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## Regime Shift of IP Lawmaking and Enforcement from WTO to the International Investment Regime

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# Regime Shifting of IP Lawmaking and Enforcement from the WTO to the International Investment Regime

James Gathii & Cynthia Ho\*

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## INTRODUCTION

Intellectual property (IP) rights are entering a new, yet largely under-studied era in which multinational companies challenge domestic as well as international laws and regulations that recognize, and in some cases are explicitly designed to protect public health before a tribunal of three private individuals without any required public health or human rights expertise in what is known as investor-state arbitration.<sup>1</sup> This threatens to unsettle the regulatory discretion countries have to safeguard public health and similar values embodied in the 1994

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1. See generally JESWALD W. SALACUSE, *THE LAW OF INVESTMENT TREATIES* (2d ed. 2015) (discussing details of investor-state disputes).

Trade Related Intellectual Property Rights (TRIPS) Agreement<sup>2</sup> of the World Trade Organization (WTO). TRIPS is notably the first international agreement to mandate nations provide “minimum” standards of IP protection;<sup>3</sup> however, since it did not impose *uniform* IP standards, countries retained some domestic discretion to tailor intellectual property rights in accordance with their policy preferences.<sup>4</sup> That discretion is now threatened by investor-state suits such as the ones initiated by Philip Morris and Eli Lilly discussed in this article. Although these suits challenge different state action, both inherently challenge the ability of nations to balance IP rights against domestic health interests. Philip Morris International challenges domestic regulations to protect citizens from the known health hazards of tobacco such as those limiting the use of trademarks on packaging even though such action has international support by entities such as the World Health Organization (WHO).<sup>5</sup> Eli Lilly, on the other hand, challenges domestic court decisions finding its patents invalid under Canadian law that utilizes TRIPS flexibilities that define the undefined minimum standards of the TRIPS Agreement.

This article provides the first systematic examination of how these disputes are intended to impact the WTO/TRIPS regime through the principle of regime shifting, which focuses on destabilizing existing understandings in one regime by actions in a second regime.<sup>6</sup> We argue that the goal of both the tobacco

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

3. Before TRIPS, international agreements only imposed obligations *if* a nation granted them. *See infra* Section II.B.

4. TRIPS, *supra* note 2, art. 1, ¶ 1; Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, ¶ 7.513, WTO Doc. WT/DS362/R (adopted Jan. 26, 2009) (“Article 1.1 clarifies that the provisions of the Agreement are minimum standards only . . . [and] grants freedom to determine the appropriate method of implementation.”).

5. The reference to Philip Morris International includes any entity associated or affiliated with this multinational tobacco company.

6. For example, the leading scholarly work in this area, Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1 (2004), examines regime shifting within the World Trade Organization, the World Intellectual Property Organization, the Bio-Diversity Convention, and Plant Genetics Resources regimes as well as the Public Health and Human Rights regimes, but does not address the international investment regime. Granted, although an international investment regime existed at this time, it was not

and pharmaceutical industries in pursuing these investment disputes is to destabilize existing explicit and implicit understandings of the balance between the interests of producers and consumers of IP rights embodied in international as well as domestic laws in at least two senses: first, by seeking to create conflicting interpretations of these laws and regulations in investor-state arbitration, and second, by seeking to rewrite these laws and regulations altogether. Thus, the preference for bringing investor-state arbitration is not merely a case of forum shopping which would entail pursuing a one-time successful case—but regime shifting designed to re-draw international and domestic laws and regulations that balance intellectual property law protections with public purposes such as safeguarding the regulatory autonomy<sup>7</sup> of states in the areas of health, human rights, and development.<sup>8</sup> For example, as we will explain, Eli Lilly's investor-state case challenging Canada's invalidation of its patents aimed to not only change patentability requirements in Canada, but potentially all WTO member countries.<sup>9</sup> In particular, Eli Lilly's dispute challenged a widely accepted TRIPS flexibility that some countries have recently considered adopting and that the U.N. Secretary General's High Level Panel on Access to Medicine has just recommended countries should embrace.<sup>10</sup> In short, IP related cases filed in

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embraced by companies to challenge intellectual property. Nonetheless, even more recent regime shifting scholarship has not focused on this phenomenon. Details of regime shifting are further discussed in Part I. *But see* Susan Strange, *Cave! Hic Dragones: A Critique of Regime Analysis*, 36 INT'L ORG. 479 (1982) (critiquing regime theory).

7. We use the phrase "regulatory autonomy" in this context to refer to both traditional regulatory laws governing products, such as regulations requiring tobacco plain packaging, as well as any laws that "regulate" intellectual property norms, whether enacted by legislation or through judicial decisions.

8. *See infra* Section II.B.

9. *See infra* Section II.B.

10. Ruth Dreifuss & Festus Gontebanye Mogae (Co-chairs of the High-Level Panel), *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. 2016). Although this is a recent report that involved substantial input, the U.N., as well as other policy makers have long recommended that states embrace TRIPS flexibilities to promote better access to lower cost drugs. *E.g.*, Paul Hunt (Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health), *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, U.N. Doc. A/61/338, ¶ 47 (Sept. 13, 2006).

investor-state dispute settlement are in our view designed to destabilize the flexibilities countries have under the TRIPS Agreement to promote public health. In addition, as later discussed, these are part of a broader destabilization agenda.<sup>11</sup>

Some of these cases relate to a broader destabilization agenda regarding public health. For example, there are thirty-nine international cases surrounding tobacco in at least ten different international courts and tribunals.<sup>12</sup> By bringing these cases, tobacco companies are not narrowly pursuing a strategy of winning, but rather of creating uncertainty about the boundaries of a broad variety of tobacco regulations.<sup>13</sup> With regard to challenges of plain packaging regulations, delays arising from tobacco industry regulations mean that the industry continues to earn revenues from tobacco sales as long as those regulations are held in abeyance. Those profits may very well far outweigh the cost of litigating these regulatory controls.<sup>14</sup> Although pharmaceutical industry litigation has not been studied in the same systematic degree as tobacco litigation, the pharmaceutical industry was one of the major architects behind the creation of minimum standards of patent and other IP protection as part of the WTO.<sup>15</sup> In addition, just as the tobacco industry challenges a variety of regulations including but not limited to those that regulate IP, so too the

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11. See *infra* Sections II.A, II.B, and II.C.

12. Sergio Puig, *Tobacco Litigation in International Courts*, 57 HARV. INT'L L.J. 383, 392–93 (2016). These cases have challenged “import and export taxes; price, sale, export, and import controls; bans on tobacco products; marketing and advertisement restrictions; labeling requirements; and brand registration recognition.” *Id.* at 393. Notably, PMI, or an entity partially owned by or related to it, is implicated in one about one-fourth of these cases. *Id.* at 393 n.51.

13. Sabrina Tavernise, *Tobacco Firms’ Strategy Limits Poorer Nations’ Smoking Laws*, N.Y. TIMES (Dec. 13, 2013), <http://www.nytimes.com/2013/12/13/health/tobacco-industry-tactics-limit-poorer-nations-smoking-laws.html>. Tavernise argues, with extensive interviewing and information from the World Health Organization and government officials from around the world, that [t]obacco companies are pushing back against a worldwide rise in antismoking laws, using a little-noticed legal strategy to delay or block regulation. The industry is warning countries that their tobacco laws violate an expanding web of trade and investment treaties, raising the prospect of costly, prolonged legal battles . . . .

*Id.*

14. We thank Martin Bjorklund for pointing this possibility out to us.

15. See generally SUSAN K. SELL ET AL., PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 75–120 (Steve Smith et al. eds., 2003).

pharmaceutical industry vigorously challenges other domestic regulatory actions, such as public health measures demanding that companies reveal clinical data and price drugs at lower cost. The investor suits are an important part of the destabilization agenda. These suits promote destabilization and may also create dissonance between the recommendations to use flexibilities to promote public health made by the World Health Organization and a variety of United Nations agencies, and the international investment law regime's promotion and protection of investor rights.

Two important shifts have made international investment law a new focus for the protection and enforcement of IP rights. First, new generation investment agreements or investment chapters nested in trade agreements, such as the North American Free Trade Agreement (NAFTA), and the Trans-Pacific Partnership Agreement (TPP), explicitly make provision for the protection of intellectual property rights as a covered asset.<sup>16</sup> Second, as we show with the examples of the investor-state suits brought by Eli Lilly and Phillip Morris, private investors have invoked and pursued the dispute settlement provisions of investor-state arbitration to challenge international and domestic IP norms.<sup>17</sup> These disputes threaten to disrupt balances struck between protecting IP rights, on the one hand, and values such as public health, as reflected in TRIPS.<sup>18</sup> Notably, it was difficult for member states to conclude

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16. *E.g.*, Trans-Pacific Partnership Agreement, art. 9.1, (Feb. 4, 2016), <https://ustr.gov/sites/default/files/TPP-Final-Text-Investment.pdf> [hereinafter TPP].

17. *See infra* Section II.A.

18. Of course, this is not the first time that domestic regulatory authority has been threatened by investor-state suits. To protect the domestic right to regulate in a variety of contexts, countries such as South Africa and Indonesia have withdrawn or sought to limit the availability of investor-state dispute settlement. *E.g.*, Mohammad Mossallam, *Process Matters: South Africa's Experience Exiting its BITs* (Glob. Econ. Governance Programme Working Paper No. 2015/97), [http://www.globaleconomicgovernance.org/sites/geg/files/GEG%20WP\\_97%20Process%20matters%20-%20South%20Africas%20experienc%20exiting%20its%20BITs%20Mohammad%20Mossallam.pdf](http://www.globaleconomicgovernance.org/sites/geg/files/GEG%20WP_97%20Process%20matters%20-%20South%20Africas%20experienc%20exiting%20its%20BITs%20Mohammad%20Mossallam.pdf); HOGAN LOVELLS, *Indonesia Terminates Its Bilateral Investment Treaty (BIT) with the Netherlands from 1 July 2015 and May Terminate All of Its BITs*, LEXOLGY (Mar. 24, 2014), <http://www.lexology.com/library/detail.aspx?g=2a596886-3ad2-464b-a510-ab3b0cff503b>. Australia has also become more skeptical of incorporating investor-state claims in agreements. *E.g.*, Leon E. Trakman & Kunal Sharma, *Indonesia's Termination of the Netherlands-Indonesia BIT: Broader Implications in the Asia-Pacific?*, KLUWER

TRIPS because many were reluctant to give up their previous discretion to elect not to provide any intellectual property protection at all. Although some reluctant states were successful in including some balancing language in TRIPS, many scholars and policy makers believe that the TRIPS Agreement already compromises public health norms.<sup>19</sup> Accordingly, a further shift that destabilizes TRIPS norms could have a more substantial impact for most countries considering that TRIPS is not the ideal balance between protecting IP rights and values such as public health.

Our story is not a linear one. Rather, it demonstrates how multinational companies are consistently engaged in creating, or threatening to create, alternative forums to challenge international and domestic laws that might pose a threat to IP rights without abandoning existing forums. Investor-state litigation is the newest arena in which IP rights are contested, but the significance of these disputes has largely been overlooked.<sup>20</sup> This article fills this gap. In addition, although this article focuses on recent disputes, namely, the two Philip Morris cases as well as the Eli Lilly case, the tobacco industry has for decades contemplated using, and threatened to use, investor-state litigation against domestic tobacco packaging and other public-regarding regulation to protect public health.<sup>21</sup> Companies have continued to pursue their agenda for strengthened IP rights concurrently in multiple forums with a view to reshaping the internal dynamics and workings of the

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ARBITRATION BLOG (Aug. 21, 2014), <http://kluwerarbitrationblog.com/2014/08/21/indonesias-termination-of-the-netherlands-indonesia-bit-broader-implications-in-the-asia-pacific/> (noting inclusion in agreement with Korea, but not in agreement with Japan).

19. Since drug patents increase the cost of drugs, this is already seen as inherently compromising the right to health. *E.g.*, U.N., Econ. & Soc. Council, Comm. on Econ., Soc. & Cultural Rights, Substantive Issues in the Implementation of the International Covenant on Economic, Soc. & Cultural Rights, Human Rights and Intellectual Property, Statement by the Comm. on Econ., Soc. & Cultural Rights on Its Twenty-Seventh Session, U.N. Doc. E/C.12/2001/15, ¶ 12 (Dec. 14, 2001). Of course, some scholars have suggested how nations can better promote public health within TRIPS constraints. *See infra* Part III.

20. *E.g.*, Henning Gross Ruse-Khan, *Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation* (Univ. of Cambridge Faculty of L. Research Paper No. 2014-21, 2014), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2463711](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711) (viewing investment claims as unlikely to succeed).

21. *Infra* Section II.A.

domestic and international IP system.<sup>22</sup> Although the desire for strengthened protection of IP is not new, what is unique about investor-state arbitration is that prevailing in such proceedings could result in a regime shift that tilts the balance more towards stronger IP rights and in the process weakens the regulatory autonomy of states in favor of health, human rights, and development.

This shift to investor-state arbitration is an important change from previous rounds of regime shifting. Not only are these investor-state dispute proceedings sending a regulatory chill and legal uncertainty on efforts by States to regulate IP industries, but if successful they would set in motion systemic changes to the IP system decidedly in favor of rights holders in the areas identified above. This new phenomenon comes at a time when the strength of IP rights is undergoing scrutiny in both the domestic and global arenas.<sup>23</sup>

We argue that this regime shifting to protect and enforce IP rights in international investment law sheds new light in at least three ways. First, unlike earlier scholarship on regime shifting that primarily focused on lawmaking activity primarily pursued by states, and to a lesser extent by inter-governmental organizations and NGOs across a variety of regimes,<sup>24</sup> this

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22. This is particularly true regarding the scope of patent rights as the cost of patented drugs increasingly strains domestic budgets. For example, the U.N. convened a High Level Panel in November 2015 to address the problem of access to medicine and create policy recommendations to better integrate human rights laws and trade rules. *E.g.*, UNITED NATIONS SECY-GEN.'S HIGH-LEVEL PANEL ON ACCESS TO MEDS., THE PROCESS, <http://www.unsgaccessmeds.org/the-process/> (last visited Feb. 21, 2017). The final report provides recommendations on how to better balance IP rights and public health, including an embrace of TRIPS flexibilities. *See* Dreifuss & Mogae, *supra* note 10.

23. *E.g.*, Dreifuss & Mogae, *supra* note 10; Council Conclusions on Strengthening the Balance in the Pharmaceutical Systems in the European Union and Its Member States, 2016 O.J. (C 269) 31. Although IP rights are not new, increasing drug costs that strain domestic budgets are likely promoting greater inquiry. *E.g.*, Tahir Amen, *The Downfall of Invention: A Broken Patent System*, HUFFINGTON POST (Aug. 16, 2016, 3:29 PM), [http://www.huffingtonpost.com/entry/the-downfall-of-invention-a-broken-patent-system\\_us\\_57b362a7e4b0edfa80d9c169](http://www.huffingtonpost.com/entry/the-downfall-of-invention-a-broken-patent-system_us_57b362a7e4b0edfa80d9c169); Jack Hoadley et al., *The Cost of a Cure: Revisiting Medicare Part D and Hepatitis C Drugs*, HEALTH AFF. BLOG (Nov. 3, 2016), <http://healthaffairs.org/blog/2016/11/03/the-cost-of-a-cure-revisiting-medicare-part-d-and-hepatitis-c-drugs/>.

24. *See, e.g.*, Helfer, *supra* note 6, at 6 (“[T]he expansion of intellectual property lawmaking into . . . diverse international fora is the result of a strategy of ‘regime shifting’ by developing countries and NGOs that are dissatisfied with

article sharply focuses on the strategic role of industry actors. In a sense therefore, we are also influenced by the insights of Transnational Legal Orders to the extent that we move beyond a state-centric approach to more generally focus on lawmaking and practice within a dynamic framework that simultaneously examines “local, national, international, and transnational public and private lawmaking and practice.”<sup>25</sup> Capturing lawmaking and practice within a single framework helps us to highlight the considerable stakes between the variety of actors involved because of their competing perspectives, values, priorities, as well as because of distributive consequences that arise.<sup>26</sup> Hence, although industry actors have previously played an important role in lobbying their home states to shift IP regulation from domestic to international law, this article shows how industry actors are for the first time pursuing international disputes that do not depend on espousal of their claims by their home state such as in the WTO dispute settlement system. Second, this litigation strategy involves both lawmaking and a shift of IP rights enforcement to investor-state arbitration where remedies are broader than at the WTO—for example investor-state arbitration allows investors to seek retrospective relief, unlike in the WTO. Such relief could include substantial damages awards against States.<sup>27</sup> Unlike litigation between

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many provisions in TRIPS or its omission of other issues and are actively seeking ways to recalibrate, revise, or supplement the treaty.”). Helfer does, however, acknowledge that it is not only states but also non-state actors who “attempt to reshape a regime’s constituent principles, norms, and rules by shifting from one discrete regime to another or between fora within the same conglomerate regime.” *Id.* at 9. For Helfer, states are a primary actor. For us, the shift to international investment law is primarily driven by private actors. In addition, we focus on the international investment law regime unlike Helfer who focused on the biodiversity, plant genetic resources, public health, and human rights regimes. *But see* Susan Sell, *Cat and Mouse: Forum-Shifting in the Battle Over Intellectual Property Enforcement* 30 (Sept. 1, 2009) (draft) (available at [https://papers.ssrn.com/abstract\\_id=1466156](https://papers.ssrn.com/abstract_id=1466156)) (focusing on both norm setting and enforcement). Of course, before the regime shifting term was coined, some had previously suggested that companies were successful in shifting from WIPO to the WTO to create stronger and more effective intellectual property enforcement. *E.g.*, SELL ET AL., *supra* note 15.

25. Terence C. Halliday & Gregory Shaffer, *Transnational Legal Orders, in* TRANSNATIONAL LEGAL ORDERS 3 (Terence C. Halliday & Gregory Shaffer eds., 2015).

26. *Id.* at 11.

27. The average award is over \$16 million, but damages have been as large as \$50 billion. *E.g.*, Susan D. Franck, *Using Investor-State Mediation Rules to Promote Conflict Management: An Introductory Guide*, 29 INT’L CTR. FOR

WTO members, investor-state arbitration gives corporations that have substantial resources access to an adjudicatory system against States that often can hardly match their resources. For example, in 2013 Phillip Morris had \$80.7 billion in annual revenue while the Gross Domestic Product of Uruguay, against which it brought an investor-state case, was \$55.7 billion.<sup>28</sup> It is notable that Uruguay would have had to settle the case with Philip Morris had billionaire philanthropist Michael Bloomberg not volunteered to fund the costs of ICSID litigation.<sup>29</sup> In addition, unlike in the WTO where third party participation is open to all WTO member States with an interest in the case, investor-state arbitration traditionally has not allowed direct third party participation. Although investment tribunals have had the power to permit consideration of amicus briefs from third parties, most agreements do not guarantee a right and there are also limits on the scope of what can be considered.<sup>30</sup> Third, unlike prior work on regime or forum shifting, this article traces this latest shift of Intellectual Property Right (IPR) protection and enforcement to international investment law where IPR holders hope to prevail in re-writing or restricting what they consider restrictive national and international laws and regulations of their products. In effect, we argue that by pursuing investor-state arbitration, investors hope to destabilize widely held understandings of the TRIPS Agreement in a manner that they may not otherwise be able to do in other forums such as the WTO.<sup>31</sup> Investor-state suits would in turn

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SETTLEMENT INV. DISP. REV. 66, 79 (2014); Glyn 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>.

28. See Leon Kaye, *Philip Morris Sues Uruguay Over Anti-Smoking Campaign*, TRIPLE PUNDIT, (Apr. 13, 2015), <http://www.triplepundit.com/2015/04/philip-morris-vs-uruguay-lawsuit-a-threat-to-smoking-restrictions-worldwide/>.

29. See Tavernise, *supra* note 13 (noting that “Uruguay has acknowledged that it would have had to drop its tobacco control law and settle with Philip Morris International if the foundation of the departing mayor of New York, Michael R. Bloomberg, had not paid to defend the law”); see also Press Release, Bloomberg Philanthropies, Bloomberg Philanthropies & The Bill & Melinda Gates Foundation Launch Anti-Tobacco Trade Litigation Fund (Mar. 18, 2015), <https://www.bloomberg.org/press/releases/bloomberg-philanthropies-bill-melinda-gates-foundation-launch-anti-tobacco-trade-litigation-fund/>.

30. See *infra* Subsection II.C.2.

31. Lawmaking between States in multilateral forums such as the WTO often balances rights such as those of intellectual property protection with

send a regulatory chill on the ability of WTO members to use TRIPS flexibilities to, for example, make essential medicines affordable.

This article illustrates this latest shift of protecting and enforcing IP rights in the international investment law regime using the examples of the recently concluded Eli Lilly and Phillip Morris investor-arbitration cases. This shift has systemic significance for at least three reasons.<sup>32</sup> First, decisions arising from investor challenges in arbitration proceedings launched by investors will create new lawmaking and enforcement dynamics that will invariably impact other forums where IP rights are protected and enforced. Second, because each regime has its own internal logic, there is no way to establish hierarchy between them to avoid inevitable conflict, particularly given that private investors are using investor-state arbitration to achieve outcomes that are likely to be more favorable to them than in other forums that are more open to concerns such as public health and the participation of NGOs. Third, because investor-state dispute settlement is triggered by ‘automatic jurisdiction’ the inevitability of conflicting decisions with national judiciaries and with the WTO regime that incorporates a carefully

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interests such as public health. This is because in multilateral forums involving both developed and developing countries, some States prioritize the interests of IP producers, but others prioritize the interests of consumers. The outcomes of such multilateral negotiations are therefore less likely to be slanted in any one direction at the expense of the other. *See, e.g.,* Eva Nanopoulos & Rumiana Yotova, *‘Repackaging’ Plain Packaging in Europe: Strategic Litigation and Public Interest Considerations*, 19 J. INT’L ECON. L. 175 (2016). For example, TRIPS reflects a compromise between the proposed strong IP protection advocated by the United States versus much weaker IP protection advocated by India. *See, e.g.,* Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay*, GATT Doc. MTN.GNG/NG11/W/71 (May 14, 1990); Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights: Communication from the United States*, GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990). Of course, when agreements are between solely developed countries, such a balance does not exist. *See* Comprehensive Economic and Trade Agreement, Can.-E.U., ch. 8, Sept. 14, 2016 [hereinafter CETA]; Transatlantic Trade and Investment Partnership [hereinafter TTIP], European Union’s Investment Chapter Proposal, [http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc\\_153955.pdf](http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153955.pdf).

32. Helfer, *supra* note 6, at 14–15 (describing systemic changes in a regime as revolutionary to the extent that counter-regime norms pose “fundamental challenges to underlying principles”).

structured balance of rights and obligations between owners and users of IP rights will likely be undermined.<sup>33</sup> In fact, unlike other scholars who have argued that regime complexity gives developing countries the flexibility to craft IP regulation that better suits their level of development and to balance between importing and exporting IP-based goods and services,<sup>34</sup> we argue that the shift of IP lawmaking and enforcement to the international investment regime is likely to run counter to the interests of these countries. This is particularly so because the balance between the rights of producers and consumers of IP rights embodied in TRIPS flexibilities, while broadly accepted, is a tenuous consensus at best as is reflected by the absence of widespread adoption in practice among WTO members, as well as the fact that some countries have been enacting free trade agreements that erode some of these flexibilities. In this sense, we see regime shifting as a politically and normatively contested process in which powerful actors seek to free themselves from domestic regulatory control and once they have achieved that objective they shift from one international regime to another international regime seeking the most hospitable one.<sup>35</sup> To the extent that regime shifting is a politically and normatively contested process, we use it in that context rather than as a neutral descriptor.

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33. Of course the balancing we have in mind here is different from one WTO agreement to another.

34. See, e.g., Sell, *supra* note 24, at 30; Laurence R. Helfer, *Regime Shifting in the International Intellectual Property System*, 7 PERS. ON POL. 39 (2009) [hereinafter Helfer 2009]; Helfer, *supra* note 6, at 13; Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571 (2009); Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?*, 46 HOUS. L. REV. 1115 (2009); Gregory C. Shaffer & Mark A. Pollack, *Hard vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance*, 94 MINN. L. REV. 706 (2010).

35. In this sense, we agree with Martti Koskenniemi when he argues that [i]n normal situations of international life the actors disagree on such matters, putting forward competing understandings and rival interpretations of the relevant rules or policies. These are situations that I like to call hegemonic contestation so as to highlight that what is at stake is not only what the general view is but who is entitled to determine it.

Martti Koskenniemi, *Hegemonic Regimes*, in REGIME INTERACTION IN INTERNATIONAL LAW: FACING FRAGMENTATION 305, 312 (Margaret A. Young ed., 2012) (emphasis omitted); see also Robert Wai, *Transnational Liftoff and Juridical Touchdown: The Regulatory Function of Private International Law in an Era of Globalization*, 40 COLUM. J. TRANSNAT'L L. 209 (2002).

This article proceeds as follows. After this Introduction, Part I delves into regime shifting theory and how the regime shift we track in this paper is intended to destabilize existing understandings of IP laws and regulations by creating counter-norms or seeking to rewrite them altogether. Part II discusses examples of the regime shift focusing in particular on Philip Morris' challenges to tobacco regulations in Australia and Uruguay as well as Eli Lilly's challenge of a Canadian Supreme Court decision that invalidated its patents. This Part also demonstrates how this shift threatens to effectively water-down TRIPS flexibilities in a manner that currently seems to preclude countervailing shifts that would better preserve public health goals. In Part III, we offer some tentative suggestions to counter the consequences of a shift to enforcement of IP rights in investor-state arbitration. Our suggestions are in two categories. The first relates to reforms for future investment treaties particularly in defining with precision key terms and rights such as ensuring States reserve their right to regulate as well as what treaty definitions of terms such as fair and equitable treatment (FET) and indirect expropriation mean. Second, this Part also suggests modifications to the procedures that govern investor-state disputes for both parties to the dispute, as well as the arbitrators.

## I. REGIME SHIFTING

### A. DEFINING REGIME SHIFTING

Before discussing the recent regime shift to the investment arena, it is important to briefly explain what we mean by a "regime," as well as "regime shifting." In using these terms, we are building on the work of international legal and political science scholars who use these terms to account and explain the increasing density of rules of international law governing discrete subject matter as well as the manner in which these disparate regimes overlap and create conflicts or convergences.

We follow Laurence Helfer's definition of a regime as comprising substantive, institutional and relational components.<sup>36</sup> A regime can focus on a single international

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36. Helfer, *supra* note 6, at 10. Of course, although Helfer was the first to discuss regime shifting regarding international intellectual property, he builds on the work of scholars who have studied international regimes. *E.g.*,

agreement or intergovernmental organization, but more broadly encompass broader interests, such as whether non-state actors can participate, even if not legally bound by the agreement.<sup>37</sup> Each regime comes with its unique “institutional features, subject matter competencies, and decision-making procedures.”<sup>38</sup> Substantively, a regime has principles, norms, and rules that prescribe state behavior.<sup>39</sup> Institutionally, a regime comprises of the “cooperative arrangements states use to create principles, norms, and rules.”<sup>40</sup> The relational aspect of a regime “focuses on the substantive issue areas that are included within a particular regime and the ways in which they intersect with the issue areas of other regimes.”<sup>41</sup> The proliferation of regimes in a variety of issue areas in international law, sometimes with overlapping, conflicting, or converging mandates has been referred to as fragmentation.<sup>42</sup> The absence of a hierarchy or conflict rules between regimes that cover the same subject matter and actors that would effortlessly resolve cases of parallel jurisdiction opens up fragmentation to States and non-state actors to explore options and opportunities between these regimes by exiting one regime and entering another with a view to establishing which regime best advances their interests.<sup>43</sup>

Regime shifting focuses on improving power dynamics by shifting from one regime with a view to directly or indirectly create alternative law or practices that conflict with those in

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INTERNATIONAL REGIMES (Stephen Krasner ed., 1983); Robert Keohane, *The Demand for International Regimes*, 36 INT’L REGIMES 325 (1982).

37. Helfer, *supra* note 6, at 10.

38. *Id.* at 8.

39. *Id.* at 11.

40. *Id.*

41. *Id.* at 12.

42. An authoritative assessment of this is contained in Martti Koskenniemi, Int’l Law Comm., Rep. of the Study Grp. of the Int’l Law Comm’n on Its Fifty-Eight Session, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, U.N. Doc. A/CN.4/L.682, ¶ 34 (Apr. 13, 2006).

43. *E.g.*, Kal Raustiala & David G. Victor, *The Regime Complex for Plant Genetic Resources*, 58 INT’L ORG. 277 (2004) (noting the non-hierarchical nature of regime complexes). Regime complexes spawned by fragmentation in turn enable actors to engage in regime shifting. *E.g.*, Karen J. Alter & Sophie Meunier, *The Politics of International Regime Complexity*, 7 PERSP. ON POL. 13, 20 (2009) (noting that “international regime complexity facilitates exit via non-compliance, regime shifting, or withdrawal from [international organizations]”).

another regime.<sup>44</sup> Although a regime shift involves shifting to a new forum, it is distinct from forum shifting because a forum shift is a one-time shift to a new forum for a single dispute. The goal of a regime shift, on the other hand, is a “longer-term strategy that seeks to create outcomes that have feedback effects in other venues.”<sup>45</sup> Actors engaged in regime-shifting believe that “such shifts will enhance their relative power or their prospects for achieving desired policy outcomes in ways that could not have been obtained in the absence of such moves.”<sup>46</sup> In particular, actors change rulemaking venues to forums “whose mandates and priorities favor their concerns and interests.”<sup>47</sup> In so doing, actors seeking a new regime seek changes in the institutional status quo that is inconsistent with their interests.<sup>48</sup> Regime shifting can also be used to relieve pressure from “domestic interest groups for lawmaking in other regimes” as well as developing rules that could be integrated into a dominant regime like the World Trade Organization.<sup>49</sup> Regime shifting is therefore a continual process of “contestation within and across forums” where rights are made and enforced.<sup>50</sup> One of the most important consequences of regime shifting is a conflict of principles, rules, and norms between regimes.<sup>51</sup> In the

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44. See generally Julia C. Morse & Robert O. Keohane, *Contested Multilateralism*, 9 REV. INT’L ORG. 393 (2014) (discussing this phenomenon; defining it as ‘contested multilateralism’).

45. Helfer 2009, *supra* note 34, at 39; see also Helfer, *supra* note 6, at 14 (defining regime shifting as “an attempt to alter the status quo ante by moving treaty negotiations, lawmaking initiatives, or standard setting activities from one international venue to another”).

46. Helfer, *supra* note 6, at 7; Amandine Orsini, *Multi-Forum Non-State Actors: Navigating the Regime Complexes for Forestry and Genetic Resources*, 13 GLOBAL ENVTL. POL. 34, 41 (2013) (arguing that through forum shifting a debate is moved from one forum to another “that better reflects an actor’s interest”).

47. Helfer 2009, *supra* note 34, at 39. Susan Sell also argues that the goal of forum shifting as she calls it is to “optimize . . . power and advantages and minimize opposition.” Sell, *supra* note 24, at 5; see also Alter & Meunier, *supra* note 43, at 21 (“[W]here actor preferences diverge and a threshold of international regime complexity occurs, explanations involving the behavior of actors or the outcomes of cooperation politics will be more ‘fuzzy’—there will be multiple paths to an outcome, involving linked sets of behaviors and events.”).

48. Morse & Keohane, *supra* note 44; see also Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323 (2004) (exploring a variety of regime shifts in the IP area).

49. Helfer, *supra* note 6, at 82.

50. Sell, *supra* note 24, at 8.

51. See Helfer, *supra* note 6, at 72.

context of IPR, Helfer argues that regime shifting, “destabilizes existing approaches to intellectual property protection and generates new dynamics of lawmaking, standard setting, and dispute settlement.”<sup>52</sup> Julia Morse and Robert Keohane, argue that regime shifting occurs “when challengers to a set of rules and practices shift to an alternative multilateral forum with a more favorable mandate and decision rules, and then use this new forum to challenge standards in the original institution or reduce the authority of that institution.”<sup>53</sup>

Regime shifting occurs in the context of a regime complex. A regime complex is made up of separate related regimes.<sup>54</sup> For example, intellectual property rights are addressed in a number of regimes, including: (i) the WTO; (ii) the World Intellectual Property Organization (WIPO); (iii) a variety of United Nations agencies; and (iv) the World Health Organization. In short, today there is an IP regime complex that involves multiple interdependent and porous regimes<sup>55</sup> that can result in inter-regime conflicts. As a result—and as we shall explain further below—when states adopt rules such as the Framework Convention on Tobacco Control, they create new tensions and conflicts with the strengthened protection of IP rights that are contained in TRIPS as well as in investment agreements. This is because treaties like the Framework Convention on Tobacco Control contain obligations that authorize signatory States to pursue measures such as plain packaging, which in turn lays the basis for investors to pursue claims to prevent States from interfering with the enjoyment of their IP rights.<sup>56</sup> In addition, different regimes have different rules that define the extent to which nongovernmental entities, including NGOs such as Medicines Sans Frontiers, as well as public private partnerships

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52. *Id.* See generally Stephan Haggard & Beth A. Simmons, *Theories of International Regimes*, 41 INT'L ORG. 491, 496 (1987) (describing general theories of international regimes and how variation and change in regimes impacts the political landscape).

53. Morse & Keohane, *supra* note 44, at 392 (quoting Helfer 2009, *supra* note 34, at 39) (noting that they borrow from Helfer who “suggests that regime shifting works by ‘broadening the policy spaces within which decisions are made and rules are adopted’”).

54. Alter & Meunier, *supra* note 43, at 13 (noting that regime complexity entails “nested, partially overlapping, and parallel international regimes that are not hierarchically ordered”).

55. Helfer, *supra* note 6, at 16.

56. See, e.g., Ruse-Khan, *supra* note 20, at 2–11.

such as the Global Fund to Fight Aids, Tuberculosis and Malaria, can participate.<sup>57</sup> Whereas regimes such as the WTO and U.N. permit broad participation of NGOs, that is not true of investor-state arbitration.<sup>58</sup> These differing regimes reflect an unstructured plurality of independent decentralized actors regarding the issue of global health. As a result, investor-state arbitration could potentially destabilize balances struck between intellectual property rights and health rights struck in the WTO or the WHO.<sup>59</sup>

In short, a shift from the WTO to investor-state arbitration involves a move to change policy and rules agreed upon in one regime, to another regime. Although our focus in this article is on regime shifting, which until the most recent shift has not involved private actors, we recognize that there is the related area of Transnational Legal Ordering that more typically focuses not only on State entities but also on individual private actors that aim to order behavior across domestic and global dimensions. Indeed, Helfer, a leading scholar of IP regime shifting, has described some of the same global activities as an evolving transnational legal order on access to medicine.<sup>60</sup> However, our aim here is to focus on the significant yet understudied shift from the WTO and other trade agreements to investment disputes as a means of destabilizing existing understandings to shape IP law, policy, and enforcement. While this is consistent with transnational legal ordering, we will primarily focus on regime shifting, including the key differences regarding institutional and enforcement mechanisms of each regime that highlight the dangers of this shift. Before our detailed description of the IP regime shift to the international

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57. See JOSHUA LEON, *THE RISE OF GLOBAL HEALTH: THE EVOLUTION OF EFFECTIVE COLLECTIVE ACTION* 126–32 (2015).

58. See, e.g., Ruse-Khan, *supra* note 20.

59. David P. Fidler, *Architecture Amidst Anarchy: Global Health's Quest for Governance*, 1 *GLOBAL HEALTH GOVERNANCE* 3 (2007) (referring to the plurality of actors involved in global governance as constituting an “unstructured plurality”).

60. Laurence R. Helfer, *Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines*, in *TRANSNATIONAL LEGAL ORDERS*, *supra* note 25, at 311; see also Gregory Shaffer & Susan Sell, *Transnational Legal Ordering and Access to Medicines*, in *PATENT LAW IN GLOBAL PERSPECTIVE* (Ruth L. Okediji & Margo A. Bagley eds., 2014).

investment arena, we will briefly explain IP regime shifting prior to this latest shift.

## B. IP REGIME SHIFTING

Regime shifting involving IP in the international arena is not a new phenomenon.<sup>61</sup> The WTO/TRIPS framework shifted IP rulemaking not only from domestic to international law, but also from prior agreements solely concerning intellectual property to the trade regime.<sup>62</sup> Multinational companies successfully lobbied the United States and Japanese governments, as well as multiple European governments.<sup>63</sup> Prior international agreements only governed IP rights *if* a nation decided to provide such rights.<sup>64</sup> In addition, although the Paris Convention for Patents modestly governed enforcement of patents, when countries were unsuccessful in strengthening rights under this agreement, they turned to the WTO.<sup>65</sup> The TRIPS Agreement provided the first-ever requirements for countries to enact domestic IP rights, backed up by an enforceable system of dispute settlement.<sup>66</sup>

Another regime shift seeking to tilt the IP regime in favor of the interests of developing countries occurred when these countries, supported by non-governmental organizations, succeeded in creating counter-norms to IP protection for access to essential medicines in forums such as the World Health Organization and the United Nations Human Rights system.<sup>67</sup>

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61. *E.g.*, Yu, *supra* note 48.

62. Moreover, this is arguably not the first regime shift impacting international IP. *E.g.*, *id.*

63. *E.g.*, PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 10 (2002); SELL ET AL., *supra* note 15, at 96–108.

64. For example, a nation that provided patents could not treat patent applications of its own nationals more favorably than those of foreign applicants. Paris Convention for the Protection of Industrial Property, arts. 2–3, Mar. 20, 1883, as last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1583; *see also* Patent Cooperation Treaty, art. 1(1), June 19, 1970, 28 U.S.T. 7645 (creating a mechanism to easily file patent applications in multiple countries without dictating substantive law for granting of patents).

65. *See, e.g.*, Helfer, *supra* note 6, at 20–21.

66. *See* TRIPS, *supra* note 2, arts. 41–49.

67. *E.g.*, Alter & Meunier, *supra* note 43, at 20; Eyal Benvenisti & George W. Downs, *The Empire's New Clothes: Political Economy and the Fragmentation of International Law*, 60 STAN. L. REV. 595, 597 (2007); Helfer 2009, *supra* note 34, at 41; Shaffer & Pollack, *supra* note 34; Heiko Baumgärtner, *Patents, Power,*

Notably, these regimes allow more access and participation for NGOs than the WTO. Thus, developing states could combine forces with NGOs to strengthen counter-norms globally. These counter-norms were also introduced into the WTO/TRIPS regime, particularly through the 2001 Doha Ministerial Declaration on TRIPS and Public Health that recognized that patent provisions of the TRIPS Agreement should not be construed as a barrier to accessing affordable medicines.<sup>68</sup>

Concurrently with the regime shift for counter-norms regarding public health, there has been a shift towards higher standards of IP protection through other free trade agreements.<sup>69</sup> Initially free trade agreements with enhanced intellectual property protection were bilateral agreements, predominantly initiated by countries like the United States and entities like EU. They were designed to obtain stronger IP rights—and also curtail some TRIPS flexibilities—than could be negotiated in the WTO forum.<sup>70</sup> By singling out a subset of WTO countries, developed countries “use their market power to leverage negotiations to their advantage over much weaker economies” that are often still enticed by the carrot of broader trade with the United States.<sup>71</sup> In addition, developed countries aimed to increase intellectual property standards by creating *uniform* patent standards that could not be obtained in TRIPS

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*and Rhetoric: Intellectual Property Rights and the Politics of Regime Complexity*, (Universität Luzern, “Glocal Governance and Democracy” Working Paper Series, Paper No. 4, 2011), <https://www.unilu.ch/fileadmin/fakultaeten/ksf/institute/polsem/Dok/Patents-Power-Rhetoric-wp04.pdf>.

68. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, ¶¶ 4–5 (2002) [hereinafter Doha Public Health Declaration].

69. Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTEL. PROP. L. 447 (2011).

70. *E.g., id.*; see also SELL ET AL., *supra* note 15 (noting a comment by a U.S. advocate that “we got 95% of what we wanted” in TRIPS). Of course, these agreements were used in conjunction with a variety of other mechanisms, including diplomatic and legal threats and industry pressure. *E.g.,* CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES* 154–64 (2009).

71. James Thuo Gathii, *The Neoliberal Turn in Regional Trade Agreements*, 86 WASH. L. REV. 421, 446 (2011). In addition, pursuing developing countries in a piecemeal fashion can also set the stage for higher multilateral IP requirements. *E.g.,* Peter Drahos, *BITs and BIPs: Bilateralism in Intellectual Property*, 4 J. WORLD INTEL. PROP. 791 (2001).

with a proposed patent law treaty.<sup>72</sup> Although developing countries were successful in defeating this, they have not forestalled the regime shift towards higher levels of protection through regional and mega-regional trade agreements.<sup>73</sup> Recently proposed agreements include the Anti-Counterfeiting Trade Agreement (ACTA), the Transpacific Partnership Agreement (TPP), and the Regional Comprehensive Economic Partnership (RCEP). Sometimes these agreements are solely between developed countries, which can then set the stage for imposing equivalent levels of protection for developing countries. Although ultimately unsuccessful, ACTA was one such example.<sup>74</sup> More recent examples whose ultimate success remains to be seen are the Transatlantic Trade and Investment Partnership (TTIP) between the United States and EU and the EU-Canada Comprehensive Economic and Trade Agreement (CETA).

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72. *E.g.*, *Eli Lilly & Co. v. Gov't of Canada*, ICSID Case No. UNCT/14/2, Second Expert Report of Daniel J. Gervais, 10–18 (NAFTA/UNCITRAL Arb. Trib. Dec. 7, 2015); *Draft Substantive Patent Law Treaty*, WIPO, [http://www.wipo.int/patent-law/en/draft\\_splt.htm](http://www.wipo.int/patent-law/en/draft_splt.htm); Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85 (2007).

73. World Intellectual Prop. Org. [WIPO], *Assemblies of the Member States of WIPO, Forty-Third Series of Meetings: General Report*, A/43/16 (Nov. 12, 2007); *see also* World Intellectual Prop. Org. [WIPO], *WIPO General Assembly, Thirty-First (15th Extraordinary) Session: Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WO/GA/31/11 (August 27, 2004) (initial proposal).

74. At the time it was negotiated, this was considered the highest standard of IP rights, yet only open to eight developed countries as a “club” agreement. *E.g.*, Daniel Gervais, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, 103 AM. J. INT’L L. 549, 555 (2009) (“The approach is neither regional nor truly multilateral; it is a ‘club approach.’”). Nonetheless, it was contemplated that ACTA would influence non-signatory developing countries. *E.g.*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, TRADE FACTS: ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA) (2008) (noting that the USTR looked forward to providing “technical assistance” to developing countries and partnering with them); Sell, *supra* note 69, at 456 (anticipating that ACTA provisions would appear in subsequent agreements that included developing countries).

## II. THE IP REGIME SHIFT TO THE INTERNATIONAL INVESTMENT AGREEMENTS

### A. EVIDENCE OF AN IP REGIME SHIFT TO ISDS AND REGULATORY CHILL

The Philip Morris challenges to tobacco laws, as well as Eli Lilly's challenge to Canada's patent laws, are evidence of a regime shift in enforcement of IP claims to investor-state arbitration.<sup>75</sup> In our view, this shift is a strategy by IP companies to destabilize the balances struck in IP regimes such as the WTO with a view to creating counter-norms or re-writing domestic and international laws and regulations that the industry considers to be inconsistent with their IP rights. This section traces this shift and its destabilization agenda.

Although plans to use investor-state dispute settlement by companies in earlier decades is likely shrouded by attorney-client privilege, there is some evidence we have uncovered to demonstrate this has been on the drawing boards since at least 1990.<sup>76</sup> In this section, we outline these plans and explain why investor-state dispute settlement is particularly favorable for companies as an avenue to challenge international or domestic regulations they argue are inconsistent with their IP rights.

The parties to the TRIPS Agreement discussed more extensive investment provisions for the forthcoming WTO, but could only agree on trade-related investment measures.<sup>77</sup> In 1988, the United States was contemplating a comprehensive agreement on investment under the auspices of the

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75. Although we recognize that some might consider the Philip Morris investment cases to be an example of parallel proceedings or forum proliferation since there is simultaneously a WTO case, we also consider this an example of regime shifting under our definition that the goal in pursuing the investment cases is to change WTO law; that might include—but is certainly not limited to—the pending WTO case regarding similar facts.

76. EUR. ROUND TABLE OF INDUSTRIALISTS, EUROPEAN INDUSTRY: A PARTNER OF THE DEVELOPING WORLD, FOREIGN DIRECT INVESTMENT AS A TOOL FOR ECONOMIC DEVELOPMENT AND COOPERATION—SUGGESTIONS FOR FUTURE IMPROVEMENTS 35 (1993); Belen Balanya et al., *MAIGALOMANIA!: Citizens and the Environment Sacrificed to Corporate Investment Agenda: A Briefing by Corporate Europe Observatory (CEO)* (1998), <http://archive.corporateeurope.org/mai/MAIGALOMANIA.txt>.

77. See, e.g., William J. Drake & Kalypso Nicolaidis, *Ideas, Interests, and Institutionalization: "Trade in Services" and the Uruguay Round*, 46 INT'L ORG. 37 (1992) (stating that investment as well as IP provisions were lobbied for inclusion into the WTO).

Organization for Economic Cooperation and Development (OECD).<sup>78</sup> This was a more favorable venue for negotiating a full-scale investment agreement than the WTO because its members are all developed countries. In 1995, the OECD Council of Ministers approved a negotiating mandate for a Multilateral Agreement on Investment (MAI) that would have strengthened and multilateralized existing bilateral investment treaties as well as regional agreements with investment provisions such as NAFTA.<sup>79</sup> Although developing countries were not privy to these negotiations, the draft signaled that the MAI was open to accession by non-members who had not been involved in the negotiations.<sup>80</sup> A leaked draft of the Agreement in 1997 led to a successful campaign to derail it by non-governmental organizations who were outraged by its pro-investor content, as well as inadequate public debate on it.<sup>81</sup>

Even as the MAI failed in the mid-1990s, companies were keenly watching and challenging the emergence of laws and regulations they regarded as adversely impacting their IP rights.<sup>82</sup> Although most countries have been reluctant to use their TRIPS patent flexibilities, companies have targeted those who attempt to do so, with the goal of discouraging other countries from doing so.<sup>83</sup> For example, when South Africa

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78. See EUR. ROUND TABLE OF INDUSTRIALISTS, *supra* note 76, at 35; Balanya et al., *supra* note 76.

79. Negotiating Group on the Multilateral Agreement on Investment (MAI), The Multilateral Agreement on Investment: Draft Consolidated Text, OECD, chs. 2–3, Apr. 22, 1998, DAF/MAI(98)7/REV1, [hereinafter MAI Negotiations Text] <http://www1.oecd.org/daf/mai/pdf/ng/ng987r1e.pdf>; Jürgen Kurtz, *NGOs, the Internet and International Economic Policy Making: The Failure of the OECD Multilateral Agreement on Investment*, 3 MELB. J. INT'L L. 213, 221 (2002).

80. See Negotiating Group on the Multilateral Agreement on Investment (MAI), Accession by Non-Member Countries (Note by the Chairman), OECD, Apr. 4, 1996, DAF/MAI(96)13, <http://www1.oecd.org/daf/mai/pdf/ng/ng9613e.pdf>; Negotiating Group on the Multilateral Agreement on Investment (MAI), Participation of Non-Members (Note by the Chairman), OECD, May 9, 1997, DAF/MAI(97)21, <http://www1.oecd.org/daf/mai/pdf/ng/ng9721e.pdf>; MAI Negotiations Text, *supra* note 79, ch. 3.

81. *E.g.*, Kurtz, *supra* note 79; see also KATIA TIELEMAN, UN VISION PROJECT ON GLOB. PUB. POL'Y NETWORKS, THE FAILURE OF THE MULTILATERAL AGREEMENT ON INVESTMENT (MAI) AND THE ABSENCE OF A GLOBAL PUBLIC POLICY NETWORK (2008), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.627.7992&rep=rep1&type=pdf>.

82. See, *e.g.*, Dreifuss & Mogae, *supra* note 10.

83. *Id.*

amended its patent act in 1997 to permit parallel imports of generic drugs, thirty-seven multinational pharmaceutical companies promptly filed suit to challenge that law.<sup>84</sup> Although the companies eventually capitulated in the face of public opposition, they have continued to monitor and oppose domestic legislation in South Africa such as the “Pharmagate” scandal which involved an extensive plot to defeat South African patent reforms.<sup>85</sup> Similarly, tobacco companies have fiercely opposed domestic legislation on packaging that have impacted their trademarks in Canada, the United States,<sup>86</sup> Australia, New Zealand,<sup>87</sup> the UK, and elsewhere.<sup>88</sup>

The tobacco companies’ actions may serve as a template for how companies seek to use investor-state disputes, or the threat of such disputes, to obtain desired levels of IP rights. For example, tobacco companies fought tobacco regulation not only in developed countries such as Canada and Australia, but also in poor countries such as Kenya,<sup>89</sup> Namibia, Gabon, Togo, and

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84. *Notice of Motion, Pharm. Mfrs.’ Ass’n of S. Afr. v. President of the Republic of S. Afr.* 1998 (2) SA 674 (High Court) (S. Afr.); see also WILLIAM W. FISHER III & CYRILL P. RIGAMONTI, *THE SOUTH AFRICA AIDS CONTROVERSY: A CASE STUDY IN PATENT LAW AND POLICY* 3 (2005), <https://cyber.harvard.edu/people/ffisher/South%20Africa.pdf>.

85. *E.g.*, Philip De Wet, *Motsoaledi: Big Pharma’s ‘Satanic’ Plot is Genocide*, MAIL & GUARDIAN: NAT’L (Jan. 17, 2014, 12:00 AM), <http://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide/>; Lotti Rutter, *Leaked PharmaGate Emails Prove Big Pharma Involvement in Scandal*, TREATMENT ACTION CAMPAIGN (Jan. 21, 2014, 12:40 AM), <http://www.tac.org.za/news/leaked-pharmagate-emails-prove-big-pharma-involvement-scandal>.

86. When the United States considered prohibiting tobacco advertising, the industry fiercely—and successfully—opposed this. See *Tobacco Control and Marketing: Hearings on H.R. 5041 Before the Subcomm. on Health & the Env’t of the H. Comm. on Energy & Commerce*, 101st Cong. (1990).

87. The tobacco industry was able to successfully lobby to defeat New Zealand’s early legislation with the help of New Zealand athletes. See, *e.g.*, GEORGE THOMSON & NICHOLAS WILSON, *AUSTRALASIAN FACULTY OF PUB. HEALTH MED., RESOURCE DOCUMENT: A BRIEF HISTORY OF TOBACCO CONTROL IN NEW ZEALAND* 41–42 (1997).

88. *E.g.*, *British American Tobacco U.K. Ltd. v. Sec’y of State for Health* [2016] EWHC (Admin) 1169 (Eng.); see also Peter Evans, *Philip Morris, British American Tobacco Challenges U.K. Cigarette-Packaging Order*, WALL ST. J. (May 22, 2015, 10:20 AM), <http://www.wsj.com/articles/philip-morris-challenges-u-k-cigarette-packaging-order-1432292719>.

89. See MINISTRY OF PUB. HEALTH & SANITATION & INT’L INST. FOR LEGISLATIVE STUD., *TOBACCO INDUSTRY INTERFERENCE IN KENYA: EXPOSING THE TACTICS* (2013), [http://tobacotactics.org/images/8/86/Ti\\_interference\\_in\\_Kenya.pdf](http://tobacotactics.org/images/8/86/Ti_interference_in_Kenya.pdf); Rachel Rose Jackson, *Tobacco Industry Accused of ‘Intimidation*

Uganda that have little or no expertise in international investment law and that cannot match the resources of these companies to effectively fight off their investor-state challenges.<sup>90</sup> Notably, for countries that did not back down from tobacco regulations, the industry initiated domestic litigation, followed in some cases by an investor-state proceeding, as well as finding States to espouse a challenge in the WTO on their behalf.<sup>91</sup> These challenges at the national level have had a significant chilling effect on the ability of governments to regulate tobacco products—at least before the conclusion of the Australia and Uruguay investment cases.<sup>92</sup> In addition, despite the relatively positive conclusion of the tobacco investment cases, these disputes, as well as Eli Lilly's dispute against Canada, may have a chilling effect on the extent to which

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*and Interference' in Kenya*, THE GUARDIAN (Mar. 2, 2015, 9:17 AM), <http://www.theguardian.com/sustainable-business/2015/mar/02/tobacco-industry-accused-intimidation-interference-kenya>; John Muchangi, *Why MPs Should Pass Tobacco Regulations*, THE STAR (Mar. 30, 2015, 9:00 AM), <http://allafrica.com/stories/201503300716.html> (detailing the efforts of British American Tobacco to derail efforts to have the government pass regulations to bring into force the Tobacco Control Act, which implements obligations under the Framework Convention on Tobacco Control).

90. *E.g.*, Tavernise, *supra* note 13. Namibia's Health Minister is reported to have said, "we have bundles and bundles of letters from them," so that "[t]hree years later, the government, fearful of a punishingly expensive legal battle, has yet to carry out a single major provision of the law, like limiting advertising or placing large health warnings on cigarette packaging." *Id.* In fact, efforts to challenge tobacco control efforts in developing countries date back to the 1980s. *E.g.*, J. Knight & S. Chapman, "Asia is Now the Priority Target for the World Anti-Tobacco Movement": Attempts by the Tobacco Industry to Undermine the Asian Anti-Smoking Movement, 13 TOBACCO CONTROL ii30, ii31 (2004) (noting that between the 1980s and 1990s "the industry built up a comprehensive dossier on its opponents including those in the Asian region").

91. See *infra* Annex One; see also Peter K. Yu, *Investor-State Dispute Settlement and the Trans-Pacific Partnership*, in INTELLECTUAL PROPERTY AND THE JUDICIARY 7 (Christophe Geiger ed., Edward Elgar Publ'g, forthcoming 2017) [hereinafter Yu, ISDS], <http://www.peteryu.com/isds.pdf> (noting the potential of ISDS destabilizing the TRIPS Agreement regime); Sergio Puig, *The Merging of International Trade and Investment Law*, 33 BERKELEY J. INT'L L. 1 (2015) [hereinafter Puig, Merging] (arguing that litigants go forum shopping between the international trade and investment regimes with a view "to destabilize governments' regulatory activity, to shape the interpretation of rules outside an ordinary process, or to re-litigate issues settled in one regime through the venue of another").

92. Yu, ISDS, *supra* note 91; Puig, Merging *supra* note 91, at 1; see also, *e.g.*, Tavernise, *supra* note 13 (noting that even developed countries like New Zealand have hesitated to enact planned tobacco regulations in light of fears of investment claims).

developing countries are willing to embrace the recommended adoption of TRIPS flexibilities for patent protection.

Our research shows that May 1994 is the first time a company disclosed its intention to bring an investor-state suit to protect IP governed by TRIPS.<sup>93</sup> At this time, Canada was preparing plain package legislation,<sup>94</sup> although Canada had contemplated generic packaging of tobacco as early as 1986.<sup>95</sup> Philip Morris wrote to the Canadian congressional committee contemplating plain packaging and asserted that those laws would constitute an expropriation of their trademarks.<sup>96</sup> To support this argument, Philip Morris included two opinions, one of which was made by former U.S. Trade Representative Carla Hills, who argued that the proposed legislation would lead to “massive [investor] compensation claims” that “would be staggering, amounting to hundreds of millions of dollars,”<sup>97</sup> and another from former U.S. Deputy Trade Representative Julius Katz. Similarly, the CEO of RJR MacDonald sent a letter to the Prime Minister of Canada arguing that the law would violate the investment chapter of NAFTA.<sup>98</sup> The committee concluded that plain packaging could be a “reasonable component” of tobacco control and recommended that legislation be developed pending outcome of research on effectiveness of such packaging.<sup>99</sup> However, the tobacco industry discredited the health minister, consistent with its lobbying goals. Thereafter, the new health minister, who was more sympathetic to trademark claims, did not pursue plain packaging.<sup>100</sup>

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93. ROGER SIMMONS, HOUSE OF COMMONS STANDING COMM. ON HEALTH, REPORT, TOWARDS ZERO CONSUMPTION: GENERIC PACKAGING OF TOBACCO PRODUCTS STANDING COMMITTEE REPORT 21 (1994).

94. *Id.*

95. *E.g.*, PHYSICIANS FOR 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 AND HOW HEALTH MINISTERS IN CANADA AND AUSTRALIA FELL FOR THEIR CHICANERY 16–19 (2008).

96. Letter from R.J. Reynolds to Standing Committee on Health (May 4, 1994).

97. Memorandum from Carla A. Hills to R.J. Reynolds and Philip Morris 18, 21 (May 3, 1994).

98. Letter to Jean Chrétien, Prime Minister of Canada 5 (Mar. 25, 1994) (warning of “possible violations . . . of NAFTA and GATT which protect trademarks and investments”).

99. SIMMONS, *supra* note 93, at 28.

100. PHYSICIANS FOR SMOKE-FREE CANADA, *supra* note 95, at 29–39.

The next time the tobacco industry considered an investor-state suit was in 2001. At that time, Philip Morris argued that the proposed bans on the use of “light” and “mild” on tobacco products would, if enacted, constitute an expropriation of trademarks.<sup>101</sup> Unlike the prior situation where an investment dispute was merely threatened, Philip Morris took action. In particular, Philip Morris filed a notice of intent to submit a claim to arbitration, under NAFTA, asserting that this constituted expropriation.<sup>102</sup> Canada did not impose the regulations; rather, in a settlement, the companies agreed to willingly remove these labels.<sup>103</sup>

More recently, the tobacco industry has brought investment cases against Uruguay and Australia after attempts to combat regulation of packaging at the domestic level failed. Notably, the contested national laws were adopted after the conclusion of the WHO Framework Convention on Tobacco Control in 2003.<sup>104</sup> The Framework Convention does not expressly require countries to bar use of trademarks, but its guidelines for implementation do suggest limiting trademarks.<sup>105</sup> After unsuccessfully challenging Uruguay’s two laws regulating trademarks on tobacco products in Uruguay’s courts,<sup>106</sup> Philip Morris initiated

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101. Philip Morris International Inc., Submission by Philip Morris International Inc. in Response to the National Center for Standards and Certification Information, No. G/TBT/N/CAN (Feb. 20, 2002), at 6–8, <http://www.essentialaction.org/tobacco/pmresponsetonoi.pdf> (arguing that the ban would be “tantamount to an expropriation of tobacco trademarks” as well as “unfair and inequitable” and in violation of NAFTA).

102. Although the actual notice of intent to submit a claim to arbitration was not made publicly available, there is nonetheless evidence that the case was filed. *E.g.*, *Plain Packaging of Tobacco Products Dispute*, <http://www.italaw.com/cases/1282>. NAFTA provides for a Notice of Intent as notification of filing of an arbitration. Other systems such as the United Nations Commission on International Trade Law (UNCITRAL) refer to it as a Notice of Arbitration.

103. Maureen McGrath, *Competition Bureau Reaches Agreement with the Three Major Cigarette Manufacturers to Stop Using “Light” and “Mild” on Cigarette Packages*, MARKETWIRED (Nov. 9, 2006, 11:13 AM), <http://www.marketwired.com/press-release/competition-bureau-reaches-agreement-with-three-major-cigarette-manufacturers-stop-using-620985.htm>.

104. WHO, *WHO Framework Convention on Tobacco Control* (2003).

105. WHO, Framework Convention on Tobacco Control, *Guidelines for Implementation of Article 11 of the WHO Framework Convention on Tobacco Control*, ¶ 46, FCTC/COP3(10) (Nov. 2008), [http://www.who.int/fctc/guidelines/adopted/article\\_11/en/](http://www.who.int/fctc/guidelines/adopted/article_11/en/).

106. The “single presentation requirement” precluded more than one variant of cigarette per brand family to avoid consumers thinking that some were healthier, while the “80/80” regulation increased the size of health warnings

an investor-state dispute against Uruguay in 2010.<sup>107</sup> Given the potential for extremely high damages that Philip Morris could have won in this case, a number of commentators suggested that the investment claim was intended to caution other countries considering similar laws that they may also be subjected to an investor-state suit.<sup>108</sup> Similarly, after failing in its domestic efforts to halt the first plain package law adopted by Australia, Philip Morris initiated an investment dispute in 2012.<sup>109</sup>

The Philip Morris investment cases are important not only for their use of investor-state disputes, but for *what* types of claims were brought against Australia and Uruguay. Both cases argued that trademarks were “expropriated,” based in large part on a claim that there was an affirmative right to use registered trademarks allegedly supported by the Paris Convention and TRIPS,<sup>110</sup> even though intellectual property experts have argued otherwise.<sup>111</sup> In an expropriation claim, an investor alleges that some conduct by a government has devalued their investment in a manner similar to, but broader than, a domestic taking of

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from 50% of the package to 80%. Ministerio de Salud Pública [Ministry of Public Health], Decreto No. 287/009, art. 1 (June 15, 2009) (Uru.); Ministerio de Salud Pública [Ministry of Public Health], Ordenanza Ministerial 466/009, art. 1 (Sept. 1, 2009) (Uru.).

107. FTR Holding S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Request for Arbitration (Feb. 19, 2010).

108. *E.g.*, Duff Wilson, *Cigarette Giants in Global Fight on Tighter Rules*, N.Y. TIMES (Nov. 13, 2010), <http://www.nytimes.com/2010/11/14/business/global/14smoke.html>; *Tobacco Control in Uruguay after the Industry Lawsuit*, FRAMEWORK CONVENTION ALLIANCE, <http://www.fctc.org/media-and-publications/media-releases-blog-list-view-of-all-313/industry-interference/1341-tobacco-control-in-uruguay-after-the-industry-lawsuit> (last visited Feb. 26, 2017).

109. Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Award on Jurisdiction and Admissibility (Dec. 17, 2015); Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Notice of Arbitration (Nov. 21, 2011).

110. *E.g.*, Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Notice of Arbitration, ¶¶ 6.7–6.11 (Nov. 21, 2011); FTR Holding S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Request for Arbitration, ¶ 85 (Feb. 19, 2010).

111. *E.g.*, PHYSICIANS FOR SMOKE-FREE CANADA, *supra* note 95, at 16–19 (discussing the WIPO’s interpretation of Article 7 of the Paris convention); Mark Davison & Patrick Emerton, *Rights, Privileges, Legitimate Interests, and Justifiability: Article 20 of TRIPS and Plain Packaging of Tobacco*, 29 AM. U. INT’L L. REV. 505 (2014).

property claim.<sup>112</sup> In addition, in both cases Philip Morris argued a violation of “fair and equitable treatment” of its trademarks.<sup>113</sup> There is no domestic analog to this claim which investor-state tribunals often construe broadly to find a violation, based in large part on an investor’s “legitimate expectations” that a government’s laws should not be modified or applied in a manner that adversely impacts an investor’s investments.<sup>114</sup> In the Australia case, Philip Morris made the most regime-challenging assertion: that it had a legitimate expectation that Australia would uphold its commitments under the TRIPS Agreement.<sup>115</sup> In addition, there was an umbrella clause claim that Philip Morris later withdrew in the Australia case according to which Australia’s TRIPS Agreement obligations were now properly before the investor-state tribunal.<sup>116</sup>

Although there are similarities between the two Philip Morris cases, there is also one difference that highlights why companies may prefer investor-state disputes to a dispute espoused on their behalf in the WTO. In the Australia case,

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112. *E.g.*, LISE JOHNSON ET AL., COLUMBIA CTR. ON SUSTAINABLE INV., INVESTOR-STATE DISPUTE SETTLEMENT, PUBLIC INTEREST AND U.S. DOMESTIC LAW 7 (2015), <http://ccsi.columbia.edu/files/2015/05/Investor-State-Dispute-Settlement-Public-Interest-and-U.S.-Domestic-Law-FINAL-May-19-8.pdf>; Vicki Been & Joel C. 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 (2003).

113. Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Notice of Claim, ¶ 8 (June 22, 2011); FTR Holding S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Request for Arbitration, ¶ 71 (Feb. 19, 2010).

114. *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 (2013).

115. Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Notice of Arbitration, ¶¶ 6.5, 7.6–7.11 (Nov. 21, 2011).

116. The Tribunal did not reach this issue because the case was dismissed on challenges to jurisdiction and admissibility. For the umbrella clause claim, see Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Notice of Arbitration, ¶¶ 7.15–7.17 (Nov. 21, 2011) (claiming failure to comply with TRIPS and Paris Convention through umbrella clause); FTR Holding S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Request for Arbitration, ¶ 86 (Feb. 19, 2010) (violation of art. 11 of the Uruguay-Switzerland BIT). For withdrawal of the umbrella clause claim, see Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Procedural Order 8, para. 34 (Apr. 14, 2014).

Philip Morris brought suit under the Hong Kong-Australia bilateral investment agreement after corporate restructuring which took place after Australia announced its intention to introduce plain packaging measures in 2010.<sup>117</sup> Such corporate restructuring has succeeded in some investment cases where tribunals effectively permitted “treaty shopping.”<sup>118</sup> Australia successfully asserted that such restructuring by Philip Morris was abusive and as a result the tribunal did not have jurisdiction over the case.<sup>119</sup>

Let us now look at another investor-state case involving IP rights. As background to discussing this case, it is important to bear in mind a 2012 publication aimed at actual or potential corporate clients issued by the global law firm, Jones Day. This publication encouraged pharmaceutical companies to use investment agreements as a “new way forward” to address unfavorable domestic patent laws.<sup>120</sup> In addition to explaining why such agreements are favorable, it argued that the tobacco case challenging Australia’s laws for violating trademarks was an example of how investment claims can be brought in lieu of domestic or WTO claims. It further argued that international investment arbitration “provides a powerful mechanism to enforce patent rights around the globe.”<sup>121</sup>

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117. In 2011, Philip Morris Hong Kong formally acquired shares in Philip Morris Australia to give Philip Morris Hong Kong standing as a foreign investor under the Hong Kong Australia BIT. *E.g.*, Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Award on Jurisdiction and Admissibility, ¶ 460 (Dec. 17, 2015).

118. *E.g.*, 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: PERCEPTIONS AND REALITY 3, 4 (Michael Waibel et al., eds., 2010); Anne van Aaken, *Perils of Success? The Case of International Investment Protection*, 9 EUR. BUS. ORG. L. REV. 1, 20 (2008).

119. The Tribunal rejected Philip Morris’ claim that there were legitimate tax or other business reasons for the restructuring; instead, it found that “the main and determinative, if not sole, reason for the restructuring was the intention to bring a claim under the Treaty, using an entity from Hong Kong.” Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int’l Trade L. [UNCITRAL], PCA Case No. 2012-12, Award on Jurisdiction and Admissibility, ¶ 584 (Dec. 17, 2015).

120. 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/](http://www.jonesday.com/treaty_protection/).

121. *Id.* at 3.

One month after the Jones Day publication, Eli Lilly filed a notice of intent to submit a claim for arbitration against Canada, indicating that it would be asserting investment claims against Canada.<sup>122</sup> The factual basis for this claim was that Canadian courts had invalidated its patent on Straterra, which Eli Lilly asserted resulted in its patent rights being improperly “expropriated,” and denied “fair and equitable treatment.” Eli Lilly subsequently added claims regarding invalidation of Zyprexa when it filed its Notice of Arbitration in 2013.<sup>123</sup>

The investment claims are premised on judicial invalidation of Eli Lilly patents for two commercially successful drugs sold under the names Straterra and Zyprexa for failing to meet the “promise doctrine,” a judicial interpretation of the core patent requirement of utility.<sup>124</sup> This doctrine only applies when a patent applicant, such as Eli Lilly, “promises” that an invention will have a particular purpose.<sup>125</sup> An application satisfies the promise doctrine if it discloses data to support the promise.<sup>126</sup> Eli Lilly had to make these 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 had expired.<sup>127</sup>

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122. *Eli Lilly & Co. v. Gov’t of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven (NAFTA/UNCITRAL Arb. Trib. Nov. 7, 2012).

123. *Eli Lilly & Co. v. Gov’t of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Notice of Arbitration (NAFTA/UNCITRAL Arb. Trib. Sept. 12, 2013).

124. *Id.* at 18–24; *see also* *Eli Lilly Can., Inc. v. Novopharm Ltd.*, [2011] F.C.R. 1288 (Can.) (invalidating patent relating to Zyprexa because it promised fewer side effects than existing antipsychotics used for long term treatment without any supporting disclosure); *Novopharm Ltd. v. Eli Lilly Can., Inc.*, [2010] F.C.R. 915 (Can.) (invalidating patent relating to Straterra because it had an implied promise to treat ADHD as a chronic condition, but did not disclose efficacy for long term use).

125. *E.g.*, *Eli Lilly Can., Inc. v. Novopharm Ltd.*, [2012] 1 F.C.R. 349, ¶¶ 70–9 (Can.) (describing the promise doctrine and the specificity of the promised utility required).

126. *Id.* ¶113.

127. *See, e.g.*, *Eli Lilly & Co. v. Gov’t of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Government of Canada Statement of Defence, ¶ 53 (NAFTA/UNCITRAL Arb. Trib. June 30, 2014); *see also* Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH. L.J. 213, 239–40 (2015) [hereinafter Ho, *Sovereignty*] (explaining how these patents are examples of how companies engage in the practice of “evergreening” to extend profits over drugs whose original patents have expired).

Canada's promise doctrine is a type of TRIPS flexibility. TRIPS flexibilities give WTO members discretion to define key patentability requirements which in turn allows them to limit patents to truly deserving inventions and promote access to lower cost drugs.<sup>128</sup> Although proponents of these flexibilities typically suggest interpreting the terms "invention" or "new," any core patentability requirement such as Canada's unique promise doctrine can provide flexibility.<sup>129</sup> Accordingly, Eli Lilly's case seeking \$500 million in damages against Canada may make South Africa and Brazil hesitant to enact domestic laws that embrace these flexibilities even though policy makers have encouraged them to do so.<sup>130</sup> Worse yet, countries that have laws to 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 agreement suggests greater encroachment on TRIPS flexibilities than the proposed 2015 draft.<sup>131</sup>

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128. For a discussion of the genesis of TRIPS flexibilities and what that entails, see, e.g., World Intellectual Prop. Org. [WIPO], Comm. on Dev. & Intellectual Prop., Fifth Session, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, ¶¶ 29–36, CDIP/5/4 (Mar. 1, 2010), [http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=131629](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629). More recently, the U.N. High-Level Panel on Access to Medicine defined this term to broadly describe norms, rules and standards that permit variations in implementations of TRIPS. Dreifuss & Mogae, *supra* note 10, at 6.

129. This is one type of TRIPS flexibility. For more examples of TRIPS flexibilities, see *infra* Annex Two (describing TRIPS flexibilities).

130. E.g., Chan Park, Achal Prabhala & Jonathan Berger, United Nations Development Programme [UNDP], *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law*, at 46 (Oct. 2013), <http://apps.who.int/medicinedocs/en/d/Js21033en/> (encouraging legal and regulatory regimes that will encourage pharmaceutical patent growth in South Africa); *UN Report Strengthens Case for Patent Reform in SA and Other Developing Countries*, SECTION 27 (Sept. 15, 2016), <http://section27.org.za/2016/09/un-report-strengthens-case-for-patent-law-reform-in-sa-and-other-developing-countries> (describing the U.N. High-Level Panel's recommendations as a minimum threshold for South Africa); AMY KAPCZYNSKI & TAMAR EZER, GLOB. HEALTH JUSTICE CTR., SUBMISSION TO THE DEPARTMENT OF TRADE AND INDUSTRY ON THE INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK (Sept. 2016), [http://media.wix.com/ugd/148599\\_721218272a1c43cbaee5ff8fda3a00cf.pdf](http://media.wix.com/ugd/148599_721218272a1c43cbaee5ff8fda3a00cf.pdf) (recommending that TRIPS flexibilities be fully used in South Africa).

131. *Compare* India's Model Bilateral Investment Treaty (BIT) art. 2.4(iii) (2016), [http://finmin.nic.in/reports/ModelTextIndia\\_BIT.pdf](http://finmin.nic.in/reports/ModelTextIndia_BIT.pdf) (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

While these investor-state cases were pending, companies advocated for an investment chapter in the Transpacific Partnership Agreement. A wide range of actors opposed this chapter including Senator Elizabeth Warren as well as a representative of the Cato Institute.<sup>132</sup> Companies with interests in protecting IP through investment agreements, including pharmaceutical companies and tobacco companies, advocated for this chapter, and in particular for the inclusion of investor-state disputes through Trade Advisory Committees which have strong influence on trade negotiators within the United States' trade machinery.<sup>133</sup> In fact, these companies were so successful that at least 80% of the provisions of the TPP's investment chapter were borrowed from the United States' free trade agreements.<sup>134</sup>

The corporate shift towards investment disputes to protect IP can also be seen as part of a broader destabilization agenda regarding public health by tobacco and pharmaceutical companies. As documented recently by Sergio Puig, the tobacco industry has pursued thirty-nine international cases challenging tobacco regulations in at least ten different courts or tribunals; Philip Morris International, the instigator of the first investment disputes concerning IP, is involved in one third of these disputes.<sup>135</sup> Although not all such disputes involve IP, they

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the Indian Bilateral Investment Treaty art. 2.6(v) (2015), [https://mygov.in/sites/default/files/master\\_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf](https://mygov.in/sites/default/files/master_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf) (excluding from scope of arbitration compulsory licenses, as well as revocation, limitation of IP if "consistent with the Law of the Host State").

132. Daniel J. Ikenson, *A Compromise to Advance the Trade Agenda: Purge Negotiations of Investor-State Dispute Settlement*, CATO INST. (Mar. 4, 2014), <https://www.cato.org/publications/free-trade-bulletin/compromise-advance-trade-agenda-purge-negotiations-investor-state>; Elizabeth Warren, *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://www.washingtonpost.com/opinions/kill-the-dispute-settlement-language-in-the-trans-pacific-partnership/2015/02/25/ec7705a2-bd1e-11e4-b274-e5209a3bc9a9_story.html).

133. See, e.g., INDUS. TRADE ADVISORY COMM. FOR CHEMICAL, PHARMACEUTICALS, HEALTH/SCIENCE PROD. & SERV. [ITAC-3], THE TRANS-PACIFIC PARTNERSHIP TRADE AGREEMENT 9 (Dec. 2, 2015), <https://ustr.gov/sites/default/files/ITAC-3-Chemicals-Pharmaceuticals-Health-Science-Products-and-Services.pdf>.

134. Todd Allee & Andrew Lugg, *Who Wrote the Rules for the Trans-Pacific Partnership?*, 3 RES. & POL. 1, 9 (2016).

135. Puig, *supra* note, 12 at 393, n.51. These cases have challenged "import and export taxes; price, sale, export, and import controls; bans on tobacco products; marketing and advertisement restrictions; labeling requirements; and brand registration recognition." *Id.*

are all designed to create uncertainty about the boundaries of domestic tobacco regulation and directly challenge public health recommendations of the World Health Organization and U.N. agencies.<sup>136</sup> Moreover, the inevitable delays in implementing domestic regulations arising from such challenges mean that the industry continues to maintain profitable sales to fund further challenges; although regime shifting is a clear goal, the continuous profit stream minimizes any costs from litigation.<sup>137</sup> The pharmaceutical industry has sought to create uncertainty not only through the Eli Lilly case, but also through a variety of other challenges. For example, the industry has disputed domestic measures to require companies to reveal clinical data and price drugs at lower costs despite the fact that such actions are consistent with public health recommendations.<sup>138</sup> Given the broader destabilization agenda of these companies, the initial investment cases here, together with the explicit inclusion of IP in newer free trade agreements, signal an intent to shift IP lawmaking and enforcement to the international investment law regime. Although there is not yet a flood of investment disputes concerning IP, the history of investment cases suggests that the tide can quickly turn.<sup>139</sup> In addition, even though some might argue that no regime shift has occurred because the first two investor-state cases concerning tobacco disputes did not result in changes to domestic law, the fact that these cases have been brought and others threatened underscores that a regime shift is happening.

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136. *E.g.*, Tavernise, *supra* note 13.

137. We thank Martin Bjorklund for pointing this out to us.

138. *E.g.*, Case T-44/13, AbbVie, Inc. v. European Meds. Agency (July 17, 2014) (showing an action by European and American companies against members of the European Union in order to obtain documents); Case T-73/13R, InterMune U.K. Ltd. v. European Meds. Agency, 2013 E.C.R. 00000 (Apr. 25, 2013) (showing an action by InterMune to gain third-party access to document); *see also* Aaron S. Kesselheim & Michelle M. Mello, *Confidentiality Laws and Secrecy in Medical Research: Improving Public Access to Data on Drug Safety*, 26 HEALTH AFF. 483 (2007) (discussing litigation relating to FDA disclosure rules).

139. Indeed, although there were virtually no investment disputes before 1994, there has been a steep increase in cases to over 600 at the end of 2014. *See* United Nations Conference on Trade and Development, *Investor-State Dispute Settlement: Review of Developments in 2014*, fig.1 (July 15, 2015), [unctad.org/en/PublicationsLibrary/webdiaepcb2015d2\\_en.pdf](http://unctad.org/en/PublicationsLibrary/webdiaepcb2015d2_en.pdf).

## B. WHY THE SHIFT COULD POTENTIALLY DESTABILIZE TRIPS FLEXIBILITIES

As noted earlier, a key feature of regime shifting is using one regime to destabilize another regime by creating conflicting norms or seeking to rewrite those norms altogether.<sup>140</sup> In our view, this has been the strategy of tobacco and pharmaceutical companies not only with respect to investor-state suits, but also with disputes at the WTO and in national courts.<sup>141</sup> For example, Philip Morris sought to have the investment tribunal require Uruguay to withdraw the challenged tobacco control regulations or to refrain from applying them against it.<sup>142</sup> This, in addition to a damage claim of U.S. \$22.267 million plus compound interest, in our view constitutes a significant chilling effect on countries considering similar tobacco control measures.<sup>143</sup> In addition, the Eli Lilly case against Canada's promise doctrine was, in our in view, tailored not only to compel a legislative change to overrule Canadian case law,<sup>144</sup> but also to obtain an interpretation that will impact the interpretation of the TRIPS Agreement, and to influence the willingness that countries may otherwise have to use TRIPS flexibilities.<sup>145</sup>

Although the Philip Morris cases are important wins for States, they are easy cases relative to potential future cases that may challenge other TRIPS flexibilities, as we note below. The wins against tobacco companies are easy because there is little doubt that tobacco products cause serious public health harms, and the domestic regulations challenged in those cases were consistent with the consensus reflected in the WHO's Framework Convention on Tobacco Control.<sup>146</sup> That consensus

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140. See *supra* Part I.

141. *Id.*

142. FTR Holding S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Arbitration Request, ¶¶ 88–92, 94 (Feb. 19, 2010) (requesting “suspension” of challenged laws).

143. See Philip Morris Brands Sarl v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Award (July 2, 2013) (seeking tribunal award damages of “at least” this amount).

144. *E.g.*, Ruth L. Okediji, *Is Intellectual Property “Investment”?* Eli Lilly v. Canada and the International Intellectual Property System, 35 U. PA. J. INT’L L. 1121, 1121–22 (2014) (noting the company’s chief patent counsel commented that the goal was to “fix” the statute to overrule the undesirable case law).

145. Other commentators agree. *E.g.*, *id.* at 1132.

146. See WHO, *supra* note 104.

is reflected, in part, in the carve-out from investor-state disputes for tobacco in the TPP.<sup>147</sup>

By contrast, the Eli Lilly dispute against Canada has attracted much less publicity than the tobacco disputes, although it in our view represents a much more significant threat to the domestic regulatory authority than the tobacco cases. While smoking is a clear public health hazard that entitles States to use their police power to regulate, as recognized by consensus in *Philip Morris v. Uruguay*, there is no such consensus on whether limiting patent protection, as Canada has done, is consistent with promoting public health.<sup>148</sup> Eli Lilly's claims fundamentally stem from the premise held by multinational pharmaceutical companies that public health is inherently consistent with stronger patent rights since profits from patents can fuel research that benefits public health.<sup>149</sup> However, this premise is not robustly supported by data; stronger patent rights lead to more *patents*, but not necessarily to more innovation that is beneficial for public health.<sup>150</sup> This is because some IP holders often patent very similar compounds to extend the patent period so that they can continue charging high

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147. TPP, *supra* note 16, art. 29.5; see also Sergio Puig & Gregory Shaffer, *A Breakthrough with the TPP: The Tobacco Carve-Out*, 16 YALE J. HEALTH POL'Y L. & ETHICS 327, 327 (2016).

148. For example, after the U.N. convened a High-Level Panel on Access to Medicine, the WIPO stated that it "is sensitive" to the assumption in the UN High Level Panel mandate that there is . . . policy incoherence between" promoting innovation through IP and providing medicine. Catherine Saez, *UN High Level Panel on Access to Medicines – First Reactions, Process Explained*, IP-WATCH (Feb. 1, 2016), <http://www.ip-watch.org/2016/02/01/special-feature-un-high-level-panel-on-access-to-medicines-first-reactions-process-explained/>.

149. *E.g.*, *Intellectual Property*, PHRMA, <http://www.phrma.org/innovation/intellectual-property> (last visited June 12, 2017) (noting that R&D is promoted by patent rights); Josh Blooms & Els Torrelee, *Should Patents on Pharmaceuticals Be Extended to Encourage Innovation?*, WALL ST. J. (Jan. 23, 2012), <https://www.wsj.com/articles/SB10001424052970204542404577156993191655000> (describing the profit loss companies experience from expired patents, and discussing whether profits promote innovation). This is arguably a cognitive bias that has been adopted by academics as well as policy makers. *E.g.*, Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 467–72 (2014).

150. Bronwyn H. Hall, *Patents and Patent Policy*, 23 OXFORD REV. ECON. POL'Y 568, 574 (2007); see also Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002*, 89 REV. ECON. & STAT. 436, 436 (2007) (looking at patent protection and pharmaceutical innovation across twenty-six countries).

prices beyond the initial patent period—a practice that is referred to as “evergreening,” since patent protection seems ever green.<sup>151</sup> Although Canada’s challenged patent law is unique, it is aimed at addressing this well-recognized phenomenon that other countries including European ones, Australia, and India have all recognized, and in some cases, enacted laws to address.<sup>152</sup> International human rights legal obligations, particularly the right to health, are also consistent with this approach, including the Canadian judiciary’s interpretation of patent law that Eli Lilly challenged in investor-state dispute settlement.<sup>153</sup> In fact, there are good arguments in favor of ISDS panels taking these human rights obligations into account when interpreting Bilateral Investment Treaties and Customary International Law.<sup>154</sup>

The Eli Lilly dispute is also much more important to regime shifting than the tobacco disputes because it directly threatens long recognized TRIPS flexibilities. The tobacco disputes primarily addressed TRIPS rules on trademarks, but outside of tobacco regulation, limiting the use of trademarks has not been seen as essential to promoting domestic health policy. By contrast, patent rights, especially on pharmaceuticals have a

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151. See JOHN R. THOMAS, CONG. RESEARCH SERV., R40917, PATENT “EVERGREENING”: ISSUES IN INNOVATION AND COMPETITION (2009); Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 550–56 (2007) (comparing U.S. jurisprudence to Indian domestic patent law and arguing that Indian law better limits and protects against the harmful effects of evergreening).

152. *E.g.*, EUROPEAN COMM’N, PHARMACEUTICAL SECTOR INQUIRY: FINAL REPORT 453 (2009) (describing this phenomenon in Europe); Mueller *supra* note 151, at 550–56. (describing this pattern in India); TONY HARRIS ET AL., PHARMACEUTICAL PATENTS REVIEW REPORT 15 (2013) (describing this pattern in Australia).

153. See, *e.g.*, Human Rights Council Res. A/HRC/32/L.23/Rev.1 (June 30, 2016) (calling on states to use TRIPS flexibilities to ensure affordable medicine); Dreifuss & Mogae, *supra* note 10, at 9 (recommending that nations minimize evergreening by rigorous definitions of patentability consistent with TRIPS flexibilities); see also HANNAH BRENNAN ET AL., GLOB. HEALTH JUSTICE P’SHIP, A HUMAN RIGHTS APPROACH TO INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES (2013), [http://media.wix.com/ugd/148599\\_c76ed6f7341fa426bc22f5ccf543ea04.pdf](http://media.wix.com/ugd/148599_c76ed6f7341fa426bc22f5ccf543ea04.pdf) (discussing human rights law as a means to creating greater access to medicine, despite IP laws).

154. *E.g.*, Harold Hongju Koh, *Global Tobacco Control as a Health and Human Rights Imperative*, 57 HARV. INT’L L.J. 433 (2016) (arguing that when tobacco companies challenge national regulations using ISDS, human rights and public health should be considered).

significant impact on the cost of drugs, and thus access to affordable medicine.<sup>155</sup> This makes TRIPS Agreement flexibilities for countries to define key patentability criteria under TRIPS to make promoting access to affordable medicine that much more significant. Since the TRIPS Agreement was concluded, the discretion or flexibility that WTO member countries have to interpret key terms such as what is an “invention,” or whether it is “new,” has been understood as key to their ability to promote affordability and accessibility of medicines. Public health policy makers consistently recommend that countries take full advantage of these flexibilities.<sup>156</sup> For example, a recent resolution on access to medicines adopted by the United Nations Human Rights Council calls on nations to utilize TRIPS flexibilities.<sup>157</sup> In our view, investor-state disputes, and indeed the threat of such suits particularly for poor countries, pose a great threat to these already under-utilized flexibilities. Below we outline some other TRIPS flexibilities that could potentially be challenged in investor-state arbitration.

### 1. Patentability Standards

Even though Eli Lilly lost its case, this does not foreclose similar investor-state challenges. Particularly vulnerable are countries that tailor their patentability standards based on their understanding of TRIPS flexibilities.<sup>158</sup> Such national patentability standards are likely to be challenged either as constituting an expropriation or as a violation of other investor protections, such as under the fair and equitable treatment standard. Worse yet, countries that have laws to take advantage of TRIPS flexibilities, such as India, may feel pressure to jettison such flexibilities to avoid vulnerability to investment claims.<sup>159</sup>

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155. Doha Public Health Declaration, *supra* note 68.

156. *E.g.*, sources cited *supra* note 130.

157. Human Rights Council Res. A/HRC/32/L.23/Rev.1, *supra* note 153.

158. *Eli Lilly & Co. v. Gov't of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Final Award (NAFTA/UNCITRAL Arb. Trib. Mar. 16, 2017) [hereinafter *Eli Lilly, Award*].

159. Even without any known direct threats of investment claims, India has already bowed to international pressure in recent years. For example, it has issued a report on a national IP policy that seems more favorable to right holders than users, contrary to its historical practice. William New & Patralekha Chatterjee, *India Releases New Intellectual Property Policy; Reactions Building*, IP-WATCH (May 13, 2016), <http://www.ip-watch.org/2016/05/13/india-releases-new-intellectual-property-policy-reactions-building/>.

A successful challenge of India's patentability standards could endanger India's status as the predominant source of low-cost generic drugs to the developing world; this is due in large part to the fact that its patent laws provide less protection for patents than most other countries.<sup>160</sup> If India tightens its patentability rules pursuant to an investor-state suit or the threat of such a suit, the only other way that India could continue to make and sell generics would be to issue compulsory licenses.<sup>161</sup> However, that would likely 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 the TRIPS Agreement, it would be left to an investor-state tribunal rather than the WTO dispute settlement system to test the consistency of such a compulsory license with the TRIPS Agreement.<sup>162</sup>

Moreover, Eli Lilly's challenge underscores that not only domestic legislation, but routine common law modification of existing law is subject to investor disputes. In particular, Eli Lilly claimed that the promise doctrine was a change to Canada's utility requirement, such that it constituted both an expropriation and violation of fair and equitable standards.<sup>163</sup> The tribunal properly rejected the assertion that there was a *dramatic* change; rather it said that "departures from precedent are to be expected" of its utility requirement.<sup>164</sup> It also suggested that common law modifications would need to be "sufficiently egregious and shocking" to constitute violation of fair and equitable standards.<sup>165</sup> Accordingly, if other tribunals follow this

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160. Of course, it is also important that India has capacity to manufacture generic drugs as well.

161. See *infra* Annex Two.

162. Indeed, this is the case with Eli Lilly, since NAFTA has such a clause. North American Free Trade Agreement, Can.-Mex.-U.S., art. 1110, Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA] (stating that expropriation claims do "not apply to the issuance of compulsory licenses granted in relation to intellectual property rights . . . consistent with Chapter Seventeen (Intellectual Property)").

163. Ho, *Sovereignty*, *supra* note 127, at 215-16.

164. According to the *Eli Lilly* Tribunal, what it had before it was "the invalidation by the Canadian judiciary of the Zyprexa and Strattera Patents through application of the promise utility doctrine." Eli Lilly, Award, *supra* note 158, ¶ 165.

165. See Eli Lilly, Award, *supra* note 158, ¶ 222, where with regard to the minimum standard of treatment of Article 1105, the Tribunal adopts the test that for there to be a violation, the act in question must be "sufficiently

approach, common law changes to patent law, such as recent US narrowing of patentability should not result in a successful investment claim.

## 2. Data Exclusivity

Yet another possible TRIPS flexibility at risk relates to undisclosed information as required under Article 39 of the TRIPS Agreement.<sup>166</sup> Although this provision is not regarded as a patent right, it is generally considered a patent flexibility since it complements patent protection.<sup>167</sup> Part of the reason why this presents an opportunity for investors is that there are extremely divergent views on what the TRIPS Agreement requires under Article 39. Some countries and companies believe that it requires United States-style “data exclusivity,” that bars generic companies from relying on the clinical data of a pioneer drug for obtaining regulatory approval for a certain period of time.<sup>168</sup> Other scholars, policy makers, and some countries, by contrast, consider it to only require “data protection,” which means protecting the data submitted to a regulatory agency from unfair competition, but not necessarily reliance on the data by a generic company that never has physical access to the data.<sup>169</sup> A few take an intermediate position and find that the TRIPS Agreement

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egregious and shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons.”

166. TRIPS, *supra* note 2, art. 39.

167. *E.g.*, MATTHIAS LAMPING ET AL., MAX PLANCK INST. FOR INNOVATION AND COMPETITION, RESEARCH PAPER NO. 14-19, DECLARATION ON PATENT PROTECTION: REGULATORY SOVEREIGNTY UNDER TRIPS (2014), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2500784](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2500784) (including this within the scope of flexibilities for patent rights).

168. *E.g.*, 21 U.S.C. § 314.108 (2012) (including a five year period of exclusivity in the United States); NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS* 392–93 (2d ed. 2005).

169. CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS* 383–92 (2007); Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 *AM. J.L. & MED.* 303, 315–16 (2008) (arguing that patents and evergreening are not complete protections); Jerome H. Reichman, *Undisclosed Clinical Test Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective* (paper presented at Moving the Pro-Development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning, Bellagio, Italy, Nov. 29–Dec. 3, 2004) (describing treaties and trade concessions for patent protections).

precludes generic companies from relying on the data of another company without paying some fee.<sup>170</sup>

India permits a generic manufacturer to immediately rely on the clinical data of an originator company to establish bioequivalence to the original in seeking approval of the generic any time after approval of the originator company.<sup>171</sup> This means that although the originator invested substantial time and money in developing clinical data, the generic company can rely on that data and invest a small amount of money in bringing the generic equivalent to market.<sup>172</sup> Although innovator companies complain this is fundamentally unfair,<sup>173</sup> they generally fail to note that the rationale for data exclusivity is identical to that of patent protection, such that providing both types of protection is duplicative.<sup>174</sup> In addition, such companies do not highlight that data exclusivity effectively provides more protection than patents by absolutely 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.<sup>175</sup> 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 or not. A generic company is not likely to undertake such a

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170. *E.g.*, SHAMNAD BASHEER, PROTECTION OF REGULATORY DATA UNDER ARTICLE 39.3 OF TRIPS: THE INDIAN CONTEXT 28–29 (2009) (looking at a model of compensating creators of data for usage); 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) (arguing for a functional equivalent to patents in “trade secret status”). However, this interpretation seems to be inconsistent with the appropriate interpretation of TRIPS since there was an explicit proposal to require cost-sharing, that was rejected. Reichman, *supra* note 169, at 10.

171. *E.g.*, CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 119 (2011) [hereinafter HO 2011].

172. *Id.*

173. *See generally* ORG. OF PHARM. PRODUCERS OF INDIA, OPPI POSITION PAPER: REGULATORY DATA PROTECTION – A BUILDING BLOCK FOR PHARMACEUTICAL R&D (2008) (arguing for the fairness of data protection).

174. *E.g.*, Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 430–32 (2012) (describing the similarities and differences between patents and statutory exclusivities).

175. *E.g.*, EUROPEAN COMM'N, *supra* note 152, ¶ 501; FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 20 (2002).

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.

A company could claim that a country that does not provide data exclusivity is indirectly expropriating its data in investor-state arbitration. After all, clinical data is expensive to develop and thus would seem to easily fall within the definition of an investment. In addition, although most investment agreements provide an exception to indirect expropriation for denial of intellectual property rights consistent with the TRIPS Agreement, lack of data exclusivity is not a prototypical denial of rights in the same way as a denial of a patent application.<sup>176</sup> In particular, there is no specific application for data exclusivity; in countries that provide this protection, it is provided automatically when a drug is approved by the domestic regulatory agency.<sup>177</sup> Moreover, the exception would still result in an investment tribunal, rather than a WTO panel deciding on whether or not this is permissible under the TRIPS Agreement. In addition, 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 legitimate interest in a country “complying” with the TRIPS Agreement by providing data exclusivity based on its belief that this is what the TRIPS Agreement requires.<sup>178</sup> This would have a potentially serious chilling effect on the ability of countries to decline to provide data exclusivity as a type of TRIPS flexibility.

### 3. Compulsory Licensing

Another likely target of an investor-state arbitration would be a compulsory license. A compulsory license is a state-mandated license to make and use a patented invention in situations where public policy counsels that the patent owners should not be permitted typical exclusivity and ability to charge a patent premium.<sup>179</sup> Although this situation seems inapposite

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176. Heled, *supra* note 174, at 431.

177. *Id.*

178. See Philip Morris Brands Sarl v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Award, ¶¶ 340–45 (July 2, 2013).

179. JEROME H. REICHMAN & CATHERINE HASENZ AHL, INT’L CTR. FOR TRADE & SUSTAINABLE DEV. (ICTSD) AND UNITED NATIONS CONFERENCE ON

of the patent right to exclude, one of the reasons compulsory licenses have historically been granted is to promote public interest, including a desire to ensure that patents on medical products were not unduly costly.<sup>180</sup> The TRIPS Agreement continues to permit nations authorities to grant such licenses by specifying the procedural requirements that must be complied with, including that the patent owner be provided “adequate remuneration.”<sup>181</sup> However, any issued compulsory licenses are likely to be challenged as constituting an expropriation since companies often regard compulsory licenses as either “breaking” their patents, or as *expropriating* their patent rights.<sup>182</sup> Scholars have been expecting such claims.<sup>183</sup> A compulsory license may very well represent a prototypical situation in which an investor believes that it needs and deserves the additional protection of investor-state arbitration because domestic laws and institutions are perceived to unfairly permit the state to seize their IP rights, regardless of the fact that this is permissible under state and international law.<sup>184</sup>

The ability to issue compulsory licenses is especially important now because countries no longer have the freedom to completely deny patents on drugs as many had done before

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TRADE & DEV. (UNCTAD), NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA 6 (2003).

180. *Id.* at 10–13.

181. TRIPS, *supra* note 2, art. 31. An amendment to the TRIPS Agreement allowing countries with pharmaceutical manufacturing capacity to manufacture drugs for countries without such capacity under a compulsory license came into effect in January 2017. See *WTO IP Rules Amended to Ease Poor Countries’ Access to Affordable Medicines*, WTO (Jan. 23, 2017), [https://www.wto.org/english/news\\_e/news17\\_e/trip\\_23jan17\\_e.htm](https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm).

182. *E.g.*, Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1069–70 (2009) (discussing characterization as “breaking” patents); see also Press Release, Merck & Co., Inc., Merck & Co., Inc. Statement on Brazilian Government’s Decision to Issue Compulsory License for STOCRIN™ (May 4, 2007) (printed by Business Wire), <http://www.businesswire.com/news/home/20070504005566/en/Merck-Statement-Brazilian-Governments-Decision-Issue-Compulsory> (referring to compulsory license as expropriation).

183. *E.g.*, Peter B. Rutledge, *TRIPS and BITs: An Essay on Compulsory Licenses, Expropriation, and International Arbitration*, 13 N.C. J.L. & TECH. ONLINE 149, 161 (2012) (describing expropriation disputes); Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT’L L. REV. 357, 359 (2010) (forecasting a rise in IPR disputes).

184. See Ho, *Sovereignty*, *supra* note 127.

TRIPS.<sup>185</sup> However, countries are typically wary of using these rights. For example, although Colombia has recently taken steps to issue a compulsory license on a cancer drug sold as Gleevec that is currently sold at a cost that is nearly double Colombia's per capita income,<sup>186</sup> it has not actually issued a license due to serious opposition.<sup>187</sup> In particular, a U.S. threat to revoke a prior offer to provide millions of dollars in aid to back Colombian peace initiatives seems to have been a factor in Colombia's reluctance to issue a compulsory license.<sup>188</sup> Since withdrawal of promised aid seems to make an impact, the threat of having to pay millions to defend against an investment suit that could result in hundreds of millions in damages could have a serious chilling effect on countries issuing compulsory licenses. This is particularly problematic since countries have already been hesitant to issue compulsory licenses without the threat of investor-state arbitration.

#### C. FURTHER RISKS POSED TO THE IP COMPLEX BY THE NATURE OF INVESTOR-STATE ARBITRATION THAT COULD POTENTIALLY EXACERBATE TRIPS DESTABILIZATION

To further emphasize why this latest regime shift to investor-state arbitration poses a huge threat of destabilizing

185. *E.g.*, SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES 59 (2005) (citing Julio J. Nogués, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, J. WORLD TRADE 81, 83 (1990) (noting nearly fifty countries that did not provide patent protection on drug or drug compounds)); *see also* TRIPS, *supra* note 2, art. 27(1) (requiring patent protection on all inventions).

186. James Love & Andrew S. Goldman, *Inside Views: Colombia Asked to Declare Excessive Price for Cancer Drug Contrary to Public Interest, Grounds for Compulsory License*, IP-WATCH (Mar. 12, 2015), <http://www.ip-watch.org/2015/12/03/colombia-asked-to-declare-excessive-price-for-cancer-drug-contrary-to-public-interest-grounds-for-compulsory-license/>.

187. Andrew Goldman & Thiru Balasubramaniam, *Switzerland Pressures Colombia to Deny Compulsory License on Imatinib*, KNOWLEDGE ECOLOGY INT'L (Aug. 18, 2015), <http://keionline.org/node/2312>.

188. Zach Carter, *Colombia Fears U.S. May Reject Peace Plan to Protect Pharma Profits*, HUFFINGTON POST (May 11, 2016, 10:47 PM), [http://www.huffingtonpost.com/entry/colombia-gleevec\\_us\\_5733d4ece4b077d4d6f224ee](http://www.huffingtonpost.com/entry/colombia-gleevec_us_5733d4ece4b077d4d6f224ee). Columbia instead issued a public interest declaration to lower the price of Glivec, which led to a price reduction of over 40%. *E.g.*, Andrew Goldman, *Colombia Finalizes 44% Price Reduction of Leukemia Drug Glivec*, KNOWLEDGE ECOLOGY INT'L (Dec. 21, 2016, 10:06 AM), <http://www.keionline.org/node/2705>. Although Columbia's approach does seem to address complaints about compulsory licenses, Columbia may have nonetheless made itself susceptible to an investor-state claim for expropriation or FET based on this price reduction.

TRIPS flexibilities, this section considers how the nature of investor-state arbitration makes this outcome more likely than not and the risks it poses to the IP regime complex as a result. This section will do so by comparing and contrasting features of investor-state dispute settlement with the WTO's dispute settlement system as well as that found in domestic legal systems.

### 1. Adjudication of Investment Claims Differs from WTO Disputes in a Pro-Investor Sense

Investment claims give investors the right to seek substantial financial compensation as damages from states that violate their rights, which is not possible in other situations. For example, a state that seeks to espouse an investor's case in the WTO does not have a right to damages since WTO disputes are designed to bring laws into compliance with WTO obligations, rather than to impose financial penalties. Although investors may seek compensation under domestic law, they are less likely to succeed than in investor-state arbitration since domestic courts tend to be more deferential to the regulatory authority of their states. Indeed, when the tobacco companies challenged regulations in Uruguay and Australia, they failed.<sup>189</sup> In Australia, the highest courts decided that the plain packaging legislation did not constitute a domestic taking since trademarks only provide a right to *exclude*, and not an affirmative right to use.<sup>190</sup> Similarly, the Eli Lilly investment claim against Canada could have resulted in a financial win—and windfall—in a context where Canadian courts concluded that Eli Lilly had no cognizable patent rights under Canadian law and Eli Lilly did not bring a domestic taking.<sup>191</sup> In that particular case, the tribunal wisely recognized that it should not function as an appellate body overseeing domestic decisions. However, whether other tribunals will follow a similar approach remains to be seen.

In addition, investment claims are also notably different—and problematic—because they can be brought even if a country is arguably in full compliance with the TRIPS Agreement. In the WTO, countries are given significant authority to decide how to

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189. See *Philip Morris Brands Sarl v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Award (July 2, 2013).

190. *JT Int'l SA v. Commonwealth*, [2012] 250 CLR 1 (Austl.); *British American Tobacco Australasia LTD v. Commonwealth*, [2012] Matter No. S389/2011.

191. *E.g.*, *Novopharm Ltd. v. Eli Lilly Can., Inc.* [2010] F.C.R. 915 (Can.).

define terms, such as what is an “invention,” but that flexibility would not necessarily persuade an investor-state tribunal that an invention that constituted an investment had not been expropriated. Although most investment agreements recognize that revocation of patent rights, as was the situation with Eli Lilly, is not an expropriation *if* it complies with TRIPS, this still permits an investment tribunal to decide whether such a revocation is consistent with the TRIPS Agreement. The Eli Lilly case demonstrates that companies may seek “interpretations” of TRIPS by investment tribunals that defy conventional interpretations.<sup>192</sup> Moreover, since the primary goal of bilateral investment treaties is to promote investment and protect investor rights, a tribunal might be more inclined towards views of IP owners, such as Eli Lilly.<sup>193</sup> Some scholars have suggested that tribunals should be sensitive and sympathetic to TRIPS Agreement flexibilities<sup>194</sup> as reflected in its preamble,<sup>195</sup> as well as in the “principles and “objectives” clauses.<sup>196</sup> There is also some support for this from WTO Panel Reports.<sup>197</sup> In addition,

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192. *E.g.*, Susy Frankel, *Interpreting the Overlap of International Investment and Intellectual Property Law*, 19 J. INT’L ECON. L. 121, 139–41 (2016) (noting that Eli Lilly’s claim that the definition of patent utility should not change after NAFTA was enacted defies analysis pursuant to the Vienna Convention).

193. This is particularly true in most older-type agreements such as NAFTA that lack any language suggesting that other policy norms be balanced. *See, 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 DISP. SETTLEMENT 252 (2015).

194. *E.g.*, Frankel, *supra* note 192; *see also* sources cited *infra* note 196 (discussing limited WTO panel use of TRIPS flexibility).

195. TRIPS, *supra* note 2, pmb. (“Recognizing that intellectual property rights are private rights . . . Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.”).

196. TRIPS, *supra* note 2, art. 7 (listing the “objectives” clause which states that agreement should benefit both producers and users of innovation in a balanced manner that recognizes social and economic welfare); *id.* art. 8 (listing the “Principles” clause which explicitly recognizes that WTO members are entitled to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”).

197. *E.g.*, Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (adopted Mar. 17, 2000) (stating that “both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind” when interpreting other TRIPS provisions); Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WTO Doc. WT/DS174/R (adopted Mar. 15, 2005) (noting that article 8 provides member states “Freedom

its design as a “minimum,” rather than as a uniform set of rules supports the discretion WTO members have to balance the protection of IP rights with competing interests such as public health.<sup>198</sup> WTO Panel Reports have also noted that the minimum standards framework means that member states have discretion on how to implement those minimum standards.<sup>199</sup> So, although patentability requirements such as what is a “new” or “useful” invention are widely understood under TRIPS to be terms that a country can flexibly define to address domestic priorities, Eli Lilly argued that its interpretation of what is “useful” should instead govern. Notwithstanding the fact that the tribunal never got to the merits of Eli Lilly’s claim on this issue, this investor-state dispute could still have a chilling effect on poor states from enacting TRIPS-consistent legislation because they cannot afford to defend against such a claim.<sup>200</sup> Notably, even though Canada won, the tribunal explicitly stated that it did *not* consider Eli Lilly’s claims to be frivolous.<sup>201</sup>

We acknowledge that chilling effects can be hard to document. After all, countries could decline to adopt domestic legislation consistent with TRIPS flexibility for many reasons other than because they have received a specific threat of investment dispute being filed against them. However, the tobacco industry has warned not only Canada against enacting tobacco regulations,<sup>202</sup> but also a wide range of developed and developing countries.<sup>203</sup> Similarly, the pharmaceutical industry

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to pursue legitimate public policy objectives” outside the scope of intellectual property rights).

198. TRIPS, *supra* note 2, art. 1.

199. Panel Report, *China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WTO Doc. WT/DS362/R (adopted Jan. 26, 2009) (stating that article 1.1. “grants freedom to determine the appropriate method of implementation”); Panel Report, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/AB/R (adopted Dec. 19, 1997) (“Members . . . are free to determine how best to meet their obligations under the TRIPS Agreement within the context of their own legal systems.”).

200. The risk of ISDS interpretations identified here is addressed by treating ISDS interpretations of domestic law—EU law in the case of the CETA Article 8.31 and the November 2015 TTIP proposal Article 3.3—as incidental and factual.

201. See Eli Lilly, Award, *supra* note 158, ¶ 455(b).

202. For regulations, we are including, but not limiting, our reference to laws that promote “plain packaging” of cigarettes.

203. See sources cited *supra* note 18 and accompanying text (developing countries); see also Sean O’Neal, *Tobacco Company that Relies on Skewing Facts*

has used a variety of mechanisms to promote its IP interests and to impede domestic action perceived to impact such interests. This includes litigation, lobbying decision-makers outside formal participatory and consultative channels and without public disclosure, and public “educational” campaigns that reflect their view.<sup>204</sup>

Canada’s successful defense against Eli Lilly’s investment suit does not reduce the potential that investor-state cases challenging patentability standards, including this case, could still have a significant chilling effect on the already limited use of TRIPS flexibilities. After all, Canada has significantly more resources than poorer countries that may lack the resources to mount a strong legal defense. Further, although Canada prevailed in a unanimous decision, it still paid more than \$1 million in attorney fees. Such costs are a substantial disincentive for a poorer country gambling on the odds of winning. As we have argued throughout this paper, the mere threat of an investment claim seeking millions of dollars has a chilling effect on the willingness of those governments to proceed with regulatory goals to protect public health that investors have protested as inconsistent with their investment rights.

Although the verification of potential chilling effects will likely need to happen after this article is published, we have gathered some information in Annex One to this article documenting the variety of challenges made by companies in response to efforts to regulate tobacco or to use TRIPS flexibilities. This information discloses that companies engage in a broad-range of concerted efforts, short of filing investor-state disputes, to prevail on states not to enact laws that are perceived to unduly limit desired IP rights.<sup>205</sup>

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*Decries John Oliver for Skewing Facts*, AV CLUB (Feb. 17, 2015, 12:56 PM), <http://www.avclub.com/article/tobacco-company-relies-skewing-facts-decries-john--215375>.

204. *E.g.*, HO 2011, *supra* note 171, at 327–48.

205. Although Annex One, *infra*, is not an exhaustive list of all the concerted initiatives of IP companies to prevail on states not to regulate their IP rights, it nevertheless demonstrates the combination of strategies that these IP companies use to achieve regulatory chill in their favor. The Annex documents, by country, the laws or regulations on tobacco regulation in question, the date on which they were proposed or came into effect, and legal and other challenges made by IP companies against these laws or regulations.

## 2. The Adjudicatory Process of Investor-State Cases is Heavily Weighted in Favor of Investors

A notable feature of investor-state claims is that they give investors a right to sue states for violating rights embodied in investment treaties made between states. However, this is a relatively new development. Until the middle of the twentieth century, state to state claims were the predominant mode of international dispute settlement and investors had to persuade their home State to espouse a case on their behalf. Allowing investors to bring suits against states was therefore considered a “revolutionary innovation” in international law.<sup>206</sup> This is a very important distinction since states tend to be cautious in asserting claims against other states and weigh a number of political considerations. For example, although countries have often asserted the existence of TRIPS Agreement violations, there have been extremely few disputes initiated under the TRIPS Agreement.<sup>207</sup> Corporations, by contrast, do not have similar political considerations and might be inclined to file claims to encourage a settlement, which is often in their favor.<sup>208</sup> Moreover, companies have been bringing an increasing number of investment claims in recent years. This may in part be attributable to broadly interpreted claims by some tribunals, especially with respect to what constitutes violation of the vague term “fair and equitable treatment.” Although such claims were at one point rare, they are now often broadly interpreted to bar countries from violating the “legitimate interests” of investors.<sup>209</sup> One commentator has noted that such broad FET claims “cover

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206. BG Group Plc. v. Republic of Argentina, U.N. Commission on Int'l Trade L. [UNCITRAL] Final Award, ¶ 145 (Dec. 24, 2007) (stating that the proliferation of bilateral investment treaties has caused a “profound transformation of international investment law,” including “[entitling investors] to seek enforcement of their treaty rights by directly bringing action against the State in whose territory they have invested”); Jan Paulsson, *Arbitration Without Privity*, 10 ICSID REV. 232, 256 (1995) (“It is dramatically different from anything previously known in the international sphere.”).

207. As just one example, countries that issue compulsory licenses are frequently criticized for violating TRIPS, but there has never been a WTO dispute.

208. *E.g.*, LAUGE SKOVGAARD POULSEN ET AL., LONDON SCH. OF ECON., COSTS AND BENEFITS OF AN EU-US INVESTMENT PROTECTION TREATY 28, 30 (2013).

209. *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 (2013).

all conceivable cases.”<sup>210</sup> Indeed, such claims are commonly brought and are the most successful investment claims.<sup>211</sup>

Dispute settlement in the investment regime is also significantly different than in the WTO. Dispute settlement in the WTO between two countries allows other WTO member countries to participate as third parties, which in turn allows them to have a voice in the determination of issues that implicate their interests. Moreover, there is an Appellate Body that has jurisdiction to review Panel decisions on questions of law. By contrast, investor-state dispute settlements, particularly those hosted by the International Center for Settlement of Investment Disputes (ICSID) are dominated by high-powered, elite private lawyers or legal academics from Europe and the United States who have more experience in the primarily private and commercial law oriented investor-state arbitration system than in the more public law oriented dispute settlement system of the WTO.<sup>212</sup> In an ICSID pool of 311 cases, 77% of the cases were decided by a small group of 39 arbitrators, and of this group 39% had one of the ‘top’ group of elite arbitrators. In addition, 29% of these cases there were two such ‘top’ arbitrators and in 9% of these cases, all three arbitrators were in this top niche of arbitrators.<sup>213</sup> A major explanation for these repeat appointments of a small cadre of arbitrators is that the system of party-appointed ‘private judges’ in investor-state arbitration consists of one group consistently appointed by investors, and another group consistently appointed by states.<sup>214</sup>

Some recent empirical evidence strongly suggests that investor recovery increases by at least 39% when investor-state

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210. F.A. Mann, *British Treaties for the Promotion and Protection of Investments*, 52 BRITISH Y.B. INT'L L. 241, 243 (1981).

211. United Nations Conference on Trade and Development, *Recent Developments in Investor-State Dispute Settlement (ISDS)*, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2013/3/REV, at 5 (2013).

212. See generally Joost Pauwelyn, *The Rule of Law Without the Rule of Lawyers? Why Investment Arbitrators Are from Mars, Trade Adjudicators from Venus*, 109 AM. J. INT'L L. 761 (2015); Joseph Weiler, *European Hypocrisy: TTIP and ISDS*, EJIL: TALK! (Jan. 21, 2015), <http://www.ejiltalk.org/european-hypocrisy-ttip-and-isd/> (explaining that investor-state arbitration is “dominated by arbitrators from private practice rather than public interest backgrounds”).

213. Sergio Puig, *Blinding International Justice*, 56 VA. J. INT'L L. 647 (2017).

214. Sergio Puig, *Social Capital in the Arbitration Market*, 25 EUR. J. INT'L L. 387, 402 (2014).

arbitration panels have a majority of pro-investor arbitrators and a State is found liable.<sup>215</sup> In addition, where there was only one pro-state arbitrator and a pro-investor arbitrator, the evidence suggested the recovery rate of a state reduced to 23%.<sup>216</sup> To compound this problem, many elite arbitrators act as counsel or as party-appointed experts when not sitting as an arbitrator which in turn creates conflicts.<sup>217</sup> Although there are rules that aim to ensure integrity of arbitrators, this ad hoc dispute settlement system is still quite different than national judicial systems, or even the dispute settlement system of the WTO that have more established mechanisms of accountability and transparency built into them.

There is also a high level of confidentiality relating to hearings and written submissions in investor-state arbitration. This confidentiality is a function of the fact that such arbitrations were based on the private commercial arbitral dispute settlement model involving solely private parties where there may be a greater justification for secrecy to protect business interests.<sup>218</sup> Typically, only parties to the dispute have full access to all the information relating to investor-state disputes, yet unlike in a dispute between private parties, investor-state arbitrations often implicate major public policy issues.<sup>219</sup>

There is also limited ability for third parties to participate even when these cases raise public policy issues. In stark contrast to the WTO system, the vast majority of investment cases do not guarantee any direct participation by third parties. Although investment tribunals have authority to *permit* amicus

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215. Puig, *supra* note 213, at 684.

216. *Id.*

217. *E.g.*, NATHALIE BERNASCONI-OSTERWALDER ET AL., INT'L INST. FOR SUSTAINABLE DEV., ARBITRATOR INDEPENDENCE AND IMPARTIALITY: EXAMINING THE DUAL ROLE OF ARBITRATOR AND COUNSEL (2010); *see also* David Graukrodger & Kathryn Gordon, *Investor-State Dispute Settlement: A Scoping Paper for the Investment Policy Community*, (Org. Econ. Cooperation & Dev. Working Papers on Int'l Inv. 2012/03, 2012) (stating that a majority of arbitrators have served as counsel for investors in other cases whereas only 10% of arbitrators have acted as counsel for states in other cases).

218. *See* Frank J. Garcia et al., *Reforming the International Investment Regime: Lessons from International Trade Law*, 18 J. INT'L ECON. L. 861, 871–72 (2015).

219. *E.g.*, Susan D. Franck, *The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law Through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521, 1544–45 (2005).

briefs from third parties in limited circumstances,<sup>220</sup> non-parties must petition tribunals who then have discretion to decide whether to grant this permission after consulting with the disputing parties.<sup>221</sup> Even if participation is granted, effectiveness may be hampered by inability to obtain access to

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220. Notably, the ICSID Convention Arbitration Rules as revised in 2006 allow for participation of amicus briefs, but 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 Rules of Procedure for Arbitration Proceedings (Arbitration Rules), 37(2) (permitting third parties to file amicus submission), <http://icsidfiles.worldbank.org/icsid/icsid/staticfiles/basicdoc/partf-chap04.htm>; see also UNICTRAL Rules on Transparency in Treaty-Based Investor-State Arbitration art. 5 (2014) (concerning submission by a non-disputing party to the treaty). For further discussion and assessment of the openness of investment disputes to third party intervention, see James Fry & Odysseas Repousis, *Towards a New World for Investor State Arbitration Through Transparency*, 48 N.Y.U. J. INT'L L. & POL. 705 (2016); Katia Gomez, *Rethinking the Role of Amicus Curiae in International Investment Arbitration: How to Draw the Line Favorably for the Public Interest*, 35 FORDHAM INT'L L.J. 510 (2012); Eugenia Levine, *Amicus Curiae in International Investment Arbitration: The Implications of an Increase in Third Party Participation*, 29 BERKELEY J. INT'L L. (2011); Alberto Salazar, *Defragmenting International Investment Law to Protect Citizen-Consumers: The Role of Amici Curiae and Public Interest Groups*, 19 L. & BUS. REV. AM. 183 (2013).

221. ICSID Rules of Procedure for Arbitration Proceedings (Arbitration Rules), 37(2) (explaining that the disputing parties do not have an absolute veto right and there are situations where amicus submissions are granted in spite of objections of the investor), <http://icsidfiles.worldbank.org/icsid/icsid/staticfiles/basicdoc/partf-chap04.htm>. Nonetheless, this is obviously a very different process than in the WTO.

all documents,<sup>222</sup> or to attend oral proceedings.<sup>223</sup> Recognizing some of these deficiencies, some newer proposed or recently concluded agreements permit broader access to third parties, including in one case an actual right to intervention.<sup>224</sup> However, this is only true for some agreements and also notably does not apply retroactively to the vast majority of existing agreements.<sup>225</sup>

In addition, unlike in the WTO, the vast majority of investor-state claims are not subject to appeal;<sup>226</sup> awards can be annulled under a limited set of circumstances;<sup>227</sup> however, these

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222. For example, the 2003 Statement of the Free Trade Commission on Non-Disputing Party Participation regarding NAFTA does not require access to documents. NAFTA, Statement of the Free Trade Commission on Non-Disputing Party Participation, <https://www.state.gov/documents/organization/38791.pdf>; see also Camilla Graham, *Amicus Curiae & Investment Arbitrations: Part 2*, A4ID ADVOCATES FOR INT'L DEV. 10 (2012); Salazar, *supra* note 220, at 186; Epaminontas Triantafilou, *A More Expansive Role for Amici Curiae in Investment Arbitration?*, KLUWER ARBITRATION BLOG, (May 11, 2009), <http://kluwarbitrationblog.com/2009/05/11/a-more-expansive-role-for-amici-curiae-in-investment-arbitration/>. Indeed, in one case, a tribunal explicitly noted that non-disputing parties did not require materials to submit informed briefs. *Aguas Argentinas, S.A. v. Argentine Republic*, ICSID Case No. ARB/03/19, Order in Response to a Petition for Transparency and Participation as *Amicus Curiae*, (May 19, 2005). *But see* TPP, *supra* note 16, art. 23(3) (stating that if an intervention is granted, the intervener may obtain copies of procedural documents except in cases of confidentiality); *Piero Foresti v. Republic of South Africa*, ICSID Case No. ARB(AF)/07/01, Award, (Aug. 4, 2010) (requiring parties to disclose briefs to amicus intervenors).

223. In most cases, this is only possible with consent of disputing parties and either disputing party has an absolute veto right on this possibility. ICSID Rules of Procedure for Arbitration Proceedings (Arbitration Rules), 32(2), <http://icsidfiles.worldbank.org/icsid/icsid/staticfiles/basicdoc/partf-chap04.htm>. Some investment agreements may, on the other hand require open hearings. *E.g.*, Dominican Republic – Central America – United States Free Trade Agreement arts. 10.17.2(a), 10.21 (2005); TPP, *supra* note 16, art. 9.24(2); CETA, *supra* note 31, art. 8.36(5).

224. TTIP, *supra* note 31, art. 23 (“The Tribunal shall permit any natural or legal person which can establish a direct and present interest in the result of the dispute (the intervener) to intervene as a third party.”).

225. Even in recent agreements, amicus briefs are not guaranteed. *Compare* TPP, *supra* note 16, art. 9.22 (stating that tribunals *may* accept non-disputing party amicus curiae submissions under certain conditions), *with* CETA, *supra* note 31, art. 8.38 (stating that the tribunal *shall* accept non-disputing party submissions).

226. 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 Group v. Republic of Argentina*, 134 S. Ct. 1198, 1201–02 (2014).

227. ICSID Rules of Procedure for Arbitration Proceedings (Arbitration Rules), art. 52, <http://icsidfiles.worldbank.org/icsid/icsid/staticfiles/basicdoc>

are usually unsuccessful.<sup>228</sup> Indeed, when the EU initiated a public consultation in 2014 to address concern about such disputes, one of the most important areas of concern for the public was the protection of the right of a country to regulate without the possibility of review by arbitral tribunals and the absence of appellate mechanisms to review arbitral tribunal decisions for legal correctness.<sup>229</sup> The EU has since included an appellate mechanism in its investment agreement with Vietnam, as well as in CETA.<sup>230</sup> Although this is a promising sign for future agreements, it obviously does not permit appeals in other agreements.

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/parta-chap04.htm (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); G.A. Res 40/72, art. 34 (Dec. 4, 2006) (listing limited grounds for setting aside an award); see also Albert Jan van den Berg, *Should the Setting Aside of Arbitral Award Be Abolished?*, 29 ICSID REV. 1 (2014) (explaining origins and current status of setting aside awards in international arbitration); Press Release, Jose Alvarez et al., International Law Experts Respond to Alliance for Justice ISDS Letter (Apr. 8, 2015) (stating that “awards are subject to review either in national courts or by ad hoc annulment committees composed of representatives drawn from rosters created by states”).

228. E.g., United Nations Conference on Trade and Development, *Recent Trends in IIAS and ISDS*, U.N. Doc. UNCTAD/WEB/DIAE/PCB/2015/1, at 8 (Feb. 2015) (noting that all five applications for annulment in 2014 were entirely rejected). But see HERBERT SMITH FREEHILLS LLP, *ICSID Annulment Awards: The Fourth Generation?*, LEXOLOGY (Feb. 18, 2011), <https://www.lexology.com/library/detail.aspx?g=7218cb56-7a64-426f-8cc0-8475303444e6> (suggesting that in some cases, annulment proceedings have been more akin to appellate review despite lack of support from language of ICSID).

229. European Comm’n., *Comm. Staff Working Document, Report: Online Public Consultation on Investment Protection and Investor-to-state dispute settlement (ISDS) in the Transatlantic Trade and Investment Partnership Agreement (TTIP)*, SWD(2015) 3 Final 18, 24 (Jan. 13, 2015), [http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc\\_153044.pdf](http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153044.pdf) [hereinafter Eur. Comm’n Working Document] (noting that vast majority of comments agree concerning the right to ensure a balance between investment protection and right to regulate, as well as broad support in favor of an appellate mechanism, with some considering it indispensable).

230. DELEGATION OF THE EUROPEAN UNION TO VIETNAM, *GUIDE TO THE EU-VIETNAM FREE TRADE AGREEMENT* 27, 54 (discussing various opportunities for parties to appeal), [http://eeas.europa.eu/archives/delegations/vietnam/documents/eu\\_vietnam/evfta\\_guide.pdf](http://eeas.europa.eu/archives/delegations/vietnam/documents/eu_vietnam/evfta_guide.pdf).

### III. LOOKING AHEAD – LEANING ON AND EXTENDING THE LESSONS LEARNED SO FAR

Given the potential for investor-state arbitration to destabilize domestic and international IP norms, including TRIPS flexibilities, this Part proposes strategies to counter this outcome. First, we recommend limiting application of investor-state claims to TRIPS norms by defining with more clarity and precision key terms in investment chapters and agreements. Second, we recommend improving the investment dispute process particularly with respect to disputes that arise under existing investment agreements. These suggestions are in addition to options already available to States such as terminating agreements to minimize liability for future claims.<sup>231</sup> The suggestions focus solely on the new regime shift from the WTO to the international investment law regime, but may not address future regime shifts to yet-to-be determined regimes. After all, regime shift theory suggests that actors are constantly seeking to shift to preferable regimes, such that regime shifting in general is unlikely to be stopped. However, we make proposals to minimize the most negative impacts of the IP regime shift we have identified. At the same time, although these proposals are aimed to combat the IP regime shift, some of the proposals may address broader concerns regarding the investment arena that apply beyond IP.

#### A. LIMITING THE INTRUSION OF THE INVESTMENT REGIME ON IP NORMS

There are a variety of ways in which countries can limit the extent to which the investment regime interferes with negotiated IP norms and obligations. Subsection 1 focuses on how pending and future agreements could provide more clarity and precision of key investor protections and the rights of States. Subsection 2 offers suggestions for improving the procedures of investor-state dispute settlement to safeguard a better balance between the rights of states and investors in the IP context.

##### 1. Carve-Outs of IP Claims from ISDS

One way to mitigate the conflict between international agreements protecting investors and those protecting IP rights is to carve-out certain IP claims from ISDS in pending and future

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231. Indeed, South Africa and Indonesia have already done so. *See* sources cited *supra* note 18.

investment treaties. This can take a variety of forms including a carve-out for all claims, only some types of investment claims, or a requirement of additional specific consent. There is already precedent for carving out specific subject areas, including national security, some types of tax,<sup>232</sup> financial institutions,<sup>233</sup> real estate,<sup>234</sup> and most recently tobacco regulation.<sup>235</sup> Many agreements currently have what could be considered a carve-out for IP claims from expropriation, although it is not a true carve out since it only excludes claims of expropriation that are consistent with TRIPS; this will thus result in an investment case proceeding to assess TRIPS consistency.<sup>236</sup> Accordingly, an actual carve out must go beyond expropriation claims. Alternatively, if TRIPS-based IP rights were not entirely precluded, limiting claims to only state to state cases would be an improvement. Even though conflict would not be completely eliminated, it would better parallel the WTO process and at least reduce the number of likely conflicts because states are more discerning in bringing disputes.<sup>237</sup> Another approach could involve only allowing investors to bring investor-state claims that implicate TRIPS if there is prior specific consent by the host

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232. *E.g.*, TPP, *supra* note 16, art. 29.4, (no FET claims for tax); *see also* William Park, *Tax Arbitration and Investor Protection*, in *THE FUTURE OF INVESTMENT ARBITRATION* 227, 238 (Catherine A Rogers & Roger P Alford eds., 2009).

233. Agreement between Canada and the Hashemite Kingdom of Jordan for the Promotion and Protection of Investments, Can.-Jordan, June 28, 2009, art. 21, <http://investmentpolicyhub.unctad.org/Download/TreatyFile/617>.

234. Agreement Between the Government of the Republic of Turkey and the Government of the Republic of Cameroon Concerning the Reciprocal Promotion and Protection of Investments, Turk.-Cameroon, Apr. 24, 2012, art. 10.4(c), <http://investmentpolicyhub.unctad.org/Download/TreatyFile/597>.

235. TPP, *supra* note 16, art. 29.5. However, whether this will survive the ratification stage is unclear. *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); Wendy Parmet, *Trade, Health, and Tobacco Exceptionalism: The TPP Tobacco Carve Out*, HEALTH AFF. BLOG (Nov. 10, 2015), <http://healthaffairs.org/blog/2015/11/10/trade-health-and-tobacco-exceptionalism-the-tpp-tobacco-carve-out/>.

236. *E.g.*, TPP, *supra* note 16, art. 9.8.5. The Eli Lilly dispute illustrates the fact that such a clause does not obviate a dispute since there is a similar clause under NAFTA.

237. *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/> (recognizing and suggesting this approach).

nation, as is already done with some tax claims.<sup>238</sup> 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.<sup>239</sup>

Alternatively, the definition of applicable investment could be narrowed to minimize conflicts between the TRIPS Agreement and investment treaties. For example, the definition of an investment could be clarified to exclude a mere application for an IP right.<sup>240</sup> This would be consistent with long-recognized intellectual property policy that there are no rights attendant to a mere application.<sup>241</sup> 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, unless there is denial of justice arising from procedural irregularities.<sup>242</sup> Using

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238. *E.g.*, Energy Charter Treaty, art. 21(5), <http://www.energycharter.org/fileadmin/DocumentsMedia/Legal/ECTC-en.pdf> (for expropriation claims, investor must refer the issue to the relevant Tax Authority); NAFTA *supra* note 162, art. 2103(6) (explaining competent authorities to assess whether the measure is an expropriation); *see also* WAYS & MEANS COMM. DEMOCRATS, *TPP in Focus: Investment and Investor State Dispute Settlement – The Need for Reform*, (Mar. 20, 2015), <https://democrats-waysandmeans.house.gov/media-center/blog/tpp-focus-investment-and-investor-state-dispute-settlement-need-reform>; TPP, *supra* note 16, art. 29.4(8).

239. *E.g.*, Park, *supra* note 232, at 233.

240. This would be contrary to some agreements that explicitly assert that a mere application constitutes an investment and also preclude tribunals from reading existing agreements broadly to include applications even when not specifically included.

241. It would also be consistent with the *Apotex* decision finding that an application for FDA approval of a drug is not an investment. *Apotex Holdings, Inc. v. United States*, ICSID Case No. ARB(AF)/12/1, Award, ¶ 7.64 (Aug. 25, 2014).

242. *E.g.*, Model Text for the Indian Bilateral Investment Treaty, art. 2.6(v), 2015, [https://www.mygov.in/sites/default/files/master\\_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf](https://www.mygov.in/sites/default/files/master_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf) (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”); *see also* Sean Flynn, *TTIP Stakeholder Statement: Protect IP from ISDS*, INFOJUSTICE (Apr. 23, 2015), <http://infojustice.org/archives/34319> (indicating that language—barring expropriation “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”—was in Canada’s original proposal, but omitted in the ultimate 2014 CETA version); Michael Geist, *Did Canada Cave on the Pharmaceutical Patent ISDS Issue in CETA?: Still No Text, but Official*

domestic law, rather than TRIPS consistency as the relevant criteria would move towards ensuring that investment tribunals have no jurisdiction to decide whether such application denials were permissible under the TRIPS Agreement.

Narrowing the scope of investment disputes in existing agreements to exclude IP is trickier. However, states can exclude certain topics from ICSID dispute under Article 25(4) of ICSID. Under this provision, an ICSID Convention State can notify ICSID of a class of dispute that is not within the jurisdiction of the Center “at any time” after approving the Convention.<sup>243</sup> This of course only governs disputes under ICSID, but considering the broad membership of this group, that would still be relevant to many countries who are signatories to the over 3000 bilateral investment treaties. As of May 2016, there are indeed notifications that eliminate consent for disputes relating to expropriation and nationalization (China), claims arising from armed conflicts (Guatemala), administrative decisions (Indonesia), and investments relating to natural resources (Jamaica).<sup>244</sup> Accordingly, it would seem that intellectual property rights could be a topic for which a similar notification is possible.

## 2. Limiting Jurisdiction – Investment Definition

The scope of the definition of an investment outside of IP can also be narrowed, particularly because some BITs have very broad definitions of what constitutes an investment.<sup>245</sup> In particular, we endorse a definition of investment consistent with the *Salini* decision, and propose that it be explicitly included in future agreements. The *Salini* tribunal found that a qualifying investment has four criteria: a certain period of performance and

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*Comments Suggests It Did*, MICHAEL GEIST BLOG (Aug. 6, 2014), <http://www.michaelgeist.ca/2014/08/canada-cave-pharmaceutical-patent-isds-issue-ceta-still-text-report-suggests/> (quoting the same language and reporting the EU’s response).

243. Convention on the Settlement of Investment Disputes Between States and Nationals of Other States, art. 25(4), Mar. 18, 1965, T.I.A.S. No. 6090, 17 U.S.T. 1270 [hereinafter ICSID].

244. Contracting States and Measures Taken by Them for the Purposes of the Convention, ICSID/8-D (Sept. 27, 2016).

245. For an extensive review, see United Nations Conference on Trade and Development, *Scope and Definition: UNCTAD Series on Issues in International Investment Agreements II*, 7–9 (2011), [http://unctad.org/en/Docs/diaeia20102\\_en.pdf](http://unctad.org/en/Docs/diaeia20102_en.pdf).

participation in the risks; contribution of the investment to the economic development of the host state such as being beneficial to the public interest or some transfer of know-how assessed in a holistic manner.<sup>246</sup> Although *Salini* is often cited, not all tribunals consider themselves to be bound by it, or even require all elements for an investment to exist; some explicitly reject the need to for investments to meet all four factors in order to establish jurisdiction.<sup>247</sup> Future investment agreements could require investor-state tribunals to find all these criteria as prerequisites for their exercise of jurisdiction. The requirement that the investment contributes to the economic development of the host state is particularly useful in the context of IP rights.<sup>248</sup>

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246. *Salini Costruttori S.p.A. v. Kingdom of Morocco*, ICSID Case No. ARB/00/4, Decision on Jurisdiction, ¶ 52 (July 16, 2001). In addition, although *Salini* was interpreting article 25(1) of ICSID, its interpretation has been affirmed in non-ICSID cases. *E.g.*, *Romak S.A. v. Uzbekistan*, Case No. AA280, 53 (Perm. Ct. Arb. 2009) (noting that even if an investor resorts to UNCITRAL, *Salini* is relevant).

247. *Philip Morris Brands Sárl v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Decision on Jurisdiction, ¶¶ 204–10, 220 (July 2, 2013) (rejecting economic development as an unnecessary element); *Quiborax v. Bolivia*, ICSID Case No. ARB/06/2, Decision on Jurisdiction, ¶ 225 (Sept. 27, 2012) (holding that “a contribution to the economic development of the host State or an operation made in order to develop an economic activity in the host State is not an element of the objective definition of investment”); *Bitwater Gauff Ltd. v. United Republic of Tanzania*, ICSID ARB/05/22, Award, ¶ 250 (July 24, 2008); *MCI Power Group v. Ecuador*, ICSID Case No. ARB/03/6, Award, ¶ 165 (July 31, 2007); *Patrick Mitchell v. Democratic Republic of Congo*, ICSID Case No. ARB/99/7, Decision on the Application for Annulment, II(B)(1) (Nov. 1, 2006); *Consortium Groupement L.E.S.I. - DIPENTA v. Algeria*, ICSID Case No. ARB/03/8, Award, ¶ 13(iv) (Jan. 10, 2005) (rejecting criteria of contribution to investment to economic development). For the view that *Salini* is not supported by ICSID’s negotiating history and doctrine, see J.D. Mortenson, *The Meaning of ‘Investment’: ICSID’s Travaux and the Domain of International Investment Law*, 51 HARV. INT’L L.J. 257, 315 (2010).

248. *E.g.*, *Phoenix Action, Ltd. v. Czech Republic*, ICSID Case No. ARB/06/5, Award, ¶ 138 (Apr. 15, 2009) (additionally requiring bona fide nature of investment to avoid abuses of corporate structure); *Joy Mining Mach. Ltd. v. Arab Republic of Egypt*, ICSID Case No. ARB/03/11, Award on Jurisdiction, ¶ 53 (July 23, 2001) (accepting *Salini* test). Indeed, some tribunals have found this element decisive. *E.g.*, *Malaysian Historical Salvors Sdn, Bhd v. Government of Malaysia*, ICSID Case No. ARB/05/10, Award on Jurisdiction, ¶¶ 123–24 (May 17, 2007); *Patrick Mitchell v. Democratic Republic of Congo*, ICSID Case No. ARB/99/7, Decision on the Application for Annulment of the Award, ¶ 33 (Nov. 1, 2006) (contribution to economic development considered essential, although not sufficient). Other scholars agree with this approach. *E.g.*, Alex Grabowski, *The Definition of Investment Under the ICSID Convention: A Defense of Salini*, 15 CHI. J. INT’L L. 287 (2014); Okediji, *supra* note 144, at 1137. *But see* CHRISTOPHER H. SCHREUER ET AL., *THE ICSID*

After all, simply obtaining a patent or trademark in a country does not directly benefit a host country in the same way investing in a physical plant would by the hiring of employees in that country and other economic benefits that would come with the physical location in the host country such as potential technology transfers.

### 3. Limiting Abusive Investor Claims

Who is a qualifying investor can and also should be narrowed in future investment agreements. One way to do so is to prevent investors from bringing abusive claims as the tribunal in *Philip Morris v. Australia* did by finding that the “principal, if not sole, purpose of the [corporate restructuring] was to gain protection under the Treaty.”<sup>249</sup> Some recent agreements are already seeking to limit corporate attempts to treaty shop for an investment agreement. For example, CETA does not permit claims by so-called “shell” or “mailbox” investors since its definition of an “investor” requires that the entity own and control investments that it has made in the country.<sup>250</sup> In addition, in an attempt to prevent reincorporation such as what Philip Morris did before filing an investment claim against Australia, CETA provides that investment claims are barred for conduct that amounts to abuse of process.<sup>251</sup> The importance of this suggestion is underlined by the fact that investor-state tribunals have not consistently rejected claims brought by investors who had manipulated nationality requirements to qualify as investors.<sup>252</sup>

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CONVENTION: A COMMENTARY 134 (2d ed. 2009); Antoine Martin, *Definition of “Investment”: Could a Persistent Objector to the Salini Tests be Found in ICSID Arbitral Practice?*, 11 GLOBAL JURIST 1 (2011).

249. Philip Morris Asia Ltd. v. Commonwealth of Australia, UNCITRAL, PCA Case No. 2012-12, Award on Jurisdiction and Admissibility, ¶ 587 (Dec. 17, 2015); see also Eric De Brabandere, “Good Faith”, “Abuse of Process” and the Initiation of Investment Treaty Claims, 3 J. INT’L DISP. SETTLEMENT 1 (2012).

250. CETA, *supra* note 31, art. 8.1; see also EUROPEAN COMM’N, INVESTMENT PROVISIONS IN THE EU-CANADA FREE TRADE AGREEMENT (CETA) (2016), [http://trade.ec.europa.eu/doclib/docs/2013/november/tradoc\\_151918.pdf](http://trade.ec.europa.eu/doclib/docs/2013/november/tradoc_151918.pdf); Kevin Ackhurst et al., *CETA, the Investment Canada Act and SOEs: A Brave New World for Free Trade*, 31 ICSID REV. 58, 62 (2016).

251. CETA, *supra* note 31, art. 8.18(3).

252. *E.g.*, Lao Holdings N.V. v. Lao People’s Democratic Republic, ICSID Case No. ARB(AF)/12/6, ¶ 32 (2014) (finding the manipulation of the nationality of the investor to gain jurisdiction at a time when the investor knew this would adversely affect the investment constituted an abuse of process); Phoenix

#### 4. Exercising Comity in Multiple Proceedings Relating to Similar Factual and Legal Issues<sup>253</sup>

In cases where a WTO treaty provision such as TRIPS is involved, a state should argue that jurisdiction is precluded by Article 23 of the DSU which grants the WTO's Dispute Settlement System exclusive competence to decide questions relating to WTO treaties.<sup>254</sup> Moreover, if there *is* a proceeding in the WTO that raises similar legal and factual issues, such as whether the TRIPS Agreement is violated, the state could request that the tribunal stay the proceeding to avoid conflicting determinations. Although it is unsettled whether international tribunals have authority to decline to exercise jurisdiction that they otherwise possess, there is some precedent for declining jurisdiction based on comity.<sup>255</sup> The logic of this is underscored by the fact that recently concluded and pending agreements include provisions that explicitly provide a precedent for staying

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Action, Ltd. v. Czech Republic, ICSID Case No. ARB/06/5, Award, ¶ 70 (Apr. 15, 2009) (rejecting a claim because it had been brought following the transfer of economic interests to a foreign company with a view to getting access to investor-state arbitration under an existing mechanism). The 2016 *Transglobal Green* decision is another recent case that could suggest a more rigorous application of this rule. Diane Desierto, *Arbitral Controls and Policing the Gates to Investment Treaty Claims Against States in Transglobal Green Energy v. Panama and Philip Morris v. Australia*, EJIL: TALK! (June 22, 2016), <http://www.ejiltalk.org/arbitral-controls-and-policing-the-gates-to-investment-treaty-claims-against-states-in-transglobal-green-energy-v-panama-and-philip-morris-v-australia/>; see also *Transglobal Green Energy, LLC v. Republic of Panama*, ICSID Case No. ARB/13/28, Award, ¶¶ 117–18 (2016) (finding intent to “internationalize” a domestic dispute by creating “artificial international jurisdiction”).

253. This question relating to disputes based on the same or similar legal and factual disputes in multiple international dispute settlement venues has received considerable attention. See, e.g., Gabrielle Kaufmann-Kohler et al., *Consolidation of Proceedings in Investment Arbitration: How Can Multiple Proceedings Arising From the Same or Related Situations Be Handled Efficiently?*, 21 ICSID REV. 59 (2006).

254. DSU, Dispute Settlement Rules: Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, art. 23, Jan. 1, 1995, 1869 U.N.T.S. 401.

255. E.g., *Legality of the Use of Force (Serb. & Montenegro v. Belg.)*, Judgment, Preliminary Objections, I.C.J. 279, ¶ 33 (Dec. 15, 2004) (suggesting inherent power to decline jurisdiction to safeguard administration of justice as underlying aim of any system of dispute settlement); Andrea K. Bjorklund, *Private Rights and Public International Law: Why Competition Among International Economic Law Tribunals is Not Working*, 59 HASTINGS L.J. 241 (2007–08).

investor-state proceedings where there is a parallel related proceeding.<sup>256</sup> In addition, the TTIP has a provision that would bar an investor from asserting another international claim concerning the “same treatment” as that alleged in a pending investor-state suit brought under the investment chapter in that treaty.<sup>257</sup>

In addition, this approach is also consistent with the policy behind the existence of investment agreements. Investor-state tribunals are designed to protect investor rights created under the investment treaty providing for the creation of such a tribunal. States do not enter into investment treaties with a view to authorizing investor-state tribunals to decide whether they have violated obligations under *other* treaties. This understanding that investor-state tribunal jurisdiction does not extend beyond the subject matter of the Bilateral Investment Treaty under which it is established should also preclude an investment tribunal to import other treaty obligations into investor-state proceedings through an MFN or umbrella clause,<sup>258</sup> not only because WTO obligations are outside the scope of an investment treaty, but also because investors should not be able to rely on WTO-created IP rights which are intended to be enforceable only by States in the WTO.

## B. LIMITING THE SCOPE OF INVESTMENT CLAIMS

The impact of investment claims on TRIPS flexibility can also be minimized if the scope of investment claims is limited. The move towards more precision in investment agreements is one way for States to better assert their sovereignty by providing more guidance to arbitrators.<sup>259</sup> For example, greater specificity

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256. CETA, *supra* note 31, art. 8.24 (requiring that the Tribunal “shall” stay proceedings if another international claim “could have a significant impact on the resolution” of the investment claim).

257. Transatlantic Trade and Investment Partnership, Trade in Services, Investment and E-Commerce, Investment Chapter proposal, EU, art. 14(2), [http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc\\_153955.pdf](http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153955.pdf) [hereinafter EU, TTIP proposal] (requiring declaration that there will be no initiation of claims before domestic or international court concerning “the same treatment as that alleged to be inconsistent” with investment chapter).

258. *See* Maffezini v. Kingdom of Spain, ICSID Case No. ARB/97/7 (Nov. 13, 2000); Rep. of the Int’l L. Comm’n, on its Fifty-Sixth Session, U.N. Doc. A/56/10, ¶¶ 76–77 (2001), <http://www.un.org/documents/ga/docs/56/a5610.pdf> (arriving at the same point).

259. *E.g.*, Caroline Henckels, *Protecting Regulatory Autonomy Through Greater Precision in Investment Treaties: the TPP, CETA, and TTIP*, 19 J. INT’L

regarding the limits of traditional investment claims, with clear language regarding inapplicability to certain IP issues, would be valuable.

### 1. Towards Better Balance in Pending and Future Agreements

There are a number of ways to limit the intrusion of investment claims on domestic regulatory space under the TRIPS Agreement which can be achieved by modifying the language of certain clauses in pending and future agreements. For example, countries can aim to categorically exclude such claims through a non-precluded measure clause, or at least minimize harm by more narrowly tailoring investment claims, as well as introducing more balancing language in general.

### 2. Non-Precluded Measure Clause

For pending and future agreements, a non-precluded measure clause tailored to promoting the balance between IP rights and other public policy is desirable. This suggestion builds upon the fact that most agreements already have non-precluded measure clauses that permit states to take actions that would otherwise be inconsistent with the agreement in certain exceptional situations, such as national security or public emergency.<sup>260</sup> Although traditional non-precluded measure clauses are fairly narrow in focusing on issues of national security and public health emergencies, they could be expanded to more broadly address public policy. Some countries have already done so. For example, the agreement between Hong Kong and New Zealand provides that the agreement “shall not in any way limit the right of either Contracting Party to take measures directed to the protection of its essential interests, or to the protection of public health.”<sup>261</sup> Notably, this clause eliminates some of the more restrictive requirements of traditional clauses that require the action to be “necessary” for the stated objective. It is also more expansive than some clauses

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ECON. L. 27, 32 (2016); *see also* Prapanpong Khumon, *Development of Rule-Based Investment Protection Provisions in Mega-FTAs: A Manifestation or a Negation from Customary International Law Principles?* (Soc’y Int’l Econ. L. Fifth Biennial Global Conf., Working Paper No. 2016/14, 2016).

260. *See, e.g.*, Kenneth J. Vandavelde, *Of Politics and Markets: The Shifting Ideology of the BITs*, 11 INT’L TAX & BUS. LAW. 159, 170–71 (1993).

261. Agreement between the Government of Hong Kong and the Government of New Zealand for the Promotion and Protection of Investments, H.K.-N.Z., art. 8(3), July 6, 1995.

because it applies to the entire agreement, rather than only to some specific claims. However, this clause is still not sufficiently protective of TRIPS flexibilities because there would likely be a dispute concerning whether some legitimate domestic actions to promote public health to affordable medicine, such as through TRIPS-consistent interpretations of patent law, constitute protection of public health.

A clause that specifically states that the agreement protecting investments does not limit the rights of parties to take measures consistent with the TRIPS Agreement, including the 2001 Doha Declaration on TRIPS Public Health and the 2014 Declaration on Patent Protection and Regulatory Sovereignty Under TRIPS initiated by the Max Planck Institute (Max Planck Declaration), would be better if possible.<sup>262</sup> This should ideally be in the investment chapter itself. Inclusion of such a clause would help counteract the narrow views of many companies concerning TRIPS flexibilities. The Max Planck Declaration, signed by forty scholars from over twenty-five countries, is consistent with the Doha Declaration, yet much more explicit regarding what nations can do consistent with the TRIPS Agreement.<sup>263</sup> For example, although there are implicit flexibilities under TRIPS that public health policy makers recognize regarding defining the scope of a patentable invention, as well as the scope of patent rights, such as its term, neither of these are affirmatively stated in the Doha Declaration. Rather, the only specific listed examples focus on compulsory licenses and international exhaustion of patent rights. The Max Planck Declaration, however, affirmatively lists all of these flexibilities. Although these are TRIPS flexibilities, the lack of explicit mention could still result in an investment tribunal failing to consider the full range of TRIPS flexibilities—especially since these decision makers are not expected to be familiar with IP issues. The Max Planck Declaration is intended to clarify what TRIPS provides, including its flexibilities. However, unless specifically mentioned in an investment agreement, it would be unlikely that this Declaration would be considered as having much probative value for purposes of interpreting the TRIPS

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262. Reto M. Hilty & Matthias Lamping, Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS (2014) (on file with the Max Planck Society at <https://www.mpg.de/8132986/Patent-Declaration.pdf>).

263. *Id.*

Agreement by an investor-state dispute settlement tribunal.<sup>264</sup> Of course, even if either or both were included, it is possible that investment tribunals will only pay lip service to their existence. After all, TRIPS flexibilities that are recognized by many scholars and policy makers have not been widely embraced in WTO Panel decisions.<sup>265</sup> In addition, companies have repeatedly challenged these flexibilities.<sup>266</sup> Nonetheless, inclusion of the language is far more preferable than traditional agreements that only provide textual support for supporting investments.

#### a. Expropriation

Although indirect expropriations have long been contemplated to have potential to improperly interfere with

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264. The extent to which the flexibilities noted in Max Planck Declaration are a core part of the TRIPS Agreement is likely a question of interpretation.

265. For example, in one case challenging Canada's patent exceptions, although Canada as well as many third parties suggested robust interpretations of flexibilities in TRIPS articles 7 and 8, the WTO panel did not fully embrace these interpretations and instead simply said that the articles must be "borne in mind" without giving these provisions a thorough application. Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, (Mar. 17, 2000); see also CHRISTOPHER GARRISON, INT'L CTR. FOR TRADE & SUSTAINABLE DEV. (ICTSD) AND UNITED NATIONS CONFERENCE ON TRADE & DEV. (UNCTAD), ISSUE PAPER NO. 17, EXCEPTIONS TO PATENT RIGHTS IN DEVELOPING COUNTRIES (2006); Denis Borges Barbosa et al., *Slouching Towards Development in International Intellectual Property*, 2007 MICH. ST. L. REV. 71, 101–02 (2007); Susy Frankel, *WTO Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property*, 46 VA. J. INT'L L. 365, 385 (2005); Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3 J. WORLD INTELL. PROP. 493, 496–501 (2000); Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS: The Resilience of the International Intellectual Property Regime* 196 (N.Y.U. Sch. L. Pub. L. & Legal Theory Res. Paper Series, Working Paper No. 12-05, Mar. 2012) (concurring that the WTO panel in the Canada case did not go far enough and suggesting how articles 7 and 8 can be better utilized in the future).

266. TRIPS-consistent compulsory licenses are frequently improperly suggested to violate TRIPS. *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. 101, 179 (2009). The use of TRIPS flexibilities to interpret patentability standards as well as data exclusivity has also been contested. *E.g.*, BIOTECHNOLOGY INNOVATION ORGANIZATION, 2016 SPECIAL 301 SUBMISSION TO UNITED STATES TRADE REPRESENTATIVE 41 (2016) (challenging the Indian Patents Act § 3(d) as allegedly inconsistent with TRIPS), <https://www.bio.org/sites/default/files/files/2016%20BIO%20Submission.pdf>; PHARMACEUTICAL RES. AND MANUFACTURERS OF AM., SPECIAL 301 SUBMISSION 2016 TO UNITED STATES TRADE REPRESENTATIVE 63 (2016) (alleging that Canada violates TRIPS).

legitimate domestic IP decisions such that many agreements have an exception for indirect expropriation claims, the Eli Lilly case illustrates that existing exceptions are inadequate. For example, many investment treaty provisions only exempt from indirect expropriation domestic action that cancels or revokes an intellectual property right *if* consistent with the TRIPS Agreement, and sometimes also with TRIPS-plus provisions.<sup>267</sup> This means that the clause could permit an investment tribunal to decide—perhaps inconsistently with WTO norms—whether domestic action is consistent with TRIPS. In addition, even recently concluded and pending agreements that aim to provide greater regulatory discretion still provide inadequate protection of TRIPS flexibilities since they do not seem to contemplate a TRIPS conflict and would still permit investor-state tribunals to find that legitimate public health regulations may constitute an indirect expropriation.<sup>268</sup>

It would be preferable to bar expropriation claims for any IP decisions if the domestic decision limiting, canceling, or revoking IP rights is consistent with domestic law,<sup>269</sup> or, alternatively, only if the domestic action amounts to abuse of process, as India has proposed.<sup>270</sup> Alternatively, if countries are not willing to agree to either of these proposals, they could at least acknowledge that this is an issue, with a process for addressing it in the near future; this is the approach taken with CETA.<sup>271</sup> This step, however, is only valuable if there is a procedure for a binding interpretation to minimize the difficulty of amendments.<sup>272</sup>

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267. *E.g.*, NAFTA, *supra* note 162, art. 1110(7); TPP, *supra* note 16, art. 9.8(5); *see also* EU, TTIP proposal, *supra* note 257, art. 5(7); CETA, *supra* note 31, art. 8.12(6).

268. *E.g.*, EU, TTIP proposal, *supra* note 257, annex I (Expropriation); TPP, *supra* note 16, annex 9-B ¶ 3(b); *see also* TPP, *supra* note 16, annex 9-B ¶ 3(b) n.37 (noting that pricing of and supply of reimbursement for drugs would be an example, but nothing else relating to drugs, such as IP rights).

269. Model Text for the Indian Bilateral Investment Treaty, art. 2.6(v), 2015, [https://www.mygov.in/sites/default/files/master\\_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf](https://www.mygov.in/sites/default/files/master_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf).

270. India suggested this in its 2015 model BIT. *See generally id.*

271. CETA, *supra* note 31, annex 8-D (Joint Declaration Concerning Art. 8.12.6) (noting that parties “agree to review the relation between intellectual property rights and investment disciplines within 3 years after entry into force of the agreement or at the request of a party”).

272. *E.g., id.*

### 3. Fair and Equitable Treatment

There are several possible ways to limit the extent to which fair and equitable treatment claims could compromise domestic flexibilities that give countries some discretion to determine the appropriate scope of IP rights. In future agreements, such claims could be entirely eliminated, or at least limited to state to state action;<sup>273</sup> alternatively the claims could be based solely on “legitimate expectations.” Importantly, affirmatively stating that legitimate expectations do not give rise to claims would be an improvement. Thus far, no concluded or pending agreement goes that far.<sup>274</sup> Alternatively, future agreements could perhaps recognize an exception predicated on alleged denial, cancellation, or modification of IP rights similar to an exception from indirect expropriation. Along similar lines, a clarification that breach of another agreement, such as TRIPS, does not constitute a breach would be an improvement over the recent TPP language that acknowledges that a breach of a separate international agreement is not necessarily a breach, yet seems to still permit tribunals to come to this conclusion—and essentially give companies like Philip Morris the ability to assert such a claim for an alleged violation of TRIPS.<sup>275</sup> Accordingly,

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273. Although this is admittedly a radical proposal, India has suggested this. Model Text for the Indian Bilateral Investment Treaty, art. 4, 2015, [https://www.mygov.in/sites/default/files/master\\_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf](https://www.mygov.in/sites/default/files/master_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf); LISE JOHNSON & LISA SACHS, COLUMBIA CTR. ON SUSTAINABLE INV., POLICY PAPER 5, THE TPP’S INVESTMENT CHAPTER: ENTRENCHING, RATHER THAN REFORMING, A FLAWED SYSTEM (Nov. 2015), <http://ccsi.columbia.edu/files/2015/11/TPP-entrenching-flaws-21-Nov-FINAL.pdf> (suggesting eliminating this entirely or leaving it only subject to state-to-state resolution).

274. Recently concluded and pending agreements still leave the door open to an FET claim based in part on breach of legitimate expectations. *E.g.*, CETA, *supra* note 31, art. 8.10(2)–(4) (on file with the European Commission) (cabining FET claims to a closed list of violations, while still noting that tribunals “may take into account whether a Party made a specific representation to an investor to induce a covered investment, that created a legitimate expectation, and upon which the investor relied,” which could result in manifest arbitrariness or denial of justice, as a type of FET claim); TPP, *supra* note 16, art. 9.6(4) (“[T]he mere fact that a Party takes or fails to take an action that may be inconsistent with an investor’s expectations does not constitute a breach of this Article, even if there is loss or damage to the covered investment as a result.”); E.U. Investment Proposal for Transatlantic Trade & Investment Partnership art. 3(4), Memorandum from E.U. to U.S. (Nov. 12, 2015) (on file with the European Commission) (stating the same).

275. TPP, *supra* note 16, art. 9.3.

another possible approach is to limit traditionally expansive fair and equitable treatment claims to a closed list of possibilities, such as denial of justice.<sup>276</sup>

Beyond limiting traditional investment claims, agreements should also preclude overly expansive interpretations of other provisions of investment claims. In particular, agreements should preclude importation of substantive provisions from other agreements through umbrella clauses. The 2016 investment chapter of CETA clarifies that although it recognized most favored nation treatments, substantive obligations in other agreements, including other international investment agreements, are not obligations that can give rise to investment claims.<sup>277</sup> This is helpful, but further adding that none of these provisions permit adjudication of claims under other agreements, such as the TRIPS Agreement, is also necessary.

#### 4. Better Balance

Even though greater precision in defining key terms in pending and future agreements is beneficial, that alone is unlikely to be a complete solution. After all, even the recent attempts to clarify the scope of expropriation and FET claims are still subject to interpretation and application by arbitrators. Given this, providing additional interpretative guidance outside of specific investment claims may be beneficial to improve the traditional lack of balance between investor rights and other norms. Whereas traditional BITs often only included clauses about investment, newer generation agreements are beginning to introduce language regarding the right to regulate. Of course, *how* competing norms are framed is critical in terms of whether they are likely to promote a better balance. For example, although Uruguay believed that its BIT had such protective

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276. CETA, *supra* note 31, art. 8.10(2); *see also* NATHALIE BERNASCONI-OSTERWALDER, INT'L INST. FOR SUSTAINABLE DEV., COMMENTARY TO THE DRAFT INVESTMENT CHAPTER ON THE CANADA-EU COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA) 17–20 (May 2013) (including Canada's proposed text for FET claims that provides a closed list of options such as denial of justice, manifest arbitrariness and targeted discrimination as well as an explanation for the distinction between this proposal and the EU's broader approach).

277. CETA *supra* note 31, art. 8.7(4).

language,<sup>278</sup> a tribunal found otherwise.<sup>279</sup> Even in the recently concluded TPP that the United States argues provides sufficient discretion to governments to regulate through explicit language,<sup>280</sup> commentators have noted that the language is unhelpful since it only permits states to regulate *consistent with* the investment provisions.<sup>281</sup> Improving the balance between investor rights and other rights builds upon existing public policy exceptions in many agreements that ensure domestic rights to enact non-precluded measures in appropriately urgent circumstances that would not result in an investment claim as discussed above.

Parties could add public policy provisions in the preamble, objectives, or even a separate declaration that might further cabin the scope of expropriation and FET claims. For example, the recently concluded agreement between Canada and the EU explicitly notes, “[p]arties reaffirm their right to regulate within their territories to achieve legitimate policy objectives, such as the protection of public health.”<sup>282</sup> Moreover, it clarifies that modification of laws that may impact an investment do not necessarily amount to a breach of an obligation.<sup>283</sup> However, affirming a right to regulate is not as strong as the TTIP proposal that more explicitly states that the investment chapter *shall not* affect the right to regulate measures that are necessary for legitimate policy objectives, such as public health. Even this stronger provision, however, would not immunize all domestic actions since it is limited to measures that are “necessary,” and

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278. Philip Morris Brands Sal v. Oriental Republic of Uruguay, 2013 ICSID Case No. ARB/10/7, Decision on Jurisdiction, ¶ 151–52, (July 2, 2013) (claiming that BIT was not applicable because article 2(1) states that when parties “recognize each other’s right not to allow economic activities for reasons of . . . public health” the “only plausible meaning” is that public health measures should be excluded, especially in light of the fact that public health is a right recognized under the Constitution).

279. *Id.* ¶ 171 (July 2, 2013) (rejecting Uruguay’s claim that the BIT excludes public health measures from the scope of the agreement).

280. *E.g.*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, UPGRADING AND IMPROVING INVESTOR-STATE DISPUTE SETTLEMENT FACT SHEET, <https://ustr.gov/sites/default/files/TPP-Upgrading-and-Improving-Investor-State-Dispute-Settlement-Fact-Sheet.pdf> (last visited Feb. 28, 2017); *see also* TPP, *supra* note 16, art. 9.15.

281. *E.g.*, JOHNSON & SACHS, *supra* note 273.

282. CETA, *supra* note 31, art. 8.9(1); *see also* EU, TTIP proposal, *supra* note 257, art. 2.1 (“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, such as the protection of public health . . .”).

283. CETA, *supra* note 31, art. 8.9(2).

also to an arbitral decision on when action clearly relates to public health. Regulation of tobacco products is clearly within this. However, modified patent laws to improve access to low cost medicine may not be seen to readily fall within this category.

How such a clause is interpreted, of course, may depend on the composition of the tribunal, as well as on other clauses in the treaty. Indeed, adding other textual bases for consideration of public policy, including public health in the preamble of the agreement and elsewhere as noted above, would also be helpful. Although such clauses would provide interpretive context that a tribunal *could* rely on, whether that happens will likely depend on the composition of the tribunal. Accordingly, how states select tribunalists is also important, as further discussed below.

### C. TOWARD BETTER BALANCE IN EXISTING AGREEMENTS

A tribunal could also minimize the impact of a regime shift with a thoughtful and balanced approach to treaty interpretation that considers competing claims on both the investors and respondent states side, as well as the broader international legal and policy context in the particular case. Two key approaches that tribunals can take in doing so are to exercise more deference to government conduct, and to apply rules that emphasize proportionality in evaluating competing claims. Each of these will be discussed below.

#### 1. Deference

One key strategy tribunals can take to minimize the harms of the IP regime shift while simultaneously improving the legitimacy of investor-state disputes would be to exercise great deference to the actions of nations. After all, one major objection to investor-state disputes is that they act as a supra-national decision-maker, yet lack any democratic input.<sup>284</sup> Since most nations have checks and balances, including appeals after negative judicial decisions, a panel of three individuals should exercise caution before it second-guesses domestic decisions. This seems particularly true where state action has an underpinning in public interest and is undertaken in a non-discriminatory manner. In such a case, where the exercise of a

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284. *E.g.*, Barnali Choudhury, *Democratic Implications Arising from the Intersection of Investment Arbitration and Human Rights*, 46 ALTA. L. REV. 983 (2009). For another incisive analysis, see Sergio Puig, *The Merging of International Trade and Investment Law*, 33 BERKELEY J. INT'L L. (2015).

sovereign prerogative cannot be attributed to motivations other than the public interest at stake, an investor should bear a higher burden of demonstrating that the burden imposed on its intellectual property rights outweighs the public interest that justified the challenged conduct.

In addition, tribunals should give sufficient weight, not only to an investor's claim, but the regulatory authority of a state in a manner that acknowledges the balance between rights of IP holders, but also how those rights should be balanced when they intersect with policies such as public health. The first investment tribunal to issue a public decision involving IP provides a useful example. In *Philip Morris v. Uruguay*, the Tribunal in part dismissed the expropriation claim on the basis that Uruguay's adoption of the challenged measure to protect public health was "a valid exercise of the State's police powers, with the consequence of defeating the claim for expropriation."<sup>285</sup> The Tribunal invoked Article 31(3)(c) of the Vienna Convention of the Law of Treaties to argue that the expropriation claim had to be read against the customary international law norm that "[p]rotecting public health has long since been recognized as an essential manifestation of the State's police power."<sup>286</sup> Thus, as long as a bona fide measure to protect public health was non-discriminatory and proportionate the Tribunal held it could not constitute indirect expropriation.<sup>287</sup> Similarly, in dismissing the fair and equitable treatment claim, a majority of the Tribunal held that "the responsibility for public health measures rests with the government and investment tribunals should pay great deference to governmental judgments of national needs in matters such as the protection of public health."<sup>288</sup> However, given universal agreement on the public health harms of smoking that were the target of Uruguay's regulation, the 2-1

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285. *Philip Morris Brands Sarl v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Award, ¶ 287 (July 8, 2016).

286. *Id.* ¶ 290–91.

287. *See id.* ¶ 305.

288. *Id.* ¶ 399. Notably, the Tribunal further held that

the present case concerns a legislative policy decision taken against the background of a strong scientific consensus as to the lethal effects of tobacco. Substantial deference is due in that regard to national authorities' decisions as to the measures which should be taken to address an acknowledged and major public health problem. The fair and equitable treatment standard is not a justiciable standard of good government, and the tribunal is not a court of appeal.

*Id.* ¶ 418.

decision supporting Uruguay's right to protect public health is not entirely surprising.

The *Eli Lilly* dispute provides a different example of how a tribunal may exercise deference in a way that in effect promotes TRIPS flexibilities without the tribunal having to determine the applicability of a public health justification for a challenged measure. Unlike the Uruguayan Tribunal which was confronted with a series of tobacco regulations, the *Eli Lilly* tribunal focused on judicial invalidation of patents. The Uruguayan tribunal therefore had to explicitly address the health-based justifications for the regulations in question in a way that the *Eli Lilly* tribunal did not. Yet both tribunals were ultimately deferential to the challenged decisions. In fact, in *Eli Lilly*, the tribunal conferred considerable deference to Canada.<sup>289</sup> This finding is significant because, according to the tribunal, Canada's promise doctrine was justified by "legitimate policy goals," and that the tribunal did not have to "opine on whether the promise doctrine is the only, or the best, means of achieving these objectives."<sup>290</sup>

## 2. Proportionality Analysis

Tribunals can also use proportionality analysis to balance protection of foreign investments against non-investment concerns in applying investment agreements that have no inherent balance. Proportionality analysis is a method of legal interpretation and decision making that should help mitigate conflicts of different principles and legitimate public policy objectives and has also been suggested as useful to enhance legitimacy of that process.<sup>291</sup> Applying proportionality analysis

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289. According to the Tribunal, NAFTA Chapter 11 Tribunals are "not an appellate tier in respect of the decisions of national judiciaries." *Eli Lilly*, Award, *supra* note 158, ¶ 221. The Tribunal also noted that considerable deference would be given to decisions of national courts and only in cases of egregious and shocking conduct would it be appropriate to "assess such conduct against the obligations of the respondent State under NAFTA Article 1105(1)." *Id.* ¶ 224.

290. *Id.* ¶ 423.

291. Benedict Kingsbury & Stephen Schill, *Public Law Concepts to Balance Investors' Rights with State Regulatory Actions in the Public Interest – the Concept of Proportionality*, in *INTERNATIONAL INVESTMENT LAW & COMPARATIVE PUBLIC LAW 75* (Stephan W. Schill ed., 2010); Alec Stone Sweet, *Investor-State Arbitration: Proportionality's New Frontier*, 4 *LAW & ETHICS HUM. RTS.* 47 (2010); Erlend M. Leonhardsen, *Looking for Legitimacy:*

does not result in an automatic win for either party, but should ensure a more thoughtful balance of competing interests through its multi-prong analysis of considering (a) whether the state action serves a legitimate government purpose and is generally suited to achieve this purpose (through some causal relationship), (b) whether the state action is “necessary” in that there is no less restrictive measure that is equally effective, and (c), whether a balance exists between the effects of the measure and the importance of the government purpose.<sup>292</sup> Proportionality has arguably already been recognized as reasonable for investment tribunals. Some tribunals have applied such analysis already.<sup>293</sup> Moreover, tribunals could follow Harold Koh’s compelling argument in favor of taking into account public health considerations, including the right to health in investor-state arbitration.<sup>294</sup>

Proportionality analysis should cabin claims for indirect expropriation as well as fair and equitable treatment. This seems particularly important to FET claims since tribunals sometimes rely too much on a breach of “legitimate expectations” in finding a claim exists. Overly expansive interpretations can be precluded with an appropriate balance between legitimate expectations and a state’s right to regulate domestic matters. As noted by one tribunal, “no investor may reasonably expect that the circumstances prevailing at the time of the investment is

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*Exploring Proportionality Analysis in Investment Treaty Arbitration*, 3 J. INT’L DISP. SETTLEMENT 95 (2012).

292. *E.g.*, Kingsbury & Schill, *supra* note 291, at 86–87 (outlining the structure of the proportionality analysis).

293. *E.g.*, Saluka Investments BV v. Czech Republic, Partial Award, U.N. Commission on Int’l Trade L. [UNCITRAL], ¶ 297 (Mar. 17, 2006); MTD Equity Sdn. Bhd. v. Republic of Chile, ICSID Case No. ARB/01/7, Award, ¶ 113 (May 25, 2004). For example, whereas older decisions tended to find an indirect expropriation based solely if the investor rights were harmed, more recent decisions consider whether there is a legitimate state action that would obviate an expropriation claim entirely – even if not explicitly stated in an investment treaty. *See* Kingsbury & Schill, *supra* note 291, at 91–94 (discussing examples where tribunals balanced state interests with the regulation’s effects on investment).

294. Koh, *supra* note 154, at 433 n.4 (2016); *see also* REGIONAL WORKING GROUPS OF THE CANADIAN COUNCIL FOR INTERNATIONAL CO-OPERATION, WHOSE RIGHTS ARE WE PROTECTING? ENSURING THE PRIMACY OF HUMAN RIGHTS OVER INVESTOR PROTECTIONS IN THE INTERNATIONAL LEGAL REGIME (Mar. 2016), [http://www.ccic.ca/\\_files/en/what\\_we\\_do/2016\\_03\\_Whose\\_rights\\_are\\_we\\_protecting.pdf](http://www.ccic.ca/_files/en/what_we_do/2016_03_Whose_rights_are_we_protecting.pdf). In fact, the author argues that this should apply not only to investor-state disputes, but also for WTO treaties.

made remain totally unchanged,” in stating that any “frustration” of investor expectations must be considered in conjunction with the “host State’s legitimate right . . . to regulate domestic matters in the public interest.”<sup>295</sup> Other tribunals have also considered the reasonableness of state actions and applied proportionality.<sup>296</sup>

In fact, recently concluded and proposed agreements tend to have more explicit terms that essentially direct tribunals to recognize competing norms that can be buttressed by proportionality analysis. For example, recent agreements have language that addresses what constitutes legitimate government purpose. Some contain a clause regarding indirect expropriation that requires arbitrators to consider the impact of government action, and its character, clearly noting that adverse economic impact on an investment alone does not establish indirect expropriation.<sup>297</sup> Agreements also state “[e]xcept in rare circumstances, nondiscriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, and the environment, do not constitute indirect expropriations.”<sup>298</sup> Even for arbitrators applying this language, thoughtful application of

295. *Saluka Investments BV v. Czech Republic*, Partial Award, U.N. Commission on Int’l Trade L. [UNCITRAL], ¶ 305 (Mar. 17, 2006); *see also* *BG Group Plc. v. Republic of Argentina*, U.N. Commission on Int’l Trade L. [UNCITRAL], Final Award, ¶ 298 (Dec. 24, 2007) (stating that there should not be a “freezing of the legal system”).

296. *Eureko B.V. v. Republic of Poland*, R.G. 2005/14005/A, Partial Award, ¶ 232 *et seq.*, (Aug. 19, 2005) (incorporating reasonableness into the fair and equitable treatment standard); *Pope & Talbot, Inc. v. Gov’t of Canada*, Award in Respect of Costs, (Nov. 26 2002), <http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/pope.aspx> (scroll to bottom of page and click “ARCHIVED – Final Award”) (considering the reasonableness of administrative agency); *see also* *Middle East Cement Shipping & Handling v. Arab Republic of Egypt*, ICSID Case No. ARB/99/6, Award, ¶ 143 (Apr. 12, 2002) (requiring better notice than what was required under domestic law given the consequences); *Kingsbury & Schill*, *supra* note 291. Notably, applying proportionality to non-precluded measures had very different results in cases based on similar facts regarding Argentina’s emergency measures to its economic crisis. *See, e.g., Kingsbury & Schill*, *supra* note 291, at 98–102.

297. TPP, *supra* note 16, annex 9-B, para. 3(a)(i); EU, TTIP proposal, *supra* note 257, annex I, para. 2(a).

298. *See* *Dominican Republic-Central America-United States Free Trade Agreement*, Oct. 31, 2005, T.I.A.S. 05-1031; *cf.* CETA, *supra* note 31, annex 8-3(A); TPP, *supra* note 16, annex 9-B(3)(b); EU, TTIP proposal, *supra* note 257, annex I(3).

a proportionality test is still necessary since this language does not provide adequate guidance concerning what is a “rare circumstance” or what method to use to balance the importance of the government action against the economic impact on the investment, or how to critically evaluate a stated government justification for its actions.<sup>299</sup>

#### D. IMPROVING THE PROCESS OF INVESTOR-STATE DISPUTES

Alternatively, the overall process of resolving investment disputes can be strengthened, that would improve outcomes for disputes involving IP. This section primarily focuses on improving the process for pending and future agreements. It also includes recommendations that States should pursue under existing agreements.

##### 1. Future Claims

A major change to the process could involve a permanent and independent investment tribunal, as well as an appellate tribunal in future investment treaties. These are not new ideas.<sup>300</sup> However, they are gaining increasing traction. This is reflected in the recently concluded agreement between the EU and Vietnam.<sup>301</sup> In addition not only has the EU suggested these measures in its negotiations with the United States for the TTIP, but it managed to recently incorporate such provisions in the investment chapter of CETA two years *after* the agreement had

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299. Indeed, when the EU sought public consultation, many were considered that this language still gave tribunals too much discretion to balance competing values that are traditionally only within the sovereign of governments and suggested that additional clarification is necessary on concepts such as what is “manifest excessiveness.” Eur. Comm’n Working Document, *supra* note 229, at 18, 69–70.

300. *E.g.*, INT’L CTR. FOR SETTLEMENT OF INVEST. DISP., POSSIBLE IMPROVEMENTS OF THE FRAMEWORK FOR ICSID ARBITRATION (2004) (suggesting consideration of an appeals facility at ICSID).

301. E.U.-Vietnam Free Trade Agreement, E.U.-Viet., Jan. 20, 2016, <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1437>; *see also* Hannes Lenk, *An Investment Court System for the New Generation of EU Trade and Investment Agreements: A Discussion of the Free Trade Agreement with Vietnam and the Comprehensive Economic and Trade Agreement with Canada*, 1 EUR. F. 665 (2016), [http://www.europeanpapers.eu/en/system/files/pdf\\_version/EP\\_EF\\_2016\\_I\\_033\\_Hannes\\_Lenk.pdf](http://www.europeanpapers.eu/en/system/files/pdf_version/EP_EF_2016_I_033_Hannes_Lenk.pdf) (highlighting the new innovative court system and the departure from the traditional arbitration-based system).

already been concluded.<sup>302</sup> Technically, the EU was simply scrubbing the document, but it added substantial changes, including a permanent investment tribunal, as well as an appellate tribunal.<sup>303</sup> There will be fifteen members of the tribunal of first instance appointed by the CETA Joint Committee for a renewable five year term,<sup>304</sup> with the actual three members of each tribunal appointed by the president on some rotation system that although currently unspecified, is different than the traditional approach in which each party selects their own arbitrator.<sup>305</sup> Perhaps most significantly, the appellate tribunal has the power to review errors of law, as well as manifest errors of fact, such that it can uphold, modify, or reverse the tribunal's award.<sup>306</sup> Moreover, CETA contains a commitment to work with other countries to create a multilateral investment court,<sup>307</sup> and other agreements may

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302. *E.g.*, CETA, *supra* note 31, art. 8.27–8.28; *see also* Press Release, European Comm'n, CETA: EU and Canada Agree on New Approach on Investment in Trade Agreement (Feb. 29, 2016), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1468>. This was noted as a savvy political move to try to persuade the United States to agree to these proposals by incorporating them in the agreement with United States' trade neighbor. *E.g.*, Stephen Drymer, *CETA Under New Management: Why is Trudeau Changing the Game?*, CTR. FOR INT'L GOVERNANCE INNOVATION (May 12, 2016), <https://www.cigionline.org/publications/ceta-under-new-management-why-trudeau-changing-game>.

303. *See, e.g.*, Press Release, European Comm'n, *supra* note 302 (noting that the inclusion was agreed "in the context of the legal review"); *see also* 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/>.

304. CETA *supra* note 31, art. 8.27.

305. *Id.* art. 8.27(7); *see also* August Reinisch & Lukas Stifter, *CETA's New Take on ISDS: Toward an International Investment Court*, CTR. FOR INT'L GOVERNANCE INNOVATION (June 22, 2016), <https://www.cigionline.org/publications/cetas-new-take-isds-toward-international-investment-court> (discussing the tribunal proposed under art. 8.27).

306. CETA *supra* note 31, art. 8.28(2).

307. *Id.* art. 8.29; *see also* Council of the European Union, Joint Interpretative Instrument on the Comprehensive Economic and Trade Agreement (CETA) Between Canada and the European Union and Its member States, Oct 27, 2016, <http://data.consilium.europa.eu/doc/document/ST-13541-2016-INIT/en/pdf> (agreeing to work "expeditiously toward the creation of a Multilateral Investment Court"); Eur. Comm'n, the Multilateral Investment Court Project, (Dec. 21, 2016), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1608>.

allow for development of an appellate review even if one is not currently in existence.<sup>308</sup>

Another improvement over the process under most investment agreements would be to introduce greater control over tribunal decisions. NAFTA introduced the Free Trade Commission, with power to issue interpretive statements<sup>309</sup> which it has used once to try to cabin overly broad FET claims; in particular, the statement suggested that a breach of a separate international agreement does not establish a FET claim.<sup>310</sup> Although that process has been controversial,<sup>311</sup> it has been somewhat helpful in reigning in overly broad FET claims.<sup>312</sup> Recently concluded and pending agreements can include provisions that provide more control. For example, CETA permits parties to adopt binding interpretations to address possible errors of tribunals.<sup>313</sup>

The impact of an investment dispute can also be mitigated. In particular, investment disputes are dangerous to domestic sovereignty not just because of the chilling effect of expensive litigation, but also because of non-monetary relief sought. For example, Philip Morris aimed to nullify the tobacco regulations

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308. *E.g.* TPP, *supra* note 16, art. 9.23.11 (“In the event that an appellate mechanism for reviewing awards rendered by investor-State dispute settlement tribunals is developed in the future under other institutional arrangements, the Parties shall consider whether awards . . . should be subject to that appellate mechanism . . .”).

309. NAFTA *supra* note 162, art. 1131(2) (providing that an interpretation of the Free Trade Commission of a provision of the agreement “shall be binding” on investment tribunals). This power is also contained in a few other U.S. agreements before TPP. *E.g.*, Bilateral Investment Treaty, art. 30(3), U.S.-Rwanda, Feb. 19, 2008, <https://www.state.gov/e/eb/rls/othr/2008/101641.htm>; Dominican Republic–Central America Free Trade Agreement, art. 10.22(3), Aug. 5, 2004, 19 U.S.C. §§ 4001–11 (2012); Singapore Free Trade Agreement, art. 15.22(2), Jan. 1, 2004, 19 C.F.R. §§ 10.501–.570 (2016).

310. NAFTA Free Trade Commission, *North American Free Trade Agreement: Notes of Interpretation of Certain Chapter 11 Provisions* (July 31, 2001), [http://www.sice.oas.org/TPD/NAFTA/Commission/CH11understanding\\_e.asp](http://www.sice.oas.org/TPD/NAFTA/Commission/CH11understanding_e.asp).

311. Some have suggested that the interpretive statement by the FTC is invalid. *E.g.*, Charles H. Brower et al., *Fair and Equitable Treatment Under NAFTA’s Investment Chapter*, 96 AM. SOC’Y INT’L L. 9, 10 (2002) (“Tribunals might conclude that [the statement] represent[ed] an ultra vires amendment of . . . NAFTA.”).

312. *E.g.*, Henckels, *supra* note 259, at 35 (noting that since the 2001 interpretation, tribunals have generally found the FET threshold to be high, although some still find a violation).

313. CETA *supra* note 31, art. 8.31.3.

in both Uruguay and Australia. If it had been successful, Philip Morris would have been able to use an investment tribunal to essentially overrule prior judicial decisions upholding the tobacco regulations. Even though it was unsuccessful, that possibility looms for future investment disputes unless an agreement explicitly states otherwise. Recently concluded agreements aim to address this. CETA, for example, clearly states that Awards cannot lead to repeal of a measure, and that companies may only obtain compensation for actual losses, and not punitive fines.<sup>314</sup> This is an important clarification because although all NAFTA countries had previously made this argument before NAFTA tribunals, it was not always accepted.<sup>315</sup> However, additional language may be desirable to prevent a tribunal from enjoining government acts as an interim measure, which is currently possible under existing agreements.<sup>316</sup> In addition, even if tribunals were precluded from ever enjoining domestic actions, even on a temporary basis, domestic laws might still be changed if a state settles a case and agrees to such action.

Given the serious chilling effect from simply asserting an investment claim, measures to reduce claims are necessary. One way to minimize investment claims is to require the losing party to pay costs.<sup>317</sup> Currently, tribunals already have power to award attorney fees and costs against investors that file frivolous claims.<sup>318</sup> However, tribunals are usually reluctant to use this

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314. CETA, *supra* note 31, art. 8.39(1), 3–4; *see also* TPP, *supra* note 16, art. 9.29(4).

315. *E.g.*, Cargill, Inc. v. United Mexican States, ICSID Case No. ARB(AF)/05/2, Award, 125–60 (Sept. 19, 2009), [http://www.italaw.com/sites/default/files/case-documents/ita0133\\_0.pdf](http://www.italaw.com/sites/default/files/case-documents/ita0133_0.pdf) (awarding damages to an investor arising from its role as a producer within the United States, a power that arguably fell outside the Tribunal’s mandate). For an explanation of how the mistake in the Cargill outcome was clarified in the TPP text, *see* Sergio Puig, *Investor-State Tribunals and Constitutional Courts: The Mexican Sweeteners Saga*, 5 MEXICAN L. REV. 239 (2013); Sergio Puig, *The Merging of International Trade and Investment Law*, 33 BERKELEY J. INT’L L. 1 (2015).

316. The EU has proposed language to bar tribunals from interim awards that would essentially provide such relief. EU, TTIP proposal, *supra* note 257 (“Tribunal may not . . . prevent the application of the treatment alleged to constitute a breach.”).

317. *E.g.*, TPP, *supra* note 16, art. 9.29(3).

318. *E.g.*, International Centre for Settlement of Investment Disputes [ICSID], Convention on the Settlement of Investment Disputes Between States and Nationals of Other States art. 61(2), <http://icsidfiles.worldbank.org/icsid/icsid/staticfiles/basicdoc/partA-chap06.htm>; United Nations Commission on

authority and typically order each side to bear its own costs. It is estimated the cost of an investor-state arbitration is over \$4 million per case regardless of who wins or loses.<sup>319</sup> Moreover, even when tribunals shift fee payment, they seem more likely to require losing states, rather than losing investors, to pay.<sup>320</sup> Of course, the Uruguay tribunal requirement that Philip Morris reimburse Uruguay for part of its costs is notably different; however, there was no similar award for Australia after it prevailed in dismissing a parallel investment claim by Philip Morris. How future tribunals will act is yet to be determined. However, recently concluded or pending agreements seem to recognize this phenomenon and explicitly include a provision that the losing party shall pay costs.<sup>321</sup>

The process of adjudicating investment claims can also be improved to promote results that are more balanced. For example, greater transparency of proceedings, as well as broader participation is needed. Recent guidelines from UNCITRAL were a step forward, but requiring all documents be made publicly accessible would be better.<sup>322</sup> In addition, permitting any interested party to participate would help to promote competing norms. CETA permits a third party to provide a submission and potentially attend a hearing, subject to the Tribunal's determination; however, there is no affirmative right for interested third parties to participate as is common in domestic proceedings, as well as the WTO.<sup>323</sup> The EU has proposed a better procedure for TTIP that would permit any "person which can establish a direct and present interest to intervene," but only to support what is sought by one of the

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International Trade Law [UNCITRAL] Arbitration Rules art. 42 (2010), <https://www.uncitral.org/pdf/english/texts/arbitration/arb-rules-revised/arb-rules-revised-2010-e.pdf>.

319. *E.g.*, Matthew Hodgson, *Counting the Costs of Investment Treaty Arbitration*, GLOBAL ARB. REV. (Mar. 24, 2014) (alluding to the traditional American "pay your own" way).

320. *See generally id.*

321. *E.g.*, CETA, *supra* note 31, art. 8.39(5).

322. *See* United Nations Commission on International Trade Law [UNCITRAL] Rules on Transparency in Treaty-based Investor-State Arbitration (2014), <http://www.uncitral.org/pdf/english/texts/arbitration/rules-on-transparency/Rules-on-Transparency-E.pdf>.

323. *Compare* CETA, *supra* note 31, art. 8.38(2), *with* FED. R. CIV. P. 24, *and* WTO, Understanding on Rules and Procedures Governing the Settlement of Disputes art. 4(11), [https://www.wto.org/english/res\\_e/booksp\\_e/analytic\\_index\\_e/dsu\\_02\\_e.htm#article4A](https://www.wto.org/english/res_e/booksp_e/analytic_index_e/dsu_02_e.htm#article4A) *and* TRIPS, annex 2, 1869 U.N.T.S. 401.

disputing parties, and only if the tribunal grants the application after disputing parties have the opportunity to comment.<sup>324</sup>

## 2. Current Claims – Options for States Facing Investor-State Arbitration

The investment cases thus far show that there are a number of factors within the control of individual states that can have an important impact on obtaining positive results within the investor-state dispute resolution.

One critical issue for states to consider is tribunal composition. As noted earlier, adjudications in the investor-state dispute arena may depend substantially on who is selected as a tribunal member. States likely are already aware of what individuals tend to rule in favor of States, or at least, do not tend to predominantly rule in favor of investors. In other words, arbitrators that have previously indicated deference for domestic government are ideal. However, given that IP issues implicate the broader WTO/TRIPS framework as well as human rights, choosing individuals who are knowledgeable about these areas is also desirable; one commentator suggests that including individuals with prior WTO experience can promote coherence and cross-fertilization.<sup>325</sup>

In addition to the composition of the tribunal, States need to take great care in pleading their case, including not only all substantive, but also procedural issues like timely raising jurisdictional issues. Notably, contrary to the views of some public health advocates and even Australia's position against Philip Morris, Canada did not dispute the jurisdiction of an investment tribunal to decide the case as only subject to state-to-state dispute under NAFTA, or subject to dispute by the WTO.<sup>326</sup> Of course, the cases are not identical since Australia

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324. CETA, *supra* note 31, art. 23.

325. Peter K. Yu, *The Investment-Related Aspects of Intellectual Property Rights*, 66 AM. U. L. REV. 829 (2017), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2840278](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2840278). Of course, this point was made in the context of a possible appellate system, but the broader point of coherence and cross-fertilization would seem equally applicable to an investment tribunal.

326. *Compare* Philip Morris Asia Ltd. v. Commonwealth of Australia, U.N. Commission on Int'l Trade L. [UNCITRAL], PCA Case No. 2012-12, Australia's Response to the Notice of Arbitration, ¶¶ 33–35 (2011) (arguing no jurisdiction for alleged breaches of TRIPS for claims that have their own dispute settlement mechanisms and objecting that permitting use of article 10 of the BIT would establish a "roving jurisdiction that would enable a BIT tribunal to make a

was addressing interpretation of an umbrella clause, whereas no such clause applied in Canada's case.

Extensively pleading all issues is essential in the investor-state disputes where third party participation is at best limited. Not only is there no affirmative right for third parties to participate, but even when they can participate, they may not be permitted to raise issues not raised by the parties.<sup>327</sup> Also, third parties may not have access to all documents, which may compromise their ability to fully address issues.<sup>328</sup> Nonetheless, to the extent that tribunals accept any third party participation, states should seek the highest amount of disclosure and transparency possible, as well as participation of third parties through amicus briefs.

### CONCLUSION

In this paper, we have shown how the protection and enforcement of IP rights has shifted to international investment law and investor-state arbitration. This shift is fundamental in several significant respects. First, it creates a new set of remedies available to holders of IP rights such as expropriation and fair and equitable treatment. Since the shift to this forum is in addition to the WTO/TRIPS forum, IP holders have the ability to seek remedies against regulatory measures even when consistent with WTO/TRIPS, and even if the IP holder cannot persuade its own country to raise a WTO challenge. International investment law presents investors an opportunity

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broad series of determinations that would potentially conflict with the determinations of the agreed dispute settlement bodies under the nominated multilateral treaties.”), *with* *Eli Lilly v. Gov't of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Canada Counter Memorial, ¶ 209 (NAFTA/UNCITRAL Arb. Trib. Jan. 27, 2015) (not seeking dismissal for lack of jurisdictions); *see also* Flynn, *supra* note 237 (noting that *Eli Lilly* and Canada memorials assume that article 110(7) permits the tribunal to decide whether Canada's actions are consistent with the IP chapter of NAFTA). Canada did mention that allegations of the IP provisions of NAFTA should be bought on a state to state basis, but made no allegation that investment claims tied to IP provisions of NAFTA were outside the tribunal's jurisdiction. *Eli Lilly v. Gov't of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Government of Canada Statement of Defence, ¶¶ 83–84 (NAFTA/UNCITRAL Arb. Trib. June 30, 2014); *see also* *Eli Lilly v. Gov't of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Canada Counter Memorial, ¶¶ 209–10 (NAFTA/UNCITRAL Arb. Trib. Jan. 27, 2015).

327. *See* sources cited *supra* notes 219–20, and accompanying text.

328. *See* sources cited *supra* note 18; *see also* Nigel Blackaby & Caroline Richard, *Amicus Curiae: A Panacea for Legitimacy in Investment Arbitration?*, in *THE BACKLASH AGAINST INVESTMENT ARBITRATION* 253, 271–72 (Michael Waibel et al. eds., 2010).

to challenge the balancing and flexibilities between the rights of producers and users embedded in the WTO regime. This is a major change from an earlier regime shift two decades ago when developing countries utilized forums outside the WTO to provide balance to the new minimum IP standards in TRIPS. However, this earlier regime shift to promote greater flexibility is now threatened by the shift to an investment regime. Investment treaties and investment chapters in trade agreements do not often contain the type of flexibilities contained in the TRIPS Agreement, such as the preambular language of Articles 7 and 8, or the subsequent Doha Public Health Declaration that were designed to promote interpretations that foster public health. Further, whereas remedies at the WTO generally are prospective modifications in the law or trade practice in question, the international investment regime permits companies to not only change the law, but to also obtain significant financial compensation. This could have a major chilling effect on legitimate domestic policy norms.

Two decades ago, developing countries began exploring alternatives within and outside the WTO to re-balance the minimum IP standards adopted by the TRIPS Agreement. In forums such as the World Health Organization and the United Nations, they sought a balance between IP rights and public health. Investor-state suits challenging public health regulations make it less likely that countries would readily invoke TRIPS flexibilities because of the possibility of being liable for hundreds of millions of dollars. Considering that even developed countries like Canada have been more cautious in adopting regulation in response to investor-state threats, there is an especially serious threat to the use of TRIPS flexibilities to promote public health for countries with few resources.

Our argument is that enforcing IP rights in investor-state arbitration represents a new round of regime shifting—this time initiated by private actors seeking to enforce their newfound investment rights in investor-state arbitration. The goal of IP holders is to undermine the flexibilities in the WTO TRIPS regime through arbitral decisions that find violations of investment provisions protecting their IP rights. In addition, newer free trade agreements with investment chapters typically have an IP chapter that has even stronger IP protections than TRIPS. This enables a further intrusion onto TRIPS flexibilities. The enhanced IP protections included in investment agreements and investment chapters of free trade agreements are hard law. By contrast, a lot of the flexibilities and balancing won by

developing countries such as the Doha Declaration on TRIPS and Public Health in the WTO are soft law incapable of enforcement in the same way that Philip Morris and Eli Lilly pursued their claims in investor-state arbitration.

In the final part of this paper, we proposed some modest strategies to counter regime shifting of IP enforcement to help ensure the bona fide authority of governments to protect public interest, especially public health. The first set of proposals recommends defining and clarifying key terms to minimize harm to domestic sovereignty and TRIPS flexibilities. The second of our proposals recommends improving the investment dispute process through a variety of reforms, including a popular current suggestion to have an independent investment tribunal, as well as an appellate tribunal. Some of these proposed reforms to the process of investment disputes are already reflected in negotiated and sometimes final texts, particularly of mega-regional trade agreements. Although this is a new development that currently does not address the vast majority of agreements relating to investor-state arbitration, it does suggest a gathering momentum to address a perennially criticized aspect of investor-state arbitration as problematic. Of course, even an independent tribunal system with appeals would not necessarily fully address the problems with the IP regime shift noted here; indeed, its genesis relates to an explosion of investor-state claims and inconsistent awards involving similar facts in general, but not specific to IP. Nonetheless, the recognized need to reform the investor-state system may suggest that there is some hope that there is a trend towards recognizing a need to fine tune the investment arbitration system. Hopefully this article has adequately explained the dangers of the regime shift to investor-state arbitration such that it may promote further discussion and proposals to robustly address the issues analyzed here.

**A: ANNEX ONE: CHALLENGES TO NATIONAL TOBACCO  
REGULATIONS BY THE TOBACCO INDUSTRY**

<b>Country</b>	<b>Plain Packaging (PP) Law</b>	<b>Other Tobacco Regulation<sup>329</sup></b>	<b>Domestic Court Challenge</b>	<b>Investor-State Challenge</b>	<b>Other Challenges</b>
Australia	Yes	Labelling Law	Yes	Yes	WTO DSS
Belgium	Planned by 2019	NA	NA	NA	Big Tobacco argues that plain packaging will encourage black market.
Bolivia	No	Health Warning Regulations	No	No	Unknown
Brazil	No	Labelling Law	No	No	Unknown
Brunei	No	Labelling Law	No	No	Unknown
Canada	Proposed in 1994	Labelling Law (The Tobacco Act of 2000 imposes restrictions on promotion, packaging, and point-of-sale restrictions. No trademark restriction) Tobacco Products Control Act (TCPA) mandating health warnings, barring ads, and	TPCA declared unconstitutional in 1995 on freedom of speech grounds.	NAFTA investor-state suit threatened against planned PP Law	Extensive lobbying against 1994 proposal, including campaign against Health Minister and threat of NAFTA-based arbitration.

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329. Labelling Regulation includes laws, regulations, standards or directives that: require tobacco products to have health warnings including the kind of graphics and writings that can appear on them, restrict tobacco advertising and promotion, provide for methods and procedures of tobacco production, regulate additives in tobacco products, and provide for measurement and testing of harmful substances in tobacco products.

		restricting promotions			
Cambodia	No	Labelling Law	No	No	Unknown
Chad	No	Labelling Law	No	No	Unknown
Chile	No	Labelling Law	No	No	Unknown
Costa Rica	No	Labelling Law	Yes	No	ISDS threat against planned PP legislation
Ecuador	No	Labelling Law	No	No	Unknown
European Union	Under consideration	Directive governing labelling, additives, advertising, notification and tracking of tobacco products	No	No	Challenge in the Court of Justice of the European Communities
Finland	No	Labelling Law	No	No	Unknown
France	Yes		Yes		Unknown
Hungary	No	Labelling Law	No	No	Unknown
India	No	Labelling Law	Yes	No	Cigarette companies argued that plain packaging would encourage black market.
Indonesia	No	Labelling Law	Yes	No	Delay in implementation by manufacturers
Ireland	Yes, but not implemented expected effective date 2017	Labelling Law	Yes	No	Threats of legal action in national Courts.
Kenya	No	Labelling Law	Yes	No	Bribery of governmental officials

Korea (South)	No	Labelling Law	No	No	Threat of ISDS suit
Lao PDR	No	Labelling Law	No	No	Unknown
Malaysia	No	Labelling Regulations	Yes	No	Tobacco companies warned Malaysia was violating its international trade agreement on passage of labelling regulations
Myanmar	No	Labelling Orders	No	No	Unknown
Namibia	No	Labelling Law	No	No	Threat of legal action under international law on passage of labelling law.
Nepal	No	Labelling Directive	No	No	Tobacco companies working with the U.S. Chamber of Commerce to fight directive because of adverse impact on U.S. foreign investment in Nepal
New Zealand	Proposed passed first reading in Parliament in February 2014	Labelling Law	No	No	Threat of ISDS suit. Evidence that New Zealand proceeding cautiously after Philip Morris case against Australia
Norway	Bill under review	Labelling Law	No	No	Unknown

Philippines	No	Labelling Law	Yes	No	Unknown
Singapore	No	Labelling Law	No	No	Unknown
Slovenia	No	Labelling Law	No	No	Lobbying on the basis that regulation would encourage black market
South Africa	Plans to introduce it	Labeling Law	Yes	No	Lobbying on the basis that regulation would encourage black market
Sweden	No	Labelling Law	No	No	Lobbying on basis that law would be tantamount to illicit censorship
Thailand	No	Labelling Law	Yes	No	Massive lobbying effort by tobacco companies to prevent implementation of law
Togo	No	Attempted to introduce labelling law	No	No	Threat of ISDS action by Philip Morris stopped enactment
Turkey	No	Labelling Law	No	No	Unknown
Ukraine	No	Labelling Law	Yes	No	U.S. Chamber of Commerce influenced Ukrainian government regulation of labelling law
United Kingdom	Yes	Labelling Law	Yes	No	Tobacco companies lobbied against

					PP on the basis that there was no evidence that legislation would affect smoking rates. Philip Morris threatened to sue in British Courts.
United States	No	Labelling Law	Yes	No	PP defeated in courts on the basis of restriction of freedom of speech. Lobbying against it in Congress.
Uruguay	No	Labelling Law	No	Yes	Threats of high cost ISDS litigation
UAE	No	Labelling Law	No	No	Unknown
Yemen	No	Labelling Law	No	No	Unknown

## B: ANNEX TWO: TRIPS FLEXIBILITIES: AN OVERVIEW

Type of Flexibility	Definition	Status
Transition Period TRIPS art. 65-66	No need to provide patents on drugs in country that did not previously provide them until 2005	Used by India, but not by most other qualifying countries (barring LDC that have a different transition period)
Patentability terms (TRIPS art. 27)	Although countries must grant patents on “inventions” that are “new,” have an “inventive step,” and are “useful,” these terms are undefined, permitting countries to be more restrictive about what is patentable.	India bars patents on drugs that are similar to existing ones unless they have improved efficacy (limiting what is a new invention) Proposed in Brazil and South Africa since 2003 (industry opposition)
Pre-Grant Opposition	Permits third parties to contest whether patent should not be granted. This might result in limiting patent term since term calculated from date of filing, not issuance.	India adopted, as has Brazil, Indonesia, Thailand, and China
International Exhaustion (TRIPS art 6)	Permits countries to consider patent rights “exhausted” by first sale globally	Argentina Brazil, Bolivia, Columbia, Ecuador, India, Panama, Peru, Philippines, Venezuela; Less than half of African countries
Compulsory License (art. 31)	Permitted, although most flexible use is to have broad grounds, such as patent owner failure to make product locally, or price affordably	Although a number of states have laws, most do not use India has broad grounds, but used minimally and is reported to have “promised” not to use after pressure
Data protection (art. 39)	Many believe countries can grant generic drugs by reference to data submitted by originator given ambiguity in TRIPS that does not expressly preclude reliance.	India, Argentina, Armenia, Belarus, Kyrgyzstan, Moldova, Tajikistan & Ukraine Recommended in Brazil and South Africa, but strong opposition

	This speeds up process for approving low-cost generics in contrast to “data exclusivity” that would bar this result.	
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