.²⁰⁸ At the same time, the tobacco industry continues to vigorously contest such regulation.²⁰⁹ Immediately after the conclusion of the

204. *Id.* ¶¶ 460, 584; Philip Morris Asia Ltd. v. Commonwealth, Australia’s Response to Notice of Arbitration, PCA Case No. 2012-12, ¶¶ 29–32 (BIT/UNCITRAL Arb. Trib. Dec. 21 2011) [hereinafter Australia’s Response to Notice of Arbitration].

205. Australia’s Response to Notice of Arbitration, *supra* note 204, ¶¶ 33–35.

206. *See generally* Philip Morris Brands Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Decision on Jurisdiction (July 2, 2013) [hereinafter P.M. v. Uru., Decision on Jurisdiction]; P.M. v. Uru., Request for Arbitration, *supra* note 1, ¶ 86 (asserting violation of unstated provisions of TRIPS).

207. *E.g.*, *Tobacco Industry Suffers Defeat as WTO Upholds Australia’s Plain Packaging Laws* GUARDIAN (May 4, 2017), <https://www.theguardian.com/global/2017/may/05/australias-defeats-wto-challenge-to-plain-packaging-of-tobacco>.

208. Countries that have already enacted plain packaging laws so far include UK, Ireland, and France. Children and Families Act 2014, c. 6 (Eng.); Public Health (Standardized Packaging of Tobacco) Bill 2014 (Bill No. 54/2014) (Ir.); Ordonnance no.2016-623 du 19 mai 2016 portant transposition de la directive 2014/40/UE sur la fabrication, la présentation et la vente des produits du tabac et des produits connexes [Ordonnance No 2016-623 of May 19, 2016 transposing Directive 2014/40/EU on the manufacture, presentation, and sale of tobacco and related products], Journal Officiel de la République Française [J.O.] [Official Gazette of France], May 20, 2016. In addition, other countries are considering such laws. *E.g.*, Canadian Cancer Society, *Plain Packaging—International Overview*, ACTION ON SMOKING AND HEALTH (May 19, 2016), <http://ash.org.uk/information-and-resources/packaging-labelling-information-and-resources/standardised-plain-packaging/plain-packaging-an-international-overview/> [https://perma.cc/4VXC-FDQB]; World Health Organization [WHO], *World No Tobacco Day 2016: Get Ready for Plain Packaging* (May 31, 2016), <http://www.who.int/campaigns/no-tobacco-day/2016/event/en/> [https://perma.cc/PX9C-FMW9].

209. For example, Britain’s recent plain package laws have been challenged in British courts. *E.g.*, David Jolly, *Tobacco Giants Sue Britain over Plain Packaging*, N.Y. TIMES (May 23, 2015), http://www.nytimes.com/2015/05/23/business/international/tobacco-plain-packaging-philip-morris-british-american-cigarettes.html?_r=0 [https://perma.cc/TJ5A-VCTX].

Uruguay case, Philip Morris issued a press statement that it was not a party to any investment disputes and that it would use “thoughtful diplomacy,” that suggests it will not assert investment claims—but could still threaten to do so.²¹⁰ Countries faced with such a threat should realize that although Uruguay prevailed, it was not a unanimous opinion and future tribunals need not follow the majority opinion. Also, even if no future investment claims are actually asserted based on plain packaging, examining how a conflict was narrowly avoided is helpful to not only show the inherent conflict between the IP and investment regimes, but also to show why the *Eli Lilly* case posed a much more serious, yet not well understood threat to TRIPS flexibility.

b. Investment Claims

This Section evaluates the extent to which tobacco regulation, such as plain package tobacco laws, might result in liability for expropriation and then FET claims. Although plain package tobacco laws such as Australia’s are recommended by the WHO, there was no decision on the merits in that case. As noted below, although the expropriation claim failed against Uruguay, another case might not find similarly. Moreover, even though a *majority* of the tribunal in Uruguay agreed that there was no FET claim, the lack of a consensus indicates vulnerability to FET claims. Although it is of course possible for an investment tribunal to read other international agreements harmoniously, as some have suggested,²¹¹ that does not mean that there is no vulnerability—especially given structural elements of investment agreements and how they are adjudicated that tilt more towards interests of investors, rather than public health.²¹²

i. Vulnerability to Expropriation Claims

Philip Morris alleged that domestic laws limiting the use of some trademarks constitute an expropriation of its investments in trademarks.²¹³ Essentially, it

210. *Philip Morris International Comments on Tribunal’s Decision in Arbitration Between PMI and Uruguay*, BUS. WIRE (July 8, 2016), <http://www.businesswire.com/news/home/20160708005828/en/Philip-Morris-International-Comments-Tribunal%E2%80%99s-Decision-Arbitration> [https://perma.cc/3S4Z-PABA].

211. *E.g.*, Harold Koh, *Global Tobacco Control as a Health and Human Rights Imperative*, 57 HARV. L. REV. 433, 444 (2016) (arguing that since the Tobacco Convention was later in time and more specific, it should prevail under rules of treaty interpretation in the context of how a WTO panel should rule, although the same principle should apply to an investment dispute).

212. Not only do most investment agreements aside from the newest agreements not have balancing language concerning other policies beyond promoting investments, but they are also interpreted by a small group of primarily commercial arbitrators that would seem likely to be more sympathetic to commercial interests, especially since there are a number of arbitrators that also act as counsel or party experts in other cases. *E.g.*, Sergio Puig, *Blinding International Justice*, 56 VA. J. INT’L L. 46 (2016); David Graukrodger & Kathryn Gordon, *Investor-State Dispute Settlement: A Scoping Paper for the Investment Policy Community*, OECD Working Papers on International Investment 44 (2012) (majority of arbitrators have served as counsel for investors in other cases whereas only ten percent of arbitrators have acted as counsel for states in other cases).

213. *P.M. v. Austl.*, Notice of Arbitration, *supra* note 1 ¶¶ 7.3-7.5; *P.M. v. Uru.*, Request for

asserted that the regulations create “substantial interference” with use of its trademarks and significant losses, such that its trademarks were expropriated.²¹⁴ Importantly, although the Australian court previously rejected a similar claim under domestic law, that does not preclude an expropriation claim which is often interpreted more broadly.²¹⁵ In some cases, tribunals have found expropriation to exist if there is substantial interference with the investment, regardless of whether there is a strong policy ground.²¹⁶

Although the Uruguay tribunal rejected Philip Morris’s assertion that there is inadequate justification for its tobacco regulations and found no expropriation consistent with some recent decisions, another investment dispute against a country for tobacco regulation could have a different outcome.²¹⁷ Uruguay was fortunate to not only have financial support to battle Philip Morris’s claim,²¹⁸ but a tribunal that was willing to accept and actually rely on supportive amicus submissions.²¹⁹ Neither of these factors is typical of most investment cases. Indeed, commentators have noted that Philip Morris brought its investment claim against Uruguay to threaten other countries and likely was not anticipating that Uruguay would receive financial support to defend itself.²²⁰

The details of the Uruguay tribunal finding, even if not binding on future tribunals, are of interest. Most notably with regard to TRIPS collisions, the tribunal concluded that there is no absolute right to use trademarks pursuant to TRIPS Article 20.²²¹ Even though this is consistent with many academic commentators and the WHO position, this does not guarantee a similar finding in a future case—especially since not all commentators agree with this position. In addition, the tribunal found that the Uruguay regulation mandating that trademarks be limited to twenty percent of the packages was not an expropriation since it did not limit how the trademarks were used.²²² However, in plain package regulation, such as

Arbitration, *supra* note 1, at ¶ 82.

214. P.M. v. Austl., Notice of Arbitration, *supra* note 1, ¶ 7.3; *see also* P.M. v. Uru., Request for Arbitration, *supra* note 1, ¶ 48, 82 (arguing that regulations deprived trademarks of commercial value and that mandatory discontinuation of trademarks constituted expropriation).

215. *See, e.g.*, Been & Beauvais, *supra* note 50.

216. *E.g.*, Metalclad Corp. v. United Mexican States, *supra* note 71; *see also* Newcomb, *The Boundaries of Regulatory Expropriation in International Law*, FOREIGN INV. L.J. 1, 11–12 (2005).

217. *E.g.*, Ursula Kriebaum, *Expropriation*, in INTERNATIONAL INVESTMENT LAW 38–41 (Marc Bungenberg et al. eds., 2015).

218. *E.g.*, *Tobacco Industry Targets Uruguay’s Gold Standard Anti-Tobacco Laws*, MIKE BLOOMBERG (Nov. 15, 2010), <https://www.mikebloomberg.com/news/tobacco-industry-targets-uruguays-gold-standard-anti-tobacco-laws/> [<https://perma.cc/U6UX-BAFP>] (indicating intent to support Uruguay government).

219. P.M. v. Uru., Award, *supra* note 203, ¶¶ 38, 43.

220. *E.g.*, Tavernise, *supra* note 81 (noting that Uruguay would have had to settle if the Bloomberg Foundation had not intervened to provide financial support).

221. P.M. v. Uru., Award, *supra* note 203, ¶ 262 (“[N]owhere does the TRIPS Agreement . . . provide for a right to use.”); *see also id.* ¶ 269 (noting “no absolute right to use” trademarks, especially for an industry that is often subject to regulation).

222. *Id.* ¶ 276.

Australia's, the use of trademarks are in fact limited when a company is barred from using logos at all. Accordingly, a country that adopts plain package regulations is still vulnerable to losing an expropriation claim even if a future tribunal were to follow the majority of the Uruguay tribunal's reasoning. In addition, although the tribunal rejected the expropriation claim against Uruguay that limited companies to one brand variant within a family, this is not typical of most tobacco regulations, such that it is likely not directly applicable to other regulations.²²³ However, the tribunal did characterize this regulation of tobacco as within police power of a nation, such that there would be no compensable expropriation, even if there were economic injury.²²⁴ In particular, the tribunal noted that the regulations were consistent with Uruguay's domestic obligation under the Constitution to legislate in the interest of public health, as well as comply with the FCTC, and the regulation was proportionate to the intended objective, citing the amicus briefs of the WHO and PAHO.²²⁵ Thus, even though Uruguay's law is not typical of most plain package laws, the rationale in support of Uruguay's law would seem helpful to countries with plain package tobacco laws *if* a future tribunal agrees. However, not only does a tribunal not need to follow this reasoning, but countries could still be hesitant to enact domestic regulation to avoid an investment dispute.²²⁶

ii. FET Claims Can Prevail Against Tobacco Regulation

FET claims regarding plain package tobacco laws are even more problematic than expropriation claims with regard to TRIPS flexibilities. In particular, a country could have TRIPS-consistent laws according to a WTO panel, yet nonetheless be liable for millions of dollars if an investment tribunal is sympathetic to the claim that FET can be based on a "legitimate expectation" of TRIPS compliance that is consistent with corporate interpretation of TRIPS.²²⁷ Although Philip Morris made this claim in its dispute against Australia, there was no decision on the merits since that dispute was dismissed. In the Uruguay case, Philip Morris did argue a legitimate expectation—but only that the laws would remain stable, and not based on TRIPS compliance. So, even though a majority of the Uruguay tribunal ruled in favor of Uruguay, there is still no decision on whether a company has a legitimate expectation of TRIPS compliance. The Uruguay tribunal suggested that legitimate expectations should be based on specific representations.²²⁸ However, other

223. In addition, the tribunal found inadequate expropriation based on evaluating the business as a whole which did not suffer losses. *Id.* ¶¶ 283–84.

224. *Id.* ¶¶ 291–307.

225. *Id.* ¶¶ 301–06.

226. *Id.* (noting countries that have declined to enact plain package tobacco laws for fear of investment suits).

227. Although one tribunal has stated that companies should not have a legitimate expectation that tobacco regulations remain static, not only need subsequent tribunals not follow that, but also it would have no impact on a FET claim premised solely on alleged TRIPS violation. *See Grand River Enter. Six Nations, Ltd. v. United States*, Award (NAFTA/UNCITRAL Arb. Trib. 2011).

228. *P.M. v. Uru.*, Award, *supra* note 203, ¶ 376.

tribunals have sometimes found violations of FET claims without specific representations to an investor, or implied commitments from general legislation or government statements to the public.²²⁹ Although some have suggested that tribunals may be inclined to require a specific representation in recent cases, a tribunal need not follow this approach and this is particularly true since many FET claims are asserted under agreements that have limited guidance concerning FET claims.²³⁰ Divergent interpretations of identical trademark articles of TRIPS seem likely not only because investment tribunals are not bound to follow WTO law, but because of different views on how key TRIPS provisions should be interpreted, as discussed below.

While a full analysis of the many TRIPS provisions cited is beyond the scope of this Article given other issues, a brief overview should be adequate to underscore the likelihood of conflicting rulings with the WTO case, or at least a challenge to TRIPS norms.²³¹ There are two TRIPS articles for which there are vastly different interpretations. One open issue is whether a nation would implicitly violate TRIPS Article 15 concerning obstacles to registration if it permitted registration, but barred use of the mark.²³² The second contested issue is whether plain packaging requirements violate TRIPS Article 20 that bars trademarks from being “unjustifiably encumbered” by special requirements. Although the Uruguay tribunal interpreted TRIPS Article 20 in a manner favorable to countries desirous of tobacco regulation, other panels need not follow the decision and, as explained below, it is possible that they may not.

Although TRIPS Article 15 is about registration, there is a substantial dispute concerning whether the owner of a trademark has an affirmative right to use with a registered trademark. Philip Morris and a number of other attorneys have asserted that plain package regulations inherently violate TRIPS Article 15.4 which bars obstacles to registration based on the nature of goods to which a trademark is applied since registration includes an implicit right to use.²³³ The argument is

229. *E.g.*, *Tecnicas Medioambientales Tecmed, S.A. v. The United Mexican States*, ICSID Case No. ARB(AF)/00/2, Award, ¶ 154 (May 29, 2003); *CMS Gas Transmission Company v. The Republic of Argentina*, ICSID Case No. ARB/01/08, Award, ¶ 277 (May 12, 2005); *Enron Corporation and Ponderosa Assets, L.P. v. Argentina Republic*, ICSID Case No. ARB/01/03, Award, ¶ 264 (May 22, 2007); *National Grid plc v. The Argentine Republic*, UNCITRAL, Award, ¶¶ 176–79 (Nov. 3, 2008).

230. *E.g.*, Caroline Henckels, *Balancing Investment Protection and the Public Interest: The Role of the Standard of Review and the Importance of Deference in Investor-State Arbitration*, 4 J. INT'L DISP. SETTLEMENT 197, 38 (2012).

231. Others have also noted that views on whether plain package measures comply with TRIPS “vary greatly.” *E.g.*, Mercurio, *Awakening*, *supra* note 55, at 900.

232. TRIPS, *supra* note 6, art. 15.4 (“nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of a trademark”).

233. *P.M. v. Austl.*, Notice of Arbitration, *supra* note 1, ¶ 6.11; *e.g.*, Julius L. Katz & Richard G. Dearden, *Plain Packaging & International Trade Treaties*, in *PLAIN PACKAGING & INTERNATIONAL TRADE TREATIES* 111 (J.C. Luik ed., 1998); Carmela Rotundo Zocco, *Plain Packaging: A Growing Threat to Trademark Rights*, LES NOUVELLES 140 (2013); Stephen Stern & Olivia Draudins, *Generic Packaging—A Bridge (Over the Bodies of IP Rights) Too Far?*, AUSTL. INTELL. PROP. L. BULL. 146 (2011).

premised on the fact that plain packaging targets only tobacco products. However, a number of scholars contest this position and note that there is no TRIPS provision that permits an affirmative right to use.²³⁴ This is also buttressed by a prior WTO panel decision, as well as traditional trademark law that does not consider trademarks to provide an affirmative right to use.²³⁵ Nonetheless, two scholars suggest that the “spirit” of the provision at least makes this a close case.²³⁶ Considering that tribunals sometimes broadly interpret claims in favor of investors and generally lack any knowledge of intellectual property law as commercial lawyers, it seems that an investment tribunal could find this provision violated. That said, although this provision was not at issue in the Uruguay case, the Uruguay reasoning concerning Article 20 suggests that it is also possible, although not guaranteed, for a tribunal to interpret this to bar an affirmative right to use.

Another contested issue is the TRIPS article that permits trademarks to be regulated, but not *unjustifiably encumbered* by special requirements, such as use in a manner that would negatively impact its ability to distinguish the goods or services of one from another.²³⁷ According to Philip Morris, plain packaging clearly encumbers its trademarks since it is barred from using logos and also restricted in the size of trademarks on the package, such that its product cannot be distinguished from others except as to price.²³⁸

There are two different issues with this TRIPS provision. Some claim that it does not apply to a law that would completely bar a use.²³⁹ However, others argue that it is illogical and inconsistent with treaty interpretation norms to interpret this provision as prohibiting some encumbrances, but not complete bans.²⁴⁰ In addition, even assuming that plain packaging is a “special form” to which Article 20 applies, Australia as well as many others assert that the rules are *justified*.²⁴¹ After all, plain

234. E.g., Mark Davison & Patrick Emerton, *Rights, Privileges, Legitimate Interests and Justifiability: Art 20 of TRIPS and Plain Packaging of Tobacco*, 29 AM. U. INT’L L. REV. 505 (2014); Benn McGrady, *TRIPS and Trademark: The Case of Tobacco*, 3 W. TRADE REV. 53 (2004); Alberto Alemanno & Enrico Bonadio, *Do You Mind My Smoking? Plain Packaging of Cigarettes Under the TRIPS Agreement*, 10 J. MARSHALL REV. INTELL. PROP. L. 450 (2011); Mercurio, *Awakening*, *supra* note 55; *see also* TRIPS, *supra* note 6 (only providing a right to exclude third parties, but not a right to use).

235. Panel Report, *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, at ¶ 7.611, WTO Doc WT/DS290/R (Mar. 15, 2005) (in discussing Article 24.5 of TRIPS, where it provides that certain measures “shall not prejudice . . . the right to use a trademark”); *JT Int’l SA v Commonwealth* [2012] HCA 43 (Austl.).

236. E.g., Susy Frankel & Daniel Gervais, *supra* note 198; *see also* Annette Kur, *The Right to Use One’s Own Trade Mark: A Self-Evident Issue*, EIPR (1996) (supporting argument that trademarks have a right to use, although not regarding the *Philip Morris* case in particular); PATRICK BASHAM ET AL., ERASING INTELLECTUAL PROPERTY: PLAIN PACKAGING FOR CONSUMER PROTECTION AND THE IMPLICATIONS FOR TRADEMARK RIGHTS (2011).

237. TRIPS, *supra* note 6, art. 20.

238. P.M. v. Austl., Notice of Arbitration, *supra* note 1, ¶ 6.8.

239. E.g., McGrady, *supra* note 235, at 62–63.

240. Frankel & Gervais, *supra* note 198, at 1172.

241. Australia’s Response to Notice of Arbitration, *supra* note 204, ¶¶ 33–35, 46, 49; Davison & Emerton, *supra* note 235; McGrady, *supra* note 234; Alemanno & Bonadio, *supra* note 234, at 463–

package tobacco laws such as Australia's have been endorsed by both the WHO and the Convention Secretariat of the WHO Framework Convention on Tobacco Control.²⁴² There are also studies that suggest such laws will reduce smoking rates.²⁴³ Not surprisingly, critics of plain package tobacco disagree;²⁴⁴ they also assert that such laws are not the least restrictive means, and the laws will increase illicit trade in tobacco products.²⁴⁵ The Uruguay tribunal did not engage in all of these issues since it found that Article 20 simply did not provide an affirmative right to use a trademark. However, it is unclear whether another tribunal would agree.

2. *Eli Lilly*

Eli Lilly has initiated the first investor-state claim that specifically threatens patent flexibilities under TRIPS.²⁴⁶ Similar to Philip Morris, Eli Lilly only initiated an investment claim after exhausting its domestic recourse. Eli Lilly began with a

66; Andrew Mitchell & David Studdert, *Plain Packaging of Tobacco Products in Australia: A Novel Regulation Faces Legal Challenge*, 307 J. AM. MED. ASSOC. 261 (2012).

242. World Health Organization [WHO], *Submission of the World Health Organization Re: Australia Plain Packaging Legislation* (June 2011); World Health Organization [WHO] Framework Convention on Tobacco Control, *Submission by the Convention Secretariat in Respect of Australia's Draft Tobacco Plain Packaging Bill 2011* (June 6, 2011).

243. E.g., Rachel Pechey et al., *Impact of Plain Packaging of Tobacco Products on Smoking in Adults and Children: An Elicitation of International Experts' Estimates*, 13 BMC PUB. HEALTH 1 (2013); Melanie Wakefield et al., *Australian Adult Smokers' Responses to Plain Packaging with Larger Graphic Health Warnings 1 Year After Implementation: Results from a National Cross-Sectional Tracking Survey*, 24 TOBACCO CONTROL ii17 (2015).

244. E.g., P.M. v. Austl., Notice of Arbitration, *supra* note 1, ¶ 6.4 (Philip Morris claims there is no credible evidence that plain packaging will reduce smoking prevalence or that it will increase effectiveness of health warning); *Researchers Find No Evidence Plain Packaging "Experiment" Will Cut Smoking*, PHILIP MORRIS INT'L, http://www.pmi.com/eng/media_center/Pages/plain_packaging_experiment.aspx [https://perma.cc/FYF6-3DHT] (last visited Mar. 24, 2016). *But see* Sarah Bosley, *If Plain Packaging Does not Deter Smoking, Why Was Industry Against It*, GUARDIAN, (Jan. 22, 2015, 6:35 PM), <http://www.theguardian.com/society/2015/jan/22/plain-packaging-not-deter-smokers-big-tobacco> [https://perma.cc/7CMP-XSGL] (noting that Philip Morris has funded studies to prove its point and that if it actually believed there was no impact, it would not so aggressively argue against plain packaging).

245. There is also disagreement on whether plain packaging might result in an increase in illicit trade in tobacco products. E.g., K. A. Evans-Reeves et al., *It Will Harm Business and Increase Illicit Trade: An Evaluation of the Relevance, Quality and Transparency of Evidence Submitted by Transnational Tobacco Companies to the UK Consultation on Standardized Packaging 2012*, TOBACCO CONTROL (Dec. 3, 2014), <http://tobaccocontrol.bmj.com/content/early/2014/11/28/tobaccocontrol-2014-051930> [https://perma.cc/KU7X-LHX3] (finding evidence submitted to UK by tobacco companies not persuasive since all information was not independent); Philip Morris Ltd., *Response to UK Consultation on Standardised Packaging*, PHILIP MORRIS INT'L (Aug. 7, 2014), http://www.pmi.com/eng/tobacco_regulation/submissions/Documents/UK%20-%20%20Standardised%20Packaging%20Submission%20PML.pdf [https://perma.cc/D244-KJZJ].

246. See, e.g., PUB. CITIZEN, U.S. *Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada's Patent Policy, Demand \$100 Million for Invalidation of a Patent* (2013), <http://www.citizen.org/documents/eli-lilly-investor-state-factsheet.pdf> [https://perma.cc/APK9-95UP]; Carlos M. Correa, *Investment Agreements: A New Threat to the TRIPS Flexibilities*, SOUTH CENTRE (May 13, 2013), <http://www.southcentre.int/question/investment-agreements-a-new-threat-to-the-trips-flexibilities/> [https://perma.cc/Y23Y-GFLE].

notice of intent to arbitrate in November 7, 2012.²⁴⁷ The actual notice of arbitration was filed on September 12, 2013 and included claims for expropriation as well as breach of minimum standards of treatment, including fair and equitable treatment.²⁴⁸

a. Factual Context

The investment claims are premised on judicial invalidation of Eli Lilly patents for two commercially successful drugs sold under the names Strattera and Zyprexa for failing to meet the “promise doctrine,” a judicial interpretation of the core patent requirement of utility.²⁴⁹ This doctrine only applies when a patent applicant, such as Eli Lilly, “promises” that an invention will have a particular purpose.²⁵⁰ An application satisfies the promise doctrine if it discloses data to support the promise.²⁵¹ Eli Lilly had to make such promises because it had already received at least one full term of patent protection for the basic chemical compound underlying each drug and was seeking additional protection after earlier patents expired.²⁵² The invalidated patent on Strattera was found to fail to satisfy its promise of treating Attention Deficit Hyperactivity Disorder (ADHD) as a chronic condition because it failed to include any data to establish that it would be efficacious for long-term use.²⁵³ The invalidated patent on Zyprexa was also found to promise a superior treatment for long term treatment of psychosis without supporting data.²⁵⁴

Although Eli Lilly has complained that Canada’s law is unique and unprecedented,²⁵⁵ a number of scholars note that other countries effectively require patent applications to make the same showing, but simply under a different, yet universally recognized patent standard, such as whether its description is adequate.²⁵⁶ In addition, it is consistent with longstanding and universally

247. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven (Nov. 7, 2012), <http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf> [<https://perma.cc/WN67-L92V>].

248. *Eli Lilly* Notice of Arbitration, *supra* note 1.

249. *Id.*

250. *See, e.g.*, *Eli Lilly Can. Inc. v. Novopharm Ltd.*, [2012] 1 F.C.R. 349, ¶ 76 (Can.).

251. *Id.*

252. *See, e.g.*, *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Canada Statement of Defence ¶ 53 (NAFTA/UNCITRAL Arb. Trib. June 30, 2014), <http://www.italaw.com/sites/default/files/case-documents/italaw3253.pdf> [<https://perma.cc/E5F2-D2W4>] [hereinafter *Canada Statement of Defence*].

253. *See* *Novopharm Ltd. v. Eli Lilly & Co.* [2010] F.C. 915 (Can. Ont.).

254. *See* *Eli Lilly Can. Inc. v. Novopharm Ltd.*, [2011] F.C. 1288, ¶ 218 (Can. Ont.).

255. *See, e.g.*, *Eli Lilly* Notice of Arbitration, *supra* note 1, ¶¶ 96, 98, 107.

256. *See, e.g.*, *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Expert Report of Timothy R. Holbrook, (Jan. 26, 2015), <http://www.italaw.com/sites/default/files/case-documents/italaw4137.pdf> [<https://perma.cc/DZ8T-P3F7>]; *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Second Expert Report of Timothy Holbrook, (Dec. 5, 2015) <http://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207020.pdf> [<https://perma.cc/G3N9-J7F5>]; Dimtry Karshedt, *The Completeness Requirement in Patent Law*, 56 B.C.L. REV. 949; Gold & Shortt, *supra* note 25, at 53–57, 61–77; *id.* But *see* *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Application for Leave to File A Non-Disputing Party Amicus Curiae Submission By

recognized patent policy to mandate disclosure of something valuable to justify the social cost of a patent, such as higher prices during the term of the patent.²⁵⁷

Canada's promise doctrine can be considered a type of TRIPS flexibility. The basic notion of TRIPS flexibilities is that countries can provide their own interpretation of key patentability requirements that are undefined to limit patents to truly deserving inventions and promote access to lower cost drugs.²⁵⁸ Although proponents of these flexibilities typically suggest interpreting the terms "invention" or "new," any core patentability requirement that is undefined in TRIPS can provide flexibility.²⁵⁹ So, although atypical among most countries, Canada's promise doctrine interpreting the requirement of "useful" is a type of TRIPS flexibility.

Canada's promise doctrine addresses a key issue in the pharmaceutical industry that is of particular concern to those who advocate using TRIPS flexibilities. In particular, the industry has a practice of sequentially patenting minor modifications or different uses of a drug after first obtaining a patent on the basic chemical compound in an attempt to maximize revenue.²⁶⁰ The industry considers this appropriate "life cycle management."²⁶¹ However, public health advocates, as well

Intellectual Property Law Professors, (Feb. 12, 2016), <http://www.italaw.com/sites/default/files/case-documents/italaw7107.pdf> [<https://perma.cc/2NXW-5WZB>] (opposing view by seven law professors). However, as explained by Canada, the opposing view of these law professors is not supported. *See* Government of Canada Observations on Issues Raised in Amicus Submissions, Case No. UNCT/14/2, April 22, 2016.

257. *See, e.g.*, *Brenner v. Manson*, 383 U.S. 519, 535–36 (1966) ("[A] patent is not a hunting license."); *Eli Lilly Can. Inc. v. Novopharm Ltd.*, [2012] 1 F.C.R. 349, ¶ 70 (Can.).

258. *See, e.g.*, WIPO, Committee on Development and Intellectual Property, Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels, CDIP/5/4 Rev., at 10–11 (Aug. 18, 2010); GERMÁN VELÁSQUEZ, SOUTH CENTRE, GUIDELINES ON PATENTABILITY AND ACCESS TO MEDICINES (2015), http://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_EN.pdf [<https://perma.cc/TXJ9-HXJA>]; SERGEY KONDRATYUK ET AL., EAST EUROPE & CENTRAL ASIA UNION OF PEOPLE LIVING WITH HIV, IMPLEMENTATION OF TRIPS PUBLIC HEALTH FLEXIBILITIES TO IMPROVE ACCESS TO MEDICINES IN BELARUS, GEORGIA, MOLDOVA AND UKRAINE 15–17 (2013), http://ecuo.org/media/filer_public/2013/12/26/analytical_report_ecuo_trips_eng.pdf [<https://perma.cc/L8WV-TH56>].

259. Indeed, some have suggested that any of the patentability requirements can be interpreted to promote flexibility, although not specifically suggesting a provision similar to Canada's. *E.g.* SISULE F. MUSUNGU & CECILIA OH, COMM'N ON INTELLECTUAL PROP. RIGHTS, INNOVATION AND PUB. HEALTH, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 34 (2005), <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> [<https://perma.cc/GHP5-MGAL>]; UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 358–361 (2005); Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 3–4 (World Health Organization [WHO] et al., Working Paper 2006).

260. *See, e.g.*, JOHN R. THOMAS, CONG. RESEARCH SERV., R40917, PATENT "EVERGREENING": ISSUES IN INNOVATION AND COMPETITION (2009); Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CAN. MED. ASSOC. J. E385 (2013); Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 HOUS. J. HEALTH L. & POL'Y 379 (2007).

261. *See, e.g.*, TONY ELLERY & NEAL HANSEN, PHARMACEUTICAL LIFECYCLE MANAGEMENT: MAKING THE MOST OF EACH AND EVERY BRAND (2012); Vandana Prajapati et al.,

as some governments including not only India, but also the EU, consider this to be an inappropriate way of “evergreening” patent profits.²⁶² Eli Lilly’s patents illustrate how Canada’s promise doctrine addresses this problem. Both of the invalidated patents were attempts to obtain additional patent protection after the original patent on the underlying chemical compound had expired. Moreover, Eli Lilly did not even make any modifications to the compound, but instead simply attempted to claim that it had a new use without any basis for that claim.²⁶³

b. Investment Claims

The *Eli Lilly* case will apparently not result in a complete collision between investment claims and TRIPS since the tribunal just ruled unanimously in favor of Canada.²⁶⁴ However, analyzing the details of the case, including the potential harm of investment claims to TRIPS norms is important since this decision is not binding on any future investment tribunal. In addition, even though Canada ultimately prevailed, including recoupment of some costs, the fact that Canada still had to engage in multi-year litigation and nonetheless pay some costs, with the risk of losing millions could be enough to have a chilling effect on the use of TRIPS flexibilities.²⁶⁵ This is especially true for developing countries that have fewer resources than Canada. Accordingly, this Section will explain Eli Lilly’s arguments and how the expropriation and FET claims could have a major chilling effect on TRIPS in a subsequent case, even though they were rejected here. In analyzing the potential impact on TRIPS flexibilities, it should be noted that although Eli Lilly’s claim were not based solely on breach of TRIPS, some investment claims were premised on breach of NAFTA provisions that are identical to TRIPS.²⁶⁶

Before discussing the specific investment claims at issue, it may be relevant to consider some specifics of the tribunal decision. Unlike the Uruguay decision, which had discrete sections on expropriation versus FET claims, the tribunal considered a number of issues as necessary pre-requisites before considering the details of the

Product Lifecycle Management Through Patents and Regulatory Strategies, 13 J. MED. MARKETING 171 (2013).

262. *E.g.*, *Novartis Ag v. Union Of India & Ors.*, (2013) 6 SCC 1 (India); TONY HARRIS ET. AL., PHARMACEUTICAL PATENTS REVIEW REPORT, at x (2013), https://www.ipaustralia.gov.au/sites/g/files/net856/f/2013-05-27_ppr_final_report.pdf [<https://perma.cc/V2WP-YC42>]; Nathalie Vernaz et al., *Patented Drug Extension Strategies on Health Care Spending: A Cost-Evaluation Analysis*, 10 PLOS MED. 1 (2013); *Commission Preliminary Report on Pharmaceutical Sector Inquiry*, (Nov. 28, 2008), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [<https://perma.cc/4K23-X6N7>].

263. *See, e.g.*, Canada Statement of Defence, *supra* note 252, ¶ 4.

264. *Eli Lilly v. Canada*, Final Award, Mar. 16, 2017 [hereinafter *Eli Lilly*, Award].

265. *See id.* ¶ 480 (requiring Canada to pay twenty-five percent of its legal costs).

266. *Eli Lilly* has also claimed that Canada is in breach of the Patent Cooperation Treaty. *See Eli Lilly Notice of Arbitration*, *supra* note 1, ¶ 45. However, this does not directly address TRIPS flexibilities and is also substantively incorrect. *See, e.g.*, Ho, *supra* note 110, at 241–42.

investment claims.²⁶⁷ For example, the tribunal first rejected Canada's argument that judicial decisions were immune from the pending investment claims unless there was a denial of justice. The tribunal also addressed two factual questions as essential predicates to Eli Lilly's investment claims. In particular, the tribunal evaluated whether (a) there was a dramatic change in Canada's utility requirement, as well as (b) whether the utility requirement as applied to Eli Lilly's patents were arbitrary and/or discriminatory.²⁶⁸ Since the tribunal found Eli Lilly failed to establish that either of these factual predicates existed, it did not need to assess the details of the expropriation and FET claims. Accordingly, many of the most concerning threats to TRIPS flexibilities in this case have been temporarily avoided. Indeed, PhARMA, the lobbying group for pharmaceutical companies issued a press release expressing disappointment that the ruling failed to address whether Canada's law complied with NAFTA, and, by implication, TRIPS.²⁶⁹ So, in other words, PhARMA was hoping that the dispute would in fact limit existing TRIPS flexibilities. Although that has not come to pass, the underlying facts can still be used to explain how TRIPS flexibilities may be systematically threatened in another case.

i. Expropriation

Eli Lilly made two claims for expropriation: (1) that the patents were directly expropriated (because the rights were taken away), and/or (2) that the patents were indirectly expropriated (because the judicial invalidations destroyed the value of the patents).²⁷⁰ Eli Lilly also alleged that although there is a specific exclusion from expropriation for intellectual property rights that are revoked, this does not apply because the patent rights were revoked inconsistently with NAFTA patent requirements.²⁷¹ This Section will focus on how the expropriation claims could have potentially challenged TRIPS flexibilities.²⁷² After all, even though the tribunal ruled in favor of Canada, a subsequent tribunal would not be bound to this decision. In addition, even the positive ruling for Canada does not mean that there is no threat to TRIPS flexibilities. To the contrary, Canada and other WTO members were simply fortunate that Eli Lilly failed to satisfy its necessary burden of proof, such

267. *E.g.*, Eli Lilly, Award, *supra* note 264, ¶ 110 (noting organization of tribunal analysis). The tribunal first evaluated whether jurisdiction was proper before any of these issues, although that is not pertinent to TRIPS issues.

268. *Id.*; *see also* ¶ 307 (noting that parties agree a “[d]ramatic change” in the utility requirement is a fundamental question and that Eli Lilly confirmed that it must establish this to win).

269. Pharma, Press Release, Pharma Statement on NAFTA Tribunal Decision in the Eli Lilly Case, (Mar. 21, 2017), <http://www.phrma.org/press-release/phrma-statement-on-nafta-tribunal-decision-in-the-eli-lilly-case> [<https://perma.cc/3KG3-ZH8Y>].

270. *See* Eli Lilly Notice of Arbitration, *supra* note 1, ¶ 102.

271. In particular, Eli Lilly alleges that the promise doctrine did not exist when the initial patents were issued, such that the exception does not apply. *See, e.g.*, Eli Lilly Notice of Arbitration, *supra* note 1, ¶ 69. However, there are disputes both as to whether the promise doctrine has been long in existence, as well as how to interpret the NAFTA exception. *See, e.g.*, Gold & Shortt, *supra* note 25, at 38, 50 (long-standing doctrine); Ho, *supra* note 110, at 259–60 (arguing that Eli Lilly's claim should be rejected).

272. However, for details on expropriation, see Ho, *supra* note 110.

that there was no need for the tribunal to address issues that could have conflicted with TRIPS norms.

An initial issue at the intersection of TRIPS and investment claims is that Eli Lilly argued that the exemption from expropriation for TRIPS-consistent claims permits an investment tribunal to decide TRIPS disputes. Even though Australia had argued that investment tribunals have no jurisdiction to decide TRIPS disputes and even though NAFTA has an explicit exception from expropriation for revocation of patent rights consistent with NAFTA (and inherently TRIPS), did not halt the dispute between Eli Lilly and Canada. Of course, Canada did not make the same objection as Australia; although it did suggest that the tribunal lacks jurisdiction to rule on breaches of international treaties such as TRIPS, it did not suggest that the dispute should be entirely dismissed on this ground.²⁷³ However, even if it had, it is unclear whether a tribunal would be sympathetic to this argument. Although a few commentators have suggested that there should be no jurisdiction, the actual text could provide a basis for a tribunal to determine whether Canada's actions are consistent with NAFTA, and by implication TRIPS, which could be why Canada did not suggest that there was no jurisdiction on this ground.²⁷⁴

Eli Lilly's assertion that the revocation of its patents was inconsistent with NAFTA could have created a critical challenge for TRIPS flexibilities. NAFTA has the same requirements for patents as TRIPS in that patents on inventions must be granted when they are "useful," among other requirements, but without defining this term; so Eli Lilly essentially challenged TRIPS patentability requirements.²⁷⁵ Eli Lilly made several arguments concerning this term. Initially, it argued that the undefined term "useful" should mean what is stated in the Oxford Dictionary and that any ambiguity should be resolved by referring to the laws of the United States and Europe which allegedly formed the basis for these terms during the negotiating process.²⁷⁶ Although WTO panels do often consult the Oxford Dictionary, that is simply a starting place for assessing the ordinary and customary meaning of terms consistent with interpretation of terms under customary interpretation of international laws.²⁷⁷ There is no precedent for suggesting that international

273. *E.g.*, Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Counter Memorial, ¶¶ 209–10 (Jan. 27, 2015) [hereinafter Eli Lilly, Counter Memorial], <http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf> [https://perma.cc/CWU5-3YWV].

274. *E.g.*, Frankel, *supra* note 114; *see also* NAFTA, *supra* note 40, art. 1110(7) (providing exception to expropriation for intellectual property rights revoked "consistent" with the NAFTA chapter on intellectual property). Canada raised a totally different jurisdictional objection based on timing of the claim, which the tribunal considered unfounded. *See* Eli Lilly, Counter Memorial, *supra* note 273.

275. *Compare* NAFTA, *supra* note 40, art. 1709, *with* TRIPS, *supra* note 6, art. 27.

276. *See* Eli Lilly Notice of Arbitration, *supra* note 1, ¶¶ 9–10 (quoting dictionary to support that "useful" means "able to be used for a practical purpose or in several ways.>").

277. *See* Andreas Sennekamp & Isabelle Van Damme, *A Practical Perspective on Treaty Interpretation: The Court of Justice of the European Union and the WTO Dispute Settlement System*, 3

agreements should be interpreted based on prior laws of members that were not included in the agreement.²⁷⁸ Then, in its notice of arbitration, Eli Lilly suggested that its drugs should be useful because they were consistent with the patent examination guidelines in effect when Eli Lilly's disputed patents were issued, and that Canada's modification of its patent laws since then to be "out of step" with NAFTA members is improper.²⁷⁹ However, the fact that Canada's laws are different than those of other NAFTA and WTO member countries is explicitly contemplated by the minimum standards of TRIPS. In addition, as other scholars have noted, patent law has never been static and in fact new innovations often require reinterpretation of relevant statutes, including reweighing of public and private interests, such that corporate investors should expect modifications in the law.²⁸⁰ Although the panel did not technically address this issue, it did not consider differences in member state laws to be necessarily of relevance.

Although the panel did not technically address whether Canada's laws comply with NAFTA, and thus TRIPS, it did provide some interesting statements. For, example, in rejecting Eli Lilly's suggestion that Canada's unique law is inherently significant, the tribunal noted that "it is difficult to see how a comparison across jurisdictions can demonstrate a change over time within a single jurisdiction."²⁸¹ In addition, the tribunal noted that although Eli Lilly assumes common law decisions "must follow in a reasonably foreseeable and predictable channel, without significant or material changes," in fact, "evolution of the law through court decisions is natural, and departures from precedent are to be expected."²⁸² Both of these statements seem consistent with TRIPS flexibilities. Of course, whether other tribunals will follow suit remains to be seen.

In addition, a different type of TRIPS flexibility was potentially vulnerable based on Eli Lilly's claim that the promise doctrine discriminates against pharmaceuticals as a field of technology in violation of NAFTA and TRIPS.²⁸³ WTO jurisprudence makes an important distinction between legitimate differentiation and improper discrimination, which is also supported by the

CAMBRIDGE J. INT'L & COMP. L. 489, 498 (2014) (dictionary as starting point for interpretation, but not complete source).

278. See *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Second Report of Dr. Daniel Gervais, ¶ 17 (Dec. 7, 2015) <http://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207018.pdf> [<https://perma.cc/73ZP-ZMYM>].

279. *Eli Lilly Notice of Arbitration*, *supra* note 1, ¶¶ 8–9. Canada continues to suggest that Canada's different definition of "useful" for some inventions is necessarily suspect for being different from NAFTA partners and because it has not been traditionally a patentability requirement for which there were different views. *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Claimant's Post-Hearing Memorial (July 25, 2016) ¶¶ 48, 62–146 (NAFTA partners), 166–175 (no prior international disagreement), <http://www.italaw.com/sites/default/files/case-documents/italaw7465.pdf> [<https://perma.cc/4VKD-ZQKG>].

280. Dreyfuss & Frankel, *supra* note 130, at 591.

281. *Eli Lilly, Award*, *supra* note 264, ¶ 377.

282. *Id.* ¶ 310; see also ¶ 324 (noting that although the promise doctrine did not play a significant role before 2005, the rule was clearly "out there", to be ignored at a patentee's peril.).

283. *Eli Lilly Notice of Arbitration*, *supra* note 1, ¶ 52.

Declaration on Regulatory Sovereignty.²⁸⁴ A WTO panel has noted that there is no prohibition against dealing with problems that may exist only in certain product areas.²⁸⁵ Notably, the panel stated that even when a country intended to regulate a particular area, it did not constitute implicit discrimination since “preoccupation” with the impact of a law to one area is not discriminatory unless there is evidence that the broader purpose is a “sham.”²⁸⁶ There is nothing to indicate that the promise doctrine is a “sham.” Indeed, the Canadian Manual of Patent Procedure uses a mechanical example in discussing this doctrine.²⁸⁷ The fact that more pharmaceutical patents are invalidated could simply reflect that the industry is violating the doctrine, rather than indicating that the doctrine discriminates against the industry.²⁸⁸

The tribunal decision is consistent with prior WTO jurisprudence, even though there was nothing to indicate that this was a goal of the tribunal. In particular, the tribunal ruled that Eli Lilly’s statistical data did not support its claim of improper discrimination that would give rise to a claim for violation of international minimum standards of treatment, or fair and equitable treatment. The tribunal noted that at most, Eli Lilly had shown a relationship between the promise doctrine and higher invalidity rates in the pharmaceutical sector; there was nothing to support a claim of improper discrimination. For example, the tribunal noted that Canada’s argument that the patent practices of pharmaceutical companies could result in more challenges was plausible²⁸⁹ and that there is no basis to infer discriminatory intent.²⁹⁰

Although there was never a parallel WTO proceeding to the *Eli Lilly* investment case, this case could have presented a greater systemic challenge than the Philip Morris disputes. After all, while TRIPS flexibilities have been repeatedly noted as important for patents, the trademark provisions in the *Philip Morris* case have not typically been discussed as an essential part of TRIPS flexibilities. In addition, the *Eli Lilly* case was the first challenge to TRIPS flexibilities on patentability that could have resulted in an interpretation of TRIPS by an

284. E.g., *Declaration on Patent Protection*, *supra* note 9, ¶¶ 6–8; see also Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. & TECH. L. REV. 445, 450–53 (2007) (agreeing with differentiation goal and further arguing that there should be no discrimination so long as there is a legitimate purpose demonstrated).

285. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 7.92, WTO Doc. WT/DS114/R (adopted Mar. 17, 2000).

286. *Id.* ¶ 7.104.

287. CANADIAN INTELLECTUAL PROPERTY OFFICE, K1A 0C9, MANUAL OF PATENT OFFICE PRACTICE (2016), ¶ 12.08.

288. Indeed, it has long been recognized that uniform patent standards may result in different application to different technologies. See, e.g., Dan Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003).

289. *Eli Lilly*, Award, *supra* note 264, ¶ 435.

290. *Id.* ¶ 438.

international body.²⁹¹ In the over twenty years since TRIPS was concluded, countries have notably been cautious in challenging TRIPS flexibilities at the WTO.²⁹² For example, even the United States, which generally robustly argues for broad IP interpretations, has not alleged that Canada's laws violate TRIPS; the United States has only noted a concern for potential innovation²⁹³ despite corporate claims that TRIPS has been violated.²⁹⁴

The outcome of the *Eli Lilly* dispute was unclear even after Uruguay prevailed against Philip Morris' claims of expropriation, since the analysis of the Uruguay tribunal—even if adopted—would not necessarily have provided immunity to Canada's ability to use TRIPS flexibilities. Notably, Uruguay's tobacco regulations were considered within its police power to protect public health.²⁹⁵ This is not surprising since the regulations are consistent with the WHO Framework Convention on Tobacco Control guidelines and no one contests that tobacco use is harmful. In contrast, there is no uniform view of whether more patents on drugs negatively impacts public health to support Canada's interpretation of "useful" to make it more difficult to obtain subsequent patents on a drug. Although public health advocates have vigorously argued that additional patents such as those obtained by Eli Lilly do not promote public health and therefore should not be granted, limiting patent rights in such a situation is very different than limiting trademarks on tobacco, a product that has universally admitted lethal consequences. Revocation of the patents at issue would not protect consumers from the same type of lethal consequences as more limited use of tobacco. Also, Canada's judicial interpretation of what is "useful" is unlike most public health issues found to be within the scope of domestic police power, which typically is associated with protecting the public from immediate public health harms, such as regulatory

291. Of course, there is an earlier WTO panel decision regarding the scope of the "limited exception" to TRIPS patent rights under article 30. But, there is no panel report regarding basic patentability under TRIPS article 27. Although the United States did initiate a dispute that alleged that Brazil's "local working" requirement violated TRIPS, including article 27, the parties settled this case. Brazil v. U.S., Notification of Mutually Agreed Solution, July 5, 2001. Some scholars have suggested that initiation of a subsequently abandoned WTO dispute may nonetheless create a chilling effect on use of TRIPS flexibilities. *E.g.*, Dreyfuss & Frankel, *supra* note 130, at 600.

292. For example, although compulsory licensing is frequently contested, no country has ever initiated a TRIPS dispute. Similarly, although India's interpretation of TRIPS patentability requirements under section 3d of its patent laws is regularly criticized, no country has initiated a TRIPS dispute against India either.

293. See MICHAEL B.G. FROMAN, OFFICE OF U.S. TRADE REP., SPECIAL 301 REPORT 66 (2015).

294. PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA, SPECIAL 301 SUBMISSION 81 (2015), <http://www.phrma.org/sites/default/files/pdf/PhRMA-2015-Special-301-Rev.pdf> [<https://perma.cc/4AQ4-ZV94>] (alleging that Canada's interpretation of utility violates TRIPS and NAFTA). Of course, the United States has taken other actions, such as entering into agreements with other countries to raise patent requirements and thus need not directly challenge TRIPS flexibilities at the WTO since it is directly circumventing them through other means.

295. *P.M. v. Uru.*, Award, *supra* note 203, ¶ 382.

measures to prevent an epidemic of infectious disease.²⁹⁶ Even if one accepts that stringent patent standards promote public health by minimizing the harm of unnecessary patent profits that made drugs unaffordable, this public health goal is more attenuated and different than other previously recognized public health harms that result in a clear and immediate harm. In addition, police power is traditionally associated with domestic legislation and regulation, not judicial interpretation. Also, the Uruguay tribunal accepted the amicus submissions of major international organizations, such as the WHO that supported Uruguay's interpretation of TRIPS whereas no amicus briefs from similar entities were involved here, although some were filed; moreover, the most detailed proposed amicus brief regarding TRIPS was not accepted by the tribunal simply because it was not authored by citizens of NAFTA member states.²⁹⁷ Even the types of patented drugs involved might seem less essential to public health than tobacco regulation. In particular, although many believe that "essential medicines" should be affordable, the patented drugs in the *Eli Lilly* dispute do not fall in this category.

Canada was fortunate that the tribunal was sympathetic to its "legitimate public policy" for the judicially crafted promise doctrine. The tribunal seemed quite deferential to Canada in assessing whether the doctrine was arbitrary. The tribunal simply reiterated Canada's explanation that the doctrine helps ensure the public receives the benefit of the patent bargain and encourages accuracy. It interestingly noted that it "need not opine on whether the promise doctrine is the only, or the best, means of achieving these objectives. The relevant point is that, in the Tribunal's view, the promise doctrine is rationally connected to these legitimate policy goals."²⁹⁸ Notably, a rational relation to policy goals seems a far lower threshold for a nation to establish than whether action is within traditional police power. The tribunal also noted that it had no role to "question the policy choices" of a nation.²⁹⁹ Moreover, it rejected Eli Lilly's contention that some uncertainty in application of the promise doctrine made it arbitrary; in its view, that is true of all legal regimes.³⁰⁰

296. *Id.* ¶¶ 298–99 (citing *Chemtura Corp. v. Canada*, Award, UNCITRAL ¶ 266 (Aug. 2, 2010); *Methanex Corp. v. United States*, Final Award of the Tribunal on Jurisdiction and Merits, UNCITRAL, Pt. IV, Ch. D, ¶ 7 (Aug. 3, 2005); *Bischoff Case*, Decision, 10 R.I.A.A. 420, 421 (1903)).

297. *See* *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Procedural Order No. 4 (Feb. 23, 2016), [hereinafter *Eli Lilly*, Procedural Order No. 4] <http://www.italaw.com/sites/default/files/case-documents/italaw7145.pdf> [https://perma.cc/27GQ-MZLJ]; *see also* *Eli Lilly & Co. v. Canada*, ICSID Case No. UNCT/14/2, Application for Leave to File Amicus Submissions (Feb. 12, 2016), <http://www.italaw.com/sites/default/files/case-documents/italaw7112.pdf> [https://perma.cc/5PVY-3NXQ].

298. *Eli Lilly*, Award, *supra* note 264, ¶ 424; *see also id.* ¶ 428 (noting that Canada had "advanced a legitimate justification. . . . Whether or not this is the preferred approach, it is plainly not an irrational one.").

299. *Id.* ¶ 426. The panel quoted from Professor Levin that "it is not the role of a NAFTA Chapter Eleven tribunal to question the policy choices of a NAFTA party." *Id.*

300. *Id.* ¶ 429.

The tribunal also found that Canada's application of the promise doctrine was not de facto discriminatory against pharmaceutical patents. The panel noted that Eli Lilly's claim of a causal relationship between the doctrine and higher invalidity rates in the pharmaceutical sector was not supported by the facts.³⁰¹ Eli Lilly's expert could only support the fact that the numbers of invalidations was not due to chance.³⁰² The tribunal noted that it was possible that the practices of such companies result in more challenges on this ground and that although it could not evaluate this claim, this helped to explain why Eli Lilly's claim of causation was lacking.³⁰³

The recent tribunal decision did not focus squarely on Eli Lilly's expropriation claim in the same way as the tribunal in the *Philip Morris* Uruguay decision. Granted, the factual context was different, and there was an initial dispute regarding whether a judicial act could even be the basis for a claim for expropriation or fair and equitable treatment. The tribunal noted that judicial acts are attributable to a state and that it could constitute an expropriation even without an actual denial of justice.³⁰⁴ However, it took care to note that an investment tribunal is not intended to provide an appellate review of domestic judicial decisions with regard to either expropriation or FET claims—a point that it reiterated more than once.³⁰⁵

ii. Fair and Equitable Treatment

Eli Lilly also alleged that Canada violated minimum standards, including fair and equitable treatment because the judicial invalidations are allegedly arbitrary and inconsistent with its legitimate expectation of a stable business and legal environment.³⁰⁶ In particular, Eli Lilly alleged that it could not have anticipated that the Canadian law on utility would be “so drastically altered” and also “retroactively applied” to invalidate its patents.³⁰⁷

Eli Lilly's FET claim is the most significant challenge to TRIPS flexibilities presented in the investment context thus far. Although the expropriation claim also

301. *Id.* ¶¶ 433, 437 (noting that the proposed causal link was based on mere assumptions).

302. *Id.* ¶ 434.

303. *Id.* ¶ 435.

304. *Id.* ¶ 221.

305. *Id.* (“[A] NAFTA Chapter Eleven tribunal is not an appellate tier with respect to national judiciaries.”); *Id.*, ¶ 225 (“[A] NAFTA Chapter Eleven tribunal is not an appellate tier with a mandate to review the decisions of the national judiciary[.]”).

306. Technically, the claim is violation of minimum standard of treatment, which includes fair and equitable treatment. NAFTA, *supra* note 40, art. 1105. However, Eli Lilly's claim does specifically mention violation of fair and equitable treatment. See Eli Lilly Notice of Arbitration, *supra* note 1, ¶¶ 81–82. FET claims that are not linked to international minimum standards of treatment could be considered broader, although even FET linked to a minimum standard of treatment can be broadly interpreted. *E.g.*, Matthew C. Porterfield, *A Distinction Without a Difference? The Interpretation of Fair and Equitable Treatment Under Customary International Law by Investment Tribunals*, INV. TREATY NEWS (Mar. 22, 2013), <https://www.iisd.org/itn/2013/03/22/a-distinction-without-a-difference-the-interpretation-of-fair-and-equitable-treatment-under-customary-international-law-by-investment-tribunals/> [https://perma.cc/965A-5DTK].

307. See Eli Lilly Notice of Arbitration, *supra* note 1, ¶¶ 82–83.

challenged the same law, there is at least an exception to expropriation for revocation of patents consistent with NAFTA and TRIPS provisions. Of course, as noted previously, the application of this exception was disputed and ultimately not even addressed by the tribunal. Nonetheless, there is at least a recognition for expropriation claims that revocation of patent and other intellectual property rights in some instances should not constitute expropriation. In contrast, there is no such exception to FET claims in NAFTA or other investment agreements. Moreover, FET claims tend to be broadly interpreted based on violating “legitimate expectations” of investors.

If the tribunal had found for Eli Lilly, that would likely have completely halted efforts by policy makers to encourage countries to modify domestic laws to better enhance TRIPS flexibilities. Importantly, a negative decision for Canada would have had a major chilling effect on the ability of any country to modify laws to take advantage of TRIPS flexibilities. This would have been contrary to the repeated recommendation of policy makers that nations modify their laws to implement TRIPS flexibilities. In addition, it would have been contrary to the embrace of such flexibilities in the Declaration of Regulatory Sovereignty.³⁰⁸

There were grounds for the tribunal to reject Eli Lilly’s argument that a country can never modify its laws after an agreement or else be found in breach of fair and equitable treatment. In particular, there is no traditional understanding that members to an agreement must not thereafter modify their laws; indeed, multiple policy reports since the conclusion of TRIPS are premised on the assumption that countries can and should modify their laws.³⁰⁹ And, Eli Lilly’s suggestion is in fact contrary to domestic patent law practice in which changes in common law regularly invalidate patents issued under a different standard.³¹⁰ The tribunal properly rejected Eli Lilly’s assumption that common law decisions must “following a reasonably foreseeable and predictable channel without significant or material changes.”³¹¹ Rather, the tribunal noted that common law evolution necessarily involves departures from precedent.³¹² However, the tribunal’s decision was not a foregone conclusion. After all, past tribunals have previously been sympathetic to investor claims, and especially FET claims, although there are no prior cases involving changes in common law. In addition, an early article by a commercial

308. See *Declaration on Patent Protection*, *supra* note 9.

309. See, e.g., *supra* note 8.

310. For example, patents have been invalidated following recent Supreme Court cases narrowing the scope of patentability. *E.g.*, *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 714–16 (Fed. Cir. 2014) (invalidating patent in light of 2014 Supreme Court decision in *Alice Corp.* narrowing patent eligibility after twice finding the patent valid); Steven Seidenberg, *After Alice: Business-method and Software Patents May Go Through the Looking Glass*, 101 A.B.A. J., Feb. 2015, at 19; Donald Vinson, *Key Cases Shaping the Future for Patent Litigation Funders*, LAW 360 (Apr. 27, 2015, 10:13 AM), <http://www.law360.com/articles/646193/print?section=ip> [<https://perma.cc/P5YC-C6MS>] (noting that patent owners may reconsider pursuing infringement in light of the potential for validity challenges).

311. Eli Lilly, Award, *supra* note 264, ¶ 310.

312. See *id.*

lawyer, the type of individual likely appointed an arbitrator by an investor, was sympathetic to Eli Lilly's position.³¹³ Accordingly, the assumption of IP scholars that this claim would necessarily fail was always questionable.³¹⁴

Moreover, even though a majority of the *Philip Morris* tribunal found no FET violation by Uruguay, the reasoning would not have been helpful to Canada against Eli Lilly's claims. First, whereas the majority in the Uruguay panel found that tobacco companies had no legitimate expectation that nations would not modify regulations, it was much less clear that the *Eli Lilly* tribunal would concur.³¹⁵ In addition, although a majority of the tribunal found that Uruguay's two regulations were not arbitrary, one tribunalist contested that the regulation not explicitly recommended by WHO guidelines violated FET. Notably, that tribunalist found it significant that "no other country in the world" had a similar requirement, as well as the fact that there was "no meaningful prior study, internal debate or external consultation."³¹⁶ These arguments seem to mirror what Eli Lilly repeatedly noted—that Canada's law is unique and that the Canadian judiciary allegedly arbitrarily imposed the disputed promise doctrine. In addition, although the dissenting tribunalist recognized that a state could legitimately enact a measure that advances a legitimate governmental objective, it is unclear that a tribunal would find a clear governmental objective in judicial cases mandating a promise doctrine, or that the doctrine in fact supports an objective of public health.³¹⁷ Notably, even though tobacco is a lethal product, the dissenting opinion in the Uruguay case was not persuaded that the "single presentation requirement" actually achieved the purpose of preventing misleading use of trademarks beyond previous laws. Also, although the majority was sympathetic to Uruguay and noted a margin of appreciation to government regulatory acts, the dissent affirmatively rejected the relevance of a margin of appreciation.

Although the reasoning of the Uruguay tribunal did not apply to the Canadian tribunal evaluating Eli Lilly's claim, the latter tribunal still found grounds to reject Eli Lilly's claim—and perhaps provide a glimmer of hope for other disputes. In particular, even though the health impacts of expensive patented drugs are not recognized in the same way as tobacco use, Canada won in a unanimous decision, whereas there was still a dissent to the overall favorable decision to Uruguay. Of course, the tribunal finding in Canada's favor did not characterize the issue as one of whether it is wise to limit patents on drugs that may result in higher cost. Rather, it simply considered whether the stated justification for the domestic law had some basis. If other tribunals used a similar criteria, that would seem to preserve TRIPS

313. See M.L. Seelig, *Can Patent Revocation or Invalidation Constitute a Form of Expropriation?*, 6 TRANS. DISP. MGMT. 1, 8–9 (2009).

314. E.g., Ruse-Khan, *Litigating Intellectual Property Rights*, *supra* note 114.

315. P.M. v. Uru., Award, *supra* note 203, ¶ 430.

316. Philip Morris v. Uru., ICSID Case No. ARB/10/7, Award, Concurring and Dissenting Opinion, ¶¶ 5, 167, (July 8, 2016).

317. *Id.* ¶ 137.

flexibilities. However, as noted earlier, the majority in the Uruguay decision required a higher threshold relating to police power. Of course, future tribunals are not bound to either approach and can adopt yet a different approach that could still encroach upon TRIPS flexibility. For example, the dissent in the Uruguay decision suggested that simply having a different approach than other countries could be suspect. So, while Canada's win is a positive development, it does not ensure that TRIPS flexibilities are immune from conflicts in future investor disputes.

Also, although the *Eli Lilly* tribunal repeatedly noted that it was not intended to provide appellate review of domestic judicial decisions, it nonetheless left open the possibility that some judicial measures *may* give rise to a claim for FET, as well as expropriation. In particular, for FET claims, the tribunal noted that such a claim could exist with respect to a decision that is "egregious and shocking," even while stating that there should be "considerable deference" to domestic courts.³¹⁸ Canada's change in the law was found not to be "dramatic" and thus failed to meet this standard. But, it remains to be seen how other tribunals might view challenges to judicial actions, which is a relatively new area in investor-disputes.

B. Potential Problems

There are a variety of potential conflicts that could arise if investment tribunals adjudicate more claims that touch upon TRIPS flexibilities. Although any TRIPS flexibility is potentially vulnerable to an investment claim, some types of TRIPS flexibilities seem more likely to be subject to such claims. Accordingly, this Section will briefly provide an overview of some flexibilities under the Declaration that are at risk.³¹⁹

1. Patentability Standards

If *Eli Lilly* prevails against Canada on any ground, it will likely have a chilling effect on domestic efforts to tailor patentability standards for any country that is subject to an investment agreement. The chilling effect is actually twofold. First, countries that had been previously considering modifying patent standards to use TRIPS flexibilities may no longer do so for fear of claims of expropriation and, especially, fair and equitable treatment. Worse yet, countries that have laws that take advantage of TRIPS flexibilities, such as India, may feel pressure to jettison such flexibilities to avoid vulnerability for investment claims. Although India has not specifically signaled any intent to modify its patent laws, its 2016 model investment

318. *Eli Lilly*, Award, *supra* note 264, ¶ 224.

319. This is of course not intended to be comprehensive, but, instead explain a range of different types of flexibilities at risk. Another possible TRIPS flexibility at risk is whether countries can impose a "local working" requirement since there was a TRIPS dispute initiated in 2001. However, since that did occur, but did not result in an actual panel report, countries may already be predisposed not to use this flexibility, such that it is not discussed here.

agreement suggests greater encroachment on TRIPS flexibilities than the proposed 2015 draft.³²⁰

Any change to Indian patent law presents a serious international problem because India is the predominant source of low-cost generic drugs to the developing world. It has thus far been able to do so because of patent laws that provide less protection than most other countries, such as the United States.³²¹ However, if that changes, the only way that India could continue to make and sell generics would be to issue compulsory licenses, but that in itself could subject India to a separate basis for an investment claim. Although many investment agreements technically have an exception to expropriation claims for compulsory licenses that are “consistent” with TRIPS, an investment tribunal would still be deciding whether a domestically issued license is consistent with TRIPS.³²² Given a wide divergence in views on TRIPS requirements by government officials and companies, a country could be vulnerable to an expropriation claim under an investment agreement for a license that not only complies with TRIPS, but would be unlikely challenged at the WTO.³²³ After all, a number of countries have issued compulsory licenses since TRIPS was enacted, and although companies and even some countries have loudly protested,³²⁴ no country has ever initiated a WTO dispute settlement proceeding.³²⁵

2. Denial of Permanent/Preliminary Injunction

Another possible TRIPS flexibility that may be at risk is the flexibility to deny permanent or even preliminary injunctions for cases of alleged patent infringement.

320. Compare Model Text for the Indian Bilateral Investment Treaty art. 2.4(iii) (2016) [hereinafter Indian Model BIT 2016], http://www.bilaterals.org/IMG/pdf/modelbit_annex.pdf [<https://perma.cc/KUY7-7PMB>] (exempting from revocation, limitation or creation of rights arguably consistent with TRIPS, which would permit an investment tribunal to decide this), with Model Text for the Indian Bilateral Investment Treaty art. 2.6(v) (2015) [hereinafter Indian Model BIT 2015], https://mygov.in/sites/default/files/master_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf [<https://perma.cc/9W7F-YR55>] (excluding from scope of arbitration compulsory licenses, as well as revocation, limitation of IP if “consistent with the law of the host state.”).

321. E.g., The Patents (Amendment) Act, *supra* note 35 (barring patents on new variations of existing compounds unless they provide improved efficacy).

322. E.g., NAFTA, *supra* note 40, art. 1110(7) (exception to indirect expropriation); TPP, *supra* note 40, art. 9.8(5) (exception to indirect expropriation).

323. E.g., Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT’L L. & COM. REG. 371 (2009); see also, Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT’L L. REV. 357, 386 (2010). Most early commentary concerning the intersection of IP and investment claims focused on compulsory licenses. E.g., Tsai-Yu Lin, *Compulsory Licenses for Access to Medicines, Expropriation and Arbitration Under Bilateral Investment Agreements—Issues Beyond TRIPS*, 40 INT’L REV. INTELL. PROP. & COMPETITION L. 152 (2009).

324. For example, Thailand and India have both issued compulsory licenses that have been strongly contested. See, e.g., Lin, *supra* note 323, at 168; Vasani et al., *supra* note 121.

325. See generally WORLD TRADE ORGANIZATION, Index of Dispute Issues, https://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#selected_subject [<https://perma.cc/PM8A-G6NP>] (last visited Mar. 21, 2016) (containing no dispute relating to compulsory licenses).

TRIPS notably requires nations to have a system in place to award such injunctions but does not demand that domestic courts grant them in particular situations.³²⁶ However, since Eli Lilly seems to believe that an issued patent needs to be forever valid to preserve fundamental patent exclusivity,³²⁷ a company could be expected to claim that injunctions are also part of patent exclusivity. A domestic court decision that declined to provide such an injunction would not be an automatic violation of investment claims. Nonetheless, it could form the basis of a claim that the value of the rights was “expropriated.” This could be yet another situation where a company could obtain greater rights than under domestic laws that do not guarantee either permanent or preliminary injunctions.³²⁸ Alternatively, a company could claim that it had a legitimate expectation that an injunction would issue, such that there is a violation of fair and equitable treatment if that does not occur. This is especially true if the *Eli Lilly* tribunal is sympathetic to Eli Lilly’s position that there should be a legitimate expectation that a patent right entitles its owner to absolute exclusivity.

3. No Data Exclusivity

Yet another possible TRIPS flexibility at risk relates to undisclosed information as required under TRIPS Article 39.³²⁹ Technically, this provision is not part of TRIPS patent rights, but it is covered in the Declaration on Patent Protection and generally considered part of the patent flexibilities that countries use.³³⁰

There are extremely divergent views on what TRIPS Article 39 requires. Some believe that TRIPS requires U.S. style “data exclusivity” that essentially bars generic companies from relying on the clinical data of a pioneer drug for obtaining regulatory approval for a certain period of time.³³¹ Other scholars, policy makers, and even some countries consider it to only require “data protection,” which means protecting the data submitted to a regulatory agency from unfair competition, but

326. TRIPS, *supra* note 6, art. 44.

327. *E.g.*, Eli Lilly Notice of Arbitration, *supra* note 1, ¶ 78 (alleging that invalidation of patents constitutes expropriation that is “contrary to the public purpose that is inherent in the grant of a patent . . . pursuant to which the patentee receives an exclusive right.”).

328. *See, e.g.*, *Ebay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006) (clarifying that patent owners are not automatically entitled to a permanent injunction even after they establish infringement).

329. TRIPS, *supra* note 6, art. 39.

330. *Declaration on Patent Protection*, *supra* note 9, ¶ 35–36.

331. *E.g.*, ORG. OF PHARM PRODUCERS OF INDIA, OPPI OPPOSITION PAPER, REGULATORY DATA PROTECTION—A BUILDING BLOCK FOR PHARMACEUTICAL R&D (2008); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 392–93 (2d ed. 2005). *See also* 21 C.F.R. § 314.108 (2012) (noting a five-year period of exclusivity in the United States: “(2) If a drug product that contains a new chemical entity was approved after September 24, 1984, in an application submitted under section 505(b) of the act, no person may submit a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved new drug application, except that the 505(b)(2) application or abbreviated application may be submitted after 4 years if it contains a certification of patent invalidity or noninfringement described in 314.50(i)(1)(i)(A)(4) or 314.94(a)(12)(i)(A)(4).”).

does not necessarily mean reliance of the data by a generic company that never has physical access to the data.³³² A few take an intermediate position and find that TRIPS precludes generic companies from relying on the data of another company without paying some fee.³³³

A company could claim that a country that does not provide data exclusivity, such as India, is indirectly expropriating its data by permitting a proposed generic company to immediately rely on clinical data of the original company to establish bioequivalence immediately after the originator is approved.³³⁴ Clinical data is expensive to develop and thus would seem to easily fall within the definition of an investment. Innovator companies complain this is fundamentally unfair for countries not to provide data exclusivity, with some arguing that this violates TRIPS.³³⁵ There is obviously no consensus on this issue. Importantly, it is considered a type of TRIPS flexibility to *not* provide data exclusivity as a matter of public policy. Although not highlighted by innovator companies, data exclusivity often provides more protection than patents by barring generic entry—even if the patented drug may in fact be subject to an invalid patent since the majority of drug patents are found invalid when challenged.³³⁶ If there is no data exclusivity, a country can quickly approve a generic equivalent and let the generic company legally contest whether the drug is properly patented.³³⁷ A generic company is not likely to

332. CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 383–92 (2008); Brook K. Baker, *Ending Drug Registration Apartheid*, 34 AM. J. L. & MED. 303, 315–16 (2008); Jerome H. Reichman, *Undisclosed Clinical Test Data under the TRIPS Agreement and its Progeny* (UNCTAD-ICTSD Dialogue Paper 2004), http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf [<https://perma.cc/5FQK-56QT>]. *But see* NUNO PIRES DE CARVALHO, *supra* note 331.

333. *See, e.g.*, Shamnad Basheer, *Protection of Regulatory Data under Article 39.3 of TRIPS: The Indian Context*, 28–29 (2009), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=934269; Aaron Xavier Fellmeth, *Secrecy, Monopoly and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement*, 45 HARV. INT'L L.J. 443, 446 (2004). However, this interpretation seems to be inconsistent with appropriate interpretation of TRIPS since there was an explicit proposal to require cost-sharing that was rejected. Draft Agreement on the Trade Related Aspects of Intellectual Property Rights, Communication from the United States, art. 33, GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990) (suggesting one alternative to permitting use of originator data would involve “payment of reasonable value of the use”).

334. *See, e.g.*, HO, ACCESS TO MEDICINE, *supra* note 32, at 119.

335. *E.g.*, PHARMA SPECIAL 301 SUBMISSION 2016, at 46, 94 (2016) (arguing that India and Brazil violate TRIPS by not providing data exclusivity); BIO SPECIAL 301 SUBMISSION 2016, at 16–17, 46 (2016) (arguing Brazil and India presently violate TRIPS by not providing data exclusivity); *see also* INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATION, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 8 (2000) (arguing that countries lacking data exclusivity, such as South Africa, Brazil, Israel and Ecuador, violate TRIPS).

336. *See, e.g.*, *Final Report of the Pharmaceutical Sector Inquiry*, at 191 (July 8, 2009), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf [<https://perma.cc/MR5Z-A6K6>]; FEDERAL TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 20 (2002).

337. *See, e.g.*, Cynthia M. Ho, *Beyond Patents: Global Challenges to Affordable Medicine*, in THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL ISSUES 302, 304 (I. Glen Cohen ed., 2013).

undertake such a contest lightly given the risks of litigation, but at least the public interest in lower cost generics is recognized and not stifled; this seems particularly important if a patent were in fact invalid. However, it is unclear whether a tribunal would be sensitive to these policy concerns. In addition, although there is an exception to indirect expropriation for denial of intellectual property rights consistent with TRIPS, lack of data exclusivity is not a prototypical denial of rights in the same way as a denial of a patent application since there is no separate application to obtain this benefit. Moreover, the exception would still result in an investment tribunal, rather than a WTO panel, deciding on TRIPS compliance.

Even if there is no finding of indirect expropriation for a country that declines to provide data exclusivity, this could still be the basis for a claim of violation of fair and equitable treatment. A company could make a claim similar to Philip Morris in the Australia case that it has a purported legitimate interest in a country “complying” with TRIPS by providing data exclusivity based on its belief that this is what TRIPS requires.³³⁸ This would obviously create a conflict with TRIPS flexibilities and have a serious chilling effect.

III. ADDRESSING CURRENT CONFLICT

Although current investment agreements pose a threat to TRIPS flexibilities, there are nonetheless steps that can be taken to minimize conflicts between TRIPS flexibilities and the investment system.³³⁹ First, the scope of covered investments could be narrowed. Second, if IP claims were not more broadly excluded, investment claims could be more narrowly construed to promote TRIPS flexibilities. Third, the scope of dispute settlement could be modified to minimize or completely eliminate conflict with TRIPS flexibilities. These can be most easily done in future treaties, but existing agreements can be amended, or at least clarifying statements could be issued in hopes of achieving similar outcomes.³⁴⁰

A. Narrow Scope

There are two primary ways in which the scope of coverage of investments could be modified to minimize overlap with IP norms. In particular, the definition of what a covered investment is could be narrowed, or investment claims themselves could be narrowed. Although some recent agreements have aimed to narrow investment claims to cabin undue impact on sovereignty, this Section goes

338. See *P.M. v. Austl.*, Notice of Arbitration, *supra* note 1, ¶ 7.7 (alleging FET claim based on violation of international law).

339. This focuses on solutions that assume countries do not exit from investment treaties, or ICSID, which is an alternative possibility, but not a complete one since it would only eliminate prospective claims.

340. This is particularly true for investment agreements to which the United States is a party since the United States has generally included language that permits nations to provide clarifying statements that should then be binding on member states. See, e.g., NAFTA, *supra* note 40, art. 1131.2; TPP, *supra* note 40, art. 27.2(2)(f); see also CETA, *supra* note 15 (permitting binding interpretations regarding intellectual property).

further to address the IP-specific conflict for future agreements. However, for existing agreements, one additional option is for states to exclude IP from ICSID disputes under Article 25(4) of ICSID.³⁴¹ Although no state has yet done so for IP, there have been notifications for other topics.³⁴² One possible downside to this is that it may be overbroad in excluding all IP, even if there were no possible TRIPS conflicts.

1. *Limit the Scope of Covered Investments*

Future agreements that could arguably exclude IP from the scope of investments are unlikely to happen. Furthermore, focusing solely on future agreements would do little to address the many existing agreements under which IP is explicitly or implicitly covered as an investment. Accordingly, this Section suggests some modest modifications such as modifying the scope of investments that results in jurisdiction, as well as modifying the type of intellectual property that is covered.

One way to minimize TRIPS collisions is to narrow the scope of what constitutes an investment that gives rise to an investor-state dispute. In particular, tribunals should only find jurisdiction if there is an investment that meets the criteria noted in the *Salini* decision, which includes contribution of investment to the economic development of the host state that is beneficial to the public interest.³⁴³ Of course, not all tribunals have followed this decision, even when they cite it.³⁴⁴ However, this is especially important in the context of intellectual property since simply obtaining a patent or trademark in a country does not directly benefit the host country in the same way as traditional types of investments. For example, investing in a physical plant would result in hiring of employees in that country as well as other economic benefits. However, mere grant of a patent will not result in any economic benefit. To the contrary, grant of a patent in a country often results in economic loss to a country when the patent is to a foreigner who can then charge

341. ICSID Convention, *supra* note 63, art. 25(4).

342. For example, Guatemala eliminated claims arising from armed conflicts, Indonesia eliminated claims for administrative decisions, and Jamaica eliminated claims relating to natural resources. International Centre for Settlement of Investment Disputes [ICSID], *Notifications Concerning Classes of Disputes Considered Suitable or Unsuitable for Submission to the Centre*, ICSID/8-D (May 2016), [https://icsid.worldbank.org/en/Pages/icsiddocs/Notifications-Concerning-Classes-of-Dispute-\(ICSID8D\).aspx](https://icsid.worldbank.org/en/Pages/icsiddocs/Notifications-Concerning-Classes-of-Dispute-(ICSID8D).aspx) [<https://perma.cc/85B3-SST8>].

343. *Salini Costruttori SpA and Italstrade SpA v. Morocco*, ICSID Case No. ARB/00/4 (Decision on Jurisdiction of 23 July 2001). In addition, although *Salini* was interpreting article 25(1) of ICSID, its interpretation has been affirmed in non-ICSID cases. *E.g.*, *Romak SA v. The Republic of Uzbekistan*, Case No. AA280, 53 (Perm. Ct. of Arb. 2009) (noting that even if an investor resorts to UNCITRAL, *Salini* is relevant).

344. *E.g.*, *Consortium Groupment v. People's Democratic Republic of Algeria*, ICSID Case NO. ARB/03/8, Award of Jan. 10, 2005, ¶ 13(iv) (rejecting criteria of contribution to investment to economic development); *LESI v. Algeria*, ICSID Case NO. ARB 05/03, Decision on Jurisdiction, ¶ 72(iv) (finding contribution to host state economic development irrelevant); *P.M. v. Uru.*, Decision on Jurisdiction, *supra* note 206, ¶ 204-210 (2013); ¶ 220 (rejecting economic development as an unnecessary element).

higher prices for a patented good. There is some academic support for following *Salini* in general, as well as with IP in particular.³⁴⁵ Notably, while there is no investor-state tribunal decision on this specific issue, the relatively recent *Apotex* decision supports the idea that mere application of a property right is not enough to be an investment that justifies an investor-state dispute.³⁴⁶

The definition of intellectual property could also be clarified to exclude a mere application. This would be consistent with long-recognized intellectual property policy that there are no rights attendant to a mere application. In addition, denials of applications and revocations of intellectual property could be entirely excluded from the scope of investments where they are consistent with domestic law, as decided by domestic courts.³⁴⁷ Using domestic law, rather than TRIPS consistency, as the relevant criteria would ensure that investment tribunals have no occasion to interpret TRIPS norms and disrupt them.

While companies would likely protest these suggestions as inconsistent with international investment provisions, such a claim fails to recognize a fundamental difference between intellectual and real property. Intellectual property rights are inherently creations of governments that should not be considered to exist if a nation finds that they fail to meet the basic requirements. Real and personal property, on the other hand, do not depend on government action to exist. In addition, if there was a problem with the process for issuing an intellectual property rights, such as arbitrary denial, the process itself could be challenged under an investment agreement as arbitrary or lacking due process. However, the simple denial of a right itself should not give rise to a claim.

2. Narrow Investment Claims

If the types of intellectual property covered under investments cannot be adequately cabined to alleviate conflicts, an alternative approach would be to narrow the scope of specific investment claims. Since expropriation and FET claims can

345. E.g., Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law is Reconceptualizing IP*, 36 MICH. J. INT'L L. 557 (2015); Okediji, *supra* note 37, at 1137; Alex Grabowski, *The Definition of Investment Under the ICSID Convention: A Defense of Salini*, 15 CHI. J. INT'L L. 287 (2014). *But see* THE ICSID CONVENTION: A COMMENTARY 134 (Schreuer et al. eds., 2009); D. Mortenson, "The Meaning of 'Investment': ICSID's Travaux and the Domain of International Investment Law", 51 HARV. INT'L L.J. 257 (2010).

346. *Apotex v. Gov't of the United States*, ICSID Case No. ARB(AF/12/1, Award on Jurisdiction and Admissibility, ¶¶ 158, 243 (June 14, 2013).

347. See, e.g., European Commission Directorate-General for Trade, *Note for the Attention of the Trade Policy Committee (Services and Investment)*, art. X.11 ¶ 5, E.U. Doc. Trade B2/CBA/eg/Ares 1151153 (Apr. 7, 2014), <http://docplayer.net/1529313-Section-1-scope-and-definitions-article-x-1-scope-of-application-a-air-services-and-related-services-in-support-of-air-services-other-than.html> [<https://perma.cc/Z8A5-WM9L>] (noting that Canada proposed that expropriation be barred for a "decision by a court, administrative tribunal, or other governmental intellectual property authority, limiting or creating an intellectual property right except where the decision amounts to a denial of justice or an abuse of right"); Indian Model BIT 2015, *supra* note 320 (stating that "revocation, limitation or creation of intellectual property rights" are excluded as investments under the treaty if "consistent with the law of the Host State.").

clearly impact TRIPS norms, this Section provides specific proposals for limiting how these claims conflict with TRIPS.³⁴⁸

3. Expropriation

Although investment agreements generally already have an exception to indirect expropriation claims for denial or revocation of intellectual property rights, the *Eli Lilly* case underscores inadequacies with the provision.³⁴⁹ After all, this provision generally only exempts claims that are consistent with TRIPS, or potentially a TRIPS-plus agreement.³⁵⁰ This means that an investment tribunal decides consistency with TRIPS, rather than a WTO tribunal.

There are a variety of possible ways to minimize the conflict. One would be to exclude intellectual property claims entirely from possible claims for indirect expropriation by investors and instead only permit them to be raised through state-to-state challenges.³⁵¹ Another possibility is to exempt from indirect expropriation IP revocations and denials that are consistent with the domestic law, so long as there is no abuse of process.³⁵² This would avoid TRIPS conflicts, but would still enable a tribunal to essentially second-guess whether domestic law was properly applied.

4. FET

The most problematic claims are Fair and Equitable Treatment claims for IP rights. Unlike the situation with expropriation claims, existing agreements do not even have any exception to such claims for any types of IP. Moreover, Philip Morris's claims against Australia highlight how creative interpretations of these claims could directly interfere with TRIPS if a panel agreed that an alleged violation of TRIPS could constitute violation of FET.³⁵³ Although most scholars that have considered the issue have argued that tribunals should interpret investment claims to preserve TRIPS flexibility, that approach seems unlikely since tribunals tend to rule in favor of investors, rather than consider other international agreements that

348. Australia's Response to Notice of Arbitration, *supra* note 204, ¶¶ 57–58 (explaining that ideally investment agreements should either exclude “umbrella” clauses that permit a tribunal to decide whether there has been a violation of any other agreement, or at least clarify that this excludes international agreements such as TRIPS to prevent claims).

349. *E.g.*, NAFTA, *supra* note 40, art. 110(2). Indeed, the existence of this provision did not prevent filing of the case against Eli Lilly as earlier discussed. *See supra* notes 267–70 and accompanying text (section on expropriation claims in *Eli Lilly* case).

350. *E.g.*, NAFTA, *supra* note 40, art. 1110(7); TPP, *supra* note 40, art. 9.8(5); CETA, *supra* note 15, art. 8.12(5).

351. *See, e.g.*, Sean Flynn, *How the Leaked TPP ISDS Chapter Threatens Intellectual Property Limitations and Exceptions*, IP WATCH (Mar. 26, 2015), <http://www.ip-watch.org/2015/03/26/how-the-leaked-tpp-isds-chapter-threatens-intellectual-property-limitations-and-exceptions/> [<https://perma.cc/DN73-HRAQ>] (recognizing and suggesting this approach).

352. India has suggested this in its 2015 draft model BIT. Indian Model BIT 2015, *supra* note 320.

353. *See, e.g.*, P.M. v. Austl., Notice of Arbitration, *supra* note 1, ¶ 7.7 (alleging FET claim based on violation of international law).

are not specifically referenced in the investment agreement. Accordingly, new FET text, or interpretive statements to clarify what existing FET claims should mean is necessary.

There are a variety of approaches that can be taken to minimize the incursion of FET claims on TRIPS flexibilities going forward. First, such claims could be entirely eliminated.³⁵⁴ Or, at least eliminate claims based on “legitimate expectations,” because those are the broadest rights and instead limit FET to situations where there is denial of justice.³⁵⁵ Alternatively, FET claims could preclude ones involving TRIPS; many agreements already preclude investment claims based on FET involving tax or other financial matters.³⁵⁶ Unless TRIPS claims are barred, or limited to denial of justice situations, there are still potential problems; for example, although the TPP attempts to clarify that breach of another agreement does not alone constitute a violation of FET, this would still permit a tribunal to consider a TRIPS breach and potentially use that as a basis for finding FET. Accordingly, the other suggested approaches are preferable.

B. Modify Dispute Settlement

Conflicts with TRIPS flexibilities may also be avoided by fundamental modifications to the dispute settlement process. There are a variety of ways this can be done. First, investment claims involving intellectual property as an investment could be limited to state to state action, or require state consent before an investor can assert a claim. Second, investment claims premised on adjudication of TRIPS rights could be excluded. Third, a hybrid dispute settlement system involving potential additional action by the WTO could be created.

One approach that would likely minimize TRIPS conflicts is to require investment claims premised on IP to be limited to claims by states. Notably, states would still have the power to assert claims, such that conflict would not be completely eliminated, although it would better parallel the WTO process and at least reduce the number of likely conflicts since states are more discerning in bringing disputes. Investment agreements already permit state-to-state adjudication and for some subject matter, only state-to-state disputes are permitted.³⁵⁷ Although there have been long standing exceptions for national security, and some types of

354. This is especially true for agreements between nations with well-developed legal systems. *See, e.g., Draft Report Containing the European Parliament's Recommendations to the Commission on the Negotiations for the Transatlantic Trade and Investment Partnership (TTIP)*, ¶ xiv, EUR. PARL. DOC. 2014/2228 (INI) (Feb. 5, 2015) (explaining that ISDS is not necessary between the United States and the European Union given their robust legal systems).

355. *See, e.g., CETA*, *supra* note 15, art. 8.10 (FET claims linked to denial of justice); *Indian Model BIT*, *supra* note 320, art. 4 (national treatment); *JOHNSON & SACHS*, *supra* note 54 (suggesting eliminating this entirely or leaving it only subject to state-to-state resolution). TPP, however, does not. *E.g., TPP*, *supra* note 40, art. 9.6.

356. *See, e.g., CETA*, *supra* note 15, art. 8.6 (excluding financial service investments); William Park, *Tax Arbitration and Investor Protection*, in *THE FUTURE OF INVESTMENT ARBITRATION* 227, 238 (Catherine A. Rogers & Roger P. Alford, eds., 2009).

357. As noted earlier, this is already the case for some types of tax claims.

tax, the TPP recently added a “carve out” of investor-disputes for tobacco regulations.³⁵⁸ However, this carve out was a political compromise after some advocated a broader exception for more types of public interests and this limited exception was noted as potentially problematic for obtaining congressional approval.³⁵⁹ Accordingly, an exclusion for IP claims may be unlikely, especially given the power of the pharmaceutical lobby.

Alternatively, investors could be permitted to still bring claims based on alleged IP investments, but only if there is first specific consent by the host nation. For example, many investment agreements not only restrict what investment claims can be brought based on taxes, but only permit arbitration after the host state and investor have first considered whether an investment claim is appropriate.³⁶⁰ A similar provision could be added that would require domestic consent before an investor can assert a claim that might comprise TRIPS flexibilities. Although some might suggest that taxes are more essential to domestic sovereignty and thus entitled to different rules that do not apply to other areas, some commentators have noted that this distinction is not robust.³⁶¹ Although companies would likely assert that this is radical and unfair, considering that there is not a long tradition of states asserting investment claims based on IP, this is not a major change. Moreover, corporate claims and interests do not align with TRIPS norms and only considering their issues would fail to preserve TRIPS flexibilities.

A more modest change that would still minimize TRIPS conflicts would be to exclude from investor claims any situation that requires adjudication of TRIPS rights. This could be based on existing language involving tax or environmental agreements that states which international agreement prevails in the event of an inconsistency.³⁶² However, whereas these existing agreements focus on an explicit conflict, the problem for IP claims may be a systemic conflict for which more than

358. TPP, *supra* note 40, art. 29.5.

359. See, e.g., Lukasz Gruszczynski, *The Trans-Pacific Partnership Agreement and the ISDS Carve-Out for Tobacco Control Measures*, 6 EUR. J. RISK REG. 652 (2015); Mike Masnick, *The TPP and the Tobacco Carve-Out Bring Together Strange Bedfellows . . . While Highlighting The Problems of the TPP*, TECHDIRT (Oct. 6, 2015), <https://www.techdirt.com/articles/20151005/15595532440/tpp-tobacco-carveout-bring-together-strange-bedfellows-while-highlighting-problems-tpp.shtml> [https://perma.cc/9PZ5-1FMM]; Wendy Parmet, *Trade, Health and Tobacco Exceptionalism: The TPP Tobacco Carve Out*, HEALTH AFFAIRS BLOG (Nov. 10, 2015), <http://healthaffairs.org/blog/2015/11/10/trade-health-and-tobacco-exceptionalism-the-tpp-tobacco-carve-out/> [https://perma.cc/WYM2-UTS9]. Congressional approval is a moot issue with regard to the TPP, but the difficulty of getting the approval of even the limited tobacco carve-out suggests difficulty with a broader exclusion of IP claims.

360. See, e.g., ECT art. 21(5) (for expropriation claims, investor must refer the issue to the relevant Tax Authority; NAFTA, *supra* note 40, art. 2103(6) (explaining that competent authorities to assess whether the measure is an expropriation); see also *TPP in Focus: Investment and Investor-State Dispute Settlement—The Need for Reform*, WAYS AND MEANS COMM. DEMOCRATS (Mar. 20, 2015), <https://democrats-waysandmeans.house.gov/media-center/blog/tpp-focus-investment-and-investor-state-dispute-settlement-need-reform> [https://perma.cc/75WV-53BS].

361. E.g., PARK, *supra* note 8, at 233.

362. See, e.g., NAFTA, *supra* note 40, arts. 103, 2103; see also Guillermo Alvarez & William Park, *The New Face of Investment Arbitration: NAFTA Chapter 11*, 28 YALE J. INT'L L. 365, 390 (2003).

a simple conflict of law choice is needed. One possibility would be to preclude adjudication of any claim that requires adjudication of a TRIPS provision unless it has been previously determined to be in violation of TRIPS by a WTO panel. This still may be inadequate, however, since investment claims do not necessarily require an actual TRIPS violation. Accordingly, this could be phrased more broadly to preclude any claim involving rights and flexibilities under TRIPS from adjudication unless and until there has been a finding of TRIPS violation by the WTO. This would preclude a systemic collision, but may not find support of countries desiring strong investment rights, such as the United States. In addition, there is a logistical problem in that not every investment case has a parallel WTO proceeding. However, this problem can be solved with a new hybrid dispute settlement proceeding.

Investment disputes based on IP that might challenge TRIPS flexibilities could minimize incursion on TRIPS norms with a hybrid system.³⁶³ For example, if there is an investment claim that inherently involves TRIPS flexibilities, but no related WTO dispute, perhaps the investment claim could be stayed while the WTO system evaluates the TRIPS issues and then the investment tribunal should defer to this ruling. Of course, there is no precedent in international law in general, but perhaps interpretive statements or amendments to existing agreements could state that tribunals should defer to the WTO. Notably, not every investment claim will involve a related WTO dispute or a direct interpretation of TRIPS rules. However, all indirect expropriation claims where the exception based on TRIPS consistency is at issue would be relevant. The harder issue is for FET claims where there is no exception for IP, let alone TRIPS consistent action by states.³⁶⁴ However, perhaps the WTO could help provide interpretive guidance on the impact of a FET ruling on TRIPS norms in such a case even if no state initiates a formal WTO dispute. For example, in a case such as Eli Lilly's challenge to Canada's norms, the WTO could potentially provide insight into the impact on TRIPS flexibilities.

A number of logistical issues would need to be addressed to put this plan in place. First, because the DSU only permits parties to bring disputes, there is no current mechanism for a WTO panel to assess TRIPS issues if no country is willing to bring a dispute.³⁶⁵ However, the existing and potential conflicts noted here indicate that there is a real threat to TRIPS flexibilities if nothing is done.

363. Another possibility is to bring investment claims within the scope of the WTO, although that seems unlikely because prior negotiations on a multilateral agreement on investment (MAI) failed and the TRIMS Agreement that was negotiated as part of the WTO fell short of goals first proposed as part of the MAI. See, e.g., Susan Sell, *Cat and Mouse: Forum-Shifting in the Battle over Intellectual Property Enforcement*, at 9 (draft, prepared for IGIS Research Seminar), www.gwu.edu/~igis/Sell%20Paper.doc [<https://perma.cc/3V5L-94NG>]. Notably, developing countries have previously argued that IP issues should be solely a matter of domestic control, and not subject to international commercial arbitration. See, e.g., M. Sornarajah, *The UNCITRAL Model Law: A Third World Viewpoint*, J. INT'L ARB. 7, 19–20 (1989).

364. Compare TPP, *supra* note 40, art 9.8(5) (exception to indirect expropriation), with TPP, *supra* note 40, art 9.6 (FET claims with no exception).

365. See, e.g., DSU, *supra* note 4, at art. 22.

Considering that the WTO Dispute Settlement was intended to be the sole process for resolving interpretations of WTO agreements such as TRIPS, amendments to ensure that this can exist in a world where investment claims based on arguable TRIPS violations would seem consistent with the original intent of the agreement. Alternatively, perhaps another WTO organ, such as the WTO General Counsel, could consider specific issues upon request. Alternatively, the WTO General Council could be tasked with finding a solution to the conflict between investment claims and TRIPS norms. This body has, in the past, found a solution to a TRIPS specific problem concerning poor countries that could not take advantage of the TRIPS compulsory licensing flexibility.³⁶⁶

Even if a complete overhaul of the dispute resolution process is not undertaken, raising awareness at the WTO of the impending conflict between investment claims and TRIPS norms would be an important first step. Notably, there has not been substantial discussion in the WTO arena thus far concerning the potential for investment claims to overshadow TRIPS rights and norms. There has been discussion of the tobacco dispute, but it tends to focus more on general domestic sovereignty, rather than a threat to TRIPS conflicts.³⁶⁷ In addition, there is virtually no discussion relating to the *Eli Lilly* case, which has a much bigger potential impact on patent flexibilities that would promote access to medicine. So, a first step might be for member states to raise this issue at a WTO meeting. India has expressed some awareness of this problem and has raised it at the World Health Assembly, but not thus far at the WTO.³⁶⁸

At the same time, increased awareness and cross-fertilization in the investment arena of TRIPS norms would be desirable. For example, perhaps pending agreements could explicitly note that they do not modify rights under TRIPS or refer to TRIPS and other documents to help provide specific contextual balance to counter investment claims. For example, just as some agreements have been adding

366. WTO Decision of the General Council, Amendment of the TRIPS Agreement, Annex to the Protocol Amending the TRIPS Agreement, WT/L/641 (Dec. 8, 2005), https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [<https://perma.cc/KYE6-KZFD>]; *Members Accepting Amendment of the TRIPS Agreement*, WORLD TRADE ORG. (Oct. 2, 2015), https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [<https://perma.cc/XPX4-MDTW>] (listing limited number of countries far fewer than the two third of member countries required to pass a WTO amendment).

367. E.g., Catherine Saez, *Tobacco Plain Packaging Discussion Lights UP Again at WTO*, IP WATCH (Feb. 25, 2015), <http://www.ip-watch.org/2015/02/25/tobacco-plain-packaging-discussion-flames-up-again-at-wto/> [<https://perma.cc/HH4R-HP4K>] (noting domestic plain package legislation in a number of countries as well as TRIPS issues, but nothing concerning potential systematic threat to TRIPS flexibilities).

368. India seems to be one of the few countries that have expressly noted investor-state provisions as potentially compromising TRIPS flexibilities. E.g., Josephine De Ruyck, *World Health Assembly Approves Plan to Strengthen Access to Essential Medicines*, IP WATCH (May 24, 2014), <http://www.ip-watch.org/2014/05/24/world-health-assembly-approves-plan-to-strengthen-access-to-essential-medicines/> [<https://perma.cc/LQ7Y-7UFZ>] (India argued that TRIPS flexibility is “under attack” through a variety of means including, but not limited to investor-state dispute settlement provisions).

development-friendly language, agreements could specifically add language that incorporates the 2001 Doha Public Health Declaration, and ideally, also the Declaration on Regulatory Sovereignty. Alternatively, interpretive statements could be issued that clarify that TRIPS flexibilities should be considered. However, considering that the NAFTA interpretive statement has not completely obviated problems with tribunal decisions that defy the actual FET requirement of NAFTA, this may be of minimal value.³⁶⁹

C. Increase Transparency and Access

Another important component to addressing the current conflict may be to promote more transparency, access, and participation with respect to individual disputes, as well as the negotiation of future agreements with investor-state provisions. Although there has been recognition of the need for transparency, the current situation is still largely cloaked in secrecy with limited participation. As noted earlier, this is particularly problematic because tribunals are deciding issues of major public concern without any accountability. In addition, given the practice of negotiating agreements in secret, it is difficult for opposing norms and views to be recognized, including those who can identify a conflict of regimes to participate.³⁷⁰

Some lessons can be learned from the EU's recent response to public criticism and concern of the TTIP. Although the EU had strongly defended investor-state disputes for years in conjunction with the United States, it did bow to public concern and initiated public consultations in an attempt to address concerns.³⁷¹ Those consultations were important to the EU's recent inclusion of an investment court, as well as an appellate body in recent agreements, as well as its proposal to do so in the TTIP.

Greater transparency and participation in individual disputes would also be advantageous. Even if investment tribunals are not ultimately accountable to the

369. Joel C. Beauvais, *Regulatory Expropriations Under NAFTA: Emerging Principles & Lingering Doubts*, 10 N.Y.U. ENVTL. L.J. 245, 295 (2002).

370. Notably, even when a court considered some negotiations—but not draft texts—must be public, this was still considered notable. William New, *IP-Watch/Yale FOIA Case Decided: USTR Can Keep TPP Texts Secret, But Maybe Not Communications With Industry Advisors*, IP WATCH (Sept. 30, 2015), <http://www.ip-watch.org/2015/09/30/ip-watchyale-foia-case-decided-ustr-can-keep-tpp-texts-secret-but-maybe-not-communications-with-industry-advisors/> [https://perma.cc/P3HN-XWDQ]; Press Release, Yale Law School Information Society Project, In IP-Watch FOIA Lawsuit Seeking Transparency on TPP Negotiations, Court Allows Government to Keep the Text of the Agreement Secret, but is Skeptical of Efforts to Shield Industry Lobbying from Public Scrutiny (Sept. 30, 2015), <http://isp.yale.edu/node/6025> [https://perma.cc/3BP8-MTIT].

371. Compare European Commission, *Incorrect Claims About Investor-State Dispute Settlement* (Oct. 3, 2013), http://trade.ec.europa.eu/doclib/docs/2013/october/tradoc_151790.pdf [https://perma.cc/6ELG-WVTY] (defending traditional investor-state disputes), with European Commission, Commission Staff Working Document, Report: Online Public Consultation on Investment Protection and Investor-to-State Dispute Settlement in the Transatlantic Trade and Investment Partnership Agreement (Jan. 13, 2015), http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153044.pdf [https://perma.cc/DQU8-2GN6] (providing results of public consultation regarding proposed new EU approach to investor-to-state disputes).

public, greater transparency could help provide tribunals with relevant information.³⁷² This may be particularly important since investment arbitrators tend to be commercial lawyers with no knowledge of IP other than as an asset; in other words, they do not view IP as inherently part of a broader balance between corporate rights and public access and interests. In addition, since most agreements lack any language acknowledging these principles in contrast to TRIPS, they do not even have any textual basis for considering such interests. Granted, arbitrators may still be inclined to favor primarily investor interests in agreements that contain no countervailing language that expressly favors public interests. However, the situation could at least be improved if third parties could explain the need to balance IP rights against other values.

Although defenders of investment agreements often note that investment tribunals *may* accept amicus briefs, they often fail to note that it is only under limited circumstances that amicus briefs are accepted, and even then, the tribunal has discretion to decline to accept briefs.³⁷³ Individual investment agreement agreements may limit some types of amicus briefs. Indeed, in the *Eli Lilly* dispute, a well-reasoned amicus brief was rejected simply because it was not authored by a national of NAFTA, even though the proceeding has global implications.³⁷⁴ Although the investment tribunal in the *Eli Lilly* dispute was following NAFTA guidelines, tribunals should broadly accept amicus briefs from any interested participant, rather than limiting it to only citizens of member states. In addition, although there is a trend towards broader access by third parties, there is still no universal recognition of a right to amicus briefs.³⁷⁵ This is particularly problematic for issues involving TRIPS, since there are necessarily global impacts. Also, notably, unlike most domestic proceedings, as well as at the WTO, there is generally no affirmative right for third parties, such as non-member countries to affirmatively participate, such that there is a particular need for amicus briefs.³⁷⁶ In addition, for

372. E.g., Miles, *supra* note 87, at 296.

373. In particular, the ICSID Convention Arbitration Rules as revised in 2006 allow amicus briefs only if they provide a different perspective than the disputing parties, the submission addresses a matter within the scope of the dispute, and the non-disputing party has a significant interest in the proceeding. ICSID Convention, *supra* note 63, Arbitration Rule 37(2); see also UNCITRAL Rules of Transparency in Treaty-Based Investor-State Arbitration art. 5 (2014); Michael D. Goldhaber, *The Rise of Arbitral Power over Domestic Courts*, 1 STAN. J. COMPLEX LITIG. 373, 411–12 (2013).

374. NAFTA Free Trade Commission, Statement of the Free Trade Commission on Non-Disputing Party Participation, § B.1 (Oct. 7, 2003), <http://www.state.gov/documents/organization/38791.pdf> [<https://perma.cc/6VV4-A449>] (limiting Tribunal discretion to accept submissions from a “person of a Party”); see also *Eli Lilly*, Procedural Order, *supra* note 297, at 2 (interpreting this to excluding those who are not present in the United States, Mexico, or Canada).

375. Compare TPP, *supra* note 40, art. 9.22 (tribunals *may* accept non-disputing party amicus curiae submissions under certain conditions), with CETA, *supra* note 15, art. 8.38 (tribunal *shall* accept non-disputing party submissions).

376. Compare CETA, *supra* note 15, art. 8.38(2), with FED. R. CIV. P. 24 and DSU, *supra* note 4, art. 4(11). Although the EU has proposed broader participation by any person with a “direct and present interest,” it is only to support what is already sought by one of the disputing parties and still discretionary after disputing parties have a right to comment. CETA, *supra* note 15, art. 23.

participation by third parties as well as amicus briefs, greater transparency of the entire proceedings is essential,³⁷⁷ rather than the historic situation where third parties lack access to relevant documents as well as the ability to attend oral proceedings.³⁷⁸ Although this principle is recognized by newer or pending agreements, they have no direct effect on the vast majority of existing agreements.

CONCLUSION

Although these first known cases to implicate TRIPS have (so far) avoided a direct collision, a collision of some sort seems inevitable given the existence of thousands of agreements under which companies can assert investment claims. At this point, it is unclear to what extent companies will bring further claims, or at least threaten to do so to obtain results that could not be obtained under TRIPS. This fundamentally threatens the inherent flexibilities under TRIPS that policy makers have been advocating countries to adopt.

This Article has aimed to shed light on this important problem so that greater attention may be devoted to minimizing this conflict and preserving the already limited flexibilities to promote public health under TRIPS. Importantly, even though states “won” the initial disputes, other nations could be challenged and it is not clear that they will necessarily win. Notably, the initial cases do not indicate that TRIPS flexibilities are immune from investment challenges. To the contrary, the *Eli Lilly* decision in particular seems to indicate that although Eli Lilly lacked adequate facts to establish its investment claim, such a claim *could* exist and, in particular, could even exist as a result of common law modifications to the law beyond denial of justice situations.

The impact of investment disputes on TRIPS flexibilities remains to be seen. After all, the outcomes of these initial cases were never certain. Even in retrospect, it is not clear how to reconcile the initial decisions. It would seem that a case involving domestic regulation of a known carcinogen would yield a unanimous opinion in favor of the state. However, the unanimous decision was in favor of Canada against Eli Lilly’s challenge to domestic common law. Nonetheless, continued attention and advocacy concerning the tension between TRIPS flexibilities and investor disputes seems especially important. Hopefully such attention will have a positive influence on tribunalists, as well as those negotiating agreements that could be modified to minimize harms to TRIPS flexibilities.

377. See, e.g., Nigel Blackaby & Caroline Richard, *Amicus Curiae: A Panacea for Legitimacy in Investment Arbitration?*, in *THE BACKLASH AGAINST INVESTMENT ARBITRATION: PERCEPTIONS AND REALITY* 271–72 (Waibel et al. eds., 2010) (noting that amici participation without full knowledge is unhelpful). Recent guidelines from UNICTRAL were a step forward, but requiring all documents be made publicly accessible would be better.

378. For example, third parties do not have a right to access documents under NAFTA. NAFTA Free Trade Comm’n, Statement of the Free Trade Commission on Non-disputing Party Participation (2003), <https://www.state.gov/documents/organization/38791.pdf> [<https://perma.cc/57AW-MBAS>].

However, a serious threat to TRIPS flexibilities remains and may be most significant regarding lower profile disputes, that nonetheless may have major repercussions for countries. For example, as this article goes to press, two additional investment cases were discovered to have been filed, although the details are not available because the documents are not publicly available. In one case, Ukraine withdrew approval of a generic version of the drug sold as Sovaldi after American pharmaceutical company Gilead Sciences filed an investment dispute.³⁷⁹ In another, case, Novartis filed an investment dispute against Columbia for contemplating a compulsory license, without actually issuing one.³⁸⁰ The lack of transparency of these reported cases makes it difficult to assess whether the claims have any merit. Nonetheless, they indicate a continuing threat to TRIPS flexibilities even after the initial “wins” in the fully litigated disputes by Uruguay and Eli Lilly.

379. E.g., Luke Eric Peterson & Zoe Williams, *Pharma Corp Withdraws Investment Arbitration After Ukraine Government Agrees to Settlement of Dispute over Monopoly Rights to Market Anti-Viral Drug*, *Inv. Arbitration Reporter* (Mar. 16, 2017), <https://www.iareporter.com/articles/pharma-corp-withdraws-investment-arbitration-after-government-agrees-to-settlement-of-dispute-over-monopoly-rights-to-market-anti-viral-drug/> [https://perma.cc/9HD9-66HP].

380. E.g., Zoe Williams, *Investigation: As Colombia Pushes for Cancer Drug Price-Cut and Considers Compulsory Licensing, Novartis Responds with Quiet Filing of an Investment Treaty Notice*, *Bilaterals.org* (Nov. 30, 2016), <http://www.bilaterals.org/?investigation-as-colombia-pushes> [https://perma.cc/D5HF-JB7S].