

LEGAL INNOVATION IN INTERNATIONAL INTELLECTUAL PROPERTY RELATIONS: REVISITING TWENTY-ONE YEARS OF THE TRIPS AGREEMENT

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INTRODUCTION

In 1994, over 150 nations converged in Punta del Este, Uruguay, and completed what was, at that time, the most ambitious multilateral intellectual property (IP) agreement ever negotiated. Built on the cornerstone of the “Great Conventions,”¹ the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)² profoundly altered the nature, scope, and economic consequences of international intellectual property regulation.³

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¹ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]; Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 1161 U.N.T.S. 3 [hereinafter Berne Convention].

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 183, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].

³ See, e.g., J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT’L L. 345 (1995) [hereinafter Reichman, *Universal Minimum Standards*] (discussing global economic consequences of the TRIPS Agreement); see also Keith E. Maskus, *Lessons from Studying the International Economics of Intellectual Property Rights*, 53 VAND. L. REV.

The presumptive goal of the Uruguay Round negotiations, and its specific manifestation in the TRIPS Agreement, was to secure export markets for a wide variety of knowledge goods in which industrialized countries had long held a competitive advantage. In more fundamental terms, the TRIPS Agreement sought to reshape the conditions of *future* global competition, particularly the extent to which developing countries could use intellectual property as a form of industrial policy in pursuit of strategic development objectives. With strong upgrades in patent and copyright protection, seminal international coverage of new subject matter, and a celebrated enforcement mechanism,⁴ the TRIPS Agreement targeted the soft underbelly of the development process.⁵ In so doing, however, it made access to knowledge and technology acquisition by firms in developing countries more costly,⁶ thereby undermining their ability to compete in a global knowledge economy, at least in the short run. More insidiously, the TRIPS Agreement heralded a potent blend of global and local politics,⁷ thus defining a new era of private sector influence in the political economy of globalized intellectual property norms.⁸ The policy

2219, 2228-30 (2000) (predicting global impact of rent transfers as a result of international patent regulation under the TRIPS Agreement).

⁴ See TRIPS Agreement, *supra* note 2, arts. 1(2), 64.

⁵ Joseph E. Stiglitz, *Information and the Change in the Paradigm in Economics*, 92 AM. ECON. REV., 460, 483 (2002) ("One of the most important determinants of the pace of growth is the acquisition of knowledge"); INT'L BANK OF RECONSTR. & DEV., WORLD BANK GROUP, LIFELONG LEARNING IN THE GLOBAL KNOWLEDGE ECONOMY: CHALLENGES FOR DEVELOPING COUNTRIES 1 (2003) ("A knowledge-based economy relies primarily on the use of ideas rather than physical abilities and on the application of technology rather than the transformation of raw materials or the exploitation of cheap labor."). See Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 473 (2001) (providing a table of estimated economic impact of TRIPS patent changes for selected countries).

⁶ U.N. Conference on Trade and Development, Geneva, Switz., *The TRIPS Agreement and Developing Countries* 36, UNCTAD/ITE/1 (1996) (providing estimates of costs of TRIPS implementation in some developing countries); INT'L BANK FOR RECONSTR. & DEV., WORLD BANK, *Global Economic Prospects and the Developing Countries* 136 (2002), available at <http://siteresources.worldbank.org/INTGEP2002/Resources/gep2002complete.pdf> (citing J. Michael Finger & Philip Schuler, World Bank, *Implementation of Uruguay Round Commitments: The Development Challenge* (1999) (manuscript)).

⁷ See Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 845-48 (2003) (discussing cooperation of US, Japan and EU firms in getting their governments to pursue the TRIPS Agreement).

⁸ See generally SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE

implications of the new rules established by the TRIPS Agreement arose first in the context of its patent provisions. In particular, South Africa played the lead role in a public health crisis that unfolded dramatically on the global stage.⁹ The moral, ethical and legally controversial arguments about the extent to which TRIPS obligations require an unraveling of the domestic social welfare calculus of a WTO member state galvanized an entire “access-to-medicines” movement that ricocheted around the world.¹⁰ The controversy produced a formal amendment to the TRIPS Agreement, known colloquially as the “Doha Declaration,”¹¹ that clarified the right of WTO member states to interpret the Agreement “in light of [its] object and purpose”¹² It also specifically reaffirmed the right of member states to protect public

GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003). In addition to the traditional state actors, several other powerful forces are at play, including large multinational corporations, industry lobbyists, internet intermediaries, international organizations, and NGOs. The biggest direct stake in TRIPS outcomes was held by a handful of industry actors, whose global monopolies depended on securing strong worldwide IP protection: the pharmaceutical industry (\$650 billion annual revenue, estimated to increase to \$1.5 trillion), the entertainment and software industries (\$800 billion), and the commercial seed industry (\$21 billion). *See generally* CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES* 9 (2009). With so much at stake, these industry players continue to exert significant pressure and influence domestically, producing new webs of multilateral IP agreements.

⁹ *See* Neil A. Lewis, *U.S. Industry to Drop AIDS Drug Lawsuit Against South Africa*, N.Y. TIMES, Sept. 10, 1999, at A3 (reporting on patent infringement controversy between U.S. pharmaceutical companies and South African government over the country’s loosening of patent laws to reduce medical costs for AIDS patients). In 1997, South Africa passed a law that permitted exceptions to national patent laws (primarily compulsory licensing and parallel importing) to reduce the price of AIDS pharmaceuticals. This resulted in an international controversy, with the United States threatening to impose unilateral trade sanctions. However, strong adverse public reaction forced the Clinton administration to back down, and the dispute was quietly settled without the involvement of the WTO’s Dispute Settlement Body.

¹⁰ *See, e.g.,* Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 821–39 (2008) (describing the origins and development of the “Access to Knowledge” movement).

¹¹ Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration], available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

¹² *Id.* ¶ 5(a).

health.¹³

Today, the access to medicines movement and its corollary, the access to knowledge movement,¹⁴ are key players in the politics of international intellectual property relations. The movements represent a globally linked and loosely organized opposition to the untested assumptions and overarching philosophy of the TRIPS Agreement. Working within a framework animated by considerations of social justice, liberty ideals and good governance, this ad-hoc alliance of activists, scholars and organizations maintains close watch over the normative contours of the multilateral IP system and promotes strategies to resist deterministic outcomes of global IP norms. In so doing, many of the alliance's chief protagonists also challenge and seek to influence domestic political processes that are inordinately influenced by the economic claims of industries whose business income flow principally from an expansive trough of IP rights. Twenty-one years later, the IP world for which the Uruguay Round laid its foundation is very different from what was imagined at the end of the negotiations in 1994. The TRIPS Agreement has neither confirmed the worst fears of developing countries nor accomplished the greatest hopes of the developed ones. Instead, both sides have inserted important points of adherence and resistance to the negotiated global IP norms, thus destabilizing many of the Agreement's implicit political and economic bargains. On the one hand, developed countries have moved aggressively to adopt ever more pervasive strategies to curtail unilateral exercises of IP policy in developing countries. At the same time, new sites of resistance to the built-in normative flexibility recognized by the TRIPS Agreement have become entrenched in a viral web of bilateral, regional and plurilateral agreements.¹⁵ For their part, some developing countries are demonstrating nascent institutional capabilities that have facilitated creative approaches to implementing TRIPS obligations, while advancing ideals of welfare unique to national circumstances. To be clear, some of these developments are not specifically directed at TRIPS obligations. Rather, as these countries institutionalize international obligations in areas such as human rights, the environment or public health, IP norms have

¹³ *Id.* ¶¶ 1, 4, 5(c).

¹⁴ Kapczynski, *supra* note 10.

¹⁵ Maira Sutton, *TPP: Internet Freedom Activists Protest Secret Trade Agreement Being Negotiated this Week*, ELEC. FRONTIER FOUND. (May 14, 2012), <https://www.eff.org/tpp-another-backroom-deal>.

become the implicit, and in some cases explicit, subject of legal innovation in a broader scheme of national welfare planning.

For my purposes in this Article, legal innovation does not consist simply of episodic responses to particular international pressures. Rather, legal innovation is (i) characterized by the potential that the selected tools for innovation are sustainable within the local legal culture; (ii) fueled by a clearly identified national development purpose or strategy; and (iii) effectuated principally by local actors. I define legal innovation as the development of new techniques, institutions and/or methods that respond to TRIPS obligations and facilitate their implementation in a manner consistent with national welfare goals. This approach turns the TRIPS Agreement inwards by encompassing local needs, priorities, and politics in a deliberate reconciliation of multilateral obligations and domestic economic, cultural and political interests. As a result, legal innovation has forged new approaches to the role of IP in national economic policy, evidenced by unfolding developments in India, South Africa and Brazil.¹⁶ Legal innovation has also engendered new domestic regimes to attract foreign investment in Malta,¹⁷ has offered opportunities for constitutional considerations to re-direct the dominance of the classical economic narrative of IP in Kenya,¹⁸ and, paradoxically, has added to existing IP standards, particularly in the realm of patentable subject matter, in ways that rebalance power equities between informal knowledge holders and patent applicants in China and India.¹⁹ Within the international IP policy space, these various forms of legal innovation may suggest that the minimum standards of the TRIPS Agreement that evoked such significant global consternation may yet offer a basis for countries to construct policy spaces in alignment with development goals. These spaces may, in turn, allow domestic institutions to interrogate the values of the Agreement in light of broader considerations of domestic human welfare. Framed in this manner, legal innovation constitutes a method for more finely honed approaches to defining sovereign responsibility for the *effects* of IP rights in society and for indirectly circumscribing the scope of Executive power in bilateral

¹⁶ See *infra* Part 3.1.2.

¹⁷ See *infra* Part 3.1.3.

¹⁸ See *infra* Part 2.1.3. (discussing the *Asero Ochieng v. Attorney-General* case, in which the Kenyan High Court overturned a TRIPS-driven anti-counterfeiting statute to preserve access to affordable, life-saving generic drugs).

¹⁹ See *infra* Part 2.1.3.

or multilateral norm-setting exercises.²⁰ In Part 1, I describe how the TRIPS Agreement ultimately opened the policy spaces conducive to legal innovation. I highlight the unfulfilled promise of the Agreement, offering a critique of the model of “hard” harmonization that it incorporates. In Part 2, I briefly review the structure and main provisions of the TRIPS Agreement, focusing on the patent provisions that were the most challenging during the negotiations. I include a short analysis of how those provisions and key aspects of the architecture of the Agreement have defined the outer limits of the scope for legal innovation efforts in developing countries. In Part 3, I consider examples of legal and institutional innovation in emerging economies and link them to the resilience of development aspirations, which are key motivators for domestic actors’ creative responses to TRIPS obligations. Finally, in Part 4, I discuss the implications of new multilateral initiatives that seek to build on the TRIPS baseline. I explore modes of legal innovation in the ongoing IP reform efforts in Brazil and South Africa. In addition, Part 4 reflects on the institutional capacity and processes of IP reform, which enable legal innovation to thrive. Specifically, IP reform initiatives facilitate legal innovation first by making national IP policy a subject of public discourse and then by creating a process in which multiple stakeholders engage in dialogue with relevant IP agencies as well as each other. Ultimately, I suggest that the instability generated by a new breed of plurilateral agreements has ushered multilateral IP norm-setting, and the TRIPS Agreement specifically, into an age of uncertainty. This age, I propose, is a harbinger for leveraging legal innovation to re-institute more defensible norms in the fabric of multilateral IP treaties. It is unclear how long the specific types of innovative oeuvres I discuss in this Article will last or to what extent developing countries can resist the inevitable backlash that will certainly continue to come from developed countries. A sustained capacity to engage in forms of legal innovation that advance a distinctive domestic welfare

²⁰ Courts in the U.S., for example, have issued a series of opinions that clearly are in tension with the maximalist narrative of the TRIPS Agreement. *See, e.g., Ass’n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013) (holding that a composition involving isolated DNA was not patent eligible); *Bilski v. Kappos*, 130 S. Ct. 3218, 3228 (2010) (holding that a business method of hedging financial losses in energy industry not patent eligible); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (holding that a medical diagnostic method that added administering steps to a natural correlation was not patent eligible); *see also infra* note 106 and accompanying text (discussing the same cases).

vision, while credibly complying with the TRIPS Agreement, will define the extent to which developing countries can meaningfully limit the potential for adverse welfare consequences from heightened costs of access to knowledge and technological inputs. But, it is the comparative national institutional capacity and agility of the developed and developing countries alike that will ultimately define the efficacy of the TRIPS Agreement and its progeny in the years to come.

1. THE UNFULFILLED PROMISE OF THE TRIPS AGREEMENT:
BARGAINING TO THE BASELINE

Few participants in the Uruguay Round negotiations anticipated the complex political and legal aftershocks that resonated after the conclusion of the TRIPS Agreement. Part 1 will present how legal innovation in response to the TRIPS Agreement was largely facilitated by the structure of the Agreement. Next, Part 1 explains how the underlying goals of the Agreement - harmonization and enforcement - opened policy spaces in which countries could conceive of the legal measures I later describe as legal innovation. Lastly, I explain how the TRIPS Agreement's minimum standards in the patent context recalibrated the global policy landscape in favor of industry and private actors, thereby placing developing countries in the strategic position of weighing compliance measures against their own domestic welfare calculus.

1.1. *TRIPS as the Source of Legal Innovation*

Two important developments suggest the TRIPS Agreement may have accomplished a goal far more significant for development, and more telling for the future of IP harmonization, than any of the normative concerns occupying the scholarly debate for the past two decades.

First, the TRIPS Agreement greatly expanded the power of domestic IP agencies in all countries regardless of development or income levels.²¹ A new professional class of IP technocrats

²¹ See, e.g., National Patent Development Strategy (2011-2020), available at <http://graphics8.nytimes.com/packages/pdf/business/SIPONatPatentDevStrategy.pdf> ("By 2020, China will become a country with a comparatively high level in terms of the creation, utilization, protection and administration of patents . . .").

emerged in both the private and public spheres, advising, strategizing, advocating or defending particular positions in domestic and international fora.²² In developing countries, the rise of a veritable cottage industry of TRIPS professionals endeavoring to shape national legal regimes to ensure TRIPS compliance also succeeded, in a few cases, in inducing the creation of new IP bureaucracies where none previously existed,²³ or in greatly expanding those that did.²⁴ Private industry consultants, technical assistance programs funded from the public purses of the U.S. and European Union, and training programs by the WTO and the World Intellectual Property Organization (WIPO) established a cultural and legal orientation about IP that emphasized particular interpretations of TRIPS and sought to strengthen national enforcement prospects of the Agreement.²⁵

The relative success of this socio-legal ordering²⁶ ultimately heightened the political costs associated with TRIPS for aid-sending and aid-receiving countries alike. In the developing countries receiving TRIPS/IP training and advice, those costs involved threat of trade sanctions or the potential loss of foreign aid should recommendations from consultants not be followed. In the developed countries, the political costs were reflected in contests between various agencies vying for control over national policy directions,²⁷ in the intensification of lobbyists' efforts to steer the direction of national strategies in the global IP arena, and in the

See generally DEERE, *supra* note 8.

²² Gregory Shaffer, *How the WTO Shapes Regulatory Governance* (U.C. Irvine Sch. of Law, Research Paper No. 2014-53) (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2507576.

²³ See, e.g., *Business and Intellectual Property Authority*, BIPA, <http://www.bipa.gov.na> (last visited Oct. 28, 2014) (stating that BIPA was established to facilitate "effective administration of business and intellectual property rights (IPRs) registration . . .").

²⁴ See also Bruce Reynolds & Susan K. Sell, *China's Role in Global Governance – Foreign Exchange and Intellectual Property: A Comparison*, (Research Ctr. for Chinese Politics & Business, RCCPB Working Paper No. 31, Nov. 2012) (noting China's increasingly assertive behavior in IP global governance and exchange rate policy).

²⁵ See generally DEERE, *supra* note 8, at 13.

²⁶ See Gregory Shaffer & Susan K. Sell, *Transnational Legal Ordering and Access to Medicines*, in RUTH L. OKEDIJI & MARGO A. BAGLEY, *PATENT LAW IN GLOBAL PERSPECTIVE* 97, 101-05 (2014) (emphasizing the importance of considering transnational legal norms alongside international law and IP law).

²⁷ Arti K. Rai, *US Executive Branch Patent Policy, Global and Domestic*, in RUTH L. OKEDIJI & MARGO A. BAGLEY, *PATENT LAW IN GLOBAL PERSPECTIVE*, 85, 89-91 (2014) (discussing differences in approaches to pharmaceutical patent policy among US agencies).

unavoidable domestic tradeoffs (or pay-offs) incurred,²⁸ including enlarged programs for IP agencies with seemingly unfettered discretion to deal with multilateral IP policy issues.²⁹

The second development has been the resilience of local interests, sometimes working in concert with transnational actors, in identifying those domestic considerations that could successfully blunt the toughest edges of multilateral IP obligations. Unlike U.S. courts or agencies that rarely engage in meaningful analyses of international obligations in interpreting domestic IP doctrines,³⁰ there is growing evidence that a range of countries are responding to TRIPS-related pressures by explicitly embracing, and then creatively limiting, the price that a maximalist global IP regime can exact from citizens and the policy costs it imposes on governments.³¹ As discussed in Part 3, these initiatives potentiate human development returns that extend beyond the creative incentives of IP rights to include recognition of new social freedoms, the hardening of equality principles in local laws, judicial independence, and a general democratic largesse. These returns are critical components of an environment in which legal innovation can flourish. What is more, they are flourishing in the precise institutional frameworks occasioned by, or deployed

²⁸ J. Michael Finger, *The Doha Agenda and Development: A View from the Uruguay Round* 14-15 (Asian Dev. Bank Econ. & Research Dep't, Working Paper No. 21, 2002), available at <http://www.adb.org/sites/default/files/pub/2002/wp021.pdf> (discussing domestic tradeoffs involved in trade negotiations and contrasting this with concessions related to TRIPS). As Professor Finger notes,

[E]xchanging market access for intellectual property rights brings with it a more challenging domestic politics than do more traditional trade agreements. It demands a broader domestic pay-off from winners to losers than trade negotiations have supported in the past. It also requires that the benefiting domestic constituency be *created* by the exchange, something trade negotiations have never done. *Id.*

²⁹ See United States Patent and Trademark Office, *USPTO 2014-2018 Strategic Plan* (2013), available at http://www.uspto.gov/about/stratplan/USPTO_2014-2018_Strategic_Plan.pdf (delineating the USPTO's plan to serve as a model for the world and to collaborate with global IP partners).

³⁰ Geri L. Haight & Philip Catanzano, *The Effects of Global Priority of Trademark Rights*, 91 MASS. L. REV. 18, 26 (2007) ("[T]here is scant case law in which a U.S. court discussed or applied the provisions of any treaty to a trademark dispute, and it is unclear how much weight U.S. judges will accord to foreign treaties and protocols unless the Supreme Court provides guidance. Several courts that addressed the issue have expressly declined to apply the treaty provisions."). See generally Ruth L. Okediji, *The Berne Convention in U.S. Courts* (on file with author) (analyzing the limited impact of Berne accession in US courts).

³¹ See *infra* Parts 3-4.

within, the transnational efforts created principally to enforce the TRIPS Agreement.

To be clear, legal innovation is also occurring in the developed countries and, as in the developing countries, these are not usually framed as a direct response to TRIPS. Nonetheless, legislative, policy and judicial decisions, together with numerous agency initiatives, arguably represent national adaptation to a penumbra of pressures related to IP harmonization efforts since the conclusion of the TRIPS Agreement. Legislation such as the America Invents Act (AIA)³² and institutions such as the new European Patent Court³³ are notable examples of such adaptation, as is the rise of sequential IP plurilateralism.³⁴ Still, other versions of legal innovation are evident in administrative plans and policies that identify the strategic priorities of bureaucracies ostensibly charged with protecting national IP interests, such as the United States Patent and Trademark Office (USPTO).³⁵

What appears to unite efforts at legal innovation across developed and developing countries is the promotion of "bureaucratized and judicialized governance[.]"³⁶ which is innovation distinctively associated with administrative agencies and courts. These institutions are typically imbued with broad discretionary powers and they have far less defined obligations to the primacy or coherence of the multilateral IP system. Within this IP ecosystem established by the WTO TRIPS Agreement, legal innovation offers a fine instrument for defining sovereign responsibility for the effects of IP rights in society across both developed and developing countries.

Courts in the U.S., for example, have issued a series of opinions that clearly are in tension with the maximalist narrative of the TRIPS Agreement.³⁷ As Professor Jerome Reichman has noted,

³² Leahy-Smith America Invents Act, Pub L. No. 112-29, 125 Stat. 284 (2011).

³³ Council Agreement 16351/12, Agreement on a Unified Patent Court, 2013 O.J. (C175) 1.

³⁴ See *infra* Part 5.

³⁵ See *e.g.*, USPTO 2014-2018 Strategic Plan, *supra* note 29 (outlining the goals of optimizing patent and trademark quality and timeliness and providing domestic and global leadership to improve IP policy, protection, and enforcement).

³⁶ See Shaffer, *How the WTO Shapes Regulatory Governance*, *supra* note 22, at 2, 10-14 (describing dynamic regulatory changes in transnational legal ordering, such as the shift in the "authority of institutions within the state").

³⁷ See, *e.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2120 (2013) (holding that a composition involving isolated DNA was not patent eligible); *Bilski v. Kappos*, 130 S. Ct. 3218, 3229-31 (2010) (holding that a business

developing countries would fare well by imitating U.S. approaches in key areas affecting the supply of public goods, such as educating its citizens,³⁸ encouraging competition³⁹ or otherwise expanding the public domain.⁴⁰ Certainly, U.S. policy in these areas is far less maximalist than what some least-developed countries have been led to implement as TRIPS-compliant legislation.⁴¹

It is important to note, however, that legal innovation is not always a one-way positive gain for public welfare.⁴² The difficulty in assessing which normative tradeoffs make sense in pursuit of the vision of the domestic public good, as reflected in the dominant economic justification for IP, is one critical reason for underscoring the importance of legal innovation by domestic actors. The classic IP economic narrative is not a complete representation of the complex processes that qualify as innovation. Values such as liberty, freedom of speech, equality and privacy also weigh importantly in the technological choices made by private firms to attract consumers to use technology and they should matter in how countries construct the scope and exercise of IP rights.⁴³ More

method of hedging financial losses in energy industry is not patent eligible); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012) (holding that a medical diagnostic method that added administering steps to a natural correlation was not patent eligible); *see also infra* Part 1.2.2. for additional discussions on the above cases.

³⁸ *See e.g.*, Jerome H. Reichman, *Richard Lillich Memorial Lecture: Nurturing a Transnational System of Innovation*, 16 J. TRANSNAT'L L. & POL'Y 143, 162 (2007) (arguing that developing countries would benefit from "experimentally . . . testing different approaches to stimulating and disseminating innovation in their national and regional systems of innovation and to defining the relevant supporting legal standards that could prove effective for different players at different levels of development . . .").

³⁹ *See e.g.*, Reichman, *Universal Minimum Standards*, *supra* note 3, at 387-88 (predicting that IP regimes that are compliant with TRIPS, but that also stimulate competition in developing countries will allow small and medium sized firms in developing countries to align interests across the globe and create greater competitive forces for larger firms).

⁴⁰ *See e.g.*, Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INT'L ECON. L. 279, 316-20 (2004) (arguing that continued advancements in global technology are dependent on a functional transnational system of innovation, especially maintaining access to public knowledge goods and inputs).

⁴¹ DEERE, *supra* note 8.

⁴² Professor Julie Cohen has noted that the very arguments that advance access to knowledge can often be in tension with some social freedoms and can compromise privacy interests. *See generally* JULIE E. COHEN, *CONFIGURING THE NETWORKED SELF: LAW, CODE, AND THE PLAY OF EVERYDAY PRACTICE* (2002).

⁴³ *Id.*

importantly, in the information society, innovation may flourish best *precisely* because there are no IP rights to control or repress the creative impulses of ordinary citizens. Social media platforms, for example, operate less on exclusive rights over content and more on models that control how users function or experience these technological spaces.⁴⁴ The TRIPS Agreement does not, and cannot, provide specific rules to regulate these technologically mediated social spaces, nor can it direct the ways in which an absence of IP rights could engender innovation. As a result, the extraordinary focus in the TRIPS Agreement on control for IP owners and the mandatory baseline that effectually transfers the locus of public policy decisions to private firms will regularly require – and motivate – new ways of conceptualizing TRIPS obligations at the national level.

1.2. *A Critique of Harmonization and Enforcement as Crowning Triumphs*

The TRIPS Agreement requires member countries to establish certain minimum, albeit robust, standards of protection for the traditional subjects of industrial property and copyright covered by the Paris and Berne Conventions.⁴⁵ It also includes, for the first time, multilateral protection for undisclosed information⁴⁶ and strengthens protection for layout designs⁴⁷ beyond the terms of the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty).⁴⁸ These new rules largely brought a measure of convergence between developed countries, although important differences remained.⁴⁹ Undoubtedly, the new normative standards alone were important improvements to the previous

⁴⁴ For example, there is no doubt that many activities on Facebook may constitute violations of copyright; yet, the capacity to engage in such activities is what makes social media socially meaningful. *Id.* However, as Professor Cohen argues, this is not necessarily a positive turn. *See generally id.* at 3–61.

⁴⁵ TRIPS Agreement, *supra* note 2, arts. 27, 27.1; *see also* Reichman, *Universal Minimum Standards*, *supra* note 3 (noting the prevailing protectionist bias currently shaping the international intellectual property arena).

⁴⁶ TRIPS Agreement, *supra* note 2, art. 39.

⁴⁷ *Id.* art. 38.

⁴⁸ Treaty on Intellectual Property in Respect of Integrated Circuits, 28 I.L.M. 1484, May 26, 1989.

⁴⁹ Jerome H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U.J. INT'L L. & POL. 11, 90–93 (1997).

multilateral regime administered by WIPO. Nonetheless, they would not have significantly advanced the goal to impose discipline on the national IP choices of the developing countries, particularly middle-income countries such as India and Brazil, whose economies and firms had proven capable of competing with the IP-intensive sectors of the developed countries.

The *piece de resistance* of the TRIPS framework was a mechanism to discipline and constrain the policy space that facilitated cheap knowledge acquisition, such as through differentiated levels of protection for IP subject matter. In order to be effective, this mechanism had to threaten, in a credible way, meaningful consequences for derogating from the newly established normative framework. Accordingly, provisions for enforcement and dispute settlement, including an outline of prescriptive and administrative legal tools countries should make available to rightsholders,⁵⁰ were the crown jewels of the TRIPS Agreement.⁵¹ Finally, the Agreement arguably flattened the world by adopting the hefty non-discrimination principles of National Treatment (NT) and Most-Favored-Nation (MFN).⁵²

These incredible changes to the international IP system were based almost entirely on a foundation of untested assumptions in both the IP and trade disciplines, with short-term sectoral interests and political expediency as the primary checks on the negotiating demands and eventual compromises agreed to at the Uruguay Round. With little to no knowledge, data or other evidence about the dynamic, long-term costs of IP harmonization for innovation and competitive growth, even for markets in the *developed*

⁵⁰ TRIPS Agreement, *supra* note 2, arts. 41–61.

⁵¹ See Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994) [hereinafter DSU] (outlining new rules for enforcing intellectual property and settling disputes); see, e.g., Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 277 (1997) (arguing that dispute settlement in the WTO, with adjustments, can be transferrable to controversies regarding intellectual property); see also Ruth L. Okediji, *Rules of Power in an Age of Law: Process Opportunism and TRIPS Dispute Settlement*, in 2 HANDBOOK OF INTERNATIONAL TRADE: ECONOMIC AND LEGAL ANALYSES OF TRADE POLICY AND INSTITUTIONS 42 (E. Kwan Choi & James C. Hartigan eds., 2005) [hereinafter Okediji, *Rules of Power*] (arguing that transferring the enforcement methods of the WTO to intellectual property rules outlined in the TRIPs Agreement is a marked benefit); Ruth Okediji, *TRIPS Dispute Settlement and the Sources of (International) Copyright Law*, 49 J. COPYRIGHT SOC'Y U.S.A. 585, 587 (2001) [hereinafter Okediji, *TRIPS Dispute Settlement*].

⁵² TRIPS Agreement, *supra* note 2, arts. 3–4.

countries, the TRIPS Agreement created a garish monument to the reality of sectoral bargains and domestic pay-offs that had long been characteristic of multilateral free trade bargains.⁵³ It did so by attempting to consolidate and freeze in time existing gains of the technological frontier and the IP legal baseline of developed countries.

The Uruguay Round Final Agreement⁵⁴ thus introduced two extraordinary realities to the world of international IP relations. First, the TRIPS Agreement portrayed IP regimes as insulated from demands for accountability to a larger global public law framework, thus framing domestic policy options as either “pro” or “anti” the objectives and requirements of TRIPS.⁵⁵ However, setting the mandatory TRIPS obligations and flexibilities in such binary terms ignores the significant amount of creativity that takes place in the carefully constructed spaces where control and access are effectively balanced. Further, it disregards the extent to which access to technology and cultural goods materially affects individual exercises of social and political rights vital to innovation and creativity. As leading IP commentators and economists have long argued, the relationship between the production and use of knowledge cannot be sensibly divorced from the equality-related aspirations that define most of the societies in which IP rights have been an important part of economic and political flourishing.⁵⁶

Second, the TRIPS Agreement established a bartering regime for the domestic public welfare goals associated with IP through the celebrated Dispute Settlement Understanding (DSU).⁵⁷ Now commonly known, exchanging heightened IP standards for concessions in trade, and even bargaining over *non-compliance* with

⁵³ Finger, *supra* note 28.

⁵⁴ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994; THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 2 (1999), 1867 U.N.T.S. 14, 33 I.L.M. 1143 (1994).

⁵⁵ See, e.g., Ruth L. Okediji, *WIPO-WTO Relations and the Future of Global Intellectual Property Norms*, 39 NETH. Y.B. INT'L L. 69 (2008) (arguing that disconnecting IP regimes from broader social and political contexts may lead to an unworkable and fragmented legal framework, citing the Uruguay Round Agreement as an illustration).

⁵⁶ See James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 L. & CONTEMP. PROBS. 33, 58-59 (2003); Yochai Benkler, *Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain*, 74 N.Y.U. L. REV. 354, 361-63 (1999).

⁵⁷ DSU, *supra* note 51; see also Okediji, *Rules of Power*, *supra* note 51; Okediji, *TRIPS Dispute Settlement*, *supra* note 51.

TRIPS or WTO obligations, has become a feature of modern IP relations.⁵⁸ Arguably, the possibility that member nations can pay for non-compliance with their international IP obligations suggests the incomplete nature of IP's most ambitious harmonization.

Certainly, the TRIPS Agreement has not produced the normative stability many imagined, desired or feared. This outcome is largely attributed to a spate of judicial opinions in the developed countries themselves where courts have repeatedly drawn limits on a variety of IP claims for reasons ranging from freedom of competition to human rights⁵⁹ and the utilitarian logic of the IP system.⁶⁰ A number of disputes before the WTO have also illustrated the degree to which developed countries differed in their own approaches to the various standards set forth in TRIPS.⁶¹ Ultimately, even the TRIPS text itself reflects incomplete harmonization. In several instances where legal or policy approaches between developed countries could not be overcome during negotiations, flexibility in how normative principles should be implemented was clearly expressed in the Agreement.⁶² Ongoing disputes⁶³ will continue to test the extent to which such

⁵⁸ The most recent example is the U.S.–Antigua dispute over the latter's failure to comply with a WTO ruling. Panel Report, *United States–Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/RW (Mar. 30, 2007); see also Panel Report, *United States–Section 110(5) of the US Copyright Act*, WT/DS160/R (June 15, 2000) [hereinafter *United States–Section 110(5)*] (noting that a Member may request authorization to suspend concessions or obligations under Article 22 of the DSU).

⁵⁹ See e.g., Case C-34/10, *Oliver Brüstle v. Greenpeace e.V.*, 2011 EUR-Lex CELEX LEXIS 2599 (Oct. 18, 2011) (banning patents on procedures involving the destruction of human embryos).

⁶⁰ See *Ass'n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2109 (2013) (explaining that without the rule that laws of nature are not patentable subject matter, "there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'" (quoting *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1301 (2012))).

⁶¹ *United States: Section 110(5)*, *supra* note 58; see also Convention on the Grant of European Patents art. 52, Oct. 5, 1973, 1065 U.N.T.S. 254, as revised Nov. 29, 2000, available at <http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/ar52.html> (defining patentable subject matter in the European Union); Patent Act, R.S.C. 1985, c. P-4 (Can.) (defining patentable subject matter in Canada).

⁶² See, e.g., TRIPS Agreement, *supra* note 2, art. 31 ("Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected[.]").

⁶³ One example is a current dispute under the North American Free Trade Agreement's (NAFTA) IP Chapter between Eli Lilly and the Canadian

flexibility remains a legal reality in multilateral IP relations.

1.3. *Patent Harmonization in the TRIPS Agreement and Competitive Equilibrium*

Most commentary on the TRIPS Agreement has focused on the minimum standards introduced, especially with respect to patents, where negotiations were the most difficult. Here, the Agreement established minimum standards of patentability rather than relying on domestic law, like the Paris Convention.⁶⁴ It expressly included process patents and, as noted by Professor Daniel Gervais, made any limits on patentable subject matter exceptional, thereby establishing protectability as the rule.⁶⁵ Moreover, a new rule not previously in the Paris Convention required patent applicants to describe inventions in a manner sufficiently “clear and complete” to ensure a person skilled in the art could replicate the invention.⁶⁶

government over the latter’s ‘promise of the patent’ doctrine. See Kazi Stastna, *Eli Lilly Files \$500M NAFTA Suit Against Canada over Drug Patents*, CBC NEWS (Sept. 13, 2014, 8:44 PM), <http://www.cbc.ca/news/business/eli-lilly-files-500m-nafta-suit-against-canada-over-drug-patents-1.1829854>. Most commentators agree that this flexibility has been an integral component of international IP law and policy, both regional and multilateral. See generally Jerome H. Reichman, Remarks at the 108th Annual Meeting of the American Society of International Law: Compliance of Canada’s Utility Doctrine with International Minimum Standards of Patent Protection (2014); 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 (2014).

⁶⁴ Paris Convention, *supra* note 1, art. 1.4 (“Patents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union . . .”).

⁶⁵ DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* (3d ed. 2008).

⁶⁶ TRIPS Agreement, *supra* note 2, art. 29. This is equivalent to the PHOSITA standard in the U.S. Despite the important disclosure function such a rule purports to advance, there are important normative challenges with constructing a hypothetical person skilled in the art that could carry out the invention and thus justify the information-for-protection bargain. See, e.g., Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1196 (2002) (noting that there are “several structural barriers that make it difficult for courts to accurately assess the level of skill in a complex technological art” and that judges and their law clerks are generally “at a rather serious disadvantage in trying to put themselves in the shoes of an ordinarily skilled scientist”); see also, e.g., Jonathan J. Darrow, *The Neglected Dimension of Patent Law’s PHOSITA Standard*, 23 HARV. J.L. & TECH. 227 (2009) (noting that the interpretation of PHOSITA has transformed from merely practicing an art to researching and discovering new

This development expressed the stylized bargain between the inventor and the public that historically animated patent law policy in industrialized countries.⁶⁷ Finally, the patent provisions included a general exception in Article 30,⁶⁸ modeled after the three-step test found in Article 9(2) of the Berne Convention.⁶⁹ Other important provisions include Article 31, which set safeguards on compulsory licensing, and Article 33, which harmonized patent terms to twenty years from the date of filing.⁷⁰ Importantly, TRIPS eliminated any discrimination based on where the invention occurred, including prohibiting discrimination based on whether the invention was locally produced or imported.⁷¹

Understanding the breadth of changes occasioned by the TRIPS Agreement in international patent law requires an appreciation of how non-discrimination norms recalibrated the competitive opportunities of technology-intensive firms. As noted earlier, the Agreement's chief accomplishments were to supply and tighten the standards not adequately covered by previous IP instruments, and to link these ambitious reforms of the multilateral system with the reality and pain of trade sanctions. However, the absence of strong institutions in most developing countries, the relatively thin policy contexts in which IP rights exist, and the stark power imbalances in global economic affairs justifiably raised developing countries' anxiety about potential adverse consequences of a one-way ratchet of IP rights.

In short, concerns about the baseline established in the TRIPS Agreement for terms of access to knowledge goods remain deeply problematic in development circles.⁷² These concerns are certainly

and improved methods within that art). In addition to being a peculiarly discipline-specific standard, it is hard to imagine that a construction exists that could meaningfully equalize the social tradeoffs of the patent bargain when an invention is sought in a developing country on the same terms as it may have been obtained in a developed country.

⁶⁷ *Id.*

⁶⁸ TRIPS Agreement, *supra* note 2, art. 30.

⁶⁹ Berne Convention, *supra* note 1, art. 9(2).

⁷⁰ TRIPS Agreement, *supra* note 2, arts. 31, 33.

⁷¹ *Id.* art. 27.1.

⁷² These concerns remain strong in copyright law, where the consequences of policy decisions restricting access to cultural or knowledge goods may not be felt for at least one generation. Prevailing economic wisdom suggests that suboptimal access to education, as an example, will produce an uneducated or ill-educated citizenry with corresponding challenges to a country's capacity to absorb technology, ultimately compromising its socio-economic trajectory. See ANTHONY CREE, ANDREW KAY & JUNE STEWARD, WORLD LITERACY FOUND., THE ECONOMIC AND SOCIAL COST OF ILLITERACY: A SNAPSHOT OF ILLITERACY IN A GLOBAL CONTEXT (2012),

justified in light of the unremitting efforts to further populate the multilateral arena with new IP agreements that seek to expand private control over critical inputs necessary for the supply of public goods. As I describe later, authentic legal innovation illustrates that the same space within the TRIPS Agreement that was constructed to give countries room to enhance or strengthen TRIPS obligations can be reconstituted to give countries room to experiment with tools designed to extract welfare gains from the local environments in which the Agreement must operate.⁷³ The ease with which the space to enhance IP rights is transformed into space to advance social welfare will be largely dependent on the nature of the tools of innovation that are utilized – legal institutions and processes, political fiat, policy instruments or appeals to higher normative claims.

2. INDUCING LEGAL INNOVATION IN INTERNATIONAL INTELLECTUAL PROPERTY RELATIONS

Part 2 provides an overview of various structural and substantive provisions of the TRIPS Agreement, focusing in particular on foundational patent limitations. Next, it provides a short explanation of how these provisions, along with the general infrastructure of the Agreement, have jointly defined the contours of legal innovation in developing countries.

2.1. *Legal Innovation and the Pillars of the TRIPS Agreement*

Three main features of the TRIPS Agreement appear, more than most, to have generated intense pressure on the welfare goals of WTO member states. These features are directly responsible for motivating legal innovation in the developing countries and resistance in some developed countries. They are: (i) non-

available at http://www.worldliteracyfoundation.org/The_Economic_&_Social_Cost_of_Illiteracy.pdf (linking illiteracy with difficulty in achieving technological literacy); Philip Stevens & Martin Weale, Nat'l Inst. of Econ. & Soc. Research, *Education and Economic Growth*, in INTERNATIONAL HANDBOOK ON THE ECONOMICS OF EDUCATION (Geraint Johnes & Jill Johnes eds., 2004), *available* at <http://core.kmi.open.ac.uk/download/pdf/7087576.pdf> (exploring the connection between education and economic growth).

⁷³ See *supra* Part 2.1.4.

discrimination principles, (ii) scope of protection and (iii) sanctions and enforcement.

2.1.1. The Flawed Architecture of the TRIPS Agreement: Non-Discrimination

It is well known that the international IP world prior to TRIPS was rife with protectionist measures in favor of domestic innovators and markets. Examples of historic and recent discrimination in procedural, administrative and evidentiary standards exist both in the U.S. and in other countries.⁷⁴ Such discrimination is explicitly justified as protectionist measures for local industries, but it is also justified by the important goal of promoting access to the class of knowledge goods at issue for the benefit of broader societal objectives.

The difficulty with a blunt non-discrimination rule as it exists in the TRIPS Agreement lies with the challenge of making ex ante determinations over which policy options designed to restore market equilibrium will, instead, distort it. Even in the advanced economies, there is significant uncertainty about when an exclusive right will serve purely monopolistic conditions, thus harming competition and markets, or when it will meaningfully reward

⁷⁴ Discrimination against foreign authors was a key feature of early U.S. copyright policy to aid in the development of a literate and educated society by ensuring cheap access to European literature. It was not until the Copyright Act of 1891 that the U.S. extended copyright protection to works of non-U.S. domiciled foreign authors, so long as their home countries accorded comparable protection to works of U.S. authors. The Act also extended protection to works of foreign authors if the U.S. joined an international agreement requiring reciprocal protection of the works of citizens from countries party to the agreement. However, protection for foreign authors and U.S. authors was conditioned on the production of their works within the U.S. (the so-called manufacturing clause). See Copyright Act of 1891, § 3, 26 Stat. 1106, 1007 (1891) (stating rules and policies governing whether a foreign author's work is capable of being copyrighted). Later amendments narrowed the scope of the manufacturing clause, but it remained in force until July 1, 1986. In more recent history, evidence of foreign inventive activity was excluded as prior art under the U.S. Patent Act. See 35 U.S.C. § 102(g)(2) (2006) (repealed 2011) (limiting the use of prior inventive activity to inventions "made in this country[,] i.e., the United States). However, such geographic discrimination was eliminated under the new first-to-file system of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

innovation and incentivize future investment in research and development (R&D).⁷⁵ The dynamic nature of technological change, prospects of market failure, and changes in other macroeconomic variables also mean that policy adjustments may themselves occasion unintended effects not easily susceptible to judgment as violations of the elusive competitive balance TRIPS sought to codify.⁷⁶

Articles 3 and 4 of the TRIPS Agreement dampen the ability of countries to engage in overt distinctions between foreign and domestic innovators and creators. The NT and MFN rules prohibit the application of different standards and normative rules with regard to the forms of IP available under domestic law and as between third countries and other WTO members.⁷⁷ An immediate consequence of the NT and MFN rules is that developing countries cannot respond to local innovation by adjusting IP rules to reflect development levels as the developed countries historically did.⁷⁸ Moreover, non-discrimination principles eliminate the possibility that policy initiatives can target local innovation exclusively without triggering fears of trade reprisals under the WTO. Of course, for the developed countries, such targeted policies are also proscribed, creating significant pressure to utilize forms of indirect favoritism through explicit regulatory schemes to promote domestic innovation, such as in the Bayh-Dole Act.⁷⁹

The fixed costs associated with investments in research and innovation are much more complex and difficult to pin down than instances of discrimination. Accordingly, preferential treatment for domestic innovators tends to remain unexamined for possible violations of minimum international standards. But even in those

⁷⁵ Stiglitz, *supra* note 5 (describing consequences of information asymmetries on the neoclassical market equilibrium model in different areas, and noting the need for government intervention in policies regulating knowledge acquisition).

⁷⁶ *Id.*

⁷⁷ TRIPS Agreement, *supra* note 2, arts. 3–4; *see also id.* art. 27.1.

⁷⁸ Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?*, 46 HOUS. L. REV. 1115 (2009) [hereinafter Reichman, *Twenty-First Century*] (noting that developed countries, such as the U.S., started with far lower levels of protection than exist today).

⁷⁹ Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified in 35 U.S.C. §§ 200–212) (permitting universities, non-profits, and small business to pursue ownership of inventions arising from federally-funded research). Historically, developing countries have lacked the capacity for similarly discriminatory regulatory schemes but this is changing. *See generally* Greg Shaffer, *How the WTO Shapes the Regulatory State* (Fourth Biennial Global Conference of the Soc’y of Int’l Econ. Law (SIEL), Working Paper No. 2014/29, 2014), available at <http://ssrn.com/abstract=2480664>.

cases where discriminatory claims arise from legal rules directed to address unique domestic interests, such as the European Community's challenge to the Fairness in Music Licensing Act,⁸⁰ developed economies have turned to a range of responses to deflect and defend against intrusive or disruptive obligations required by the TRIPS Agreement. Indeed, as I discuss later, when faced with political stakes, developed countries may simply choose noncompliance with international obligations as a way to satisfy domestic interest group demands. Whether developing countries have the political will to confront these instances of discriminatory policies in the developed countries is uncertain, even in cases where the developed nations' practice of favoring local innovators is a clear violation of the TRIPS non-discrimination principles.⁸¹ As I have argued before, pursuing enforcement of TRIPS obligations is not a politically costless exercise.⁸² Choosing not to confront such examples of discrimination could reflect political wisdom, preserve developing countries' own domestic discriminatory practices (or the opportunity to design them) and supply developing countries with strategic leverage in later battles with the developed countries.

2.1.2. *Legal Innovation and the Prohibition on Discrimination*

It should be no surprise that discriminatory treatment remains pervasive in multilateral IP relations. The TRIPS Agreement may have blunted the worst cases of discrimination between local and foreign inventors, but the mandate to treat innovators equally puts pressure on the very basis for competitive advantage in globally integrated markets. Countries at all levels of development have adopted a range of measures and practices to safeguard domestic industries from foreign competition and to distinguish domestic

⁸⁰ *United States: Section 110(5)*, *supra* note 58 (finding that 17 U.S.C. § 110(5), known as the Fairness in Music Licensing Act, permits, under certain conditions, the playing of radio and television music in public places without the payment of a royalty fee inconsistent with Articles 9(1) of the TRIPS Agreement).

⁸¹ *See, e.g.*, 35 U.S.C. §§ 200-212 (highlighting the explicit preference for domestic innovation in the Bayh-Dole Act - for example, see § 204, entitled "Preference for United States Industry"). This arguably is an impermissible subsidy under the GATT rules. *See* Agreement on Subsidies and Countervailing Measures, Apr. 15, 1994, Annex 1A, Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 14 (1994) (stating factors and rules to determine whether a subsidy is permissible).

⁸² Okediji, *Rules of Power*, *supra* note 51.

innovators – and by proxy domestic welfare concerns – from the constraints of the TRIPS Agreement. Some legislative initiatives, such as the U.S. expansion of prior user rights,⁸³ make explicit distinctions between U.S. and foreign inventors and are arguably a violation of TRIPS.⁸⁴ Other measures, such as a reduction in patent application fees, are less clearly objectionable.⁸⁵ Partly, it is *how* discrimination occurs that may make it more acceptable to trading partners rather than *whether* countries discriminate in favor of their citizens. The micro-entity fee reduction in the AIA, for example, applies to foreign natural persons but not foreign universities, even though U.S. universities can qualify for the discount.⁸⁶ This ingenious distinction is legal innovation at its finest; an international rule is arguably violated, but not in a way that would justify the economic or political costs of the WTO dispute process.

One clear consequence of the TRIPS non-discrimination norms, then, has been to divert discriminatory practices to institutional processes, similar to the micro-entity provision of the AIA mentioned above. Various examples occur in other IP subject matter categories and outside the legislative context. For example, in copyright cases, courts often adopt choice of law rules that prioritize the ability of American plaintiffs to exploit their works in foreign territories, regardless of the applicability of the copyright law of the foreign country.⁸⁷ Another example is the European Patent Office Enlarged Board of Appeals decision in *University Patents v. SmithKline Beecham*, which gave the facially neutral Article 55 of the European Patent Convention a somewhat discriminatory effect, as the provision's six month grace period is

⁸³ 35 U.S.C. § 273 (2012).

⁸⁴ Dennis Crouch, *How the AIA Violates TRIPS*, PATENTLY-O (Aug. 28, 2012), <http://patentlyo.com/patent/2012/08/how-the-aia-violates-trips.html> (noting that the expanded prior user rights are not available as a defense to a charge of infringement lodged by a U.S. university).

⁸⁵ *Id.*

⁸⁶ Leahy-Smith America Invents Act, Pub L. No. 112-29, § 11(g), 125 Stat. 284 (2011); *see also* Crouch, *supra* note 84 (arguing that discrimination between U.S. and foreign universities with respect to fee reduction may pass muster if it is construed as a subsidy. However, it is ambiguous whether the distinction between a fee discount and a subsidy matters in the context of unfair trade measures under WTO rules).

⁸⁷ *See* Graeme W. Austin, *Domestic Laws and Foreign Rights: Choice of Law in Transnational Copyright Infringement Litigation*, 23 COLUM.-VLA J.L. & ARTS 1 (1999) (contending that U.S. Courts utilize choice of law strategies in order to apply U.S. copyright law to claims of copyright infringement that occurred abroad).

measured from the *actual* filing date of the European Patent Application, not any earlier Paris Convention priority date to which an applicant is otherwise entitled.⁸⁸ Thus, applicants who file in a home country first and seek to take advantage of Paris Convention priority would not be able to benefit from the grace period.⁸⁹

Of course, diversion to institutional processes may backfire, requiring costly political actions. The Obama Administration's veto⁹⁰ of the International Trade Commission's exclusion order⁹¹ in the Samsung and Apple patent dispute⁹² is a recent example of a facially neutral procedure that potentially reflects significant discriminatory impetus in favor of a U.S. firm.⁹³ The complexity of regulating standard essential patents makes this particular instance difficult to present as an unequivocal case of discriminatory policy in favor of a local firm. But this is, of course, precisely the point of the argument: it is highly improbable that governments can tell *ex ante* whether a particular policy designed to address domestic

⁸⁸ Case G-3/98, *University Patents, Inc. v. SmithKline Beecham Biologicals SA* (Eur. Pat. Office Enlarged Bd. App. 2000), *available at* <http://www.epo.org/law-practice/case-law-appeals/pdf/g980003ex1.pdf>.

⁸⁹ *Id.* My thanks to Margo Bagley for pointing this out to me.

⁹⁰ Letter from Michael B.G. Froman, Ambassador, U.S. Trade Rep., to Hon. Irving A. Williamson, Chairman, U.S. Int'l Trade Comm'n (Aug. 3, 2013), *available at* [http://www.ustr.gov/sites/default/files/08032013 %20Letter_1.PDF](http://www.ustr.gov/sites/default/files/08032013%20Letter_1.PDF) (vetoing USITC's decision).

⁹¹ Certain Elec. Devices, Including Wireless Commc'n Devices, Portable Music and Data Processing Devices, and Tablet Computers, Inv. No. 337-TA-794 (June 4, 2013), *available at* http://www.usitc.gov/secretary/fed_reg_notices/337/337-794_notice06042013sgl.pdf (awarding in favor of Samsung and imposing a limited ban on importation and sales of certain Apple products).

⁹² Litigation between the two companies has expanded to over fifty disputes in ten different countries, with potential damages of over \$1 billion. *See, e.g., Australian Court to Fast-track Samsung Appeal on Tablet Ban*, REUTERS (Oct. 27, 2011, 12:59 AM), *available at* <http://www.reuters.com/article/2011/10/27/us-apple-samsung-australia-idUSTRE79Q0SN20111027> (chronicling the ongoing patent dispute between Samsung and Apple in Australia and other significant countries in 2011); Chloe Albanesius, *Every Place Samsung and Apple Are Suing Each Other*, PC MAG. (Sept. 14, 2011, 12:59 PM), *available at* <http://www.pcmag.com/article2/0,2817,2392920,00.asp> (noting the many countries where Samsung and Apple are currently engaged in patent disputes).

⁹³ This implicates a broader question of whether injunctive relief should be available for infringement of standard essential patents. *See generally* NAT'L RESEARCH COUNCIL, PATENT CHALLENGES FOR STANDARD-SETTING IN THE GLOBAL ECONOMY: LESSONS FROM INFORMATION AND COMMUNICATIONS TECHNOLOGY (2013).

market imperfections will, instead, confer unjustifiable market power or competitive advantage to local firms and sectors. Moreover, even within the traditional jurisprudence of the General Agreement on Tariffs and Trade (GATT), not every form of discrimination was proscribed.⁹⁴ The TRIPS Agreement offers no similar guidance to governments regarding how IP policy can be used explicitly in permissible discriminatory fashion, what forms such discrimination can take in order to accommodate local needs, what domestic market conditions may justify interventionist policies, and what the nature and timeframe of those policies should be.

Another approach to legal innovation with regard to the WTO non-discrimination rules (and indeed all other rules) is non-compliance with globally agreed norms as interpreted by the dispute settlement process. Non-compliance with a panel or Appellate Body decision could be viewed as a choice available to powerful states willing and able to risk the reputational (and other) effects of violations of agreed upon international rules. In regard to the TRIPS Agreement, however, non-compliance is better viewed as a form of legal innovation that, in the short term, internalizes the political costs of derogation from TRIPS obligations or transfers those costs to other policy arenas or agencies.⁹⁵

For example, in *U.S.-Section 211 Appropriations Act*,⁹⁶ otherwise known as the "Havana Club Rum" dispute, the EU filed a complaint alleging that § 211 of the 1998 Omnibus Appropriations Act was a violation of the TRIPS Agreement. This provision prohibited the registration or renewal in the United States of a trademark if it was previously abandoned by an owner whose business and assets had been confiscated under Cuban law.⁹⁷

⁹⁴ For example, GATT permits "the charging by a state enterprise of different prices for its sales of a product in different markets . . . provided that such different prices are charged for commercial reasons, to meet conditions of supply and demand in export markets." See Interpretative Note to the General Agreement on Tariffs and Trade, art. XVII.

⁹⁵ See, e.g., Ana Radelat, *Cuba Appeals to USPTO in Battle to Keep Control of Havana Club Rum Trademark*, CUBA NEWS (July 1, 2012), available at <http://www.thefreelibrary.com/Cuba+appeals+to+USPTO+in+battle+to+keep+control+of+Havana+Club+rum...-a0301479927> (discussing the conundrum faced by the United States Patent and Trademark Office (USPTO) when asked by Cuba to suspend cancellation of its trademark registration until the embargo is abolished).

⁹⁶ Appellate Body Report, *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R (Jan. 2, 2002), available at http://wto.org/english/tratop_e/dispu_e/cases_e/ds176_e.htm.

⁹⁷ *Id.* ¶¶ 3-7, at 1-5.

Moreover, no U.S. court could recognize or enforce the assertion of such rights.⁹⁸ Despite a finding by the WTO Appellate Body that § 211 violates the NT and MFN obligations of the TRIPS Agreement,⁹⁹ the U.S. has not complied with the ruling, which has in turn been the subject of on-going discussions¹⁰⁰ at the WTO TRIPS Council.¹⁰¹ The U.S. Supreme Court declined to hear the matter,¹⁰² leaving the question of U.S. compliance with its international obligations squarely with the political process. Such constructive disengagement with the multilateral process in the face of unyielding national political considerations is also a form of legal innovation.

2.1.3. *Legal Innovation and Scope of Patentable Subject Matter Under TRIPS*

On scope of IP subject matter, the most important change for patents under the TRIPS Agreement occurred via Article 27. This Article requires countries to make patents available in all fields of technology, provided that the inventions are “new, involve an inventive step and are capable of industrial application,” unless commercial exploitation of the invention would violate, among other things, “*ordre public* or morality”¹⁰³ Though this provision eliminated the possibility of significant limits on patentable subject matter, there is evidence that Article 27 is not an

⁹⁸ *Id.*

⁹⁹ *Id.* ¶¶ 258–68, at 74–77.

¹⁰⁰ See *EU, Cuba Spar with US over ‘Havana Club’ Rum*, EUBUSINESS, (June 25, 2013, 10:08 PM), <http://www.eubusiness.com/news-eu/wto-cuba-us-patent.pet> (last visited Oct. 1, 2014) (discussing controversy stemming from the US’ “failure to void a trademark law” despite the WTO striking down this law over 10 years prior to the controversy).

¹⁰¹ The TRIPS Council, which is open to all members of the WTO, is responsible for administering the TRIPS Agreement. *Work of the TRIPS Council*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm (last visited Oct. 9, 2014).

¹⁰² See generally *Havana Club Holding, S.A. v. Galleon S.A.*, 203 F.3d 116 (2d Cir. 2000).

¹⁰³ TRIPS Agreement, *supra* note 2, arts. 27(1)–(2). The TRIPS Agreement also contains additional exceptions such as diagnostic, therapeutic and surgical methods, plants, animals other than microorganisms, and “essentially biological processes.” *Id.* art. 27(3).

unbounded *carte blanche* to industry,¹⁰⁴ nor does it appear to inhibit constitutionally-driven policy limits to patents.¹⁰⁵ The U.S. Supreme Court has creatively interpreted important policy bases for limiting patent subject matter eligibility in controversial cases involving new technologies.¹⁰⁶ As I have argued elsewhere, the role of local institutions in balancing the incentive to commercialize innovation with interests underlying the distinctive policy goals of the patent system to promote the progress of society has been steadily redefined in recent years.¹⁰⁷ Indeed, leading patent law scholars have noted that there is increasingly less consistency among both developed and developing countries on issues of patent subject matter eligibility.¹⁰⁸ Consequently, important room for legal innovation exists within the context of Article 27.

Innovative responses by courts to an enlargement of patent

¹⁰⁴ GERVAIS, *supra* note 65, at 341-53.

¹⁰⁵ See, e.g., *Ass'n for Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2117 (2013) ("Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."); *Asero Ochieng v. Attorney-Gen.*, Petition No. 409 of 2009, (H.C.K.) (Kenya), available at <http://www.escri-net.org/sites/default/files/Judgment-Petition-No-409-of-2009%20Anti%20counterfeit%20case.pdf> (holding that the Anti-Counterfeit Act violated the Kenyan Constitution because it precluded access to essential medicines and therefore infringed the fundamental right of life, human dignity, and health).

¹⁰⁶ See, e.g., *Ass'n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2116 (2013) ("As we have recognized before, patent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'"); *Bilski v. Kappos*, 130 S. Ct. 3218, 3229 (2010) ("If a high enough bar is not set when considering patent applications of this sort, patent examiners and courts could be flooded with claims that would put a chill on creative endeavor and dynamic change."); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301 (2012) ("[T]here is a danger that the grant of patents . . . will inhibit future innovation premised upon them . . .").

¹⁰⁷ Ruth L. Okediji, *Public Welfare and the International Patent System*, in PATENT LAW IN GLOBAL PERSPECTIVE 1 (Ruth L. Okediji & Margo A. Bagley eds., 2014) [hereinafter Okediji, *Public Welfare*].

¹⁰⁸ See generally Margo A. Bagley, *Patent Barbarians at the Gate: The Who, What, When, Where, Why and How of US Patent Subject Matter Eligibility Disputes*, in PATENT LAW IN GLOBAL PERSPECTIVE 149, 150, 185 (Ruth L. Okediji & Margo A. Bagley eds., 2014) [hereinafter Bagley, *Patent Barbarians*]; Dan L. Burk, *Patent Law's Problem Children: Software and Biotechnology in Transatlantic Context*, in PATENT LAW IN GLOBAL PERSPECTIVE 187, 212 (Ruth L. Okediji & Margo A. Bagley eds., 2014).

rights have not been limited to the developed world. In a seminal case on the African continent, *Asero Ochieng v. Attorney-General*, the Kenyan High Court overturned a TRIPS-driven anti-counterfeiting statute¹⁰⁹ strongly supported by the United States and the pharmaceutical sector¹¹⁰ in order to preserve access to generic medicines.¹¹¹ The Court explained that the statute did not sufficiently distinguish between counterfeit drugs and generic medicines, thus undermining the fundamental human right to health (i.e., access to affordable life-saving drugs) guaranteed by the Kenyan Constitution.¹¹²

Outside the judicial context, biodiversity-rich countries such as China, India and Brazil have enacted laws that limit access to biological and genetic resources. These laws are specifically designed to encourage downstream IP owners to share the benefits gained from such resources with the providing country or indigenous communities.¹¹³ These innovations through the legislative process lie at the intersection of patent and environmental protection regimes, introducing new and critically important dimensions to national patent policies. Even further, they have injected new momentum into negotiations at WIPO for an international instrument mandating disclosure of source in patent applicants when genetic resources have been used in the inventive process.¹¹⁴ Although the precise scope of such an

¹⁰⁹ The Anti-Counterfeit Act, No. 13 (2008), KENYA GAZETTE SUPPLEMENT No. 97, 261 (Kenya).

¹¹⁰ See, e.g., Suleiman Mbatiah, *KENYA: Pharmaceutical Companies Pushing Anti-Counterfeit Law*, INTER PRESS SERVICE NEWS AGENCY (June 14, 2010), <http://www.ipsnews.net/2010/06/kenya-pharmaceutical-companies-pushing-anti-counterfeit-law> (last visited Oct. 9, 2014) (discussing the important role that multinational pharmaceutical companies played in Kenya's anti-counterfeit law); *World Anti-Counterfeit Day*, U.S. EMBASSY BLOG: NAIROBI (June 12, 2012), <http://blogs.usembassy.gov/nairobi/> (last visited Oct. 9, 2014) (discussing how the U.S. embassy in Kenya has worked to promote the Anti-Counterfeit Act).

¹¹¹ Asero Ochieng, Petition No. 409 of 2009, *supra* note 105.

¹¹² *Id.* ¶¶ 75–78.

¹¹³ Bagley, *Patent Barbarians*, *supra* note 108, at 176.

¹¹⁴ The IGC, created by WIPO in 2000, held its first session in 2001 to discuss IP protection for genetic resources (GRs), traditional knowledge (TK), and traditional cultural expressions (TCEs). World Intell. Prop. Org. [WIPO], Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore [hereinafter IGC], 1st Sess., WIPO Doc. WIPO/GRTKF/IC/1 (Apr. 30–May 3, 2001), available at http://wipo.int/meetings/en/details.jsp?meeting_id=4295. The IGC's current

international disclosure requirement remains highly contested, the geopolitical space already subject to a disclosure requirement is significant. If successful at WIPO, the work of the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) will represent a seminal international agreement springing from the national laws of the major emerging economies. It will also reinforce the growing need for multilateral IP norms to align with relevant international regimes or face being disrupted when those norms invariably become a part of national obligations in key countries. Already the Convention on Biological Diversity (CBD),¹¹⁵ which recognizes sovereign rights over natural resources in member states, and the recent entry into force of the Nagoya Protocol,¹¹⁶ have engendered a powerful set of international norms

mandate from WIPO is to work on “text-based negotiations . . . [to] reach[] [an] agreement on a text(s) of an international legal instrument(s) which will ensure the effective protection of GRs, TK, and TCEs.” WIPO, *Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)*, 43rd Sess., at Annex D, 2, WIPO Doc. WO/GA/43/14 (Aug. 14, 2013), available at http://wipo.int/edocs/mdocs/govbody/en/wo_ga_43/wo_ga_43_14.pdf. The most recent twenty-sixth session was held in February 2014. WIPO, IGC, 26th Sess., WIPO Doc. WIPO/GRTKF/IC/26 (Feb. 3–7, 2014), available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=31362. The latest draft text on genetic sources was submitted to the WIPO General Assembly in September 2014. See generally WIPO, *Consolidated Document Relating to Intellectual Property and Genetic Resources (Rev. 2)*, WIPO Doc. WIPO/GRTKF/IC/26 (Feb. 7, 2014), available at http://wipo.int/meetings/en/doc_details.jsp?doc_id=267381; see also WIPO, *IGC 26 Update: Negotiators Advance on Text on IP & Genetic Resources*, IGC NEWS (Feb. 12, 2014), http://www.wipo.int/tk/en/news/igc/2014/news_0004.html (last visited Oct. 9, 2014) (briefing the progress at the IGC’s 26th session). However, the Assemblies could not agree on any further progress on text-based work.

¹¹⁵ Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79.

¹¹⁶ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Oct. 29, 2010, UNEP/CBD/COP/DEC/X/1 (ensuring that indigenous or source communities are involved in the process by which materials and knowledge harvested from their environments are used); see also Catherine Saez, *Nagoya Protocol Enters into Force, Will Be Tested in Months to Come*, IP WATCH (Sept. 10, 2014), <http://www.ip-watch.org/2014/10/09/nagoya-protocol-enters-into-force-will-be-tested-in-months-to-come/> (explaining the defining features of the protocol and highlighting potential points of regulatory friction in the international community).

that govern an important area of technological developments.¹¹⁷

It is unlikely that the multilateral IP system can remain aloof from such muscular regimes. What is more, it is imprudent for the system to fail to consider how national innovation addressed through other regulatory processes can cohere with the IP framework. Regardless of whether the IGC process is successful, the rate of innovation and patent filings in countries such as India,¹¹⁸ China¹¹⁹ and Brazil¹²⁰ suggest that, whether or not knowledge from developing countries is formally internalized in the multilateral IP system, innovation based on traditional bodies of knowledge will invariably affect the strategies and practices of IP firms. The emerging environment of the Nagoya Protocol and implementing national rules will create a de facto integration of those norms in the multilateral IP framework in a manner that is unlikely to exalt IP rightsholders' interests over domestic welfare priorities.

2.1.4. *Legal Innovation and Enforcement*

Most scholars agree that the possibility of effective transnational IP enforcement was one of the major triumphs of the

¹¹⁷ The Nagoya Protocol establishes a legal framework for access and benefit sharing regimes to ensure that indigenous or source communities are involved in the complex web of innovation in which materials and knowledge harvested from their environments are used. Nagoya Protocol, *supra* note 116, art. 1 ("The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.").

¹¹⁸ See *Statistical Country Profiles: India*, WIPO STAT. DATABASE (last updated Mar. 2014), http://www.wipo.int/ipstats/en/statistics/country_profile/countries/in.html (noting that patent filings in India exceeded 18,173 applications).

¹¹⁹ See *Statistical Country Profiles: China*, WIPO STAT. DATABASE, http://www.wipo.int/ipstats/en/statistics/country_profile/countries/cn.html (last updated Mar. 2014) (noting that patent filings in China exceeded 561,377 applications).

¹²⁰ See *Statistical Country Profiles: Brazil*, WIPO STAT. DATABASE (last updated Mar. 2014), http://www.wipo.int/ipstats/en/statistics/country_profile/countries/br.html (noting that patent filings in Brazil exceeded 6,597 applications).

Uruguay Round,¹²¹ giving countries an opportunity to sanction violators of agreed provisions.¹²² The TRIPS Agreement has produced far less litigation between developed and developing countries than anticipated; indeed, most of the disputes have been between the developed countries, a trend few foresaw in 1994.¹²³ Further, among these disputes, compliance has remained uneven, especially by the U.S., which has yet to implement several panel reports to date.¹²⁴ This limited data suggests that neither determining what constitutes a TRIPS violation nor achieving enforcement on the ground is a simple task.

Several reasons may explain the relative inactivity around TRIPS enforcement and compliance. First, the enforcement provisions of TRIPS recognize the political costs of dispute settlement and thus explicitly promote settlement outside the DSU process.¹²⁵ Disputes between more powerful countries involve gap-filling exercises in which policy differences between the two are forcibly resolved, sometimes to provide political cover from domestic interest group politics that may have constrained appropriate compliance with the international norm.¹²⁶

Between two differently situated countries, legal innovation in dispute settlement may offer an opportunity to recalibrate particular expectations or secure promises that have yet to materialize in specific areas of international economic regulation. The *United States – Subsidies on Upland Cotton* dispute between Brazil and the United States, which resulted in permission for Brazil to suspend TRIPS obligations to the U.S., is an example of this strategic use of the DSU process.¹²⁷ Cotton subsidies have historically been a sensitive trade issue for the U.S.¹²⁸ Similarly,

¹²¹ See, e.g., Dreyfuss & Lowenfeld, *supra* note 51.

¹²² *Id.* at 277.

¹²³ See generally Okediji, *TRIPS Dispute Settlement*, *supra* note 51.

¹²⁴ Edward Lee, *Measuring TRIPS Compliance and Defiance: The WTO Compliance Scorecard*, 18 J. INTELL. PROP. L. 401, 411–12 (2011) (noting that the U.S. has yet to correct its nine-year-old violations arising out of the Section 110(5) and Havana Club Rum disputes).

¹²⁵ Okediji, *Rules of Power*, *supra* note 51.

¹²⁶ Ruth L. Okediji, *Toward an International Fair Use Doctrine*, 39 COLUM. J. TRANSNAT'L L. 75, 89 (2000).

¹²⁷ Panel Report, *United States – Subsidies on Upland Cotton*, WT/DS267/R (Sept. 8, 2004).

¹²⁸ Jasper Womach, CONG. RESEARCH SERV., RL 32442, COTTON PRODUCTION AND SUPPORT IN THE UNITED STATES 18 (2004) (“To stabilize and support farm incomes, in the face of highly variable prices caused by fluctuating world supply and demand conditions, major crops produced in the United States, including

Brazil has a strong cotton industry and, like other developing countries, a high interest in better access to agricultural markets as part of the Uruguay Round bargain.¹²⁹ Bringing the WTO complaint and defending it vigorously was a form of legal innovation in itself and likely politically positive for both countries, quite aside from the merits of the case. Though the stakes for both countries were sufficiently high to justify the costs of undertaking the DSU process, the risk of cross-retaliation against U.S. IP industries was significant for the United States, which ultimately reached a resolution with Brazil.¹³⁰

Cross-retaliation in the TRIPS context leaves considerable uncertainty about the general efficacy of the dispute settlement process for developing countries, most of which have no meaningful recourse to address WTO violations by the developed countries.¹³¹ Whether cross-retaliation is a credible threat at least partially depends on the relative influence of domestic interest groups and IP-intensive industries on lawmakers.¹³² If the political calculation of the complaining country is wrong about the clout of domestic IP industries in the offending country generally, or of a particular IP sector, permission by the WTO to cross-retaliate by suspending TRIPS obligations is unlikely to produce compliance

cotton, have been subsidized since the 1930s.”).

¹²⁹ See Carmen G. Gonzalez, *Institutionalizing Inequality: The WTO Agreement on Agriculture, Food Security, and Developing Countries*, 27 COLUM. J. ENVTL. L. 433, 451 (2002) (stating that Brazil advocated for the elimination of import restrictions and export subsidies).

¹³⁰ Steven Suppan, *Unconditional Surrender: The U.S.-Brazil Deal to End WTO-Authorized Retaliation*, INSTITUTE FOR AGRICULTURE AND TRADE POLICY, (Oct. 9, 2014) <http://www.iatp.org/blog/201410/unconditional-surrender-the-us-brazil-deal-to-end-wto-authorized-retaliation>.

¹³¹ See, e.g., Arvind Subramanian & Jayashree Watal, *Can TRIPS Serve as an Enforcement Device for Developing Countries in the WTO?*, 3 J. INT'L ECON. L. 403 (2000) (claiming that developing countries have few mechanisms for forcing developed countries to comply with WTO obligations); Frederick M. Abbott, *Cross-Retaliation in TRIPS: Options for Developing Countries* (Int'l Ctr. for Trade & Sustainable Dev. (ICTSD), Issue Paper No. 8, 2009), available at <http://ictsd.org/downloads/2009/06/cross-retaliation-in-trips.pdf> (supporting the claim that developing countries do not have equal bargaining power as developed countries to enforce WTO obligations); see also Gabriel L. Slater, *The Suspension of Intellectual Property Obligations Under TRIPS: A Proposal for Retaliating Against Technology-Exporting Countries in the World Trade Organization*, 97 GEO. L.J. 1365, 1377 (2009) (asserting that developing countries have few enforcement tools against developed countries, and advocating issuance of temporary compulsory licenses or suspension of TRIPS obligations as an alternative).

¹³² Peter K. Yu, *Are Developing Countries Playing a Better TRIPS Game?*, 16 UCLA J. INT'L L. & FOREIGN AFF. 311, 340 (2011).

by the offending country. Moreover, suspending TRIPS obligations is likely the least-preferred outcome of the WTO complainant.¹³³ The credibility of a cross-retaliation threat with regard to TRIPS can be limited by the sheer complexity of applying criteria developed for goods (such as the principle that the level of suspension be “equivalent”) to IP rights that are not easily susceptible to valuation.¹³⁴ Moreover, even where a developing country is able to satisfy the hefty requirements of DSU Article 22.3,¹³⁵ cross-retaliation under TRIPS can affect interests of innocent countries, further complicating the political risks of cross-retaliation as an enforcement option for the complainant.

Consider, for example, that ownership of copyright in a jointly authored work belongs to an American author and a Brazilian author. If the U.S. is the offending country, and cross-retaliation against it has been authorized, how would suspension of copyright protection in the work of joint-authorship by the WTO complainant proceed? Particularly with cultural goods designed to be easily de-anchored from their place of origin,¹³⁶ determining the national identity and value of the IP rights that can be suspended is itself an exercise requiring immense analytical investment.¹³⁷ In addition to the complexity of determining economic value and to which country ownership of an authorial work should be attributed, the ease with which digital goods transcend borders makes it exceptionally difficult to police where goods embodying

¹³³ See generally Abbott, *supra* note 131; Yu, *supra* note 132 (arguing that the negative economic impact caused from suspending obligations, and raising trade barriers, would likely be much greater on developing countries than on developed countries).

¹³⁴ Werner Zdouc, *Cross-Retaliation and Suspension Under the GATS and TRIPS Agreement*, in *THE LAW, ECONOMICS AND POLITICS OF RETALIATION IN WTO DISPUTE SETTLEMENT* 515 (Chad P. Bown & Joost Pauwelyn eds., 2010).

¹³⁵ DSU, *supra* note 51, art. 22.3.

¹³⁶ Compare *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 37 (2003) (holding that unaccredited copying of material from the public domain does not violate the Lanham Act, because “origin” of “goods” under Lanham Act § 43(a)(1)(A) refers to the producer of physical goods, rather than the creator of the underlying creative expression embodied within those goods), with 17 U.S.C. § 101 (2012) (defining a “United States work” to include works first published “simultaneously in the United States and a foreign nation . . .” and works published by United States nationals).

¹³⁷ Frederick M. Abbott, *Cross-Retaliation in TRIPS: Issues of Law and Practice*, in *THE LAW, ECONOMICS AND POLITICS OF RETALIATION IN WTO DISPUTE SETTLEMENT* 536 (Chad P. Bown & Joost Pauwelyn eds., 2010).

suspended IP rights may end up and how they can be distinguished in the market.¹³⁸

The difficulties posed by cross-retaliation are not insurmountable. In particular, Professor Frederick Abbott has explored particular kinds of IP that could be the focus of cross-retaliation.¹³⁹ Further, other benefits are obtainable from trade-retaliation measures if the country's market size makes such retaliation feasible.¹⁴⁰ Cross-retaliation holds seductive promise for developing countries seeking to enforce trade obligations against more powerful advanced economies. But, in choosing between enforcement strategies directed at IP-intensive economies, the power of IP industries, while significant, should not be the only factor in deciding what would work best among a range of retaliatory trade options.¹⁴¹ In short, the ineffectiveness of cross-retaliation confirms the structural weakness of the bargain that developing countries struck when they exchanged strong IP rights for yet unfulfilled promises of access to agriculture markets, all the

¹³⁸ A similar point was made by the arbitrators in the WTO arbitration known as "Bananas III" (European Community v. Ecuador). "[I]nterference with private property rights of individuals or companies may be perceived as more far reaching under the TRIPS Agreement, given the potentially unlimited possibility to copy phonograms or use other intellectual property rights." Decision by the Arbitrators, *European Communities – Regime for the Importation, Sale and Distribution of Bananas—Recourse to Arbitration by the European Communities Under Article 22.6 of the DSU* ("Bananas III"), WT/DS27/ARB/ECU, ¶ 157 (Mar. 24, 2000); see also Zdouc, *supra* note 134, at 524 (discussing the complexities of attributing intellectual property rights to specific countries under the TRIPS Agreement).

¹³⁹ See Abbott, *Issues of Law and Practice*, *supra* note 137, at 536 (explaining how to cross-retaliate against the TRIPS agreement).

¹⁴⁰ Joost Pauwelyn, *The Calculation and Design of Trade Retaliation in Context: What is the Goal of Suspending WTO Obligations?*, in *THE LAW, ECONOMICS AND POLITICS OF RETALIATION IN WTO DISPUTE SETTLEMENT* 34, 64-65 (Chad P. Bown & Joost Pauwelyn eds., 2010) (exploring the obvious retaliatory and compliance-inducing goals of WTO suspension, but also concluding that the practice achieves other "ancillary objectives" such as compliance, compensation or sanction).

¹⁴¹ *But see* Zdouc, *supra* note 134, at 525-26 (arguing that retaliation under TRIPS may have a "snowball effect" across a wide range of IP industries and galvanize a large enough coalition to pressure non-complying governments); see also Alan O. Sykes, *Optimal Sanctions in the WTO: The Case for Decoupling (and the Uneasy Case for the Status Quo)*, in *THE LAW, ECONOMICS AND POLITICS OF RETALIATION IN WTO DISPUTE SETTLEMENT* 339, 347-50 (Chad P. Bown & Joost Pauwelyn eds., 2010) (discussing the political calculations and consequences governments weigh when formulating retaliatory action plans).

while still dealing with a power (not law) driven trade system.¹⁴²

Dispute settlement entails significant economic costs¹⁴³ and the risk of loss can have consequences not wholly in line with the interests of a developed country complainant. In *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*,¹⁴⁴ the United States complained that China's customs measures for disposal of infringing goods did not comply with Article 59 of the TRIPS Agreement, which required that "competent authorities shall have the authority to order the destruction or disposal of infringing goods"¹⁴⁵ The Chinese measures allowed seized goods to be donated to social welfare organizations, sold to the rightsholder or auctioned as a last resort.¹⁴⁶ The United States objected to these practices, arguing that "Article 59 requires full authority to be granted to dispose of or *destroy* confiscated infringing goods"¹⁴⁷ The WTO Panel rejected the United States' argument, stating that the language "shall have the authority" does not mean the authority must be exercised in a particular way, and it certainly does not require it to be exercised in the way the United States argued.¹⁴⁸ Although the United States won on the other issue before the Panel,¹⁴⁹ the real goals of weakening China's regulatory and interpretive discretion and eliminating channels by which infringing goods could remain in circulation in China, and possibly beyond, were not achieved.

¹⁴² See generally JOHN H. JACKSON, *THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS* (2d ed. 1997).

¹⁴³ See Timothy Stostad, *Trappings of Legality: Judicialization of Dispute Settlement in the WTO, and Its Impact on Developing Countries*, 39 CORNELL INT'L L.J. 811 (2006) (discussing the costs associated with dispute settlement procedures and the barriers these costs place on poorer countries).

¹⁴⁴ Panel Report, *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009) [hereinafter *China – Measures*].

¹⁴⁵ TRIPS Agreement, *supra* note 2, art. 59.

¹⁴⁶ *China – Measures*, *supra* note 144, ¶ 7.194.

¹⁴⁷ *Id.* ¶ 7.199 (emphasis added).

¹⁴⁸ *Id.* ¶ 7.238.

¹⁴⁹ *Id.* ¶ 7.139 (finding that the Chinese Copyright Law Article 4(1) was inconsistent with Article 5(1) of the Berne Convention (1971), as incorporated by Article 9.1 of the TRIPS Agreement, which requires that foreign copyright owners receive the same level of protection as domestic owners of similar protected works).

2.2. *The Reality of TRIPS Enforcement: Underwhelming and Political*

Despite initial excitement about the enforcement prospects of the TRIPS Agreement, “the reality of sovereign interaction is that diplomacy, power and domestic politics remain potent forces in determining whether and how states will comply with their international obligations.”¹⁵⁰ Binding dispute settlement under TRIPS was designed to facilitate greater consistency, predictability and enforcement of international IP norms. But, the process established by the DSU encourages countries to settle disputes through diplomatic channels to avoid unduly straining the WTO system. This practice has in turn produced inconsistent, non-transparent and unpredictable outcomes even between countries with similar alleged violations.¹⁵¹ Moreover, as noted earlier, private bartering over TRIPS violations has been an important component of contemporary trade relations, especially among developed countries in disputes with one another,¹⁵² while disputes between developed and developing countries have seemed more likely to invoke the full gamut of the formal DSU process.¹⁵³ Developed countries have leveraged the DSU process to exert pressure on developing countries and extract compliance in ways that escape the scrutiny of the international community.¹⁵⁴

¹⁵⁰ Okediji, *TRIPS Dispute Settlement*, *supra* note 51, at 634.

¹⁵¹ *Id.* at 617.

¹⁵² See, e.g., *United States – Section 110(5)*, *supra* note 58 (outlining the United States’ measures affecting the cross-border supply of gambling and betting services and the United States failure to comply with DSB recommendations and rulings).

¹⁵³ See Stostad, *supra* note 143, at 830 (stating that the WTO has increased the probability of disputes being filed against developing countries by 4.7 times).

¹⁵⁴ Okediji, *TRIPS Dispute Settlement*, *supra* note 51, at 617. Even mere threats of invoking the DSU process have accomplished compliance in some developing countries. See Rufus H. Yerxa & Demetrios J. Marantis, *Assessing the New WTO Dispute System: A U.S. Perspective*, 32 INT’L L. 795, 808–09 (1998) (discussing the effectiveness of threatening to file a case to induce WTO-consistent behavior from another country). Developing countries are often at a bargaining disadvantage because they rely on developed countries for financial aid and military assistance. See Hansel T. Pham, *Developing Countries and the WTO: The Need for More Mediation in the DSU*, 9 HARV. NEGOT. L. REV. 331, 347 (2004) (discussing the theoretical benefits of the DSU’s objective goal of limiting dispute to legal issues and insulating developing countries from political pressure).

The fact that the DSU emphasizes opt-out possibilities and encourages extra-legal resolution of disputes suggests that the reality of diplomacy and politics as vital components of cooperative relations between sovereign states was not lost to the TRIPS negotiators.

From 2005 to 2011, 419 total WTO challenges were brought under the DSU process, of which there were only 29 IP challenges. Twenty of the IP challenges were against developed countries.¹⁵⁵ As Professor Pauwelyn notes, the expectation of an enforcement onslaught against developing countries has not materialized; only 9 of the 27 TRIPS disputes were North-South cases.¹⁵⁶ Finally, of all the IP disputes, only 8 matters were pursued to a WTO decision, and all but one found a violation.¹⁵⁷ These statistics confirm that (1) TRIPS enforcement was neither the crowning triumph nor the devastating disaster that some critics predicted; and (2) that diplomacy, politics and the developed-developing country power imbalance remain strong factors in TRIPS enforcement and compliance, but that the balance of strategic interests could flow to either party. There is no set stage or script that would advantage one party over another, and legal innovation by courts and IP agencies reflect the capacity to reset the normative global IP balance, even if indirectly.

In sum, except in a few instances, dispute settlement under TRIPS has not proven to be an outright victory for developed countries as might have been anticipated in 1994. Instead, this crown jewel of the demandeur countries has become a potentially valuable tool to *all* countries, opening explicit room for discretion and legal innovation even in areas that the TRIPS Agreement was not intended to explicitly address or proscribe.

¹⁵⁵ Lee, *supra* note 124, at 405; see also Joost Pauwelyn, *The Dog that Barked but Didn't Bite: 15 Years of Intellectual Property Disputes at the WTO*, in RESOLUTION OF INTELLECTUAL PROPERTY DISPUTES (Jacques de Werra ed., 2010), available at <http://ssrn.com/abstract=1708026> (comparing high expectations with the less successful reality of settling IP disputes under TRIPS).

¹⁵⁶ Pauwelyn, *supra* note 155, at 6 ("Secondly, the onslaught of IP enforcement by developed countries against developing countries did not materialize. Only 9 of the 27 TRIPS disputes (and 4 of the 9 TRIPS panels) were North-South cases.").

¹⁵⁷ *Id.*

2.3. *The Triumph of Legislation in Developing Countries*

If dispute settlement and compliance have been unremarkable in the past twenty-one years, what change did the TRIPS Agreement effect? Among most developing countries, TRIPS-required IP legislation was adopted relatively promptly (some may argue too quickly in many cases).¹⁵⁸ This included pharmaceutical patent legislation even in countries whose generic industries were most threatened by the new global norms, namely Brazil and India.¹⁵⁹

Prior to the TRIPS Agreement, Brazil provided very limited patent protection for pharmaceutical products and processes.¹⁶⁰ Its prompt compliance with the new international rules allowed pharmaceutical patent owners to start filing applications in Brazil immediately. These applications were largely ignored until 2001 when new legislation mandated regular examination of chemical and pharmaceutical *product* patents.¹⁶¹ The same law, however, declared that pharmaceutical and chemical *process* applications would be rejected, because TRIPS only referred to product patents.¹⁶² A separate law provided that applications based on foreign pharmaceutical product patents would be granted without

¹⁵⁸ SISULE F. MUSUNGU & CECILIA OH, COMM'N ON INTELLECTUAL PROP. RIGHTS, INNOVATION & PUB. HEALTH, WORLD HEALTH ORG., THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 7-8 (2005) (stating that a majority of developing countries had established patent legislation meeting TRIPS requirements prior to the deadline).

¹⁵⁹ India's initial efforts to implement the mailbox system generated the first TRIPS dispute. See Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997) (recommending India bring its regime up to TRIPS standards). The United States brought a claim against India alleging that it had failed to implement the required legislation. *Id.* A WTO Appellate Body decision agreed. *Id.* For a compelling analysis of this seminal decision, see Jerome H. Reichman, *Securing Compliance with the TRIPS Agreement After US v. India*, 1 J. INT'L ECON. L. 585 (1998).

¹⁶⁰ Claudia Schulz & Mark Wu, *The TRIPS Agreement and Intellectual Property Protection in Brazil*, 98 AM. SOC'Y INT'L L. PROC. 100, 100 (2004).

¹⁶¹ *Id.*

¹⁶² Lei No. 10.196 de 14 de Fevereiro de 2001 (Braz.); see also Schulz, *supra* note 160, at 100-01 (describing the difficulty of the implementation in Brazil of the TRIPS Agreement, which should have been incorporated immediately into domestic law, but was not, due to misunderstandings at the Brazil Patent and Trademark Office).

a secondary novelty requirement.¹⁶³ However, Brazil did maintain a local working requirement, which authorizes compulsory licensing if a patentee fails to work the patent locally.¹⁶⁴ The U.S. alleged this local working aspect of Brazilian patent law violated the TRIPS Agreement and brought a complaint pursuant to the DSU.¹⁶⁵ Brazil argued that the provisions were necessary to help it protect against the threat of HIV/AIDS consistent with the terms of the TRIPS Agreement.¹⁶⁶ The United States later withdrew the complaint,¹⁶⁷ leaving the issue an open question of international patent law¹⁶⁸ and adding to the possible innovative responses to deal with specific national interests.¹⁶⁹ Indeed, the United States' withdrawal could have been motivated by a political calculation that the risks of a WTO finding that local working requirements are TRIPS consistent would only encourage other countries to adopt a similar domestic policy.¹⁷⁰

¹⁶³ Schulz, *supra* note 160, at 101.

¹⁶⁴ *Id.*

¹⁶⁵ Request for Consultations by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/1 (June 8, 2000).

¹⁶⁶ Notification of Mutually Agreed Solution, *Brazil – Measures Affecting Patent Protection*, WT/DS199/4 (July 19, 2001); *see also* GERVAIS, *supra* note 65, at 340 (“During the dispute, Brazil defended their ‘local working’ requirement as necessary to ensure access to medicines, especially in light of the threat HIV/AIDS posed to Brazil.”) (footnote omitted).

¹⁶⁷ Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT’L L. 365, 366 n.4 (2002).

¹⁶⁸ The Paris Convention allowed member states to impose compulsory licenses for failure to work a patent after a delay. Paris Convention, *supra* note 1, art. 5A.

¹⁶⁹ It seems clear that local working requirements are not a violation of the prohibition of discrimination under Article 27(1). *See* GERVAIS, *supra* note 65, at 340 (“It can be inferred from art. 27(1) that importation must be accepted among the WTO members [sic] states as a legally effective working of a patent under national law.”).

¹⁷⁰ A U.S. government report states that the reason for withdrawal was a commitment from Brazil to provide advance notice and consult with the U.S. if it chooses to issue a compulsory license for failure to work a patent. *See* U.S. TRADE REP., THE 2005 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 33 (2005) (discussing intellectual property rights protection for patents and trademarks). Arguably, this underscores the real interest of the United States: constraining unilateral exercises of discretion even when they are within the permissible boundaries of the TRIPS Agreement.

Like Brazil, the pre-TRIPS patent law adopted in India in 1970 contained an express prohibition on pharmaceutical product patents, but allowed limited duration pharmaceutical process patents.¹⁷¹ As a result, India became a globally recognized producer of low-priced generic pharmaceuticals,¹⁷² supplying its own vast national market and much of the developing world as well. When India joined the WTO in 1995, it made three major amendments to the Patents Act of 1970 to comply with its TRIPS obligations.¹⁷³ The first allowed applicants to file for pharmaceutical product patents for which they could be awarded exclusive marketing rights for five years from the date of the patent grant.¹⁷⁴ The second amendment provided for a twenty-year patent term, reversal of the burden of proof for process patent infringement from the patentee to the alleged infringer, and modifications to compulsory licensing requirements.¹⁷⁵ In 2005, a third amendment offered patent protection to pharmaceuticals and made India “substantially compliant with TRIPS.”¹⁷⁶

Although some TRIPS proponents expressed skepticism as to whether developing countries would ignore or fail to enforce TRIPS requirements,¹⁷⁷ developing countries have not ignored the legislation requirements, and indeed, many have exceeded them.¹⁷⁸ Even in Brazil and India, where national development strategies were purposefully designed around the absence of pharmaceutical patent protection, legislation consistent with TRIPS obligations has been adopted and foreign rights are being exercised in local

¹⁷¹ Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1576 (2009).

¹⁷² *Id.* at 1578.

¹⁷³ V.K. Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health*, 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 323, 330-31 (2012).

¹⁷⁴ *Id.* at 330.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.* at 331.

¹⁷⁷ See, e.g., Charles S. Levy, *Implementing TRIPS – A Test of Political Will*, 31 L. & POL'Y INT'L BUS. 789, 789 (2000) (arguing that TRIPS compliance requires adopting an entirely new body of law for developing countries, impacting whether developing countries will conform and whether developed countries will hold nonconforming developing countries accountable).

¹⁷⁸ See *infra* notes 183–187 and accompanying text (discussing TRIPS-plus provisions in developing countries).

institutions. Despite being the object of criticism and threats by the U.S., the reality is that since making its law TRIPS-compliant, India has issued many pharmaceutical patents. The same is true for Brazil. Legislative compliance with the TRIPS Agreement, to the dismay of TRIPS critics, has been widespread even in the least developed countries, which could have benefited from WTO extensions.¹⁷⁹

In short, global friction over TRIPS implementation has not been focused on whether compliant legislative changes have been adopted. Rather, the friction is focused on the ways in which TRIPS flexibilities have been utilized, be they in the governing statutes, in the courts or in administrative agencies, which, as the following section suggests, are poised to be the leading laboratories of legal innovation.

3. THE REALITY OF TRIPS: INSTITUTIONS OF DEVELOPMENT AND THE CHALLENGE OF COHERENT IMPLEMENTATION

Part 3 presents three case studies of legal innovation in three countries: India, Brazil and Malta. Together, these nations highlight how legal innovation can be achieved through judicial processes, institutional action or industrial policy. Ultimately, each of these case studies exemplifies the role of legal innovation in shaping national development strategies and domestic policy prerogatives. Lastly, Part 3 presents a short explanation of the manner in which developed countries have resisted innovative efforts in the developing world and the justifications for that hostility.

3.1. *Legal Innovation in the Developing Countries*

Following the TRIPS Agreement, commentators voiced concerns that stronger IP minimum standards could constrain development, reduce employment and economic growth, threaten public health interests and undermine access to essential

¹⁷⁹ See, e.g., DEERE, *supra* note 8 (“Over a third of the WTO’s 106 developing country members included a broad range of TRIPS-plus provisions in their laws. Over half of the countries in this TRIPS-plus group were LDCs—the same countries that the economic literature anticipates would adopt the lowest levels of IP protection.”).

technologies and knowledge.¹⁸⁰ Critics warned that heightened IP standards would lead to devastating price increases in many critical imported technologies, such as seeds, medicines and educational materials.¹⁸¹ Furthermore, limiting the ability of these countries to reverse-engineer, adapt and build upon existing technologies from developed countries could impede national industrial development.¹⁸² Beyond these concerns, developing countries faced significant financial and administrative challenges in implementing and enforcing the new standards. Although TRIPS provides several so-called “flexibilities” that could have ameliorated some of these concerns, many developing countries did not take advantage of them—at least not explicitly. Instead, many countries established laws exceeding the minimum requirements of TRIPS, colloquially known as “TRIPS-plus” provisions.¹⁸³ Counterintuitively, nations with the least flexibility and the highest levels of TRIPS-plus protection are often the least-developed countries.¹⁸⁴

A large body of scholarship suggests that countries deviated from their own local interests due to intense political, economic

¹⁸⁰ See, e.g., *id.* at 9–10 (explaining that in advocating for weaker IP minimum standards, “developing countries sought to employ the same strategies of copying and reverse engineering that had served developed countries at similar stages of development” and that “[f]or the poorest and smallest countries . . . the potential economic returns of higher IP protection were a . . . distant prospect”); Molly Land, *Rebalancing TRIPS*, 33 MICH. J. INT’L L. 433, 435–45 (2012) (arguing that TRIPS limits countries’ ability to “foster innovation and protect human health and welfare”) (citation omitted); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 828 (2007) (contending that TRIPS requires countries “to adopt one-size-fits-all legal standards that ignore their local needs, national interests, technological capabilities, institutional capacities, and public health conditions.”).

¹⁸¹ DEERE, *supra* note 8, at 9; THE FUTURE CONTROL OF FOOD: A GUIDE TO INTERNATIONAL NEGOTIATIONS AND RULES ON INTELLECTUAL PROPERTY, BIODIVERSITY AND FOOD SECURITY (Geoff Tansey & Tasmin Rajotte eds., 2008); Ellen F.M. ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT’L L. 27, 41 (2002); Mohammad Towhidul Islam, *Implications of the TRIPS Agreement in Bangladesh: Prospects and Concerns*, 6 MACQUARIE J. BUS. L. 1, 6 (2009).

¹⁸² *Id.*

¹⁸³ *Id.* at 13 (“Over a third of the WTO’s 106 developing country members included a broad range of TRIPS-plus provisions in their laws.”).

¹⁸⁴ *Id.* (“Over half of the countries in this TRIPS-plus group were LDCs—the same countries that the economic literature anticipates would adopt the lowest levels of IP protection.”); see also *id.* at 100–02 (presenting in tables and graphs a negative trend between the strength of IP protection and countries’ GDP per capita as of 2003). Many of these countries were beneficiaries of the largesse of the TRIPS technical assistance described in Part 1.

and trade-related pressures from developed countries.¹⁸⁵ For example, bilateral trade and investment agreements were offered to developing countries in exchange for agreements to forego flexibilities or implement TRIPS-plus standards.¹⁸⁶ In other cases, where bilateral negotiations failed, developed countries resorted to unilateral coercion through threats of trade sanctions, diplomatic engagement and industry pressure from multinational corporations.¹⁸⁷

Despite a global environment fraught with tension and deep turmoil over the use of TRIPS flexibilities, it is unlikely that development gains can rapidly accrue based merely on adoption of normative rules in national laws, necessary though they may be. Some developing countries appear to have recognized this and embraced the need for progressive responses to TRIPS obligations.¹⁸⁸ Certain aspects of the political bureaucracy in a number of developing countries, for example, have cleverly imposed limits on national IP agencies that had proven more easily captured by the technical assistance bounty offered through a variety of transnational actors.¹⁸⁹ Further, local agents in developing countries, sometimes motivated by domestic turf battles rather than altruistic concerns over misguided IP policies, formed collaborative partnerships with the access to knowledge movement in order to exert their own pressures in the national policy sphere.¹⁹⁰ The capacity to recognize and curtail forum-shopping by TRIPS entrepreneurs is a development that has been aided in part by the access to knowledge network¹⁹¹ and the highly

¹⁸⁵ See, e.g., *id.* at 104, 114–16, 150–51 (chronicling a multitude of pressures that caused developing countries to adopt strong IP standards against their economic interests).

¹⁸⁶ *Id.* at 150–155; Land, *supra* note 180, at 442, n.45.

¹⁸⁷ DEERE, *supra* note 8, at 159–164; see also Okediji, *Public Welfare*, *supra* note 107, at 58, n.30 (explaining how developing countries have used TRIPS-plus requirements over other types of agreements).

¹⁸⁸ See *infra* Part 4.2–3.

¹⁸⁹ See Deere, *supra* note 8 (describing ways in which IP agencies in developing countries are influenced by foreign organizations and rightsholders). See also Carolyn Deere, *The Politics of Reform in Developing Countries*, in *INTELLECTUAL PROPERTY AND SUSTAINABLE DEVELOPMENT: DEVELOPMENT AGENDAS IN A CHANGING WORLD* 21, 30–32 (Ricardo Meléndez-Ortiz & Pedro Roffe eds., 2009); Pedro Paranaguá, *Brazil's Copyright Law Reform: Tropicália 3.0?* 54–59 (2014) (unpublished S.J.D. thesis, Duke University School of Law) (on file with author) (describing the influential role of rightsholders and copyright agencies in Brazil's copyright reform process).

¹⁹⁰ Kapczynski, *supra* note 10, at 825–39; Deere, *supra* note 8, at 30–32.

¹⁹¹ See, e.g., Letter to Francis Gurry, Dir. Gen., World Intell. Prop. Org. (Feb.

visible influence of IP interest group pressure on domestic policies in the developed countries. Institutions and new processes are therefore emerging in developing countries to challenge the dominant narrative of the substantive provisions of the TRIPS Agreement.

Three case studies suggest the rise of legal innovation to address the welfare challenges related to TRIPS implementation and compliance. These cases did not arise from the shadows of flexibilities, but rather from the sunlight of hard doctrine.

3.1.1. India – An Example of Judicial Innovation

After India's independence from Britain in 1947, it was left with a patent system that favored foreigners and a health care system dependent on imported medications sold at a premium.¹⁹² In response, India's leaders demanded changes to the patent system. A committee was appointed in 1948 to review patent laws to ensure conformity with identified national interests.¹⁹³ Based on recommendations from the committee report, the 1911 Patents Act was amended in relation to the working of inventions and compulsory licensing.¹⁹⁴ A second report, issued in 1959, recommended radical modifications of existing patent laws, emphasizing the need to spur domestic innovation and to avoid international pressure to join international conventions requiring national treatment.¹⁹⁵

7, 2012), available at http://www.ghwatch.org/sites/www.ghwatch.org/files/AfricaIPSummit2012_0207.pdf (100 signatories, mostly NGOs, expressing "significant disappointment" regarding the content and organization of U.S.-backed Africa Intellectual Property Forum: Intellectual Property, Regional Integration and Economic Growth in Africa); William New, *US, WIPO Training Programme on IP Rights in Africa Comes Under Fire*, INTELL. PROP. WATCH (Dec. 2, 2012), <http://www.ip-watch.org/2012/02/12/us-wipo-training-programme-on-ip-rights-in-africa-comes-under-fire/> (detailing international reaction to the proposed African IP summit).

¹⁹² 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, 509-10 (2007).

¹⁹³ *Id.* at 510-11.

¹⁹⁴ *Id.* at 511; see also *History of Indian Patent System*, INTELL PROP. INDIA, <http://ipindia.nic.in/ipr/PatentHistory.htm> (last visited Sept. 18, 2014) (outlining the history of the Indian patent system from 1856-2005).

¹⁹⁵ Mueller, *supra* note 192, at 511-12; *History of Indian Patent System*, *supra*

In 1970, India enacted a national patent law prohibiting patents on pharmaceutical products.¹⁹⁶ By 1979, the number of patent applications by foreign filers had decreased to less than a quarter of the number filed in 1968.¹⁹⁷ Conversely, the new patent law led to a significant increase in Indian generic drug manufacturing and a dramatic decline in the price of medicines sold in India.¹⁹⁸ India soon became known as a “pirate” or “copycat” nation because generic drug companies could (and did) legally copy pharmaceutical products patented outside of India.¹⁹⁹ The ability to copy pre-existing pharmaceuticals, with only minimal R&D investments and no patent royalties to pay, allowed these companies to produce drugs far cheaper than those of any foreign competitor.²⁰⁰

In this patent-free environment, the Indian generics industry soared and drug prices plummeted, forcing many multinational drug companies to leave India.²⁰¹ The number of pharmaceutical facilities skyrocketed, with over twenty thousand Indian companies supplying ninety-five percent of the pharmaceutical market in that country. This resulted in huge boosts to India’s

note 194.

¹⁹⁶ Mueller, *supra* note 192, at 512–13.

¹⁹⁷ *Id.* at 513–14; Kapczynski, *supra* note 171, at 1577–78.

¹⁹⁸ Mueller, *supra* note 192, at 514.

¹⁹⁹ See, e.g., Donald G. McNeil, Jr., *Selling Cheap ‘Generic’ Drugs, India’s Copycats Irk Industry*, N.Y. TIMES (Dec. 1, 2000), <http://www.nytimes.com/2000/12/01/science/01PIRA.html> (describing the emergence of an industry of pharmaceutical piracy due to India’s relaxation of patent laws); see also Mueller, *supra* note 192, at 514 (“The eventual economic effect of the India Patents Act, 1970, was a dramatic increase in domestic generic drug manufacturing and a sharp decline in the price of medicines sold in India The ‘pirate’ label was unduly pejorative, however, and contradicted the basic principle of territoriality in patent law. No violations of any foreign patent laws occurred so long as the copied drugs were made and sold only in India . . .”).

²⁰⁰ David K. Tomar, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT’L L.J. 579, 584 (1999) (noting that India could produce a drug for as little as \$90 million, compared to a price tag of at least \$300 million in Western countries in the late 1990s); see also B.K. KEAYLA, *Conquest by Patents*, in TRIPS AGREEMENT ON PATENT LAWS: IMPACT ON PHARMACEUTICALS AND HEALTH FOR ALL 9 (1998) (describing how, in 1998, the brand-name antacid Zantac was being sold in the U.S. for more than one hundred times the price of the Indian generic version).

²⁰¹ B.K. KEAYLA, *Conquest by Patents*, in TRIPS AGREEMENT ON PATENT LAWS: IMPACT ON PHARMACEUTICALS AND HEALTH FOR ALL 9 (1998).

economy and employment rates, with pharmaceutical companies directly employing five million, and another twenty-four million indirectly.²⁰²

Over time, India's pharmaceutical industry not only expanded production, but also grew more technically sophisticated.²⁰³ The industry developed expertise in reverse engineering drugs and rapidly diversified.²⁰⁴ However, because the manufacturing boom resulted largely from copying existing drugs, it did not result in increased innovation in new drugs.²⁰⁵ Today, R&D investment by Indian firms appears to be on the rise, although relative to Western companies, this investment is still minimal.²⁰⁶ Despite positive signs in the Indian pharmaceutical industry,²⁰⁷ commentators have expressed concern that the critical dominance of local firms could be lost in a recent wave of mergers and acquisitions purposefully designed to eliminate Indian generic competition in global markets.²⁰⁸

The active role of the Indian judiciary in IP cases makes this outcome unlikely. A highly controversial decision by the Indian

²⁰² KPMG, THE INDIAN PHARMACEUTICAL INDUSTRY: COLLABORATION FOR GROWTH, INDUSTRIAL MARKETS (2006) [hereinafter KPMG, INDIA], available at <http://www.in.kpmg.com/pdf/indian%20pharma%20outlook.pdf>.

²⁰³ Kapczynski, *supra* note 171, at 1578.

²⁰⁴ *Id.*

²⁰⁵ Mueller, *supra* note 188, at 515.

²⁰⁶ *Id.* at 516, n.132 (remarking on the minimal R&D investment levels for Indian drug companies in the 1990s – around one to two percent of total revenue – compared to an average of fifteen percent among Western companies); *id.* at 537–38 (identifying that while small Indian pharmaceutical firms still rely solely on reverse-engineering drugs, top Indian generic companies have increased their R&D investments, and Ranbaxy, one of India's three largest pharmaceutical companies, spends around seven to nine percent of its total revenue on R&D).

²⁰⁷ *Id.* at 537–41 (noting that (1) major Indian drug companies are increasing investments in R&D; (2) many patents worth billions of dollars will expire in the coming years; and (3) under India's new patent laws, drug manufacturers can continue to copy pharmaceuticals available in the Indian market prior to 1995).

²⁰⁸ See William Greene, *The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market* 8-9 (U.S. Int'l Trade Comm'n., Office of Economics, Working Paper No. 2007-05-A, 2007) (observing that since the passing of the 2005 patent law, large Indian pharmaceutical companies have acquired foreign generics producers in first-world countries to better access their domestic markets, but small Indian pharmaceutical companies that were formerly engaged solely in copying are being acquired by domestic and foreign companies with broader market strategies).

Supreme Court, *Novartis AG v. Union of India*,²⁰⁹ illustrates the kind of creative legal innovation designed to establish a uniquely national-focused approach to TRIPS compliance and implementation.

At issue in the case was a 1998 Novartis patent application for the anti-leukemia drug Gleevec, which claimed the solid (or "beta crystalline") form of a compound (imatinib mesylate) previously patented in 1996.²¹⁰ After the Indian Patent Office rejected the application,²¹¹ Novartis appealed to the Indian Patent Appeals Board (IPAB).²¹² The IPAB affirmed rejection of the Gleevec patent under the now infamous Section 3(d) of the Indian Patent Act, which provides that a "new form of known substance" is not an invention unless it results in significant enhancement of efficacy.²¹³ On final appeal, the Indian Supreme Court affirmed the IPAB rejection of Novartis's Gleevec application, clarifying that "efficacy" under Section 3(d) refers to "therapeutic efficacy," weighed by strict and narrow standards.²¹⁴ The Court held that a "mere change of form with properties inherent to that form" does not qualify as "'enhancement of efficacy' of a known substance."²¹⁵ Put differently, because Gleevec was merely the inherent solid form of the earlier known substance, it did not qualify as an enhancement of efficacy.²¹⁶

The United States and other countries have expressed concern

²⁰⁹ See generally *Novartis AG v. Union of India & Ors.*, A.I.R. 2013 S.C. 1311 (India), available at <http://supremecourtfindia.nic.in/outtoday/patent.pdf>.

²¹⁰ Pyrimidine Derivatives and Processes for the Preparation Thereof, U.S. Patent No. 5,521,184 (filed Apr. 28, 1994 as a continuation-in-part of an abandoned application filed on Apr. 2, 1993) (issued May 28, 1996).

²¹¹ See *Novartis AG v. Natco Pharma Ltd.*, Controller of Patents and Designs, Indian Patent Office, Application No. 1602/MAS/1998 (Jan. 25, 2006), available at <http://indiankanoon.org/doc/1352538> (concluding in a judicial opinion to not proceed with the application for Patent No. 1602/MAS/1998).

²¹² *Novartis AG v. Union of India & Ors.*, IPAB Order No. 100/2009 (June 26, 2009) [hereinafter *Novartis IPAB*], available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>.

²¹³ The Patent Act, No. 39 of 1970, as amended by Patents Act, No. 15 of 2005, § 3(d) (India); *Novartis IPAB*, *supra* note 209.

²¹⁴ *Novartis*, A.I.R. 2013 S.C. 1311, available at <http://supremecourtfindia.nic.in/outtoday/patent.pdf>.

²¹⁵ *Id.*

²¹⁶ *Id.*

over this application of India's TRIPS-compliant Patent Act.²¹⁷ The international responses and accompanying political pressure on India over the decision have continued to play out on the international stage.²¹⁸ In February 2014, the U.S. International Trade Commission held hearings on the impact of India's trade policies on U.S. economic interests, with a particular emphasis on the recent Gleevec decision.²¹⁹ The U.S. Chamber of Commerce called on the U.S. government to place India on its controversial priority watch list,²²⁰ which happened on October 14, 2014.²²¹

²¹⁷ See Lisa Kilday, *Global IP Reaction to India's Rejection of the Novartis Drug Patent*, IPWATCHDOG (May 28, 2013, 7:30 AM), <http://www.ipwatchdog.com/2013/05/28/global-ip-reaction-to-indias-rejection-of-the-novartis-drug-patent/id=40778> (describing India's Patent Act, the Indian Supreme Court's rejection of the patent for Novartis' drug Gleevec, and the debate as to whether the Patent Act is still TRIPS compliant).

²¹⁸ *Id.*

²¹⁹ *Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy*, Inv. No. 332-543, USITC Pub. 78 FR 54677 (Feb. 6, 2014) (Final), available at http://www.usitc.gov/secretary/fed_reg_notices/332/332_543_notice02062014sgl.pdf; see also *US Trade Panel Begins Critical Hearings on Indian Policy*, BUSINESS STANDARD (Feb. 13, 2014), http://www.business-standard.com/article/economy-policy/us-trade-panel-begins-critical-hearings-on-indian-policy-114021300075_1.html (describing the investigation by the U.S. International Trade Commission into India's trade, investment, and industrial policies, focusing on India's intellectual property rights regime as of 2003); *US Trade Panel Launches Probe Against India's Trade Policies*, THE ECONOMIC TIMES (Feb. 12, 2014, 10:53 PM), http://articles.economictimes.indiatimes.com/2014-02-12/news/47270048_1_indian-ipr-linda-dempsey-global-intellectual-property-center (noting that the USITC began investigations into India's trade and investment policies on the United States).

²²⁰ U.S. CHAMBER OF COMM., 2014 SPECIAL 301 SUBMISSION 54 (2014), available at http://www.worldipreview.com/media/project_wipr/document/special-301-2014-gipc.pdf ("The Chamber strongly recommends that India be designated a Priority Foreign Country."). In a WTO dispute, the European Communities claimed that Sections 301-310 of the Trade Act of 1974 are inconsistent with several WTO provisions. See Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R (Dec. 22, 1999) [hereinafter *United States – Section 301-310*]. The panel found that Sections 301-310 were not inconsistent with U.S. obligations under the WTO. *Id.* at 350. The panel noted that its conclusions are based on U.S. administration undertakings in which the United States pledged to base any section 301 determinations on "panel or Appellate Body findings adopted by the DSB." *Id.* at 331. The Panel observed that should the U.S. assurances be repudiated or removed, the "conclusions would no longer be warranted." *Id.* at 351.

Whether such a move by the United States is TRIPS-compliant is questionable.²²² The fact that the United States is pursuing soft unilateral action, and not a WTO process, suggests it is not.

Arguably, the Gleevec decision is simply a straightforward

²²¹ See Biswajit Dhar & TC James, *Inside Views: USTR's Investigations on IP Rights Against India: Is There a Tenable Case?*, IP WATCH (Oct. 20, 2014), <http://www.ip-watch.org/2014/10/20/ustrs-investigations-on-ip-rights-against-india-is-there-a-tenable-case/> (positing that India's placement on the Priority Watch List by the USTR stemmed from concerns about "exclusions from patentability provided in Section 3(d) of the Patents Act, the use of compulsory licences and India's refusal to introduce market exclusivity while protecting data on clinical trials before marketing approval is given to a pharmaceutical product, [and] inadequacy of measures to prevent online piracy of films.").

²²² Article 23(2) of the Dispute Settlement Understanding requires that Members seeking the redress of violations "shall":

[N]ot make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding

Id. at 22-23 (emphasis added). The panel decision in *United States – Section 301-310* also emphasized the potential impact of unilateral actions on the WTO system:

Members faced with a threat of unilateral action, especially when it emanates from an economically powerful Member, may in effect be forced to give in to the demands imposed by the Member exerting the threat To put it differently, merely carrying a big stick is, in many cases, as effective a means to having one's way as actually using the stick. The threat alone of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members. It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures.

United States – Section 301-310, *supra* note 220, at 325; see also Sean Flynn, *US Uses Special 301 To Bully Ukraine, Likely Violating WTO*, TECHDIRT (May 17, 2013, 12:01 AM), <https://www.techdirt.com/articles/20130513/16505323067/us-uses-special-301-to-bully-ukraine-likely-violating-wto.shtml> (describing the United States' listing the Ukraine as a "Priority Foreign Country" under Section 301 of the Trade Act to trigger investigations into Ukrainian trade activity and whether the proposed unilateral adjudication by the U.S. constitutes a threat intended to control Ukrainian behavior, which would be prohibited within the WTO framework in light of the *Section 301-310* decision).

application of India's domestic patent law pursuant to TRIPS Article 27. After all, the TRIPS Agreement does not mandate consistency in how its minimum standards are construed, but only that they must be present in national laws. There is no real controversy that India's law and the Court's application are TRIPS-compliant. Accordingly, the extent to which developed countries and firms have expressed dissatisfaction with the Indian Court's ruling, and why the Gleevec decision occasioned such intense global debate, is particularly puzzling.²²³ One explanation is that in light of India's competitive position in the generics market, the decision may appear simply to mask the kind of trade protectionism that the TRIPS Agreement was supposed to have eliminated. Thus while the law and decision are unassailable on grounds of textual conformity, firms from developed countries likely find the spirit of the Gleevec decision inconsistent with their *own* perception of the "purpose and objective" of the TRIPS Agreement.

A deeper and potentially more troubling explanation may co-exist with the first. Back in 1994, developing countries negotiated the TRIPS Agreement in a context of extremely limited technical capacity. Not only did IP issues not rank highly on the list of demands by developing and least-developed countries for the Uruguay Round, but IP issues did not attract the same level of social agitation or intuitive understanding domestically as, for example, the prospect of a bad deal in agriculture. The lack of technical capacity in IP, coupled with the absence of a well-mobilized domestic coalition, made compromises over TRIPS rules ultimately easier for developing countries to accept in the framework of a package deal in which enhanced market access for agricultural goods was exchanged for increased IP protection.²²⁴ That some developing countries might have overcome this capacity gap twenty-one years after the TRIPS Agreement, and what to expect from those countries once that occurred, is not something developed countries likely contemplated.

In reality, the framework in which contemporary international

²²³ See USTR, SPECIAL 301 REPORT 38 (2013), available at <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf> ("The United States is concerned that the recent decision by India's Supreme Court with respect to India's prohibition on patents for certain chemical forms absent a showing of 'enhanced efficacy' may have the effect of limiting the patentability of potentially beneficial innovations.").

²²⁴ See generally Gonzalez, *supra* note 129 (analyzing how agreements on agricultural trade were held hostage to agreements concerning other trade-related issues, including intellectual property rights).

relations unfolds remains deeply marked with vestiges of colonial rationalization that ascribe the basest motives to non-Western values, priorities, institutions and knowledge forms, or, at best, subordinates them to those that emerged from the West.²²⁵ The sociopolitical response to the Gleevec decision—the shock and awe it attracted—unfortunately reveals continuing skepticism (or surprise) that courts outside of advanced economies can credibly analyze IP doctrines and make intelligent assessments about what best serves the social values and welfare of their societies. At the most elemental level, the overheated reaction to Gleevec and the ensuing threats of unilateral reprisal also fundamentally question the right of national judicial institutions to do so.

3.1.2. Brazil – An Example of Institutional Innovation

Brazil's *Anuência Prévia* (Prior Consent) law, established in 1999, created a unique and controversial patent examination process to comply with the TRIPS requirement of pharmaceutical patentability.²²⁶ This system divides the examination of pharmaceutical patent applications between two agencies: the National Institute of Intellectual Property (INPI) and the National Sanitary Supervision Agency (ANVISA).²²⁷ INPI is responsible for examining the legal sufficiency of patent applications, analogous to the U.S. Patent and Trademark Office.²²⁸ ANVISA, on the other

²²⁵ See generally Antony Anghie, "The Heart of My Home": Colonialism, Environmental Damage, and the Nauru Case, 34 HARV. INT'L L.J. 445 (1993); Antony Anghie, *The Grotius Lecture: ASIL 2010 International Law in a Time of Change: Should International Law Lead or Follow?*, 26 AM. U. INT'L L. REV. 1315 (2011).

²²⁶ The provisional version of the Prior Consent law, Industrial Property Law No. 9,279 of May 14, 1996 (Braz.), amended by Provisional Measure No. 2,006 of Dec. 14, 1999 (Braz.), was eventually codified in Industrial Property Law No. 10,196 of Feb. 14, 2001, art. 229 (Braz.) [hereinafter Law No. 10,196], which limited the provision to pharmaceutical patents. See Edson Beas Rodrigues Junior & Bryan Murphy, Brazil's Prior Consent Law, 16 ALB. L.J. SCI. & TECH. 423, 426-27 (2006) (noting that Law No. 10,196's applicability was "confined to . . . pharmaceutical-related patents").

²²⁷ Law No. 10,196, *supra* note 226; see also, e.g., Rodrigues & Murphy, *supra* note 226, at 427 (describing how the shift to Prior Consent "partly vest[ed]" regulatory confidence in ANVISA where previously it had been solely vested in INPA).

²²⁸ See *Meet the INPI*, INPI, http://www.inpi.gov.br/portal/artigo/conheca_o_inpi (last updated Dec. 28, 2012) (describing the role and operations of INPI as processing, disseminating, and managing the Brazilian system of granting and securing intellectual property rights).

hand, is a separate agency devoted to protecting and promoting “public health” in Brazil,²²⁹ analogous to the U.S. Food and Drug Administration.²³⁰ Under the Prior Consent law, INPI no longer has the authority to grant patents on its own; rather, after determining that an application is patentable, it must forward the application to ANVISA for its consent, purportedly based on public health considerations.²³¹

However, according to a 2008 Resolution issued by ANVISA, ANVISA believes that it also has the authority to engage in a secondary analysis of patentability. It claims, “[a]fter having received the patent applications submitted by INPI, ANVISA will carry out its analysis with respect to the prior consent thereto, assessing whether said applications meet the patentability requirements.”²³² In other words, under the Brazilian two-stage examination process, two different agencies examine patentability using different criteria, with the second (ANVISA) likely being of lesser technical competence.²³³ In effect, this system allows ANVISA to veto any pharmaceutical patent, despite an INPI

²²⁹ See *The Agency*, ANVISA, <http://portal.anvisa.gov.br/wps/portal/anvisa-ingles/anvisaingles/Agencia> (last visited Jan. 25, 2014) (presenting the myriad ways ANVISA protects and promotes public health).

²³⁰ See *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Feb. 22, 2014) (“[The] FDA is responsible for protecting the public health . . . by helping to speed innovations that make medicines more effective, safer, and more affordable . . . [and by] regulating the manufacturing, marketing and distribution of tobacco products . . .”).

²³¹ Law No. 10,196, *supra* note 226, art. 229-C (“The granting of patents on pharmaceutical products or processes shall depend on the prior consent of the National Sanitary Supervision Agency (ANVISA).”); see also, e.g., Lisa L. Mueller, *Recent Brazilian Jurisprudence Concerning the Scope of ANVISA’s Prior Consent*, BRIC WALL (Oct. 14, 2013), <http://bricwallblog.wordpress.com/tag/prior-consent> (contextualizing Law No. 10,196 within ANVISA’s government mandate to protect the public health by preventing the production of potentially harmful products and services).

²³² Resolution (RDC) No. 45 of June 23, 2008 (Braz.).

²³³ See, e.g., Eduardo Da Gama Camara, Jr., *Brazil: Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA*, MONDAQ (last updated July 22, 2013), <http://www.mondaq.com/article.asp?articleid=253068> (arguing that the introduction of ANVISA patent review was a means for the Brazilian government to take control of the “sensitive field of pharmaceuticals” and that the argument that ANVISA is more technically qualified than INPI to evaluate the safety of pharmaceutical patents is clearly hollow: first, only 4% of applications submitted to ANVISA for approval are denied and second, ANVISA has contracted INPI examiners to carry out its patent analysis).

determination of patentability, resulting in a doubly unpredictable patent application outcome.²³⁴

Following the 2008 ANVISA Resolution, INPI brought an administrative proceeding that contested ANVISA's ability to carry out this dual patentability analysis. During the proceeding, the Attorney General's Office issued an opinion declaring that ANVISA should be limited to examining issues closely related to its institutional purpose of promoting public health.²³⁵

In 2013, ANVISA issued a new Resolution, amending the previous 2008 ANVISA Resolution.²³⁶ The new 2013 Resolution states that ANVISA will review the patent applications "in light of the public health."²³⁷ The application will be considered contrary to public health if it (1) "presents a health risk" or (2) the application is "of interest to drug policy or pharmaceutical services" and "do[es] not meet the patentability requirements."²³⁸ Although the 2013 Resolution more explicitly invokes ANVISA's institutional purpose, it makes no progress in resolving the dual legal analysis because it lists patentability as an element of public health.²³⁹

ANVISA's implementation of the Prior Consent law for pharmaceutical patent examination could be viewed as a violation of TRIPS Article 27.1, which prohibits discrimination against particular fields of patentable technologies.²⁴⁰ ANVISA only reviews pharmaceutical applications, and it denies approval to approximately 5% of those applications (usually all deemed patentable by INPI). This suggests that ANVISA is doing either (or both) of the following: (1) applying a stricter standard of patentability than INPI, which may be discriminatory because this stricter standard thereby applies only to pharmaceuticals; or (2) applying extraneous considerations related to public health, which

²³⁴ See Rodrigues & Murphy, *supra* note 226, at 427 (explaining that ANVISA performs the second round of review, taking into consideration the impacts of a patent on social interests relating to public health, and that in the case of a disagreement between ANVISA and INPI over the patentability of an invention, the patent will not be approved).

²³⁵ PGF/AGU se posiciona quanto às competências do INPI e ANVISA no processo de Anuência prévia das patentes de produtos/processos farmacêuticos, Op. Att'y Gen. No. 210/PGF/AE/2009 (Braz.).

²³⁶ Resolution (RDC) No. 21 of Apr. 10, 2013 (Braz.); Resolution No. 45, *supra* note 232.

²³⁷ Resolution No. 21, *supra* note 237.

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ TRIPS Agreement, *supra* note 2, art. 27.1.

may also be discriminatory because such considerations are being applied only to pharmaceuticals.²⁴¹

In addition to scholarly criticisms, the U.S. Trade Representative (USTR) has also stated that the Brazilian Prior Consent system “raises concerns with respect to Article 27 of the TRIPS Agreement.”²⁴² More recently, in a 2013 report, the USTR expressed stronger criticisms of this system and urged Brazil to adopt a more transparent and predictable examination process.²⁴³ Nothing in Brazil’s controversial patent reform process thus far suggests this will happen, and nothing in the TRIPS Agreement requires such change.

In a separate legal dispute, INPI is also attempting to “correct” the terms of certain agrochemical and pharmaceutical patents. When Brazil joined the WTO, like other developing countries, it was allowed a transitional period to introduce pharmaceutical and agrochemical patents. TRIPS Article 70.8 provided that developing countries utilizing this transitional period must allow inventors to file such patents as of January 1, 1995, but that a decision to grant could be delayed until January 1, 2005.²⁴⁴ Pursuant to TRIPS, the term of any such “mailbox patent” is twenty years from the filing

²⁴¹ See ANVISA, *Propriedade Intelectual de Produtos e Processos Farmacêuticos: Situação dos Processos* (Jan. 11, 2006), available at http://www.anvisa.gov.br/medicamentos/intelectual/situacao_processos.pdf (displaying the progress of various patents through ANVISA review); Rodrigues & Murphy, *supra* note 226, at 448–54 (arguing that the Prior Consent Law is discriminatory and violates TRIPS).

²⁴² See USTR, NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 33–34 (2005), available at http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_NTE_Report/asset_upload_file383_7446.pdf (considering that Law No. 10,196 “includes some problematic provisions, including a requirement that Health Ministry approval be obtained prior to the issuance of a pharmaceutical patent”); see also DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009) (highlighting the irony that a call for greater predictability of the examination process is coming from the U.S., where the patent administrative system has been under serious criticism about its shortcomings in stewarding the nation’s innovation capacity).

²⁴³ See USTR, SPECIAL 301 REPORT, *supra* note 223, at 45.

²⁴⁴ TRIPS Agreement, *supra* note 2 (“[T]he United States is concerned about recent regulations that provide Brazil’s sanitary regulatory agency, ANVISA, with the authority to review pharmaceutical patent applications for meeting patentability requirements. These regulations appear to contravene an earlier opinion by the Federal Attorney General that clarified that ANVISA did not have this authority. The United States urges Brazil to continue to work with stakeholders to ensure that its patent examination process is transparent and predictable.”).

date.²⁴⁵ Brazil adopted this mailbox consideration for applications “filed between January 1, 1995 and May 14, 1997”²⁴⁶ and did not take advantage of the transition period. The mailbox applications were to be reviewed until December 31, 2004, and the term of these patents was set to twenty years from the date of filing, but not less than ten years from the grant.²⁴⁷

INPI has been examining and issuing mailbox patents well past the deadline of December 31, 2004, and these patents had been receiving terms of ten years from grant. Because of the delayed processing time, however, the effective patent terms have, in many cases, been much longer than twenty years from filing, the minimum established by TRIPS. On September 12, 2013, INPI filed thirty-three lawsuits seeking a corrected term of the mailbox patents, nullification of the patents and a request to suspend rights while the lawsuit is pending.²⁴⁸ Many U.S. and EU companies are likely to settle.²⁴⁹

INPI’s strategy reflects a novel use of its administrative power to roll back rights to the minimum required under TRIPS, despite the fact that Brazil had voluntarily established a system in which the extended term was clearly of its own making. Since the TRIPS Agreement sets a floor and not a ceiling for patent terms (and other provisions), Brazil arguably has the right to “claw back” the longer patent terms. Brazil’s ability to reverse previously issued patent terms that are greater than the TRIPS Agreement requires is a remarkable and unusual display of the degree of the innovation possible in adjusting national rules to advance domestic interests. INPI’s lawsuits also reveal, again, the sheer breadth of normative power residing in the highly technical and bureaucratic setup of national patent offices.²⁵⁰

It is worthwhile to consider why Brazil exhibits such a high level of legal innovation. Since the 1970s, Brazil has played an active role in seeking to limit the effect of the international patent

²⁴⁵ See TRIPS Agreement, *supra* note 2, art. 33.

²⁴⁶ Law No. 10,196, *supra* note 226, art. 229.

²⁴⁷ *Id.* art. 229-B; Industrial Property Law No. 9,279, *supra* note 226, art. 40.

²⁴⁸ See Lisa L. Mueller, Gustavo de Freitas Morais & Justin Duarte Piné, *The Problem of Mailbox Patents and Patent Term in Brazil*, BRIC WALL (Oct. 1, 2013), <http://bricwallblog.wordpress.com/2013/10/01/the-problem-of-mailbox-patents-and-patent-term-in-brazil> (elaborating on the series of events leading up to INPI’s filing in the Federal Court of Rio de Janeiro).

²⁴⁹ Confidential interview with a U.S. organization involved in the litigation by INPI.

²⁵⁰ PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* (2010).

system on its development policy.²⁵¹ As early as 1967, Brazil made a conscious decision that patent law would be its IP priority as part of a national industrial policy plan that included ensuring access to technology for Brazilian firms.²⁵² Accordingly, the country was committed to a global system in which a panoply of patent options to facilitate such access would remain available.²⁵³ The evidence from Brazil since then has been consistent. It has utilized every forum possible to advance development-related IP goals, while at the same time advancing protection for patents as the country experiences technological growth. Brazil's domestic calibration of its laws occurs not only through the Patent Act, but also by utilizing a series of institutional procedures that ensure the welfare of Brazil is at the forefront of its patent system.²⁵⁴

By initiating and staunchly defending trade disputes with the developed countries, Brazil has established a norm of constructive engagement with the TRIPS framework and proven that it is comfortable with asserting claims that preserve its discretion over the appropriate balance between access and protection of knowledge assets. Brazil is willing to defend its domestic implementation prerogative as a core right of the TRIPS Agreement, making it difficult for advanced economies to make idle threats.²⁵⁵ The patent reform process unfolding nationally demonstrates the evolving role of patent law in Brazilian society;²⁵⁶ it reflects the complex deliberation over the appropriate contours of patent policy for a country with a patent office that functions like those in the developed countries, but a society that reflects the welfare challenges of the developing countries.

²⁵¹ See Draft Resolution, U.N. Doc A/C.2/L.565 (Nov. 8, 1961) [hereinafter Brazilian Draft Resolution] ("It is in the best interest of all countries that the international patent system be applied in such a way as to reconcile the legitimate claims of patent holders with the needs and requirements of the economic development of under-developed countries.").

²⁵² Confidential Memo from the Brazilian Ministry of External Relations, Mission in Geneva, Apr. 18, 1967 (declassified Sept. 12, 2004).

²⁵³ See Brazilian Draft Resolution, *supra* note 251 ("Access to experience in the field of applied science and technology is essential to accelerate the economic development of under-developed countries.").

²⁵⁴ Law No. 10,196, *supra* note 226. In addition to the self-actuated initiatives of ANVISA described above, Brazil also requires that technology-transfer agreements register with the patent office. Moreover, it has strong disclosure requirements for patents based on genetic resources.

²⁵⁵ See, e.g., *supra* Part 1.3.1. (discussing U.S. WTO complaint about Brazil's local working law and withdrawal of same).

²⁵⁶ CHAMBER OF DEPUTIES CTR. FOR STRATEGIC STUD. & DEBATES, BRAZIL'S PATENT REFORM: INNOVATION TOWARDS NATIONAL COMPETITIVENESS (2013).

3.1.3. Malta – A Modern Example of IP as Industrial Policy

Malta became obligated to adopt and implement the TRIPS Agreement in 1995 when it became a member of the WTO.²⁵⁷ Although the Maltese legal framework provides adequate protection for patent holders,²⁵⁸ the relatively small size of the Maltese market historically discouraged many drug manufacturers from pursuing separate patent protection there.²⁵⁹ Generic manufacturers are thus able to exploit opportunities to produce these unprotected drugs and ship them throughout the EU due to the principle of regional exhaustion that follows from the primacy of free movement of goods in the European Community.²⁶⁰

Malta only recently became a strategically advantageous location for generic pharmaceutical manufacturing, based on its implementation of a *Bolar* exception as established in the U.S. case *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*²⁶¹ *Bolar* exceptions generally provide infringement exemption for research and tests performed in conjunction with applications for regulatory approval. Although *Bolar* exceptions exist in numerous countries, jurisdictions apply them unevenly.²⁶²

²⁵⁷ Malta and the WTO, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/countries_e/malta_e.htm (last visited Feb. 21, 2014).

²⁵⁸ Patents & Designs Act, ch. 417 (2002) (Malta).

²⁵⁹ KPMG, MALTA: THE HUB FOR WORLD-CLASS PHARMACEUTICAL COMPANIES 1 (2011) [hereinafter KPMG, MALTA], available at <http://www.kpmg.com/MT/en/IssuesAndInsights/Doing%20Business%20in%20Malta/Documents/Pharmaceutical%20companies.pdf> (explaining that Malta has become an ideal location for pharmaceutical companies to do business due to Malta's "unique legal framework, solid incentives[,] and highly skilled labour market").

²⁶⁰ *International Exhaustion and Parallel Importation*, WIPO, http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm.

²⁶¹ *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that the traditional experimental use exception for patent infringement does not apply to pre-market testing done by generic manufactures and those that have been submitted to a regulatory agency).

²⁶² For a comparison of different *Bolar* exceptions, see Maria Chetcuti Cauchi, *Malta's Bolar Exemption: An Incentive for Investment and Innovation*, THE EXECUTIVE, no. 32 (2011), at 7–8 (describing how different states within the EU have more narrowly and more broadly interpreted the *Bolar* exemption since the

The Maltese *Bolar* exception was adopted with a liberal brush, creating a wide exception that includes acts “consist[ing] of making or using such product for purely experimental purposes or for scientific research” and acts “done for purposes which can reasonably be related to the development and presentation of information required by the law of Malta or any other country that regulates the production, use, or sale of medicinal or phytopharmaceutical products.”²⁶³ This exception broadly allows experiments and scientific research. Further, Malta enacted additional, pro-access IP rules within an enhanced institutional setting targeted at the development of a local pharmaceutical industry.²⁶⁴

Malta provides an unusual case study for legal innovation within the TRIPS context. Notwithstanding its generally strong IP rules, it was the combination of Malta’s investment in a solid business environment, implementation of key pro-innovation patent rules, and leverage of its geographical location to attract and build from technologies not protected domestically that transformed the country’s economic profile. Since territoriality remains a cornerstone of IP protection,²⁶⁵ the failure of large pharmaceutical firms to file patents in Malta presented an opportunity for the country to court generic firms. As a result, Malta gained a reputation of being “the ideal location for pharmaceutical companies.”²⁶⁶ Its pharmaceutical exports

EU set a lower bar with the adoption of a new European pharmaceutical regulatory directive in 2004).

²⁶³ Patents & Designs Act, § 27(6)(b), ch. 417 (2002) (Malta).

²⁶⁴ Malta extended permitted use to private and noncommercial use, as well as for any development and presentation of information. The Maltese government made a strategic decision to work with local educational institutions to offer special courses to train workers in pharmaceutical manufacturing, pharmacology, and related courses. The goal was to create a skilled workforce, which would in turn support a pharmaceutical industry. Moreover, Malta enacted business-friendly laws including low taxes, worker training programs, and loan guarantees to induce generic pharmaceutical investment. Generic pharmaceutical manufacturers are the main players in this industry. See generally *Malta: A Healthy Location for the Pharmaceutical Industry*, PHARMABOARDROOM (Jan. 1, 2011), <http://www.pharmaboardroom.com/article/country-report-malta-a-healthy-location-for-the-pharmaceutical-industry>.

²⁶⁵ See Hanns Ullrich, *TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy*, 4 PAC. RIM L. & POL’Y J. 153, 189 (1995) (“This is so because there is neither a central granting authority for intellectual property operating on a global scale, nor a central administration or a court system having worldwide jurisdiction over matters of validity or enforcement.”).

²⁶⁶ KPMG, MALTA, *supra* note 259, at 1.

increased from just €26 million in 2005²⁶⁷ to €206 million in 2011.²⁶⁸ The pharmaceutical industry in Malta today employs 1,000 people, out of a total private work force of only 110,000, and exports over €200 million in products.²⁶⁹

The Malta narrative is insufficiently robust to draw any grand conclusions for developing countries in their forays in legal innovation. Nevertheless, Malta's explicit framing of IP as industrial policy, if adopted by other countries, offers new justifications (and challenges) when evaluating the WTO-consistency of particular interpretations or applications of TRIPS obligations.

3.2. *Assessing the Pathways of Legal Innovation*

India, Brazil and Malta are different countries and their interests in the multilateral IP regime differ in strategic intent and focus. What unites the developments described above is an orientation of IP to focus on, and align with, domestic priorities. In each of these cases, the tools of innovation are embedded within the larger national legal framework. Thus, their credibility is less assailable by critics. That these tools are part of national systems also suggests they can be sustainably used in the foreseeable future. In each example, the tools reflect a distinctive national strategy in which access to knowledge and national welfare are tightly linked across a number of related technical subjects (trade, environment, industrial policy and IP). As a result, efforts to undo the accomplishments yielded by these tools, or to undermine them, are less likely to succeed in the short term given the spread of political risk across agencies. Moreover, the tools are durable and agile because they are anchored largely in processes and not legislative text.

In sum, in India, the tools of innovation include a coordinated arc of legislation, patent office action and judicial intervention. In Brazil, it has been a highly sophisticated mix of administrative competencies and a policy commitment to access to technology. And in Malta, it was a decision to use TRIPS as a basis for

²⁶⁷ EUR. FED'N OF PHARM. INDUS. & ASS'NS, THE PHARMACEUTICAL INDUSTRY IN FIGURES: KEY DATA 2007 UPDATE 14 (2007).

²⁶⁸ EUR. FED'N OF PHARM. INDUS. & ASS'NS, THE PHARMACEUTICAL INDUSTRY IN FIGURES: KEY DATA 2013, 18 (2013).

²⁶⁹ KPMG, MALTA, *supra* note 259, at 1.

constructing an entire industry in which business interests and welfare outcomes have been, even if just temporarily, perfectly aligned.

These public manifestations of how countries explicitly seek the welfare benefits associated with access to technology, access to medicines or access to knowledge suggest that, at least for the three case studies, the forms of legal innovation employed are likely to continue and will not just be episodic engagements with the multilateral knowledge governance system. Further, the methods of innovation employed in the case studies above are by no means the only tools available—there are other forms of innovation that have been, and will continue to be, devised in developing and developed countries alike. For example, new patent examination guidelines were recently adopted in Argentina for pharmaceutical patents that, among other things, instruct patent examiners to reject new use, new form and new formulation patents, somewhat along the lines of India's infamous patent law.²⁷⁰ Other examples include "flexibilities-plus" rules adopted in some European countries, such as those limiting the scope of gene patents to the actual function of the genes (Germany), or so called "bidders exceptions" or "breeders exceptions" regarding plant variety protection laws.²⁷¹

The heightened local awareness of IP rights (in no small part fueled by the global access to knowledge movements), and the effect of IP rights on the fundamental conditions of human flourishing, suggest that developing and least-developed countries will have new levels of domestic public accountability to the IP regimes they negotiate globally. Twenty-one years after the TRIPS Agreement, there are signs that the design of global IP policy, and the pressure to accept responsibility for its effects, will not be defined by the exclusive, private interests of firms in technologically elite markets. A clear result of these expressions of legal innovation, notwithstanding reprisals by developed countries, is that a variety of new actors will have the space to participate in shaping the intersection between multilateral IP obligations and the domestic welfare imperatives that animate that generation and their communities.

²⁷⁰ See Adoption of Guidelines for Patentability Examination of Patent Applications for Chemical and Pharmaceutical Inventions, Joint Resolutions 118/2012, 546/2012, 107/2012 (2012) (Braz.).

²⁷¹ See Carlos M. Correa, *Patent Protection for Plants: Legal Options for Developing Countries* 29-30 (South Centre Research Paper No. 55, 2014) (on file with author).

3.3. *Legal Innovation as Hegemony – Resistance in the Developed Countries*

Even in developed countries, there is a lack of uniformity, and at times, a lack of compliance with the enforcement procedures that these very countries pushed for. The WTO has found two U.S. violations of TRIPS: (1) the WTO Appellate Body *Havana Club Rum* decision,²⁷² and (2) the WTO Copyright Panel decision regarding § 110(5) of the U.S. Copyright Act,²⁷³ both of which have remained uncorrected for over a decade.²⁷⁴ The U.S. is an outlier in this context compared to other countries such as Canada, India, China and the EU, all of which have addressed their TRIPS violations within an average of 10 months.²⁷⁵

As one of the most ardent supporters of robust enforcement procedures, the U.S. sets a poor (or perhaps from a legal innovation perspective, a “good”) example, especially when compared with developing countries that are required to use much scarcer resources to implement costly fixes. In one regard, longer compliance times may positively signal the importance of filtering the decisions of international bodies through democratic processes that can better secure nationally meaningful compliance with TRIPS obligations. Nonetheless, it is not surprising that dynamic, innovative economies at times find the TRIPS shoes too tight for comfort.²⁷⁶ Legal innovation has become more necessary in the developed countries as they struggle under the weight of a globalized market in which old political alliances are no longer sufficient to overcome the economic power and asserted political interests of the emerging countries.

The vulnerability of Western markets to new systems, production networks and legal initiatives originating from developing countries across various public law regimes will

²⁷² Appellate Body Report, *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R (Jan. 2, 2002); see also *supra* notes 96–102 and accompanying text (discussing the *Havana Club Rum* decision).

²⁷³ *United States – Section 110(5)*, *supra* note 58.

²⁷⁴ Lee, *supra* note 124, at 412.

²⁷⁵ *Id.*

²⁷⁶ Reichman, *Twenty-First Century*, *supra* note 78, at 1119 (predicting correctly that “efforts to rig a regime for short-term advantages may turn out, in the medium-and long-term, to boomerang against those who pressed hardest for its adoption).

require that developed countries do more than simply dig their heels in IP maximalism. Legal innovation does not emerge overnight; reform processes, advocacy movements and political engagement often take years to produce the type of tools witnessed in India and Brazil. Furthermore, the calcified versions of legal innovation deployed by developed countries through threats of trade sanctions or aggressive diplomacy belies the strategic importance and superiority of legal innovation that occurs more indirectly in the developing countries through processes of engaging domestic stakeholders.

4. LEGAL INNOVATION IN THE MAKING: THE POSSIBLE INFLUENCE AND ROLE OF UNFORMED LAWS

Part 4 presents how, in the wake of the TRIPS Agreement, multilateral initiatives such as the Anti-Counterfeiting Trade Agreement (ACTA) and the Trans-Pacific Partnership (TPP) signal a new era of uncertainty in multilateral IP norm-setting. There is value in briefly reviewing ongoing reform initiatives – “legal innovation in the making” – to better appreciate the dynamic forces that interact and react to engender particular forms of innovation. Part 4 thus explores prospects of legal innovation within the Brazilian and South African IP reform efforts. I posit that the political and social maneuvering associated with IP reform enables legal innovation to thrive by making national IP policy a subject of public discourse and engaging multiple stakeholders with relevant IP agencies. Ultimately, the uncertainty and fear generated in the wake of modern plurilateral IP agreements likely force countries to embrace legal innovation more quickly, and may herald the re-institution of more defensible norms in the fabric of multilateral IP treaties.

4.1. *Plurilateralism as Legal Innovation in the New Political Economy of IP Relations*

The rapid rise of networked information technologies radically altered many of the assumptions embedded in the copyright provisions of the TRIPS Agreement. In its “bargain to the baseline” mode, the Agreement focused on the existing technological frontier and addressed copyright standards for a world that had been fundamentally restructured by the conclusion

of the Uruguay Round. Tim Berners-Lee launched mosaic in 1993, just as the ink was drying on the TRIPS Agreement.²⁷⁷ With the high pace of technological advances in the 1990s, the TRIPS negotiations simply did not foresee many of the questions that would frame the contours of IP protection in the digital economy.²⁷⁸ The WIPO Copyright Treaty (WCT)²⁷⁹ and WIPO Performers and Phonograms Treaty (WPPT)²⁸⁰ thus were negotiated at WIPO to secure authorial interests in the face of new and evolving technological platforms;²⁸¹ the technologies most critical to political, cultural and economic opportunities today were not even within the orbit of the TRIPS negotiations. As discussed below, terms of access and use of digital cultural goods have, nevertheless, been glossed with a similar focus on preserving private authorial control over the production and utility of knowledge goods. Differently from TRIPS, however, these terms emerged from a newly constructed political alliance of select developed countries.

4.1.1. *The Digital Gap in TRIPS and Sites of Resistance: SOPA and PIPA*

The WCT entered into force two years after the conclusion of the Uruguay Round.²⁸² Still, the robust new layers of rights

²⁷⁷ STEPHANIE SAMMARTINO MCPHERSON, TIM BERNERS-LEE: INVENTOR OF THE WORLD WIDE WEB 66 (2009).

²⁷⁸ Alex Shepard, *ACTA on Life Support: Why the Anti-Counterfeiting Trade Agreement Is Failing and How Future Intellectual Property Treaties Might Avoid a Similar Fate*, 12 WASH. U. GLOBAL STUD. L. REV. 673, 676 (2013) ("Being a product of the mid-90s, TRIPS was not concerned with many of the technological innovations that would form the basis for modern digital copyright infringement."); see also Haochen Sun, *Overcoming the Achilles Heel of Copyright Law*, 5 NW. J. TECH. & INTELL. PROP. 265, 276 (2007) (remarking that when the TRIPS Agreement was created, it did not anticipate the future challenges "posed by digital technology to the protection and enforcement of copyright.").

²⁷⁹ World Intellectual Property Organization [WIPO] Copyright Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 65 (1997) [hereinafter WCT].

²⁸⁰ WIPO Performances and Phonograms Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 76 (1997) [hereinafter WPPT].

²⁸¹ Sun, *supra* note 278, at 276 ("[T]he WCT and WPPT mainly set out provisions protecting the new right of making available, and the use of technological measures and rights management information by right holders.").

²⁸² WCT, *supra* note 279.

provided by the WCT²⁸³ could not satisfy the level of control demanded by copyright owners and could not keep pace with the social and cultural expectations of consumers occasioned by new technologies.

Copyright reform efforts are now underway in a number of countries as nations attempt to tackle the challenges of the networked information economy. The “digital gap” in the international IP system leaves policy space for a variety of forms of domestic legal innovation responsive to new digital platforms. In the copyright arena, however, such innovation is not necessitated by the constraints imposed by TRIPS, but rather by a need to preserve policy flexibilities in a continuum of unknowns. This flexibility is necessary to respond to an ever-changing copyright landscape that affects economic, cultural and liberty interests far more pervasively than IP rights were presumed to do.

Yet, as some countries experiment with expanding fair use and fair dealing exceptions,²⁸⁴ Creative Commons licensing²⁸⁵ and expanding access to orphan works²⁸⁶ to establish a “zone of access and use” that might accommodate the unwieldy intersection of personal liberty and copyright rights, other countries have tried to push back with restrictive, secretive international agreements that contain even more robust protection and enforcement provisions that incorporated in the TRIPS Agreement. Many commentators have documented the notorious beginning—and end—of some of these efforts, but a brief summary will highlight a few instructive points and link them to legal innovation efforts.

In the United States, the Stop Online Piracy Act (SOPA) was proposed as a bill “to promote prosperity, creativity, entrepreneurship, and innovation by combating the theft of U.S.

²⁸³ See *id.* art. 11 (requiring protection against circumvention of technological protection measures); *id.* art. 12 (stating rights management information obligations).

²⁸⁴ See, e.g., IAN HARGREAVES, DIGITAL OPPORTUNITY: A REVIEW OF INTELLECTUAL PROPERTY AND GROWTH 4-5 (2011) (outlining an expansion of fair dealing exceptions in U.K. copyright).

²⁸⁵ See, e.g., Pedro Paranaguá, *Brazil's Copyright Reform: Schizophrenia?*, INTELL. PROP. WATCH (Feb. 8, 2011), available at <http://www.ip-watch.org/2011/02/08/inside-views-brazils-copyright-reform-schizophrenia> (reporting the withdrawal of Brazil's practice of Creative Commons licensing through the Ministry of Culture).

²⁸⁶ Copyright (Amendment) Act, No. 27, Acts of Parliament, 2012 (India), available at <http://www.wipo.int/edocs/lexdocs/laws/en/in/in066en.pdf> (providing for compulsory licensing of orphan works).

property, and for other purposes.”²⁸⁷ It then points out in its savings clauses that “[n]othing in this Act shall be construed to impose a prior restraint on free speech or the press protected under the 1st Amendment to the Constitution.”²⁸⁸ SOPA’s counterpart in the Senate, The PROTECT-IP Act (PIPA),²⁸⁹ was introduced to “prevent online threats to economic creativity and theft of intellectual property.”²⁹⁰ Though the Act did not have a specific First Amendment disclaimer as SOPA did, PIPA had strikingly similar provisions that, if passed, many feared would have had grave implications for First Amendment free speech rights and access to knowledge more broadly.

For example, SOPA and PIPA would have allowed the U.S. Justice Department to obtain court orders *in rem* against owners of foreign websites suspected of enabling or facilitating copyright violations.²⁹¹ Such orders against foreign websites would have blocked the websites without any opportunity to respond or appeal, resulting in censorship and a direct infringement on the freedom of speech.²⁹² The legislation would have not only permitted the Justice Department to shut down websites, but also to do so without due process given the *in rem* proceedings.²⁹³ Proponents of the SOPA/PIPA legislation argued that existing provisions in the Copyright Act were insufficient to prevent infringing activity from foreign websites, and that websites facilitating downloading of pirated works hurt copyright owners as well as the economy in general.²⁹⁴

Opposition and outright resistance to SOPA/PIPA were swift and unequivocal. Opponents organized an Internet “blackout” in which Wikipedia, Google and over 115,000 other websites replaced their homepages with an all-black page protesting SOPA and

²⁸⁷ Stop Online Piracy Act, H.R. 3261, 112th Cong., at 1 (1st Sess. 2011).

²⁸⁸ *Id.* at 2.

²⁸⁹ PROTECT IP Act of 2011, S. 968, 112th Cong. (1st Sess. 2011).

²⁹⁰ *Id.*

²⁹¹ See generally, John Kennedy, Mary Rasenberger & M. Lorrane Ford, *SOPA and PIPA – Attempts to Stop Online Piracy by Foreign Internet Sites*, 1 INTERNET L. & PRAC. § 12:51 (2012).

²⁹² *Id.*

²⁹³ *Id.*

²⁹⁴ See Timothy J. Toohey, *Piracy, Privacy, and Internet Openness: The Changing Face of Cyberspace Law*, in UNDERSTANDING DEVELOPMENTS IN CYBERSPACE LAW 97 (2012) (explaining how Congress enacted SOPA and PIPA in response to media companies claiming that their legal protections for intellectual property needed to be substantially strengthened).

PIPA.²⁹⁵ Many view this protest as an excellent example of a more democratic, user-empowered nature of the global digital environment. The moral, economic and political success of the corporations opposed to SOPA and PIPA reflected a new kind of partnership with the public interest that, for the first-time, rivaled the longstanding alliance of content industries and the U.S. IP agencies. That partnership – and the global reach of the “digital protest” – has indefinitely re-shaped the nature of the policy space available for IP. At a minimum, the public is more emboldened, and the days in which IP owners can push changes to legislation without consideration of the public’s reaction are likely long-gone. Both SOPA and PIPA were tabled after the blackout protest, but strains of their principal goals are likely to re-appear elsewhere.²⁹⁶

4.1.2. ACTA and the Political Gap in TRIPS: Becoming My Brother’s Keeper

Before there was SOPA/PIPA, however, there was ACTA, negotiated from 2007 to 2010 by the United States, the EU, Switzerland, Canada, Australia, New Zealand, Mexico, Singapore, Morocco, Japan and South Korea.²⁹⁷ The Agreement was negotiated in secret outside of the traditional (and more transparent) multilateral IP fora, such as the WTO and WIPO.²⁹⁸ In October 2011, eight out of these eleven countries signed the Agreement, with the EU, Mexico and Switzerland pledging continued support and vowing to sign “as soon as practicable.”²⁹⁹

²⁹⁵ *Id.* at 5-6.

²⁹⁶ *Id.* at 6-7.

²⁹⁷ *Anti-Counterfeiting Trade Agreement*, ELEC. FRONTIER FOUND., <https://www.eff.org/issues/acta> (last visited Jan. 25, 2014) [hereinafter EFF, ACTA]. For a seminal volume exploring different aspects of ACTA, see THE PLURILATERAL ENFORCEMENT AGENDA: THE GENESIS AND AFTERMATH OF ACTA (Pedro Roffe & Xavier Seuba eds., 2014).

²⁹⁸ *Id.*

²⁹⁹ See *Joint Press Statement of the Anti-Counterfeiting Trade Agreement Negotiating Parties*, OFF. OF THE U.S. TRADE REPRESENTATIVE (Oct. 1, 2011), available at <http://www.ustr.gov/about-us/press-office/press-releases/2011/october/joint-press-statement-anti-counterfeiting-trade-ag> (detailing a press release explaining the proliferation of counterfeit and pirated goods, delineating the final round negotiations in Tokyo, Japan, and outlining the next steps for enforcing the ACTA); see also *KEI’s ACTA Timeline*, KNOWLEDGE ECOLOGY INT’L, <http://keionline.org/timelines/acta> (last visited Oct. 7, 2014) (detailing major events, press releases, and commentary on the ACTA).

The pledge of continued support may simply be lip service in some of these abstaining countries; for example, ACTA was firmly rejected by a 92% majority in the European Parliament in 2012 and improved public support in the future seems highly unlikely.³⁰⁰ Other developing countries, such as India and Brazil, are also firmly opposed to ACTA and have criticized such efforts to bypass existing international IP fora.³⁰¹

In the copyright context, ACTA served as a model of the most troubling features of a new breed of multilateral IP negotiations: (1) *nondemocratic process*: in addition to the secretive and exclusionary negotiation process, the actual enforcement, interpretation and amendments of ACTA would be controlled unilaterally by a non-democratic "ACTA Committee" consisting of unelected members from signatory countries only; (2) *freedom of speech and censorship*: several ACTA provisions would increase ISPs' liability for users' infringing activities beyond existing law, which may encourage excessive filtering, blocking and interference with freedom of expression; (3) *privacy and due process*: the agreement would increase the ease and speed of information exchanges between enforcement authorities, copyright holders and ISPs, which threatens the privacy of user information; (4) *users' rights*: ACTA would require legal protection against circumvention of technological protection measures, even if the reason for disabling the lock is fair, non-infringing use; and (5) *excessive civil and criminal penalties*: ACTA would implement a regime of overzealous statutory damages with no proportionality to the crime and no exceptions for innocent infringement; criminal

negotiations).

³⁰⁰ See, e.g., Don Melvin, *EU Parliament Rejects ACTA Anti-Piracy Treaty*, BLOOMBERG BUSINESSWEEK (July 4, 2012), <http://www.businessweek.com/ap/2012-07-04/eu-parliament-holds-key-vote-on-anti-piracy-treaty> (explaining how other major countries such as China, India and Brazil were either not invited or have refused to join ACTA negotiations; also explaining how ACTA would end up restricting the ability of Congress to provide intellectual property reform); Olivia Solon, *What Is ACTA and Why Should You Be Worried About It?*, WIRED MAG. (Jan. 24, 2012) (U.K.), <http://www.wired.co.uk/news/archive/2012-01/24/acta-101> (explaining how online activists have begun mounting online opposition to ACTA, with future opposition planned; ACTA opposed by online activists, internet companies, and members of the European Parliament); see also EFF, *ACTA*, *supra* note 297 (explaining how the European Parliament overwhelmingly opposed ACTA and how the American public can oppose it as well).

³⁰¹ EFF, *ACTA*, *supra* note 297 (explaining how India and Brazil have rejected ACTA from its onset and criticized its efforts to bypass existing international fora).

penalties would also apply for “significant willful” infringement even if there were no “direct or indirect motivation of financial gain,” without *any* of the traditional copyright limitations, such as fair use.³⁰²

At least six of the member nations had to ratify the ACTA in order to give it effect. Currently, only Japan has ratified the treaty,³⁰³ although there were indications as of 2013 that Canada was moving towards ratification.³⁰⁴ Many have argued that the crushing rejection of the ACTA by the EU makes international implementation unlikely,³⁰⁵ although the United States has vowed to continue fighting for more ratifications.³⁰⁶

4.1.3. Reinventing SOPA/PIPA? The “New” TPP

Like the ACTA, the TPP is being negotiated in highly secretive regional negotiations,³⁰⁷ but WikiLeaks released proposed drafts of

³⁰² *Id.*; see also Art Brodsky, *Public Knowledge Statement on Anti-Counterfeiting Trade Agreement*, PUBLIC KNOWLEDGE (Oct. 6, 2010), <http://publicknowledge.org/issues/acta> (pointing out the flaws in the way the ACTA agreement was reached).

³⁰³ *Conclusion of the Anti-Counterfeiting Trade Agreement (ACTA) by Japan*, MINISTRY OF FOREIGN AFF. OF JAPAN (Oct. 5, 2012), http://mofa.go.jp/policy/economy/i_property/acta_conclusion_1210.html; see also EFF, *ACTA*, *supra* note 297 (listing the states that negotiated, signed, and subsequently ratified the ACTA).

³⁰⁴ Maira Sutton, Electronic Frontier Foundation (“EFF”), *US Trade Office Calls ACTA Back from the Dead and Canada Complies*, EFF.ORG (Mar. 1, 2013) [hereinafter EFF, *US Trade Office*], <https://www.eff.org/deeplinks/2013/03/us-trade-office-calls-acta-back-dead-and-canada-complies> (last visited Sept. 24, 2014).

³⁰⁵ See, e.g., David Meyer, *ACTA Rejected by Europe, Leaving Copyright Treaty Near Dead*, ZDNET (July 4, 2012, 11:02 AM), <http://www.zdnet.com/acta-rejected-by-europe-leaving-copyright-treaty-near-dead-7000000255> (arguing that since the European Union “flatly reject[ed]” the ACTA, and six of the eight non-EU signing countries must ratify the ACTA for it to come into force, survival of the treaty depends on U.S. ratification).

³⁰⁶ See U.S. TRADE REPRESENTATIVE, 2013 TRADE POLICY AGENDA AND 2012 ANNUAL REPORT (2013), available at <http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/2013-tpa-2012-ar> (reporting that discussions on ACTA were priority agenda items sponsored by the United States in TRIPS Council meetings in 2012); see also EFF, *US Trade Office*, *supra* note 304, at 1 (observing that the United States is working with Japan “to ensure that ACTA can come into force as soon as possible” and that Canada introduced a bill on intellectual property ensuring compliance with the ACTA, responding to U.S. pressure).

³⁰⁷ Current parties to negotiations include the United States, Australia,

the TPP Intellectual Property Rights Chapter.³⁰⁸

The first leaked draft of the TPP indicated that negotiators, particularly the U.S. negotiators, were pushing for the adoption of IP minimum standards far more restrictive than those currently required by TRIPS and more extreme standards than those in the controversial ACTA.³⁰⁹ The second proposed draft text of the TTP was leaked in October 2014. This draft similarly reflects robust proposals to heighten liability and enhance copyright protection beyond any existing multilateral copyright instrument. Digital rights management, ISP liability and copyright term lengths remain disputed issues among negotiating parties.³¹⁰ Similar to the TRIPS Agreement, the draft reveals differences of approach to the breadth and nature of copyright enforcement.³¹¹

Canada, Japan, Mexico, Singapore, Malaysia, Vietnam, Brunei, Chile, Peru, and New Zealand. See *Trans-Pacific Partnership Agreement*, EFF.ORG, <https://www.eff.org/issues/tpp> (last visited Jan. 20, 2014) (naming nations negotiating the Trans-Pacific Partnership Agreement); see also Lydia DePillis, *Everything You Need to Know About the Trans Pacific Partnership*, WASH. POST WONKBLOG (Dec. 11, 2013), <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/12/11/everything-you-need-to-know-about-the-trans-pacific-partnership> (discussing the membership of the Trans Pacific Partnership, China's absence, and how this regional trade agreement is a response to the WTO being too cumbersome for "high-standard" trade deals).

³⁰⁸ See *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, WIKILEAKS.ORG (Nov. 13, 2013) [hereinafter WIKILEAKS], <http://wikileaks.org/tpp> (displaying the leaked draft's contents).

³⁰⁹ See generally Sean Flynn, Margot E. Kaminski, Brook K. Baker & Jimmy H. Koo, *Public Interest Analysis of the US TPP Proposal for an IP Chapter* (Am. Univ. Wash. College of Law PIJIP Research Paper Series, Paper No. 21, 2011), available at <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1023&context=research> (providing a preliminary analysis of the initial leaked drafts of the TTP). See also Carolina Rossini & Yana Welinder, *All Nations Lose with TPP's Expansion of Copyright Terms*, ELEC. FRONTIER FOUND. (Aug. 8, 2012), <https://www.eff.org/deeplinks/2012/08/all-nations-lose-tpps-expansion-copyright-terms> (arguing that all nations will be harmed by having to adopt extended copyright terms that give excessive protection to large U.S. record and movie production companies that lobbied for such changes in the U.S.).

³¹⁰ See *Updated Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter (second publication)*, WIKILEAKS.ORG (Oct. 16, 2014), <https://wikileaks.org/tpp-ip2/> [hereinafter WIKILEAKS 2].

³¹¹ Jeremy Malcom & Maira Sutton, *Latest TPP Leak Shows US Still Pushing Terrible DRM and Copyright Term Proposals – and New Threats Arise*, EFF.ORG (Oct. 16, 2014), <https://www.eff.org/deeplinks/2014/10/latest-tpp-leak-shows-us-still-pushing-terrible-drm-and-copyright-term-proposals>. In particular, the United States is pushing for a broader enforcement of criminal liability, which would extend to acts of non-commercial infringement. *Id.* Canada disagrees, arguing that criminal remedies should only apply to commercial conduct. In

Commentators vigorously criticize the TPP's IP Chapter for its inconsistency with existing laws in every TPP member country, including the U.S. itself. In particular, the obvious retreat from policy flexibilities available in TRIPS that allow countries to experiment with social welfare policies, including addressing the supply of public goods, has been very controversial.³¹² The future of the TPP is still unclear and the shape of its IP Chapter is even more so. But ongoing national copyright reform efforts in many key countries suggest that there is plenty of room to anticipate conflicts over the extent to which multi-stakeholder national reforms can be dialed back to accommodate multilateral rules that might emerge. To the extent the two tracks produce conflict, it will only create more room to engage in the kind of legal innovation we have witnessed in the twenty-one years of the TRIPS Agreement. At its most fundamental, legal innovation is a testament to the irreducibility of the "local" and the "domestic" despite a world permeated with multilateral disciplines. The IP reform efforts in Brazil and South Africa, briefly discussed below, are good examples of the resilience of the domestic welfare impulse where IP policy is concerned. These reform efforts are, in themselves, forms of legal innovation directed at defining the relationship between TRIPS and any future multilateral engagement in IP norm-setting processes.

4.2. *Brazil's IP Reform*

Brazil recently launched a patent reform process and issued a patent reform report in 2013.³¹³ The report outlines paths to stimulate innovation in Brazil and to strengthen national industries.³¹⁴ Although the report is generally an outline

addition, the draft contains a new rule against formalities. *Id.* This language appears to be agreed upon by the negotiating parties and could present difficulties should any of the negotiating parties seek to re-introduce formalities into copyright protections that reach beyond minimum international standards. See Krista Cox, *New WikiLeaks of the Trans-Pacific Partnership Agreement Intellectual Property Chapter – Analysis of Copyright Provisions*, ARL POL'Y NOTES (Oct. 16, 2014), <http://policynotes.arl.org/post/100163582662/new-wikileaks-of-the-trans-pacific-partnership>.

³¹² Flynn et. al, *supra* note 309, at 2–4.

³¹³ CHAMBER OF DEPUTIES, *supra* note 256.

³¹⁴ *Id.* at 10 (discussing the use of seminars and debates involving a wide range of representatives to produce innovative new ideas to develop the scope of Brazilian patent legislation).

recommending patent policy moving forward, it has produced some results.

The first is a patent reform bill.³¹⁵ This bill limits patent terms to a strict maximum of twenty years, in contrast to the current Patent Act, which authorizes some extensions beyond twenty years.³¹⁶ It clarifies that new-use patents and new forms of known substances are not considered inventions.³¹⁷ It also heightens the inventive step standard, creates a pre-grant opposition system, updates ANIVSA's Prior Consent mechanism, clarifies the protection of undisclosed pharmaceutical test data and implements the public non-commercial use mechanism as set forth by TRIPS.³¹⁸ Additionally, the report resulted in a Presidential Decree creating the Council of Intellectual Property Rights.³¹⁹ The report emphasizes the importance of economic, social and technological advancement in developing countries.³²⁰

To improve on the patent system, the report makes a series of recommendations. It recommends heightened non-obviousness standards so that frivolous patents are not granted and incremental innovations are widely developed.³²¹ Additionally, it advocates that new-use and polymorph patents should not be granted, as they do not meet the patentability requirements of novelty and non-obviousness.³²² The report also calls for an avenue for pre-grant opposition, allowing for an increase in the quality of patents.³²³ Although the current Brazilian patent law already allows for compulsory licenses, the report calls for a more elaborate public non-commercial-use mechanism.³²⁴ Finally, a warning is offered against examining software patent applications without an "extensive public consultation . . . regarding the risks

³¹⁵ H.R. 5402/2013 (May 2013).

³¹⁶ CHAMBER OF DEPUTIES, *supra* note 256, at 13-14.

³¹⁷ *Id.* at 14.

³¹⁸ *Id.*

³¹⁹ *Id.*

³²⁰ *Id.* at 39. The original Patent Act, passed in 1997, intended to reach these same goals. But, the report argues that none of this took place after the original Patent Act was passed. Furthermore, the strengthened IP rights following the original Patent Act had a negative impact on access to health products and processes.

³²¹ *Id.* at 65.

³²² *Id.* at 127.

³²³ *Id.* at 70-78.

³²⁴ *Id.* at 90-99.

and eventual benefits that the practice can offer to Brazil[.]”³²⁵

The Brazilian process is highly unstable, politically controversial, and its future is uncertain. Nonetheless, it has produced important signals about Brazil’s orientation toward the role of patent law in its economic development. As an unfolding process, nothing in the draft bill can technically be a basis for a TRIPS complaint. However, the principles, concerns and proposals in the draft bill have an important normative influence on Brazil’s existing patent law and institutions. Not only do the draft provisions reflect an intention to maximize TRIPS flexibilities, they also point forward to the development of doctrine in areas that TRIPS did not fully occupy. In short, the reform process has been an experiment station in which new ideas, while not fully formed, nonetheless suggest an expanding capacity and agility to leverage patent law in the design of Brazil’s future economy.

Brazil is also engaged in an intensely watched and contested copyright reform process. In late November 2011, the third version of Brazil’s copyright reform draft bill was leaked.³²⁶ The leaked bill contains many new and modified provisions, including the addition of works for hire with employer control limited to ten years, the exhaustion of copyrights after the first authorized sale in a WTO member country, the authors’ ability to put their works into the public domain during their lifetime and expanded compulsory licenses.³²⁷ Exceptions to copyright infringement are expanded³²⁸ to include space-shifting, reproductions for persons with more than just visual disabilities, reproductions of lectures, addresses, and lessons by the intended audience, reproductions for conservation and preservation purposes, and musical performances in religious temples—while, at the same time, further restricting public performance exceptions.³²⁹

³²⁵ *Id.* at 205.

³²⁶ See Pedro Paranaguá, *Inside Views: Brazil’s Leaked Copyright Reform Draft Bill Shows Latest Thinking*, INTELL. PROP. WATCH (Dec. 12, 2011, 7:26 PM) [hereinafter Paranaguá, *Leaked Draft*], <http://www.ip-watch.org/2011/12/12/brazils-leaked-copyright-reform-draft-bill-shows-latest-thinking> (last visited Oct. 8, 2014) (describing the leaked content of the Brazilian copyright reform).

³²⁷ *Id.*

³²⁸ See Pedro Mizukami, *Brazilian Copyright Reform Draft Bills Comparative Tables*, INFOJUSTICE.ORG, <http://infojustice.org/wp-content/uploads/2012/08/Brazilian-Copyright-Reform-Comparative-Table.pdf> (last visited Oct. 8, 2014) (displaying a table of the proposed changes to copyright law in the leaked Brazilian reform).

³²⁹ Another controversial bill at the Brazilian Chamber of Deputies is the

Like the patent reform process, the final landing strip for the Brazilian copyright reform is not yet clear. Nonetheless, some of the bold initiatives and massive efforts to engage the Brazilian polity already reveal a deep understanding of the cultural impact of copyright policy in society. The reform process has already committed itself to rhetoric about access to knowledge that, even if not borne out in formal law, will undoubtedly shape the conceptual framework of the knowledge economy and the expectations of the Brazilian society for some time to come.

4.3. *South Africa's Draft IP Policy*

In 2013, the Republic of South Africa's Department of Trade and Industry issued a Draft Policy for its framework on intellectual property.³³⁰ Because South Africa does not have a national IP policy, the DTI sought to ensure coherence through the new policy framework.³³¹ The document provides a basic outline of the policy objectives and provides background on issues that IP policy should address, such as public health, agriculture, genetic resources, indigenous knowledge, the Internet, software issues and various

Marco Civil bill. See Pedro Mizukami, *Copyright Week: What Happened to the Brazilian Copyright Reform*, INFOJUSTICE.ORG (Jan. 20, 2014), <http://infojustice.org/archives/31993> (last visited Oct 8, 2014) (discussing the recent history of copyright law reform in Brazil and controversy over the Marco Civil bill for "eschewing a notice-and-takedown system"). The initial version of the bill, which was the result of a public-consultation process, promoted free speech and open access by requiring a court order for all content removals. *Id.* Under this proposed system, "content would be removed from the Internet only in response to a court order, eschewing a notice-and-takedown system," which can be found in other countries such as the U.S. *Id.* This court-order system empowered creators and sharers of online information and improved the power imbalance between users, service providers, and the entertainment industry. *Id.* Unfortunately, concessions were made to industry lobbyists, and the current version of Marco Civil creates an exception: the Marco Civil court-order system is not applicable to copyright infringement. *Id.* This means that content removal involving copyright infringement will be subject to Brazil's copyright reform bill, rather than Marco Civil. As of its third draft, the copyright reform bill has a notice and takedown structure similar to that adopted by the U.S. See Paranaguá, *Leaked Draft*, *supra* note 329 (discussing the leaked draft's new ISP liability, including the new notice-and-takedown structure).

³³⁰ DEP'T. OF TRADE & INDUS., DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY (IP) OF SOUTH AFRICA: A POLICY FRAMEWORK (2013), available at http://www.ip-watch.org/weblog/wp-content/uploads/2013/09/SA-IP-Policy-Sept-2013-36816_gen918.pdf.

³³¹ *Id.* at 5.

copyright and patent reforms.³³²

The framework importantly addresses “Patent[s] and Access to Public Health.”³³³ This section emphasizes that because South Africa is using a depository system, which grants weak patents, it limits access to public health.³³⁴ South Africa, like India, pushes for pre- and post-opposition of patents to “foster the spirit of granting stronger patents.”³³⁵ Referencing the flexibilities allowed to developing countries by the Doha Declaration, the framework recommends amending the Patents Act to be “amenable to issues related to access to public health.”³³⁶ To further promote public health, it recommends introducing compulsory licensing that adheres to international treaties.³³⁷

In the section on agricultural and genetic resources, the framework recommends that developing countries should not provide patent protection for plants and animals, with an exception for certain types of biotechnology-related patents.³³⁸ In particular, the framework recommends an amendment to South Africa’s PVP (plant-variety-protection) system to allow farmers to “reuse, resell and exchange seeds.”³³⁹

Regarding the advancement of developing countries, the framework encourages the expanded use of the flexibilities afforded by the TRIPS Agreement and firmly rejects any trade agreements that are TRIPS-plus in nature.³⁴⁰ The framework is particularly blunt in cautioning against advice or agreements involving developed nations: “South Africa . . . must cautiously filter advice coming from these developed nations and their institutions as they may undermine the multilateral arrangements or may not be sensitive to IP and development.”³⁴¹

Pharmaceutical companies in particular have reacted negatively to the new proposals. The Innovative Pharmaceutical Association of South Africa hired a lobbying firm to oppose the draft policy and to persuade the South African government to

³³² *Id.* at 3.

³³³ *Id.* at 8.

³³⁴ *Id.* at 8–9.

³³⁵ *Id.* at 10.

³³⁶ *Id.* at 9.

³³⁷ *Id.* at 21.

³³⁸ *Id.* at 22.

³³⁹ *Id.*

³⁴⁰ *Id.* at 34.

³⁴¹ *Id.* at 35.

strengthen patent protection, rather than weaken it.³⁴² On the other hand, health activist groups, including the Treatment Action Campaign and Médecins Sans Frontières, strongly support South Africa's draft IP framework and have condemned the pharmaceutical lobbying attempt.³⁴³

Similar to the Brazilian reform process, South Africa's Draft Policy creatively establishes the contours of the domestic IP debate in a way that delimits the role of the multilateral system without violating the TRIPS Agreement. The Draft Policy is neither explicitly legal nor political. Instead, it employs a cultural framework in which the sole organizing thrust is the question of how IP law can advance South African interests in the areas that are relevant to the country's stylized vision of the future, while at the same time identifying ways that will not lead to that land of promise.

Indeed, it is interesting to note how concerns about TRIPS obligations or violations are not a major theme of the report, nor is the theme anti-TRIPS as such. Rather, in a manner presaging legal innovation, the Draft Policy proceeds in terms that may best be described as "in spite of TRIPS." The future of the Draft Policy or any prospects of hard law emerging from its pages are highly uncertain. However, that may not be the purpose of the Draft Policy. Instead, the Policy is best understood as a first step in concretizing and formalizing a vision of welfare that the country can own. This distinctive mark of ownership over IP policy is, by itself, a material step in the advancement of the benefits classically linked to a socially accountable knowledge economy.

4.4. *TRIPS, Legal Innovation and the Age of Uncertainty*

The parallel efforts of plurilateralism, with its stronger and less flexible IP provisions, and national reform efforts, with bold experimentation of maximalist interpretations of TRIPS flexibilities, clearly illustrate that the national context has once

³⁴² See Linda Daniels, *Concerns Erupt over Leaked Pharma Lobbying Plan Against IP Policy in South Africa*, INTELL. PROP. WATCH (Jan. 22, 2014, 3:14 PM), <http://www.ip-watch.org/2014/01/22/concerns-erupt-over-leaked-pharma-lobbying-plan-against-ip-policy-in-south-africa> (explaining how the South African Trade and Industry Minister named a pharmaceutical company's lobbying attempt against the implementation of a new intellectual property policy for the country "a plan for genocide").

³⁴³ *Id.*

again become the reference point for international IP relations. Despite ongoing plurilateral talks, countries will continue to delineate their own appropriate national borders in the shadows of the TRIPS Agreement. National reform movements will likely continue to grow and spread to other countries.³⁴⁴ While plurilateral efforts reflect a top-down approach to harmonization, national IP policies and reform initiatives often reflect just the opposite. History is clear that the latter approach, in which national laws evolve and eventually converge, is the more sustainable of the two. This is perhaps even more important in light of the necessary link IP law must have to economic growth and development in all countries.³⁴⁵

The TRIPS Agreement represents an effort to change the role of the state in relation to markets and in relation to its obligations to its citizens;³⁴⁶ a myriad of dynamic forms of legal innovation suggests that while the former is plausible, the latter is untenable. This heralds an uncertain future for the TRIPS Agreement. The implausibility of a stable future for TRIPS as originally imagined is further accentuated by the complex web of actors who interact to influence, negotiate and control international IP standards.

As noted in Part 1, the TRIPS Agreement attempted to create a system of equality and non-discrimination among member states through two principles: NT and MFN. Although these provisions may establish formal equality, in reality, the TRIPS Agreement falls short of creating a system of substantive equality between

³⁴⁴ For example, India recently announced that it will be developing a comprehensive national IP policy over the next six months. See *Govt Signals IPR Recast Ahead of Modi's US Visit*, INDIAN EXPRESS BUS. (Sept. 9, 2014, 5:00 AM), <http://indianexpress.com/article/business/economy/govt-signals-ipr-recast-ahead-of-modis-us-visit>; see also Patralekha Chatterjee, *India's IP Policy on Stage as Modi Heads to US*, IP-WATCH (May 9, 2014), <http://www.ip-watch.org/2014/09/05/indias-ip-policy-on-stage-as-new-leader-heads-to-us> (discussing the possibility of significant changes to India's IP rights regime). The first draft of India's IP policy was opened for public comment in January 2015. See Peter Leung, *India Releases First Draft of National IP Rights Policy*, MANAGING INTELL. PROP. (Jan. 6, 2015), <http://www.managingip.com/Article/3414568/India-releases-first-draft-of-National-IP-Rights-Policy.html>.

³⁴⁵ For an in-depth discussion of the tenuous relationship between strong IPRs, FDI, and economic growth in developing countries, see generally KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 78 (2000) (examining the multifaceted, economic impact of expanded intellectual property rights due to the emergence of global policy making) and Reichman, *Twenty-First*, *supra* note 78 (analyzing the reactive role being played by developing countries in the formation of global policy on intellectual property rights).

³⁴⁶ Shaffer, *supra* note 79.

developed and developing countries.³⁴⁷ This one-size-fits-all model fails to account for critical distinctions between member countries, including political and democratic limitations. Similarly, in the developing and least-developed countries, TRIPS and the new multilateral processes fail to distinguish between the political and cultural costs of economic and technological barriers to development. The trade principles of formal equality serve to exacerbate substantive inequities between developed and developing member states, particularly by impeding nuanced trade, development and investment efforts that differentiate between states by development status.³⁴⁸

To reach a measure of substantive equality between the developed and developing world, effective economic and technological development efforts require *some* differential treatment among states, or as some critics argue, "positive discrimination."³⁴⁹ This will necessitate a reassessment of current principles of formal non-discrimination and an acknowledgement that legal innovation will respond to any effort to enforce a harmonized national IP environment without regard to national welfare interests. Scholars recognize that textual recognition of positive discrimination is an uphill battle. Nonetheless, some suggest that the development of exceptions or flexible interpretations of non-discrimination by legislative and judicial actors at the domestic and international levels remains possible.³⁵⁰

³⁴⁷ See, e.g., Denis Borges Barbosa et al., *Slouching Towards Development in International Intellectual Property*, 2007 MICH. ST. L. REV. 71, 114–18 (2008) ("[A] relatively small percentage of the complaints filed with the WTO have been filed by developing countries, and developed countries like the United States have refused to implement WTO rulings adverse to their domestic interests. These facts suggest that, 'after a decade of operation the WTO remains a rich man's club beyond the reach of most developing nations.'"); Margaret Chon, *Intellectual Property and Theories of Developmental Justice*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS PLUS ERA 256, 259, 279 (Daniel Gervais ed., 2d ed. 2014) (advocating for "substantive equality" over "formal equality," departing from a strict application of the principle of non-discrimination by taking into account not only whether a country is rich or poor, but also each country's development status with respect to international intellectual property law and development-sensitive human needs).

³⁴⁸ Barbosa et al., *supra* note 347, at 114–15.

³⁴⁹ Tomer Broude, *The Rule(s) of Trade and the Rhetos of Development: Reflections on the Functional and Aspirational Legitimacy of the WTO*, 45 COLUM. J. TRANSNAT'L L. 221, 257–58 (2007).

³⁵⁰ See, e.g., Barbosa et al., *supra* note 347, at 117 (supporting an approach where both domestic and international "lawmaker[s] would exercise more skepticism towards the validity of a regulation where it conflicts with a development-sensitive human need, as defined in part by the Millennium

In other words, a call for additional legal innovation yet persists.

CONCLUSION

Legal innovation with regard to the TRIPS Agreement is not occurring in isolation. Rather, it reflects part of a broader transformation in international economic relations – one in which the increased political and economic leverage of middle-income developing countries has made multilateral bargains much harder to obtain. However, the weaknesses of the TRIPS Agreement could be, ultimately, also its greatest triumph. Developed countries may learn the lesson that bargaining towards the baseline of existing economic and institutional realities, whether in developing country markets or in their own domestic markets, is a short-term strategy at best. For the developing countries, there are prospects that opportunities at the national level to dial back policy losses attributable to imbalanced capacity and lack of resources for international negotiations can, and likely will, emerge. This has clearly been the case with respect to the outcomes of the Uruguay Round.

For both sets of countries, the twenty-first year of the TRIPS Agreement is an opportunity to acknowledge and embrace various forms of resistance and innovation in international intellectual property relations. Rather than unraveling the TRIPS Agreement, such innovation may, instead, serve to strengthen those TRIPS norms around which all countries can respond to the compliance and welfare costs of the forced convergence of global IP norms. At a minimum, twenty-one years of TRIPS should have taught the global community that national welfare considerations will inevitably resist, and legal innovation will invariably emerge, to counter the imprudence of a treaty that attempts to subvert the very territorial and self-seeking national ends for which IP law exists. It is in this complicated context of power, law and economic

Development Goals”); Broude, *supra* note 349, at 258 (“[A]ny formalization of differentiation smacks of discrimination that might unsettle MFN [(Most Favored Nation)] as a fundamental principle of the WTO’s trade functionality, regardless of its pervasive erosion through regionalization. The GATT/WTO system therefore may be more comfortable with an informal and inevitably non-transparent system of *de facto* differentiation.”); Chon, *supra* note 347 (noting some potential ways of informal and *de facto* differentiation for nations and lawmakers).

interdependence that the TRIPS Agreement “comes of age”³⁵¹ yet again.

³⁵¹ J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 441 (2000).