

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

*Ruth L. Okediji\**  
*William L. Prosser Professor of Law,*  
*University of Minnesota Law School*

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## INTRODUCTION

In 1994, over 150 nations converged in Punta del Este, Uruguay and completed what, at that time, was the most ambitious multilateral intellectual property agreement ever negotiated. Built on the cornerstone of the Paris Convention for Industrial Property<sup>1</sup> and the Berne Convention for the Protection of Literary and Artistic Works,<sup>2</sup> the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)<sup>3</sup> by most accounts profoundly altered the nature, scope, and economic consequences of international intellectual property regulation.<sup>4</sup> The goal of the Uruguay Round negotiations in general, and the TRIPS Agreement specifically, was to secure important export markets for a wide variety of goods from the developed countries. With strong upgrades of patent protection, enhanced copyright protection, and seminal coverage of new subject matter,<sup>5</sup> the TRIPS Agreement targeted the soft underbelly of the development process by making access to knowledge and technology acquisition by local firms in developing countries more costly.<sup>6</sup> More insidiously, the Agreement heralded a potent

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<sup>1</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

<sup>2</sup> Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as amended Sept. 29, 1979, 1161 U.N.T.S. 3 [hereinafter Berne Convention].

<sup>3</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

<sup>4</sup> 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*]; see also Keith E. Maskus, *Lessons from Studying the International Economics of Intellectual Property Rights*, 53 VAND. L. REV. 2219 (2000).

<sup>5</sup> TRIPS Agreement, *supra* note 3, arts. 9–13, 27, 28, 33.

<sup>6</sup> THE WORLD BANK GROUP, *LIFELONG LEARNING IN THE GLOBAL KNOWLEDGE ECONOMY: CHALLENGES FOR DEVELOPING COUNTRIES I* (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).

blend of global and local politics,<sup>7</sup> thus defining a new era of private sector influence in the political economy of globalized intellectual property norms.<sup>8</sup>

Twenty years later, the IP world for which the Uruguay Round laid a foundation is arguably very different from what many imagined at the end of the negotiations. The immediate policy implications of the rules established by the TRIPS Agreement were felt first in the context of access to essential medicines in which South Africa played the lead role in a public health crises that unfolded dramatically on a worldwide stage.<sup>9</sup> 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 member state galvanized an entire “access to medicines” movement that has ricocheted around the world.<sup>10</sup> It also produced a formal “amendment” to the TRIPS Agreement known colloquially as the “Doha Declaration,”<sup>11</sup> which clarified the right of WTO member states to interpret the TRIPS Agreement “in light of its object and purpose,”<sup>12</sup> and specifically reaffirmed the right of states to protect public health.<sup>13</sup>

The access-to-medicines movement, and its corollary, the access-to-knowledge movement,<sup>14</sup> represent a globally-linked and loosely-organized resistance to the TRIPS

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<sup>7</sup> See Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 845–46 (2003) (discussing cooperation of US, Japan and EU firms in getting their governments to push the TRIPS Agreement through).

<sup>8</sup> SUSAN L. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (2003).

<sup>9</sup> 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 DSB. See Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement*, 27 YALE J. INT'L L. 365, 366 n.4 (2002); Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 949– 956 (2000).

<sup>10</sup> See, e.g., Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804 (2008).

<sup>11</sup> Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration], available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>12</sup> *Id.* ¶ 5(a).

<sup>13</sup> *Id.* ¶¶ 1, 4, 5(c).

<sup>14</sup> Kapczynski, *supra* note 10.

Agreement. Working within a framework animated by considerations of social justice, liberty ideals, and good governance, this global alliance maintains vigilant watch over the normative contours of the multilateral IP system and advocates strategies to resist deterministic outcomes of IP norms. In so doing, these movements also challenge and seek to influence national political processes that are inordinately influenced by the economic claims of industries whose business income flow principally from the trough of an expansive web of IP rights. There are, in reality, several sub-texts of these movements that go beyond “access” to the tangible goods that embody creative ideas or expression. An example of note is the recent focus on rules that govern Internet architecture or so-called “net neutrality,” advocated largely by the same proponents of access to knowledge.<sup>15</sup> While the most impassioned debates have turned on technical characteristics of information communication technologies and the virtue of open-versus-closed systems of information,<sup>16</sup> at the heart of the policy contests lie deep anxiety over the extent to which legal and technological protocols of information networks impede on social and cultural freedoms. The net-neutrality debates seem far removed from the basic intellectual property norms codified in the TRIPS Agreement. However, viewing TRIPS norms as a global mandate that countries should, for example, grant the strongest rights of control over the content and structure of platforms that facilitate access to cultural goods precisely highlights the tension points for developing countries. The defining concern about the TRIPS Agreement since 1994 has been the extent to which it circumscribes national policy choices that could facilitate human development, economic growth, and public welfare, all of which are indisputably linked to individual access to culture, economic, and political processes.

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<sup>15</sup> See, e.g., Christopher S. Yoo, *Network Neutrality and the Economics of Congestion*, 94 GEO. L.J. 1847, 1850 (2006) (defining net neutrality as a “call for regulatory limitations on network owners' ability to discriminate against particular content, applications, and devices”).

<sup>16</sup> See, e.g., Mark Cooper, *Open Communications Platforms: The Physical Infrastructure as the Bedrock of Innovation and Democratic Discourse in the Internet Age*, 2 J. TELECOMM. & HIGH TECH. L. 177 (2003).

Twenty years later, the TRIPS Agreement has neither confirmed the worst fears of developing countries nor accomplished the greatest hopes of the developed economies. Instead, both sides have inserted unexpected and important points of adherence and resistance to the global IP norms established by TRIPS, thus destabilizing many of its implicit political and economic bargains. Recently, developing countries are demonstrating nascent institutional capability that has facilitated creative approaches to balancing TRIPS obligations and advancing ideals of welfare unique to national circumstances. It is unclear how long these innovative oeuvres will last, or how committed developing countries are to resist the inevitable backlash that will come from the developed countries. A sustained capacity to engage in forms of legal innovation that can both advance a distinctive domestic welfare vision, while credibly complying with the TRIPS Agreement, will define the extent to which developing countries can meaningfully limit their potential for adverse welfare consequences.

The Uruguay Round Final Agreement<sup>17</sup> introduced two extraordinary realities to the world of international IP relations. First, the 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.<sup>18</sup> Setting the mandatory obligations 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. This binary relationship between TRIPS obligations and TRIPS flexibilities further ignores the extent to which access to technology and cultural goods materially affects individual exercises of social and political rights that are also vital to innovation and creativity. The relationship between

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<sup>17</sup> 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).

<sup>18</sup> 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).

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 flourished.<sup>19</sup>

Second, the TRIPS Agreement established a bartering regime for the domestic public welfare goals associated with IP through the celebrated Dispute Settlement Understanding (DSU).<sup>20</sup> As is now well-known, exchanging heightened IP standards for concessions in trade, and even bargaining over *non-compliance* with TRIPS or WTO obligations, has become a feature of modern IP relations.<sup>21</sup>

In this article, I argue that the TRIPS Agreement may have accomplished a goal far more significant for development than any of the normative challenges that have occupied the scholarly debate for the past two decades. Unlike U.S. courts or agencies that only rarely meaningfully engage in an analysis of international IP obligations,<sup>22</sup> there is growing evidence that a range of countries including India, Kenya, South Africa, Brazil, and Malta, are responding to TRIPS-related pressures by explicitly embracing, and then creatively limiting, the price a maximalist global IP regime can exact from citizens and the policy costs it imposes on governments. These initiatives potentiate development returns that extend beyond IP to include

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<sup>19</sup> James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 L. & CONTEMP. PROBS. 33, 58–59 (Winter/Spring 2003); Yochai Benkler, *Free as the Air to Common Use: First Amendment Constraints on the Enclosure of the Public Domain*, 74 N.Y.U. L. REV. 354, 361–63 (1999).

<sup>20</sup> Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 33 I.L.M. 1226 (1994) [hereinafter DSU]; see also 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*]; Ruth L. Okediji, *Rules of Power in an Age of Law: Process Opportunism and TRIPS Dispute Settlement*, in HANDBOOK OF INTERNATIONAL TRADE: ECONOMIC AND LEGAL ANALYSES OF TRADE POLICY AND INSTITUTIONS (E. Kwan Choi & James C. Hartigan eds., 2005) [hereinafter Okediji, *Rules of Power*].

<sup>21</sup> 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 US Copyright Act*, WT/DS160/R (June 15, 2000) [hereinafter *United States—Section 110(5)*].

<sup>22</sup> 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.”).

recognition of new social freedoms, the hardening of equality principles in local laws, judicial independence, and a general democratic largesse. As noted before, these are critical components of an environment in which legal innovation can flourish.

I define legal innovation as the sustainable development of new techniques, institutions, or methods specifically designed in the light of TRIPS obligations, and that facilitate implementation of those obligations in a manner consistent with or that reconcile national welfare goals as the primary justification for IP protection. In so doing, these techniques or methods may forge new approaches to the role of IP in national economic policy as evidenced in South Africa and Brazil,<sup>23</sup> engender new domestic regimes to attract foreign investment as illustrated by Malta,<sup>24</sup> offer opportunities for other subject-matter norms to influence the direction of IP norms as in Kenya,<sup>25</sup> or, paradoxically, add to existing IP standards in ways that rebalance the power equities between informal knowledge holders and patent applicants as China, India, and other countries have done in regard to new limits on patent eligible subject matter.<sup>26</sup> Within the IP policy space, these various forms of legal innovation may suggest that the minimum standards approach of TRIPS that has evoked such significant consternation may yet offer a basis for countries to construct policy spaces in alignment with development goals and that, importantly, allow domestic institutions to interrogate the values of the TRIPS Agreement in light of broader considerations of how to foster domestic human welfare.

To be clear, legal innovation has also occurred in the developed countries although these are not usually understood as a direct response to TRIPS. Across developed and developing countries, legal innovation offers a fine instrument for defining sovereign responsibility for the

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<sup>23</sup> See *infra* Part II.A(ii).

<sup>24</sup> See *infra* Part II.A(iii).

<sup>25</sup> See *infra* notes 80–83 and accompanying text (discussing the *Asero* case, in which the Kenyan High Court overturned a TRIPS-driven anti-counterfeiting statute to preserve access to affordable, life-saving generic drugs).

<sup>26</sup> See *infra* Part I.B(ii).

*effects* of IP rights in society. 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.<sup>27</sup> Indeed as Professor Jerry Reichman has noted, developing countries would fare well by imitating U.S. approaches in key areas affecting the supply of public goods such as education,<sup>28</sup> encouraging competition,<sup>29</sup> or otherwise expanding the public domain.<sup>30</sup> Nonetheless, it is also important to note that legal innovation as currently observed in the developed country context (or at the multilateral level) is not a one way positive gain for public welfare. Professor Julie Cohen has recently noted, for example, that often the very arguments that advance access to knowledge can be in tension with some social freedoms and compromise privacy interests.<sup>31</sup> The difficulty of assessing which normative tradeoffs make sense in pursuit of the vision of the public good reflected in the dominant economic justification for IP is one critical reason for underscoring the importance of legal innovation by domestic actors. This economic narrative is not a complete representation of the complex processes that qualify as innovation; other values such as liberty, freedom of speech, equality, and privacy also weigh importantly in the technological choices made to attract consumers to use technology and should matter in how we construct the scope and exercise of IP rights.<sup>32</sup> More importantly, in the information society innovation flourishes sometimes *precisely* because there are no IP rights to control or repress creative impulses of

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<sup>27</sup> 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); *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); *Bilski v. Kappos*, 130 S. Ct. 3218, 3228 (2010) (holding that a business method of hedging financial losses in energy industry not patent eligible); see also *infra* note 77 and accompanying text (discussing the same cases).

<sup>28</sup> See generally Jerome H. Reichman, *Nurturing a Transnational System of Innovation*, 16 J. TRANSNAT'L L. & POL'Y 143 (2007).

<sup>29</sup> See Reichman, *Universal Minimum Standards*, *supra* note 4, at 387–88.

<sup>30</sup> See 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).

<sup>31</sup> JULIE E. COHEN, *CONFIGURING THE NETWORKED SELF: LAW, CODE, AND THE PLAY OF EVERYDAY PRACTICE* (2002).

<sup>32</sup> *Id.*



ordinary citizens. Social media platforms such as Facebook, Twitter, Snap Chat, and others operate less on exclusive rights over content and more on models that control how users can function or experience these technological spaces.<sup>33</sup> There is no doubt, for example, that many things consumers can do on Facebook may constitute violations of copyright, but it is the capacity to engage in such activities that make social media socially meaningful. The TRIPS Agreement does not (and cannot) explicitly speak to the rules that should regulate these technologically facilitated social spaces, nor to the ways in which the absence of IP rights can engender innovation. Thus, the extraordinary focus on control for IP owners, and the mandatory provisions that, in effect, transfer the locus of public policy decisions to private firms will require new ways of conceptualizing TRIPS obligations.

In Part I, I briefly review the structure and main provisions of the TRIPS Agreement, focusing on the patent provisions that were the most complex 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 II, I highlight examples of legal and institutional innovation in emerging economies, and the resilience of development aspirations as a key motivator for the creative responses to TRIPS obligations by domestic actors. For my purposes, legal innovation is not simply episodic responses to particular pressures. Rather legal innovation must be characterized by the potential that the selected tools for innovation are sustainable within the local legal culture, fueled by a clear national purpose, and effectuated by local actors. The three examples examined in Part II evidence these features. I also explore examples of innovation in the making of ongoing reform efforts in Brazil and South Africa. In Part III, I review the prospects of new multilateral initiatives based on the TRIPS Agreement, and suggest a way forward for re-instituting more

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<sup>33</sup> As professor Cohen argues, this is not necessarily a positive turn. *See id.*

defensible norms in the fabric of multilateral IP treaties. Finally, I conclude with some observations about the future of IP harmonization as the TRIPS Agreement “comes of age,”<sup>34</sup> yet again.

## I.

### THE PROMISE OF TRIPS: BARGAINING TO THE BASELINE

#### *A. The Promise: Harmonization and Enforcement as Crowning Triumphs*

The TRIPS Agreement, effective on January 1, 1995, 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.<sup>35</sup> It also included, for the first time, multilateral protection for undisclosed information<sup>36</sup> and strengthened protection for layout designs<sup>37</sup> beyond the terms of the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty).<sup>38</sup> Additionally, new rules for IP enforcement and dispute settlement arguably were a key objective of TRIPS proponents and, when negotiations were successfully completed, became the crown jewels of the Agreement.<sup>39</sup> Finally, the Agreement arguably flattened the world by adopting the hefty nondiscrimination principles of National Treatment (NT) and Most-Favored-Nation (MFN) well known in international trade law.<sup>40</sup>

Most commentary on the TRIPS Agreement has focused on the minimal 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

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<sup>34</sup> 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 (2000).

<sup>35</sup> TRIPS Agreement, *supra* note 3, arts. 27, 27.1; *see also* Reichman, *Universal Minimum Standards*, *supra* note 4.

<sup>36</sup> TRIPS Agreement, *supra* note 3, art. 39.

<sup>37</sup> *Id.* art. 38.

<sup>38</sup> Treaty on Intellectual Property in Respect of Integrated Circuits, May 26, 1989, 28 I.L.M. 1484.

<sup>39</sup> *See* DSU, *supra* note 20; *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, 276 (1997); *see also* Okediji, *TRIPS Dispute Settlement*, *supra* note 20; Okediji, *Rules of Power*, *supra* note 17.

<sup>40</sup> TRIPS Agreement, *supra* note 3, arts. 3–4.

law as was the case under the Paris Convention.<sup>41</sup> It expressly included process patents and, as noted by Professor Daniel Gervais, essentially made any limits on patentable subject matter exceptional and protectability the rule.<sup>42</sup> Moreover, the stylized bargain between the inventor and the public that has historically animated patent law policy in the industrialized countries was partially expressed in a new rule, not previously in the Paris Convention, requiring patent applicants to describe the invention in a manner sufficiently “clear and complete” so a person skilled in the art can carry it out.<sup>43</sup> Finally, the patent provisions include a general exception in Article 30,<sup>44</sup> modeled after the three-step test found in Article 9(2) of the Berne Convention.<sup>45</sup> Other important provisions include Article 31 which sets safeguards on compulsory licensing and Article 33 harmonizing patent term to twenty years from the date of filing.<sup>46</sup> Importantly, TRIPS eliminated any discrimination based on where the invention occurred, including prohibiting discrimination based on whether the invention is locally produced or imported.<sup>47</sup>

Understanding the breadth of changes occasioned by the TRIPS Agreement in patent law requires an appreciation of how non-discrimination norms re-calibrated the competitive opportunities of technology-intensive firms. In a close examination of its structure, the Agreement’s chief accomplishments were to supply or tighten the standards not adequately

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<sup>41</sup> 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, . . .”).

<sup>42</sup> DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* (3d ed. 2008).

<sup>43</sup> TRIPS Agreement, *supra* note 3, 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 ordinary 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). 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.

<sup>44</sup> TRIPS Agreement, *supra* note 3, art. 30.

<sup>45</sup> Berne Convention, *supra* note 2, art. 9(2).

<sup>46</sup> TRIPS Agreement, *supra* note 3, arts. 31, 33.

<sup>47</sup> *Id.* art. 27.1.

covered by previous IP instruments, and to link these ambitious reforms of the multilateral system with the reality and pain of trade sanctions. As a treaty of “minimum standards,” countries were allowed to effectuate stronger rules and, in several instances where legal or policy approaches between developed countries could not be overcome, flexibility in how normative principles should be implemented was clearly expressed in the text.<sup>48</sup>

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 country anxiety about potential adverse consequences of a one-way ratchet of IP rights. These concerns remain strong in areas such as copyright where the consequences of policy decisions restricting access to cultural or knowledge goods may not be felt for at least one generation. Sub-optimal access to education, as an example, will produce an uneducated or ill-educated citizenry with corresponding challenges in a country’s capacity to absorb technology ultimately compromising its socio-economic trajectory. In short, concerns about the baseline for terms of access-to-knowledge goods established in the TRIPS Agreement remain deeply problematic in development circles. These concerns are certainly 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 such as education. Nonetheless, real legal innovation suggests that the same space within the TRIPS Agreement constructed to give countries room to enhance or strengthen TRIPS obligations can be re-constituted to give countries room to experiment with tools designed to extract welfare gains from the environment in which the Agreement currently operates. The ease with which the space to enhance IP rights is transformed into space to advance the social good will be largely

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<sup>48</sup> See, e.g., *id.* 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.”).

dependent on the nature of the tools of innovation that are utilized—legal institutions and processes, political fiat, or appeals to higher normative claims. For the developing countries, legal institutions and processes appear to rank most highly as the tool of choice,<sup>49</sup> perhaps because of the kind of obligations that have most been felt to limit sovereign policy discretion.

### *B. Structural Characteristics Favoring Innovation*

Three main features of the TRIPS Agreement appear, more than most, to have generated intense pressure on the welfare goals of WTO member states, and are directly responsible for motivating legal innovation in the developing countries (and resistance in some developed countries). They are: 1) nondiscrimination principles; 2) scope of protection; and 3) sanctions and enforcement.

#### *(i) The Architecture of the TRIPS Agreement: Nondiscrimination*

It is well-known that the international IP world pre-TRIPS was rife with protectionist measures in favor of domestic innovators and domestic markets. Examples of historic and recent discrimination in procedural, administrative, and evidentiary standards abound both in the U.S. and in other countries.<sup>50</sup> These protectionist measures are usually justified by the important goal of promoting access to the class of knowledge goods at issue for the benefit of broader societal objectives.

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<sup>49</sup> See *infra* Part II.

<sup>50</sup> For example, 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 wasn't 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 Act of March 3, 1891, § 3, 26 Stat. 1106, 1007 (1891). 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 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 America Invents Act, Pub L. No. 112-29, 125 Stat. 284 (2011).

Articles 3 and 4 of the TRIPS Agreement blunted the ability of countries to engage in overt distinctions between foreign and domestic innovators and creators. The national treatment and most-favored-nation 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.<sup>51</sup> As between developed and developing countries, an immediate consequence of the national treatment and most-favored-nation rules is that developing countries cannot apply mechanisms of graduated response to local innovation by adjusting IP rules to reflect development levels as the developed countries did historically.<sup>52</sup> Moreover, the nondiscrimination 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 such as in the Bayh-Dole Act, to promote domestic innovation.<sup>53</sup> As I discuss later, when faced with extreme political stakes, developed countries also simply choose noncompliance with international obligations as a way to satisfy domestic interest group demands. An important point to note is that even where favoring local innovators is clearly a violation of the non-discrimination principles, as is the case arguably with the Bayh-Dole Act,<sup>54</sup> whether developing countries have the capacity or political will to confront those instances is uncertain. Alternatively, choosing not

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<sup>51</sup> TRIPS Agreement, *supra* note 3, arts. 3–4, *see also id.* art. 27.1.

<sup>52</sup> 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).

<sup>53</sup> Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (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).

<sup>54</sup> *Id.* This arguably is an impermissible subsidy under the GATT rules. *See* Agreement on Subsidies and Countervailing Measures, Apr. 15, 1994, Annex 1A, Agreement Establishing the World Trade Organization, 33 I.L.M. 1226 (1994).

to confront such examples of discrimination could supply these countries with strategic leverage in later battles.

The TRIPS Agreement may have blunted the worst cases of discrimination between local and foreign inventors, but the goal of equal treatment of innovators puts pressure on the very basis for competitive advantage in globally integrated markets. It is no surprise, then, that discriminatory treatment remains pervasive in multilateral IP relations. Countries at all levels of development have engaged in less transparent but equally protective measures to safeguard domestic industries and distinguish domestic welfare concerns from the requirements of the global IP marketplace. Some legislative initiatives, such as the U.S expansion of prior user rights in 35 U.S.C § 273,<sup>55</sup> are explicit and arguably a violation of TRIPS.<sup>56</sup> Other measures, such as a reduction in patent application fees are less clearly objectionable.<sup>57</sup> Partly, it is *how* discrimination occurs that may make it more palatable to trading partners rather than whether countries discriminate in favor of their citizens. The micro-entity fee reduction in the America Invents Act (AIA), for example, applies to foreign natural persons but not foreign universities even though U.S. universities can qualify for the discount.<sup>58</sup> This ingenious distinction is legal innovation at its best; an international rule clearly is violated but not in a way that would justify the economic or political costs of the WTO dispute process.

One clear consequence of the non-discrimination norms has been to divert discriminatory practices to institutional processes similar to the micro-entity provision of the U.S.'s AIA

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<sup>55</sup> 35 U.S.C. § 273 (2012).

<sup>56</sup> 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).

<sup>57</sup> *Id.*

<sup>58</sup> America Invents Act § 11(g), Pub L. No. 112-29, 125 Stat. 284 (2011); *see also* Crouch, *supra* note 56 (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).

mentioned above. Other 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.<sup>59</sup> Another example is the EPO Enlarged Board of Appeals decision in the *University Patents v. SmithKline Beecham* case, that gives the facially neutral EPC Article 55 a somewhat discriminatory effect as the provision's six month grace period is 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.<sup>60</sup> 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.<sup>61</sup>

Of course, diversion to institutional processes may backfire, requiring costly political actions masked by facially neutral discretionary executive or regulatory fiat. The Obama Administration's veto<sup>62</sup> of the ITC exclusion order<sup>63</sup> in the infamous Samsung and Apple patent dispute<sup>64</sup> is a recent example of a facially neutral procedure that arguably reflects significant discriminatory impetus in favor of a U.S. firm.<sup>65</sup>

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<sup>59</sup> 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).

<sup>60</sup> *University Patents, Inc. v. SmithKline Beecham Biologicals SA*, Case T 0377/95 (EPO Enlarged Bd. App. 2000), available at <http://www.epo.org/law-practice/case-law-appeals/pdf/g980003ex1.pdf>.

<sup>61</sup> *Id.* My thanks to Margo Bagley for pointing this out to me.

<sup>62</sup> Letter from Michael B.G. Froman, U.S. Trade Rep., to Irving A. Williamson, Int'l Trade Comm'n Chairman (Aug. 3, 2013), available at [http://ustr.gov/sites/default/files/08032013 Letter\\_1.PDF](http://ustr.gov/sites/default/files/08032013%20Letter_1.PDF) (vetoing ITC decision).

<sup>63</sup> In the Matter of Certain Electronic Devices, Including Wireless Communication Devices, Portable Music and Data Processing Devices, and Tablet Computers, USITC Inv. No. 337-TA-794 (June 2013) (awarding Samsung a limited ban on sales of certain Apple products).

<sup>64</sup> 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., Chloe Albanesius, *Every Place Samsung and Apple Are Suing Each Other*, PC MAG. (Sept. 14, 2011), <http://www.pcmag.com/article2/0,2817,2392920,00.asp>; *Australian Court to Fast-track Samsung Appeal on Tablet Ban*, REUTERS (Oct. 27, 2011), <http://www.reuters.com/article/2011/10/27/us-apple-samsung-australia-idUSTRE79Q0SN20111027>.

<sup>65</sup> This implicates a broader question of whether injunctive relief should be available for infringement of standards essentials patents. See NAT'L RESEARCH COUNCIL. PATENT CHALLENGES FOR STANDARD-SETTING IN THE GLOBAL ECONOMY: LESSONS FROM INFORMATION AND COMMUNICATION TECHNOLOGY (2013).



Finally, a third approach to legal innovation with regard to the WTO non-discrimination rules (and indeed all other rules) is explicit non-compliance with globally agreed norms as interpreted by the dispute settlement process. While non-compliance could be viewed simply as a derogation from mandatory norms, in reality it is a form of legal innovation that internalizes the political cost of non-compliance, or transfers those costs to other policy arenas or agencies.<sup>66</sup> In *U.S.—Section 211 Appropriations Act*,<sup>67</sup> 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.<sup>68</sup> Moreover, no U.S. court could recognize or enforce the assertion of such rights.<sup>69</sup> Despite a finding by the WTO Appellate Body agreeing that § 211 violates the national treatment and most-favored-nation obligation of the TRIPS Agreement,<sup>70</sup> U.S non-compliance with the WTO ruling has been the subject of on-going discussions at the WTO TRIPS Council<sup>71</sup> over the matter of U.S compliance.<sup>72</sup> The U.S. Supreme Court declined to hear the matter,<sup>73</sup> leaving the question of U.S compliance with its international obligations squarely with the political process. Such constructive “disengagement”

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<sup>66</sup> See, e.g., Ana Radelat, *Cuba Appeals to USPTO in Battle to Keep Control of Havana Club Rum Trademark*, CUBA NEWS (June 18, 2012), <http://www.cubanews.com/sections/cuba-appeals-to-uspto-in-battle-to-keep-control-of-havana-club-rum-trademark> (discussing the conundrum faced by the USPTO when asked by Cuba to suspend cancellation of its trademark registration until the embargo is abolished).

<sup>67</sup> Appellate Body Report, *United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R (Jan. 2, 2002).

<sup>68</sup> *Id.* ¶ 2.1

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* ¶ 9.1

<sup>71</sup> 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](http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm) (last visited Feb. 21, 2014).

<sup>72</sup> See *EU, Cuba Spar Over ‘Havana Club’ Rum*, EUBUSINESS (June 25, 2013), <http://www.eubusiness.com/news-eu/wto-cuba-us-patent.pet>.

<sup>73</sup> *Havana Club Holding, S.A. v. Galleon, S.A.*, 203 F.3d 116 (2d Cir. 2000) *cert. denied*, 531 U.S. 918 (2000).

in the face of unyielding political considerations is also a form of legal innovation around the edges of the TRIPS Agreement.

(ii) *Scope of Protection*

On scope of IP subject matter, the most important change for patents occurred via Article 27, which 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 things, “ordre public or morality.”<sup>74</sup> Though this provision eliminated the possibility of significant limits on patentable subject matter, there is evidence that Article 27 is not an unbounded *carte blanche* to industry,<sup>75</sup> nor does it appear to inhibit constitutionally-driven policy limits to patents.<sup>76</sup> The U.S. Supreme Court has creatively interpreted important policy bases for limiting patent subject matter eligibility in controversial cases involving new technologies.<sup>77</sup> And as leading patent law scholars have noted, there is increasingly less consistency among both developed and developing countries on issues of patent subject matter eligibility.<sup>78</sup> Consequently, important room for legal

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<sup>74</sup> TRIPS Agreement, *supra* note 3, art. 27. The TRIPS Agreement also contains additional exceptions such as diagnostic, therapeutic and surgical methods, plants, animals other than microorganisms, and “essentially biological processes.” *Id.*

<sup>75</sup> GERVAIS, *supra* note 42 at 341–353.

<sup>76</sup> *See, e.g., Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 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.*, (2010) Petition No. 409 of 2009 (H.C.K.) (Kenya).

<sup>77</sup> *See, e.g., Ass’n for Molecular Pathology*, 133 S. Ct. at 2116 (“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.’”); *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 . . .”); *Bilski v. Kappos*, 130 S. Ct. 3218, 3228 (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.”).

<sup>78</sup> *See, e.g., 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* (Ruth L. Okediji & Margo A. Bagley eds., forthcoming 2014) [hereinafter Bagley, *Patent Barbarians*]; Dan Burk, *Patent Law’s Problem*

innovation exists within the context of Article 27. As I have argued elsewhere, the role of local institutions in balancing the incentive to commercialize innovation and interests underlying the distinctive policy goals of the patent system to promote the progress of society has been steadily redefined in recent years.<sup>79</sup>

Innovative responses by courts to an enlargement of patent 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 statute,<sup>80</sup> strongly supported by the United States and the pharmaceutical sector,<sup>81</sup> in order to preserve access to generic medicines.<sup>82</sup> 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.<sup>83</sup>

Outside the judicial context, biodiversity-rich countries such as China, India, and Brazil have enacted laws that limit access to and inventive use of biological and genetic resources, specifically to encourage downstream IP owners to share the benefits gained from such resources with the providing country,<sup>84</sup> introducing new and critically important dimensions to national patent policies. These national innovations lie at the intersection of patent and environmental protection regimes, and have injected new momentum into WIPO's IGC negotiations for an

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*Children*, in PATENT LAW IN GLOBAL PERSPECTIVE (Ruth L. Okediji & Margo A. Bagley eds., 2014); Margo A. Bagley, *The New Invention Creation Activity Boundary in Patent Law*, 51 WM. & MARY L. REV. 577 (2009).

<sup>79</sup> Ruth L. Okediji, *Public Welfare and the International Patent System*, in PATENT LAW IN GLOBAL PERSPECTIVE (Ruth L. Okediji & Margo A. Bagley eds., 2014) [hereinafter Okediji, *Public Welfare*].

<sup>80</sup> Anti-Counterfeit Act, No. 13 (2008), KENYA GAZETTE SUPPLEMENT No. 97, 261 (Kenya).

<sup>81</sup> See, e.g., *World Anti-Counterfeit Day*, U.S. EMBASSY BLOG: NAIROBI (June 12, 2012), <http://blogs.usembassy.gov/nairobi/2012/06/12/world-anti-counterfeit-day>; Suleiman Mbatiah, *Kenya: Pharmaceutical Companies Pushing Anti-Counterfeit Law*, INTERPRESS SERVICE NEWS AGENCY (June 14, 2010),

<http://www.ipsnews.net/2010/06/kenya-pharmaceutical-companies-pushing-anti-counterfeit-law>.

<sup>82</sup> *Asero Ochieng v. Attorney-Gen.*, (2010) Petition No. 409 of 2009 (H.C.K.) (Kenya).

<sup>83</sup> *Id.* ¶¶ 75–78.

<sup>84</sup> Bagley, *Patent Barbarians*, *supra* note 78, at 176.

international instrument mandating disclosure of source by patent applicants when genetic resources have been used in the inventive process.<sup>85</sup> Although the precise scope of such an international requirement remains highly contested (as is the very principle of disclosure), the geopolitical space already subject to such a requirement is significant. If successful at WIPO, the IGC process 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 as is the case here. The entry into force of the Convention on Biological Diversity (CBD),<sup>86</sup> which recognizes sovereign rights over natural resources in member states, and the associated Nagoya Protocol,<sup>87</sup> which establishes a legal framework for access and benefit sharing regimes<sup>88</sup> 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, has engendered a powerful set of international norms that govern an important area of new technological developments. It is implausible to think that the multilateral IP system can remain aloof from these muscular regime complex, and imprudent to fail to consider how national innovation stemming from other legal regimes could

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<sup>85</sup> 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). *See* Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore [hereinafter IGC], 1st Sess., WIPO/GRTKF/IC/1 (Mar. 16–May 3, 2001), [http://wipo.int/meetings/en/details.jsp?meeting\\_id=4295](http://wipo.int/meetings/en/details.jsp?meeting_id=4295). The IGC’s current mandate from WIPO is to work on “text-based negotiations . . . [to] reach[] an agreement on a text(s) of an international legal instruments(s) which will ensure the effective protection of GRs, TK, and TCEs.” WIPO, 43rd sess., WO/GA/43/14 (Aug. 14, 2013), [http://wipo.int/edocs/mdocs/govbody/en/wo\\_ga\\_43/wo\\_ga\\_43\\_14.pdf](http://wipo.int/edocs/mdocs/govbody/en/wo_ga_43/wo_ga_43_14.pdf). The most recent twenty-six session was held in February 2014. *See* IGC, 26th Sess., WIPO/GRTKF/IC/26 (Feb. 3–7, 2014), *available at* [http://www.wipo.int/meetings/en/details.jsp?meeting\\_id=31362](http://www.wipo.int/meetings/en/details.jsp?meeting_id=31362). The latest draft text on genetic sources will be submitted to the WIPO General Assembly in September 2014. *See Consolidated Document Relating to Intellectual Property and Genetic Resources (Rev. 2)*, WIPO/GRTKF/IC/26 (Feb. 7, 2014), [http://wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=267381](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>.

<sup>86</sup> Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79.

<sup>87</sup> 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.

<sup>88</sup> *Id.*

cohere within the IP framework. Whether the IGC process is successful, the rate of innovation and patent filings in countries such as India, China, and Brazil suggest that whether or not new innovation is formally internalized in the multilateral IP system, domestic legal innovation that is linked to strong public law regimes will invariably affect the strategies and practices of IP firms, eventually creating a de facto integration of those norms in the multilateral IP framework.

(iii) *Sanctions and Enforcement*

Most scholars agree that the possibility of effective IP enforcement was one of the major triumphs of the Uruguay Round,<sup>89</sup> giving countries an opportunity to sanction violators of agreed provisions.<sup>90</sup> 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 back in 1994. Further, among these disputes, compliance has remained uneven, especially by the U.S. which, to date, has yet to implement several panel reports.<sup>91</sup> As this data may suggest, determining what is a TRIPS violation is not a simple task nor is achieving enforcement on the ground.

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.<sup>92</sup> 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

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<sup>89</sup> See, e.g., Dreyfuss & Lowenfeld, *supra* note 39.

<sup>90</sup> *Id.* at 277.

<sup>91</sup> 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).

<sup>92</sup> Okediji, *Rules of Power*, *supra* note 20.

politics that may have constrained appropriate compliance with the international norm.<sup>93</sup> As between two differently situated countries, dispute settlement may offer an opportunity to recalibrate particular expectations 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., could be an example of this strategic use of the DSU process.<sup>94</sup> Cotton subsidies have historically been a sensitive trade issue for the U.S.<sup>95</sup> Similarly, Brazil has a strong cotton industry and, like other developing countries, had a high interest in better access to agricultural markets as part of the Uruguay Round bargain.<sup>96</sup> Bringing the WTO complaint and defending it vigorously were acts that, quite aside from the merits of the case, were likely politically positive for both countries.

Nevertheless, these cases of cross-retaliation in the TRIPS context leave considerable uncertainty generally about how effective is the dispute settlement process for developing countries.<sup>97</sup> Speaking specifically of cross-retaliation, its effectiveness as a credible threat at least partially depends on the relative influence of the domestic interest group vis a vis IP-intensive

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<sup>93</sup> Ruth L. Okediji, *Toward an International Fair Use Doctrine*, 39 COLUM. J. TRANSNAT'L L. 75 (2000).

<sup>94</sup> Panel Report, *United States—Subsidies on Upland Cotton*, WT/DS267/R (Sept. 8, 2004).

<sup>95</sup> 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 cotton, have been subsidized since the 1930s.”).

<sup>96</sup> 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).

<sup>97</sup> 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); Frederick M. Abbott, *Cross-Retaliation in TRIPS: Options for Developing Countries* (ICTSD Issue Paper No. 8, 2009), available at <http://ictsd.org/downloads/2009/06/cross-retaliation-in-trips.pdf>; see also Gabriel L. Slater, Note, *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 (2009).

industries on lawmakers.<sup>98</sup> If the domestic calculus of the complaining country is wrong, permission to cross-retaliate by suspending TRIPS obligations is unlikely to produce the strong compliance in the area of dispute that is likely the preferred outcome of the complainant.<sup>99</sup> The credibility of a cross-retaliation threat in regards to TRIPS is also affected by the sheer complexity of applying criteria developed for goods, such as the principle that the level of suspension be “equivalent” to IP rights which are not easily susceptible to valuation.<sup>100</sup> Even where a developing country is able to satisfy the hefty requirements of DSU Article 22.3,<sup>101</sup> cross-retaliation under TRIPS can affect interests of innocent states, further complicating the political risks of this enforcement option for the complainant.

Consider, for example, that ownership of copyright in a jointly authored work belongs to an Argentinian author and a Brazilian author. If Argentina 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 that are legally designed to be easily de-anchored from its origin or that of the author,<sup>102</sup> determining the value of IP and which associated rights can be suspended is, alone, an exercise requiring immense analytical investment.<sup>103</sup> In addition to the complexity of determining value and to which country a work belongs, the ease with which digital goods transcend borders make

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<sup>98</sup> Peter K. Yu, *Are Developing Countries Playing a Better TRIPS Game?*, 16 UCLA J. INT’L L. & FOREIGN AFF. 311, 340 (2011).

<sup>99</sup> See generally Abbott, *supra* note 97; Yu, *supra* note 98.

<sup>100</sup> 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. Brown & Joost Pauwelyn eds., 2010).

<sup>101</sup> DSU, *supra* note 20, art. 22.3.

<sup>102</sup> *Compare Dastar Corp. v. Twentieth Century Fox Film Corp.*, 123 S. Ct. 2041, 2050 (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”).

<sup>103</sup> Frederick 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. Brown and Joost Pauwelyn eds. 2010).

it exceptionally difficult to police where goods embodying suspended IPRs may end up and how they could be distinguished in the market.<sup>104</sup> The difficulties posed by cross-retaliation are not insurmountable and strategic identification of particular kinds of IP that could be the focus of cross-retaliation has been explored by Professor Fred Abbott.<sup>105</sup> Further, other benefits can be obtained from trade-retaliation measures if feasible given the country's market size.<sup>106</sup> But for cross-retaliation which holds such seductive promise for developing countries seeking to enforce trade obligations against advanced economies, the main point is that in choosing between enforcement strategies against 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.<sup>107</sup> In short, the relative ineffectiveness of cross-retaliation in relation to TRIPS obligations again confirms the weakness of the bargain developing countries struck in exchanging strong IP rights for now unfilled commitments in access to agriculture, while still dealing fundamentally with a power (not law) driven trade system.<sup>108</sup>

Second, dispute settlement entails significant economic costs,<sup>109</sup> and the risk of loss can have consequences not wholly in line with the interests of a developed country Complainant. In

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<sup>104</sup> A similar point was made by the arbitrators in EC-Bananas III (Ecuador) "interference with private property rights of individuals or companies may be perceived as more far reaching . . . given the potentially unlimited possibility to copy phonograms or use other intellectual property rights." Decision by the Arbitrators, EC—Regime for the Importation, Sale, and Distribution of Bananas ("Bananas III"), WT/DS27/ARB/ECU (Mar. 24, 2000); see also, Zdouc, *supra* note 100, at 524.

<sup>105</sup> See Abbot, *supra* note 97; Abbot, *supra* note 103, at 536.

<sup>106</sup> 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 (Chad P. Brown & Joost Pauwelyn eds., 2010) (exploring the goal of WTO suspension and concluding that no single goal exists. Instead, there are a variety of goals such as compliance, compensation or sanction).

<sup>107</sup> *But see* Zdouc, *supra* note 100, 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. Brown & Joost Pauwelyn eds., 2010).

<sup>108</sup> JOHN H. JACKSON, THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS (2d ed. 2002).

<sup>109</sup> 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).



*China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*,<sup>110</sup> the U.S. 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.”<sup>111</sup> The Chinese measures allowed seized goods to be donated to social welfare organizations, sold to the rights-holder, or as a last resort, auctioned.<sup>112</sup> The U.S. objected to these practices, arguing that “Article 59 requires full authority to be granted to dispose of or *destroy* confiscated infringing goods.”<sup>113</sup> The WTO Panel rejected the U.S. argument, stating that the language “shall have the authority” does not mean the authority must be exercised in a particular way, and certainly not in the way the U.S. argued.<sup>114</sup> And although the U.S. won on the other issue before the Panel,<sup>115</sup> 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. In short, dispute settlement under TRIPS has not proven, except in very few instances, to be an outright victory for developed countries, and instead has opened up explicit room for discretion in areas that TRIPS did not anticipate. The lesson may be that the absence of a clear signal of sovereign discretion in the TRIPS text does not mean that a TRIPS dispute panel will not find that such discretion exists.

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<sup>110</sup> Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009) [hereinafter *China—Measures*].

<sup>111</sup> TRIPS Agreement, *supra* note 3, art. 59.

<sup>112</sup> *China—Measures*, *supra* note 110, ¶ 7.194

<sup>113</sup> *Id.* at ¶ 7.199 (emphasis added).

<sup>114</sup> *Id.* at ¶ 7.238.

<sup>115</sup> *Id.* at ¶ 7.139.

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

Despite the initial excitement about the enforcement prospects of TRIPS, “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.”<sup>116</sup> Binding dispute settlement under TRIPS was designed to facilitate greater consistency, predictability, and enforcement of international IP norms. Understandably, the process established by the DSU encourages countries to settle disputes through diplomatic channels to avoid unduly straining the WTO system.<sup>117</sup> Private bartering over TRIPS violations has thus been an important component of trade relations especially among developed countries in disputes with one another,<sup>118</sup> while disputes between developed and developing countries seem more likely to invoke the full gamut of the formal process.<sup>119</sup> Developed countries leverage the DSU process to exert pressure on developing countries and extract compliance in ways that escape the scrutiny of the international community.<sup>120</sup> 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.

Assessments of IP disputes brought before the WTO from 2005 to 2011 show that of the 419 total WTO challenges, only 29 IP challenges were brought, of which 20 were against

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<sup>116</sup> Okediji, *TRIPS Dispute Settlement*, *supra* note 20, at 634.

<sup>117</sup> *Id.* at 617.

<sup>118</sup> *See, e.g., United States—Section 110(5)*, *supra* note 12.

<sup>119</sup> *See* Stostad, *supra* note 109, at 830 (stating that the WTO has increased the probability of disputes being filed against developing countries by 4.7 times).

<sup>120</sup> Okediji, *TRIPS Dispute Settlement*, *supra* note 20, 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 LAW. 795, 808–09 (1998). 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).

developed countries.<sup>121</sup> Additionally, the expectation of an enforcement onslaught against developing countries has not materialized; only 9 of the 27 TRIPS disputes were North-South cases.<sup>122</sup> Finally, of all IP disputes, only 8 matters were pursued to a WTO decision, with all but one finding a violation.<sup>123</sup> 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 innovations by courts and IP agencies reflect the capacity to reset the normative global IP balance, even if indirectly.

(i) *The Triumph of Legislation in Developing Countries*

Among most developing countries, TRIPS-required IP legislation was adopted relatively promptly (some may argue too promptly in many cases).<sup>124</sup> This includes pharmaceutical patent legislation even in countries whose generic industries were most significantly threatened by the new global norms, namely, Brazil and India.<sup>125</sup>

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<sup>121</sup> Lee, *supra* note 91, 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>

<sup>122</sup> Pauwelyn, *supra* note 121.

<sup>123</sup> *Id.*

<sup>124</sup> CECILIA OH & SISULE MUSUNGU, 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).

<sup>125</sup> India's initial efforts to implement the mail box system generated the first TRIPS dispute. See Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/D550/AB/R (Dec. 19, 1997). The U.S. 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. 585–601 (1998).

Prior to TRIPS, Brazil provided very limited patent protection for pharmaceutical products and processes.<sup>126</sup> Its prompt compliance with the new international rules allowed pharmaceutical patent owners to immediately start filing applications in Brazil; these applications were largely ignored until 2001 when new legislation mandated regular examination of chemical and pharmaceutical *product* patents.<sup>127</sup> The same law, however, declared that pharmaceutical and chemical *process* applications would be rejected, because TRIPS only referred to product patents.<sup>128</sup> A separate law provided that applications based on foreign pharmaceutical product patents would be granted without a secondary novelty requirement.<sup>129</sup> However, Brazil did maintain a local working requirement, which authorizes compulsory licensing if a patentee fails to work locally.<sup>130</sup> The U.S. alleged that this local working aspect of Brazilian patent law violated the TRIPS Agreement and brought a complaint pursuant to the DSU.<sup>131</sup> Brazil argued that these provisions were necessary to help it protect against the threat of HIV/AIDS consistent with the terms of the TRIPS Agreement.<sup>132</sup> The U.S. later withdrew the complaint,<sup>133</sup> thus leaving this an open question of international patent law<sup>134</sup> and adding to the scope of room for innovative responses to deal with specific national interests.<sup>135</sup> Indeed, the U.S. withdrawal could have been made on an assessment of the risks of a WTO finding that local

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<sup>126</sup> Claudia Schulz, *The TRIPS Agreement and Intellectual Property in Brazil*, 98 AM. SOC'Y INT'L L. PROC. 100, 100 (2004).

<sup>127</sup> *Id.*

<sup>128</sup> *Id.* at 100–01.

<sup>129</sup> *Id.* at 101.

<sup>130</sup> *Id.*

<sup>131</sup> Request for Consultations, *Brazil—Measures Affecting Patent Protection*, WT/DS199/1 (Aug. 6, 2000).

<sup>132</sup> Mutually Agreed Solution, *Brazil—Measures Affecting Patent Protection*, WT/DS199/4 (July 19, 2001); *see also* GERVAIS, *supra* note 42, at 340.

<sup>133</sup> Champ & Attaran, *supra* note 9, at 366.

<sup>134</sup> The Paris Convention allowed member states to impose compulsory licenses for failure to work a patent after a delay. *See* Paris Convention, *supra* note 1, art. 5A.

<sup>135</sup> It seems clear that local working requirements are not a violation of the prohibition of discrimination under Article 27(1). *See* GERVAIS, *supra* note 42 at 340.

working requirements are TRIPS consistent, thus signaling other countries who for other reasons may want to adopt a similar domestic policy.<sup>136</sup>

Like Brazil, the pre-TRIPS patent law adopted in India in 1970 contained an express prohibition on pharmaceutical product patents, but did allow limited duration pharmaceutical process patents.<sup>137</sup> As a result, India became a globally recognized producer of low-priced generic pharmaceuticals,<sup>138</sup> 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.<sup>139</sup> The first allowed applicants to file for pharmaceutical product patents, for which they could be awarded exclusive marketing rights for five years from patent grant.<sup>140</sup> The second amendment provided for a twenty-year patent term, reversal of the burden of proof for process patent infringement, and modifications to compulsory licensing requirements.<sup>141</sup> In 2005, a third amendment offered patent protection to pharmaceuticals and made India “substantially compliant with TRIPS.”<sup>142</sup>

Although some TRIPS proponents expressed skepticism as to whether developing countries would ignore or fail to enforce TRIPS requirements,<sup>143</sup> developing countries have not ignored the legislation requirements, and indeed, many have exceeded them.<sup>144</sup> Even in Brazil

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<sup>136</sup> 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., 2005 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 33 (2005). This may point to the real interest of the U.S., namely constraining unilateral exercises of discretion even within the permissible boundaries of the TRIPS Agreement.

<sup>137</sup> Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1577 (2009).

<sup>138</sup> *Id.* at 1578.

<sup>139</sup> 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, 328 (2012).

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> *See, e.g.*, Charles S. Levy, *Implementing TRIPS—A Test of Political Will*, 31 L. & POL'Y INT'L BUS. 789, 789 (2000).

<sup>144</sup> *See infra* notes 149–153 and accompanying text (discussing TRIPS-plus provisions in developing countries).

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 institutions. The reality is that since making its law TRIPS compliant, India has issued many pharmaceutical patents as has Brazil. Legislative compliance with the TRIPS Agreement, to the dismay of commentators, has been wide-spread even in the least developed countries despite WTO extensions.<sup>145</sup> In short, global friction over TRIPS implementation has not been focused on whether compliant legislative changes have been adopted, but rather on the ways in which TRIPS flexibilities have been utilized, whether in the governing statutes or by the courts or administrative agencies which, as the following section suggests, may be poised to be the leading laboratories of legal innovation.

## II.

### **THE REALITY OF TRIPS: INSTITUTIONS OF DEVELOPMENT AND THE CHALLENGE OF COHERENT IMPLEMENTATION**

#### *A. Legal Innovation in the Developing Countries*

In negotiating the TRIPS Agreement, developing countries voiced concerns that stronger IP minimum standards could constrain development, reduce employment and economic growth, and threaten public health interests and access to essential technologies and knowledge.<sup>146</sup> For example, critics warned that heightened IP standards would lead to devastating price increases in

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<sup>145</sup> See, e.g., CAROLYN DEERE, THE IMPLEMENTATION GAME 13 (2009) (“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.”).

<sup>146</sup> See, e.g., *id.* at 9–10; Molly Land, *Rebalancing TRIPS*, 33 MICH. J. INT’L L. 433, 435–46 (2012) (arguing that TRIPS limits countries’ ability to “foster innovation and protect human health and welfare”); 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”).

many critical imported technologies, such as seeds, medicines, and educational materials.<sup>147</sup> Furthermore, national industrial development could be impeded by limiting the ability of these countries to reverse-engineer, adapt, and build upon existing technologies from developed countries.<sup>148</sup> 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 arguably could have ameliorated some of the concerns, many developing countries did not take advantage of them. Instead, many countries established laws exceeding the minimum requirements of TRIPS, colloquially known as TRIPS-plus provisions.<sup>149</sup> Counterintuitively, nations with the fewest flexibilities and the highest levels of TRIPS-plus protection are often the least-developed countries.<sup>150</sup> A large body of scholarship suggests that countries deviated from their own local interests due to intense political, economic, and trade-related pressures from developed countries.<sup>151</sup> For example, bilateral trade and investment agreements were offered to developing countries in exchange for agreements to forego flexibilities or implement TRIPS-plus standards.<sup>152</sup> In other cases, where bilateral negotiations failed, developed countries resorted to unilateral coercion through trade-sanction threats, diplomatic threats, and industry pressures from multinational corporations.<sup>153</sup>

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. Consequently,

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<sup>147</sup> DEERE, *supra* note 145, at 9.

<sup>148</sup> *Id.*

<sup>149</sup> *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.”).

<sup>150</sup> *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 102.

<sup>151</sup> *See, e.g., id.* at 104, 114–16, 150–51.

<sup>152</sup> *Id.* at 150–155; Land, *supra* note 151, at 442 & n.45.

<sup>153</sup> DEERE, *supra* note 145, at 159–164; *see also* Okediji, *Public Welfare*, *supra* note 79, at 58 & n.30.

institutions and new processes are constructively challenging the dominant narrative of the substantive provisions of the TRIPS Agreement. Three important case studies could suggest the rise of legal innovation in the developing countries to address the immediate welfare challenges related to TRIPS implementation and compliance. These cases are not arising from the shadows of flexibilities as such, but rather from the sunlight of hard doctrine.

*(i) 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.<sup>154</sup> As India's leaders demanded changes to the patent system, a committee was appointed in 1948 to review patent laws and ensure they were in line with national interests.<sup>155</sup> Based on recommendations from the report, the 1911 Patent Act was amended in relation to the working of inventions and compulsory licensing.<sup>156</sup> 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.<sup>157</sup>

In 1970, India enacted a national patent law prohibiting patents on pharmaceutical products.<sup>158</sup> By 1979, the number of patent applications by foreign filers had decreased to less than a quarter of the number filed in 1968.<sup>159</sup> Conversely, the new patent law led to a significant increase in Indian generic drug manufacturing and a dramatic decline in the price of medicines

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<sup>154</sup> Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 UNIV. OF PITT. L. REV. 491, 513–14 (2007).

<sup>155</sup> *Id.* at 511.

<sup>156</sup> *Id.*; see also *History of Indian Patent System*, INTELL PROP. INDIA, <http://ipindia.nic.in/ipr/PatentHistory.htm> (last visited Feb. 22, 2014)

<sup>157</sup> Mueller, *supra* note 154, at 512; *History of Indian Patent System*, *supra* note 156.

<sup>158</sup> Patent Act, No. 39 of 1970, § 162(1) (India).

<sup>159</sup> Mueller, *supra* note 154, at 513–14; Kapczynski, *supra* note 137, at 1578.



sold in India.<sup>160</sup> India soon became known as a “pirate” or “copycat” nation, because generic drug companies could (and did) legally copy pharmaceutical products patented outside India.<sup>161</sup> 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.<sup>162</sup> For example, in the late 1990s, India could produce a drug for as little as \$90 million, compared to a price tag of at least \$300 million in Western countries.<sup>163</sup> In 1998, the brand-name antacid Zantac for sale in the U.S. was more than 100 times the price of the Indian generic version.<sup>164</sup> In this patent-free environment, the Indian generic industry soared, and drug prices plummeted, forcing many multi-national drug companies to leave India.<sup>165</sup> The number of pharmaceutical facilities skyrocketed, with over 20,000 Indian companies supplying 95% of pharmaceutical market in India. This resulted in huge boosts to India’s economy and employment rates, with pharmaceutical companies directly employing 5 million, and another 24 million indirectly.<sup>166</sup>

Over time, India’s pharmaceutical industry not only expanded production, but also grew more technically sophisticated.<sup>167</sup> The industry developed expertise in reverse engineering drugs and rapidly diversified.<sup>168</sup> However, because the manufacturing boom resulted largely from copying of existing drugs, it did not result in increased innovation in new drugs.<sup>169</sup> Today, R&D

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<sup>160</sup> Mueller, *supra* note 154, at 514.

<sup>161</sup> 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>; see also Mueller, *supra* note 154, at 514.

<sup>162</sup> David K. Tomar, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WISC. INT’L L. REV. 579 (1999)

<sup>163</sup> *Id.*

<sup>164</sup> B.K. KEAYLA, CONQUEST BY PATENTS: TRIPS AGREEMENT ON PATENT LAWS: IMPACT ON PHARMACEUTICALS AND HEALTH FOR ALL 9 (1998).

<sup>165</sup> *Id.*

<sup>166</sup> KPMG, THE INDIAN PHARMACEUTICAL INDUSTRY: COLLABORATION FOR GROWTH 8 (2006) [hereinafter KPMG, INDIA], available at <http://www.in.kpmg.com/pdf/indian%20pharma%20outlook.pdf>.

<sup>167</sup> Kapczynski, *supra* note 137, at 1578.

<sup>168</sup> *Id.*

<sup>169</sup> Mueller, *supra* note 154, at 515.

investment by Indian firms appears to be on the rise, although relative to Western companies, the investment is still minimal.<sup>170</sup> And despite positive signs in the Indian pharmaceutical industry,<sup>171</sup> the critical dominance of local firms could be lost in a recent wave of mergers and acquisitions designed purposefully to eliminate Indian generic competition in global markets.<sup>172</sup>

The landscape in India is further complicated by the active role of the Indian judiciary in IP cases. A highly controversial decision by the Indian Supreme Court, *Novartis AG v. Union of India*,<sup>173</sup> illustrates the kind of legal innovation designed to create a uniquely national-focused approach to TRIPS compliance and implementation. This kind of innovation is credible, compliant, and creative. 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.<sup>174</sup> After the Indian Patent Office rejected the application,<sup>175</sup> Novartis appealed to the Indian Patent Appeals Board (IPAB).<sup>176</sup> 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.<sup>177</sup> On final appeal, the Indian Supreme Court affirmed the IPAB rejection of the Novartis’s Gleevec application, clarifying that “efficacy”

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<sup>170</sup> *Id.* at 515 (discussing minimal R&D investment levels for Indian drug companies in the 1990s, around 1–2%); *id.* at 537 (discussing rising R&D investment levels for top Indian generic companies, around 7–9%).

<sup>171</sup> *Id.* at 537 (noting that major Indian drug companies are increasing investments in R&D; (2) many patents worth billions of dollars will expire in coming years; and that under India’s new patent laws, drug manufacturers can continue to copy pharmaceuticals available in the Indian market prior to 1995).

<sup>172</sup> See William Greene, *The Emergence of India’s Pharmaceutical Industry and Implications for the U.S. Generic Drug Market* 8 (U.S. Int’l Trade Comm., Office of Economics, Working Paper No. 2007-05-A, 2007)

<sup>173</sup> *Novartis AG v. Union of India*, Nos. 2706–16, slip op. at 90–91 (S.C. Apr. 1, 2013) (India), available at <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>.

<sup>174</sup> 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).

<sup>175</sup> See *Novartis AG v. Natco Pharma and Others*, Controller of Patents and Designs, Indian Patent Office, Application No. 1602/MAS/1998 (Jan. 25, 2005), available at <http://indiankanoon.org/doc/1352538>.

<sup>176</sup> *Novartis v. Union of India & Others*, IPAB Order No. 100/2009 (June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm> [hereinafter *Novartis IPAB*]

<sup>177</sup> Patent Act, No. 39 of 1970, as amended by Patents Act, No. 15 of 2005, § 3(d) (India); *Novartis IPAB*, *supra* note 176.

under Section 3(d) refers to “therapeutic efficacy,” weighed by strict and narrow standards.<sup>178</sup> 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.”<sup>179</sup> Put differently, because Gleevec was merely the inherent solid form of the earlier known substance, it did not qualify as an enhancement of efficacy.<sup>180</sup> The U.S. and other countries have expressed concern over this application of India’s TRIPS-compliant Patent Act.<sup>181</sup> The international responses, and accompanying political pressure on India over the decision, has continued to play out on the international stage.<sup>182</sup> Just recently, 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.<sup>183</sup> The fact that the U.S. is pursuing unilateral action and not a WTO process is telling. The United States Chamber of Commerce has called on the U.S. government to place India on its controversial priority watch list.<sup>184</sup> Whether such a move by the U.S. is TRIPS compliant is questionable.<sup>185</sup>

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<sup>178</sup> *Novartis AG v. Union of India*, Nos. 2706–16, slip op. at 90–91 (S.C. Apr. 1, 2013) (India), available at <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>.

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> See Lisa Kilday, *Global IP Reaction to India’s Rejection of the Novartis Drug Patent*, IPWATCHDOG (May 28, 2013), <http://www.ipwatchdog.com/2013/05/28/global-ip-reaction-to-indias-rejection-of-the-novartis-drug-patent/id=40778>.

<sup>182</sup> *Id.*

<sup>183</sup> *Trade Investment, and Industrial Policies in India: Effects on the U.S. Economy*, USITC Inv. No. 332-543 (Feb. 6, 2013), available at [http://www.usitc.gov/secretary/fed\\_reg\\_notices/332/332\\_543\\_notice02062014sgl.pdf](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](http://www.business-standard.com/article/economy-policy/us-trade-panel-begins-critical-hearings-on-indian-policy-114021300075_1.html); *US Trade Panel Launches Probe Against India’s Trade Policies*, ECONOMIC TIMES (INDIA) (Feb. 12, 2014), [http://articles.economictimes.indiatimes.com/2014-02-12/news/47270048\\_1\\_indian-ipr-linda-dempsey-global-intellectual-property-center](http://articles.economictimes.indiatimes.com/2014-02-12/news/47270048_1_indian-ipr-linda-dempsey-global-intellectual-property-center).

<sup>184</sup> 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](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 U.S. pledged to base any section 301 determinations on “panel or Appellate Body findings adopted by the

It is arguable that the Gleevec decision is simply a straightforward application of India's domestic patent law pursuant to TRIPS Article 27. After all, the TRIPS Agreement is not a harmonization agreement; it does not mandate consistency in how the 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 is TRIPS compliant. Accordingly, there should be some puzzlement about the extent to which the developed countries and firms have expressed dissatisfaction with Indian Court's ruling and why the Gleevec decision occasioned such intense global debate.<sup>186</sup> 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 arguably are

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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.

<sup>185</sup> Article 23(2) of the Dispute Settlement Understanding requires that Members "shall":

(a) not 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; . . .

The panel decision in *United States—Section 301-310*, *supra* note 184, 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.

*Id.* at 327; *see also* Sean Flynn, *US Uses Special 301 To Bully Ukraine, Likely Violating WTO*, TECHDIRT (May 17, 2013), <https://www.techdirt.com/articles/20130513/16505323067/us-uses-special-301-to-bully-ukraine-likely-violating-wto.shtml>.

<sup>186</sup> *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.").

unassailable on grounds of textual conformity, developed country firms likely find the spirit of the Gleevec decision inconsistent with the “purpose and objective” of the TRIPS Agreement.

A deeper and potentially more troubling explanation may co-exist with the first. Back in 1994, the TRIPS Agreement was negotiated in a context of extremely limited capacity among the developing countries. Not only did IP issues not rank highly on the list of political demands by developing and least-developed countries for the Uruguay Round, but domestically, IP issues did not attract the same level of social agitation or intuitive understanding as, say, the prospect of a bad deal in agriculture. The lack of capacity coupled with the absence of a well-mobilized domestic coalition made compromises over TRIPS 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.<sup>187</sup> That developing countries might have overcome this capacity gap twenty years after TRIPS, and what to expect from these countries once that occurred, is not something developed countries likely have contemplated. In reality, the framework in which contemporary international relations unfold remain 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 emerging from the West.<sup>188</sup> The socio-political 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 doctrine and make intelligent assessments about what best serves the social values and welfare of the societies with whose interests the court is

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<sup>187</sup> See generally Gonzalez, *supra* note 96.

<sup>188</sup> 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).

charged. At the most elemental level, the overheated reaction to Gleevec, and threats of unilateral reprisal, also fundamentally questions their right to do so.

(ii) *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.<sup>189</sup> 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).<sup>190</sup> INPI is responsible for examining the legal sufficiency of patent applications, analogous to the U.S. Patent and Trademark Office.<sup>191</sup> ANVISA, on the other hand, is a separate agency devoted to protecting and promoting “public health” in Brazil,<sup>192</sup> analogous to the U.S. Food and Drug Administration.<sup>193</sup> 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.<sup>194</sup> However, according to a 2008 resolution issued by ANVISA, it believes that it also has the authority to engage in a secondary analysis of patentability: “After having received the patent applications submitted by INPI, ANVISA will carry out its analysis with respect to the prior consent thereto, assessing whether

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<sup>189</sup> 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, 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, Jr., & Bryan Murphy, *Brazil's Prior Consent Law*, 16 ALB. L.J. SCI. & TECH. 423 (2006).

<sup>190</sup> Law No. 10,196, *supra* note 189; see also, e.g., Rodrigues & Murphy, *supra* note 189.

<sup>191</sup> See *Meet the INPI*, INPI, [http://www.inpi.gov.br/portal/artigo/conheca\\_o\\_inpi](http://www.inpi.gov.br/portal/artigo/conheca_o_inpi) (last updated Dec. 28, 2012).

<sup>192</sup> See *The Agency*, ANVISA, <http://portal.anvisa.gov.br/wps/portal/anvisa-ingles/anvisaingles/Agencia> (last visited Jan. 25, 2014).

<sup>193</sup> See *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Feb. 22, 2014).

<sup>194</sup> Law No. 10,196, *supra* note 189, 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>.

said applications meet the patentability requirements.”<sup>195</sup> In other words, under the Brazilian two-stage examination process, patentability is examined twice by two different agencies, using different criteria, with the second (ANVISA) likely being of lesser technical competence.<sup>196</sup> In effect, this system allows ANVISA to veto any pharmaceutical patent, despite an INPI determination of patentability, resulting in a highly unpredictable examination process.<sup>197</sup> Following the 2008 ANVISA Resolution, INPI brought an administrative proceeding that contested ANVISA’s ability to carry out this duplicative patentability analysis. During this 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.<sup>198</sup>

In 2013, ANVISA issued a new resolution, amending the previous ANVISA Resolution of 2008.<sup>199</sup> The new resolution states that ANVISA will review the patent applications “in light of the public health.”<sup>200</sup> The application will be considered contrary to public health when it (1) “presents a health risk” or (2) the application is “of interest to drug policy or pharmaceutical services” and “do not meet the patentability requirements.”<sup>201</sup> Although the 2013 Resolution more explicitly invokes ANVISA’s institutional purpose, it makes no progress in resolving the duplicative legal analysis because it lists patentability as an element of public health.<sup>202</sup>

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<sup>195</sup> Resolution (RDC) No. 45 of June 23, 2008 (Braz.).

<sup>196</sup> 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>.

<sup>197</sup> See Rodrigues & Murphy, *supra* note 189, at 427.

<sup>198</sup> 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.).

<sup>199</sup> Resolution (RDC) No. 21 of Apr. 10, 2013 (Braz.); see also Resolution No. 45, *supra* note 195.

<sup>200</sup> Resolution No. 21, *supra* note 199.

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

Some argue that ANVISA's implementation of the Prior Consent for pharmaceutical patent examination is discriminatory and in violation of TRIPS Article 27.1, which prohibits discrimination against particular fields of patentable technologies.<sup>203</sup> Because ANVISA only reviews pharmaceutical applications, and because it denies approval to approximately 5% of those applications (which were all deemed patentable by INPI), logically this means that ANVISA is either (or both): (1) applying a stricter standard of patentability than INPI, which may be discriminatory because this stricter standard thereby applies only to pharmaceuticals; or (2) it is applying extraneous considerations related to public health, which may also be discriminatory because such considerations are being applied only to pharmaceuticals.<sup>204</sup> Beyond 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."<sup>205</sup> More recently, in a 2013 report, the USTR expressed stronger criticisms of this convoluted system and urged Brazil to adopt a more transparent and predictable examination process.<sup>206</sup> Nothing in Brazil's ongoing patent reform process yet suggests this will happen, and nothing in TRIPS requires it to. Indeed, it is ironic 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.<sup>207</sup>

In a separate legal dispute, INPI is also attempting to "correct" the term of certain agrochemical and pharmaceutical patents. When Brazil joined the WTO, it was allowed a

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<sup>203</sup> TRIPS Agreement, *supra* note 3, art. 27.1.

<sup>204</sup> 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](http://www.anvisa.gov.br/medicamentos/intelectual/situacao_processos.pdf); Rodrigues & Murphy, *supra* note 189, at 448–54 (arguing that the Prior Consent law is discriminatory and violates TRIPS).

<sup>205</sup> See USTR, NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 33 (2005), available at [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2005/2005\\_NTE\\_Report/asset\\_upload\\_file383\\_7446.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_NTE_Report/asset_upload_file383_7446.pdf)

<sup>206</sup> See USTR, SPECIAL 301 REPORT, *supra* note 186, at 45.

<sup>207</sup> DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009).



transitional period to introduce pharmaceutical and agrochemical patents. TRIPS Article 70(8) provides that developing countries utilizing this transitional period allow inventors to file such patents as of January 1, 1995, although a decision to grant could be delayed until January 1, 2005.<sup>208</sup> According to TRIPS, the term of any such “mailbox patent” is 20 years from the filing date. Brazil adopted this mailbox consideration for applications “filed between January 1, 1995 and May 14, 1997”<sup>209</sup> 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 20 years from the date of filing, but not less than 10 years from the grant.<sup>210</sup> INPI has been examining and issuing mailbox patents well past the deadline of Dec. 31, 2004, and these patents had been receiving terms of 10 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 33 lawsuits seeking a corrected term of the mailbox patents, nullification of the patents, and a request to suspend rights while the lawsuit is pending.<sup>211</sup> Many U.S. and EU companies are likely to settle.<sup>212</sup> 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 voluntarily had established a system where the extended term was clearly of its own making. Since TRIPS sets a floor and not a ceiling for patent term (and other provisions) Brazil arguably could maintained the status quo. The facility to unravel rights greater than TRIPS requires even *after* those rights have been granted to applicants is a remarkable and unusual display of the degree of innovation possible in

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<sup>208</sup> TRIPS Agreement, *supra* note 3.

<sup>209</sup> Industrial Property Law No. 10,196, *supra* note 190, art. 229.

<sup>210</sup> *Id.* art. 229-B; Industrial Property Law No. 9,279, *supra* note 190, art. 40.

<sup>211</sup> See Lisa Mueller, Gustavo de Freitas Morais & Justin Duarte Pine, *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>.

<sup>212</sup> Confidential interview with a U.S. organization involved in the litigation by INPI.

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.<sup>213</sup>

It is worthwhile to consider why Brazil exhibits such a high level of legal innovation. Since the 1970's, Brazil has played an active role in seeking to limit the effect of the international patent system on its development policy.<sup>214</sup> 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.<sup>215</sup> Accordingly, the country was purposefully committed to a global system in which a panoply of patent options to facilitate such access would remain available.<sup>216</sup> The evidence from Brazil since then has been consistent. It has utilized every fora possible to advance development-related IP goals, while at the same time advancing protection for patents as it experiences technological growth. Brazil's domestic calibration of its laws occurs not only through the Patent Act per se, but by utilizing a series of institutional procedures that preserve the welfare of Brazil as the highest motivation of the patent system. In addition to the self-actuated initiatives of ANVISA described above, for example, Brazil also requires that technology-transfer agreements be registered with the patent office. Moreover, it has strong disclosure requirements for patents based on genetic resources.<sup>217</sup> Brazil is willing to defend its domestic TRIPS implementation prerogative as a core right of the TRIPS

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<sup>213</sup> PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* (2009).

<sup>214</sup> 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.").

<sup>215</sup> Confidential Memo from the Brazilian Ministry of External Relations, Mission in Geneva, Apr. 18, 1967 (declassified Sept. 12, 2004).

<sup>216</sup> See Brazilian Draft Resolution, *supra* note 214 ("Access to experience in the field of applied science and technology is essential to accelerate the economic development of under-developed countries.").

<sup>217</sup> Law No. 10,196, *supra* note 189.

Agreement, making it difficult for advanced economies to make idle threats.<sup>218</sup> The current patent reform process unfolding nationally fully demonstrates the careful deliberation over the role of patent law in Brazil. And by initiating and staunchly defending trade disputes with the advanced countries, Brazil has established a norm of constructive engagement with the TRIPS framework and is clearly comfortable with asserting claims that preserve its discretion over the appropriate balance between access and protection of IP.

*(iii) Malta – An Example of ‘Offensive’ Compliance*

Malta was obligated to adopt and implement the TRIPS Agreement in 1995 when it became a member of the WTO.<sup>219</sup> Although the Maltese legal framework provides adequate protection for patent holders,<sup>220</sup> the relatively small size of the Maltese market historically discouraged many drug manufacturers from pursuing separate patent protection there.<sup>221</sup> 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 Community.

Malta has only recently become a strategically advantageous location for generic pharmaceutical manufacturing, based on its implementation of a Bolar exception established in the U.S. case *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*<sup>222</sup> Bolar exceptions generally provide infringement exemption for research and tests performed in conjunction with

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<sup>218</sup> See, e.g., *supra* Part I.C(i) (discussing U.S. WTO complaint about Brazil’s local working law and withdrawal of same).

<sup>219</sup> *Malta and the WTO*, WORLD TRADE ORG., [http://www.wto.org/english/thewto\\_e/countries\\_e/malta\\_e.htm](http://www.wto.org/english/thewto_e/countries_e/malta_e.htm) (last visited Feb. 21, 2014).

<sup>220</sup> Patents & Designs Act, ch. 417 (Malta) (2002)

<sup>221</sup> 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>.

<sup>222</sup> *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

applications for regulatory approval. Although Bolar exceptions exist in numerous countries, they are unevenly applied across jurisdictions.<sup>223</sup> 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.”<sup>224</sup> Therefore, experiments and scientific research are broadly allowed in a fairly permissive manner. Malta also extends permitted-use to private and noncommercial use, as well as for any development and presentation of information.<sup>225</sup>

Along with the research exception, 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 to create a skilled workforce to support a pharmaceutical industry.<sup>226</sup> Moreover, Malta enacted business-friendly laws including low taxes, worker training programs, and loan guarantees to induce generic pharmaceutical investment.<sup>227</sup> Generic pharmaceutical manufacturers are the main players in this industry.<sup>228</sup>

Malta provides an unusual case study for legal innovation within the TRIPS context. Although a geographically-small developing country, Malta adopted very strong IP rules. But it was its investment in a solid business environment plus leveraging its geographical location to take advantage of opportunities to attract and build innovation not protected domestically that

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<sup>223</sup> 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.

<sup>224</sup> Patents & Designs Act, ch. 417 § 27(6)(b) (Malta).

<sup>225</sup> *Id.*

<sup>226</sup> *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>.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

transformed the country's economic profile. Despite minimum standards of IP protection in TRIPS, territoriality still remains a cornerstone of IP protection.<sup>229</sup> Accordingly, the failure of large firms to file patents in Malta opened an opportunity for the country to invite generic firms. As a result of this “proactive” use of TRIPS, Malta is quickly gaining a reputation of being “the ideal location for pharmaceutical companies.”<sup>230</sup> Its pharmaceutical exports increased from just €26 million in 2005<sup>231</sup> to €206 million in 2011.<sup>232</sup> 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.<sup>233</sup>

India, Brazil and Malta are radically different countries and their interests in the multilateral IP regime differ in strategic intent and focus. What unites the recent 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 credible is less assailable by critics. That these tools are part of national systems also suggests that they can be sustainably used for the foreseeable future. And in each example, the tools reflect a distinctive national strategy in which access to knowledge in broad conceptual frames and national welfare are tightly linked across a number of related technical subjects (usually trade, environment, 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

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<sup>229</sup> 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.”).

<sup>230</sup> KPMG, MALTA, *supra* note 221.

<sup>231</sup> EUROPEAN FED'N OF PHARMACEUTICAL INDUS. & ASS'N, *THE PHARMACEUTICAL INDUSTRY IN FIGURES: KEY DATA 2007 UPDATE 14* (2007).

<sup>232</sup> EUROPEAN FED'N OF PHARMACEUTICAL INDUS. & ASS'N, *THE PHARMACEUTICAL INDUSTRY IN FIGURES: KEY DATA 2013 UPDATE 18* (2013).

<sup>233</sup> KPMG, MALTA, *supra* note 221.

anchored largely in processes and not legislative text. To sum up, in India the tools of innovation include a coordinated arc of legislation, patent office action, and judicial application. In Brazil, it was 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 constructing an entire industry in which business interests and welfare outcomes have been , even if just temporarily, perfectly aligned.

The purposeful integration of IP into the legal and institutional environment of developing and least-developed countries is a new phenomenon for those countries, though it has long been part of the design of domestic IP systems in the developed economies. These public manifestations of how countries explicitly seek the welfare interest associated with access to technology, access to medicines, or access to knowledge suggests that at least for these 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 as might be the case with the Kenyan court decision in *Asero Ochieng v. Attorney-General*,<sup>234</sup> important though the case might be. In particular, heightened local awareness of IP rights (in no small part fueled by the global access movements) and their effect on the fundamental conditions of human flourishing means that developing and least-developed countries will have new levels of domestic public accountability to the IP regimes they negotiate globally.

Twenty years after the TRIPS Agreement, there are signs that the design of global IP policy or the felicity 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, despite mounting evidence of reprisals by developed countries, is that a variety of new actors will have the space to participate in shaping the intersection between multilateral

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<sup>234</sup> See also *supra* notes 80–83 and accompanying text.

IP obligations and whatever are the domestic welfare imperatives that animate that generation and their communities.

### *B. 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. As noted earlier, the WTO has found two U.S. violations of TRIPS: (1) the WTO Appellate Body “Havana Club Rum” decision;<sup>235</sup> and (2) the WTO Copyright Panel decision regarding § 110(5) of the U.S. Copyright Act,<sup>236</sup> both of which have remained uncorrected for over a decade.<sup>237</sup> The U.S. is an outlier in this context compared to other countries such as Canada, India, China and the EU, all of whom have addressed their TRIPS violations within an average of 10 months.<sup>238</sup> As one of the most ardent supports 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 violation 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 meaningful compliance of TRIPS obligations. Nonetheless, it is not surprising that dynamic, innovative economies find the TRIPS shoes too tight for comfort at times. As Professor Reichman rightly predicted, “efforts to rig a regime for short-term advantages may turn out, in the medium-to long-term, to boomerang against those who pressed hardest for its adoption.”<sup>239</sup> Legal innovation

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<sup>235</sup> Appellate Body Report, *United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R (Jan. 2, 2002); *see also supra* notes **Error! Bookmark not defined.**–73 and accompanying text (discussing the Havana Club Rum decision).

<sup>236</sup> *United States — Section 110(5)*, *supra* note 12.

<sup>237</sup> Lee, *supra* note 121.

<sup>238</sup> *Id.*

<sup>239</sup> Reichman, *Twenty-First Century*, *supra* note 52, at 1119.

has proven this to be true, as the developed economies struggle under the weight of a globalized world 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, productions networks and legal initiatives originating from developing countries across various public law regimes will require the developed countries to do more than simply dig their heels in IP maximalism. Nowhere has this proven more accurate than the spectacular failure by the developed countries to address copyright in the digital environment—something TRIPS, in its “bargain to the baseline” mode, could not accomplish. But before addressing the legal innovation in the global copyright context, it is important to observe that legal innovation does not emerge overnight. Rather, reform processes, advocacy movements, and political engagement often take years to produce the tools analyzed earlier. There is thus 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 even in countries that are enjoying the capabilities afforded by existing innovation tools.

### **III. LEGAL INNOVATION IN THE MAKING: THE NORMATIVE INFLUENCE AND ROLE OF UNFORMED LAWS**

#### *A. Brazil’s Patent Reform*

Brazil has recently launched a patent reform process and issued a patent reform report in 2013.<sup>240</sup> The report outlines paths to stimulate innovation in Brazil and to strengthen national industries.<sup>241</sup> Although the report is generally an outline recommending patent policy moving

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<sup>240</sup> CHAMBER OF DEPUTIES CENTER FOR STRATEGIC STUDIES AND DEBATES, BRAZIL’S PATENT REFORM: INNOVATION TOWARDS NATIONAL COMPETITIVENESS (2013).

<sup>241</sup> *Id.* at 1.



forward, it has produced some concrete results. The first is a patent reform bill.<sup>242</sup> 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.<sup>243</sup> It clarifies that new-use patents and new forms of known substances are not considered to be inventions.<sup>244</sup> It also increases 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.<sup>245</sup> Additionally, the report resulted in a Presidential Decree creating the Council of Intellectual Property Rights.<sup>246</sup>

The report emphasizes the importance of economic, social, and technological advancement in developing countries.<sup>247</sup> The original Patent Act, passed in 1997, was intended to reach these same goals. But the report argues that none of this took place after the original Patent Act was passed.<sup>248</sup> Furthermore, the strengthened IP rights following the original Patent Act have had a negative impact on access to health products and processes.<sup>249</sup>

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.<sup>250</sup> Additionally, new-use and polymorph patents should not be granted, as they do not meet the patentability requirements of novelty and non-obviousness.<sup>251</sup> The report also calls for an avenue for pre-grant opposition, allowing for an

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<sup>242</sup> See Bill no. H.R. 5402/2013

<sup>243</sup> CHAMBER OF DEPUTIES, *supra* note 240, at 13–14.

<sup>244</sup> *Id.* at 14.

<sup>245</sup> *Id.*

<sup>246</sup> *Id.*

<sup>247</sup> *Id.* at 39.

<sup>248</sup> *Id.* at 40–49.

<sup>249</sup> *Id.* at 49.

<sup>250</sup> *Id.* at 65.

<sup>251</sup> *Id.* at 127.

increase in the quality of patents.<sup>252</sup> Although the current Brazilian patent law already allows for compulsory licenses, the report calls for a more elaborate public non-commercial-use mechanism.<sup>253</sup> Finally, a warning is offered against examining software patent applications without an “extensive public consultation . . . regarding the risks and eventual benefits that the practice can offer to Brazil.”<sup>254</sup>

The Brazilian process is highly unstable and politically risky, and its future is uncertain. Nonetheless, as noted earlier, it has produced important signals about Brazil’s orientation toward the role of patent law in development. As an unfolding process, nothing in the draft bill can technically be a basis for a TRIPS complaint that, in principle, requires that formal legal obligations fly in the face of TRIPS standards. However, the principles, concerns, and proposals in the draft Bill, and indeed the report, have an important normative influence on Brazil’s existing patent law and institutions. Not only do the draft provisions reflect an intention to fully 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 normative ideas, while not fully formed, nonetheless suggest an expanding capacity and agility to leverage patent law in the design of Brazil’s future economy.

### *B. 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.<sup>255</sup> Because South Africa does not have a

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<sup>252</sup> *Id.* at 70–78.

<sup>253</sup> *Id.* at 90–99.

<sup>254</sup> *Id.* at 205.

<sup>255</sup> THE DEP’T. OF TRADE AND 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](http://www.ip-watch.org/weblog/wp-content/uploads/2013/09/SA-IP-Policy-Sept-2013-36816_gen918.pdf).

national IP policy, the DTI sought to ensure coherence through the new policy framework.<sup>256</sup>

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, internet and software issues, and various copyright and patent reforms.<sup>257</sup> The framework importantly addresses “Patent[s] and Access to Public Health.”<sup>258</sup> This section emphasizes that because South Africa is using a depository system, which grants weak patents, it limits access to public health.<sup>259</sup> South Africa, like India, pushes for pre- and post-opposition of patents to “foster the spirit of granting stronger patents.”<sup>260</sup> 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.”<sup>261</sup> To further promote public health, it recommends introducing compulsory licensing that adheres to international treaties.<sup>262</sup>

In the section on agricultural and genetic resources, the framework recommends that developing countries do not provide patent protection for plants and animals, with an exception for certain types of biotechnology-related patents.<sup>263</sup> In particular, the framework recommends an amendment to South African’s PVP (plant-variety-protection) system to allow farmers to “reuse, resell and exchange seeds.”<sup>264</sup>

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<sup>256</sup> *Id.* at 5.

<sup>257</sup> *Id.* at 3.

<sup>258</sup> *Id.* at 5.

<sup>259</sup> *Id.* at 5–6.

<sup>260</sup> *Id.* at 17.

<sup>261</sup> *Id.* at 6.

<sup>262</sup> *Id.* at 21.

<sup>263</sup> *Id.* at 22.

<sup>264</sup> *Id.*

In the copyright realm, the framework recommends broad exemptions to copyright legislation for use by educators, researchers, and libraries.<sup>265</sup> The framework also expresses concerns over software and internet technologies in developing countries such as South Africa, and recommends ensuring that low-cost and open-source software products are considered, while also allowing software to be reverse engineered to accommodate local needs.<sup>266</sup>

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.<sup>267</sup> The framework was 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.”<sup>268</sup>

Pharmaceutical companies 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 strengthen patent protection, rather than weaken it.<sup>269</sup> Conversely, 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.<sup>270</sup>

Similar to the Brazilian reform process, South Africa’s Draft IP Policy creatively establishes the contours of the domestic IP debate in a way that delimits the role of the multilateral system without violating TRIPS. The draft policy is neither legal nor political.

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<sup>265</sup> *Id.* at 30.

<sup>266</sup> *Id.*

<sup>267</sup> *Id.* at 35.

<sup>268</sup> *Id.*

<sup>269</sup> See Linda Daniels, *Concerns Erupt Over Leaked Pharma Lobbying Plan Against IP Policy in South Africa*, INTELLECTUAL 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>.

<sup>270</sup> *Id.*

Instead, it employs a cultural frame in which the sole organizing thrust is the question of how patent law can advance South African interests in the areas that are relevant to the country's stylized vision of the future, and the identification of 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. Neither is the theme anti-TRIPS as such. Rather, in a manner that presages 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. But 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 ecology.

DRAFT

### III.

#### **SEEING THROUGH A GLASS DIMLY: THE IMPLAUSIBLE FUTURE OF TRIPS AS ONCE IMAGINED**

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

The rapid rise of networked information technologies, and the new digital markets created, radically altered the assumptions of the copyright provisions in TRIPS. In its "bargain to the baseline" mode, the TRIPS 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. With the high pace of technological advances in the 1990s, the TRIPS negotiations simply did not foresee many of the innovations that would be the basis of the

digital economy.<sup>271</sup> The WIPO Copyright Treaty (WCT)<sup>272</sup> and WIPO Performers and Phonograms Treaty (WPPT)<sup>273</sup> were negotiated within the context of WIPO to address how to maintain authorial control.<sup>274</sup> Thus the technologies most critical to political, cultural, and economic opportunities are not within the ambit of the TRIPS Agreement. 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.

The WCT entered into force two years after the conclusion of the Uruguay Round.<sup>275</sup> Still, the robust and new layers of rights provided by the WCT<sup>276</sup> could not provide the level of control demanded by copyright rights owners, and could not keep pace with the rate of technological change. Copyright reform efforts are now underway throughout the world 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. 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 to deal with an ever-changing copyright landscape that increasingly affects economic, cultural, and liberty interests far more pervasively than IP rights were intended to do. Yet, as countries experiment

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<sup>271</sup> 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); see also Haochen Sun, *Overcoming the Achilles Heel of Copyright Law*, 5 NW. J. TECH. & INTELL. PROP. 265, 276 (2007)

<sup>272</sup> World Intellectual Property Organization [WIPO] Copyright Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 65 (1997) [hereinafter WCT].

<sup>273</sup> WIPO Performances and Phonograms Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 76 (1997).

<sup>274</sup> Sun, *supra* note 271, 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.”).

<sup>275</sup> WCT, *supra* note 272.

<sup>276</sup> See *id.* art. 11 (requiring protection against circumvention of technological protection measures); *id.* art. 12 (stating rights management information obligations).

with expanding fair use and fair dealing exceptions,<sup>277</sup> Creative Commons licensing,<sup>278</sup> and expanding access to orphan works,<sup>279</sup> to establish a “zone of access and use” that might accommodate these personal copyright rights owners are pushing back with restrictive, secretive international agreements. On the other hand, both domestic and international experiments expanding intermediary liability have been defeated by an unprecedented coalition of users and intermediaries.<sup>280</sup>

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. property, and for other purposes.”<sup>281</sup> 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.”<sup>282</sup> SOPA’s counterpart in the Senate, The PROTECT-IP Act (PIPA),<sup>283</sup> was introduced to “prevent online threats to economic creativity and theft of intellectual property.”<sup>284</sup> Though the bill did not have a specific First Amendment disclaimer as SOPA did, PIPA had strikingly similar provisions that, if passed, would have had grave implications for First Amendment free speech rights and access to knowledge more broadly.

SOPA and PIPA would have allowed the U.S. Justice Department to obtain court orders in rem against owners of foreign websites that were suspected of enabling or facilitating

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<sup>277</sup> 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).

<sup>278</sup> See, e.g., Pedro Paranauga, *Brazil’s Copyright Reform: Schizophrenia?*, INTELL. PRO. WATCH (Feb. 8, 2011), <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).

<sup>279</sup> Copyright (Amendment) Act, 2012, ¶ 17 (2012) (India), available at [http://copyright.gov.in/Documents/CRACT\\_AMNDMNT\\_2012.pdf](http://copyright.gov.in/Documents/CRACT_AMNDMNT_2012.pdf) (providing for compulsory licensing of orphan works).

<sup>280</sup> See, e.g., Mike Scott, Safe Harbors Under the Digital Millennium Copyright Act, 9 N.Y.U. J. LEGIS. & PUB. POL’Y 99, 115–21 (2006).

<sup>281</sup> H.R. REP. NO. 112-3261, at 1 (2011).

<sup>282</sup> *Id.* at 2.

<sup>283</sup> S. 968, 112th Cong. (2011).

<sup>284</sup> *Id.*

copyright violations.<sup>285</sup> Such orders against foreign websites would have allowed the websites to be blocked without any opportunity to respond or appeal, resulting in censorship and a direct infringement on the freedom of speech.<sup>286</sup> The legislation would have permitted the Justice Department to not only shut down websites, but to do so without due process using *in rem* proceedings.<sup>287</sup> 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 not only copyright owners but the economy in general.<sup>288</sup>

Opposition and outright resistance to SOPA/PIPA was 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 PIPA.<sup>289</sup> This protest is an excellent example of the more democratic, user-empowered nature of the global digital environment. Both SOPA and PIPA were tabled after this blackout protest, but strains of the principal goals are likely to appear elsewhere.<sup>290</sup>

#### *B. ACTA and the Political Gap in TRIPS: Becoming my Brother’s Keeper*

The Anti-Counterfeiting Trade Agreement (ACTA) was negotiated from 2007 to 2010 by the United States, the EU, Switzerland, Canada, Australia, New Zealand, Mexico, Singapore,

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<sup>285</sup> 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).

<sup>286</sup> *Id.*

<sup>287</sup> *Id.*

<sup>288</sup> Timothy J. Toohey, *Piracy, Privacy, and Internet Openness: The Changing Face of Cyberspace Law*, 2012 WL 2244536 (ASPATORE), at 2 (2012).

<sup>289</sup> *Id.* at 4.

<sup>290</sup> *Id.*



Morocco, Japan, and South Korea.<sup>291</sup> The agreement was negotiated in secret outside of the traditional (and more transparent) multilateral IP fora such as the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).<sup>292</sup> 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.”<sup>293</sup> 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.<sup>294</sup> Other developing countries such as India and Brazil are also firmly opposed to ACTA and have criticized such efforts to bypass existing, more democratic international IP forums.<sup>295</sup>

In the copyright context, ACTA served as a model of the most troubling features of this 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 speech; (2) *privacy and due process*: the agreement will increase the ease and speed of

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<sup>291</sup> Electronic Frontier Foundation (EFF), *Anti-Counterfeiting Trade Agreement (ACTA)*, EFF.ORG, <https://www.eff.org/issues/acta> (last visited Jan. 25, 2014) [hereinafter EFF, ACTA].

<sup>292</sup> *Id.*

<sup>293</sup> See Joint Press Statement of the Anti-Counterfeiting Trade Agreement Negotiating Parties in Tokyo, Oct. 1, 2011, available at <http://www.ustr.gov/about-us/press-office/press-releases/2011/october/joint-press-statement-anti-counterfeiting-trade-ag>; see also Knowledge Ecology International (KEI), *ACTA Timeline*, KEIONLINE.ORG, <http://keionline.org/timelines/acta> (last visited Jan. 25, 2014) (detailing major events, press releases, and commentary on the ACTA negotiations).

<sup>294</sup> See, e.g., Don Melvin, *EU Parliament Rejects ACTA Anti-Piracy Treaty*, BLOOMBERG BUSINESSWEEK (July 4, 2012); Olivia Solon, *What Is ACTA and Why Should You Be Worried About It?*, WIRED MAG. (UK) (Jan. 24, 2012), <http://www.wired.co.uk/news/archive/2012-01/24/acta-101>; see also EFF, ACTA, *supra* note 291.

<sup>295</sup> EFF, ACTA, *supra* note 291.

information exchanges between enforcement authorities, copyright holders, and ISPs, which threatens the privacy of user information; (3) *users' rights*: ACTA will require legal protection against circumvention of technological protection measures, even if the reason for disabling the lock is fair, non-infringing use; and (4) *excessive civil and criminal penalties*: ACTA will implement a regime of overzealous statutory damages with no proportionality to the crime and no exceptions for innocent infringement, as well as criminal penalties apply for “significant willful” infringement even if there is no “direct or indirect motivation of financial gain,” without *any* of the traditional copyright limitations such as fair use, which has now become an unwelcome doctrine in the international copyright sphere.<sup>296</sup>

ACTA must be ratified by at least six of the member nations. Currently, only Japan has ratified the treaty,<sup>297</sup> although there were indications as of 2013 that Canada was moving towards ratification.<sup>298</sup> Many have argued that the crushing rejection of ACTA by the EU makes international implementation unlikely,<sup>299</sup> although the United States recently has vowed to continue fighting for more ratifications.<sup>300</sup>

### *C. Reinventing SOPA/PIPA? The “New” TPP*

Like ACTA, the TPP Agreement is being negotiated outside more democratic forums such as the WTO and WIPO, and instead is being developed through highly secretive regional

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<sup>296</sup> *Id.*; see also *The Anti-Counterfeiting Trade Agreement (ACTA)*, PUBLICKNOWLEDGE.ORG, <http://publicknowledge.org/issues/acta> (last visited Jan. 25, 2014).

<sup>297</sup> *Conclusion of the Anti-Counterfeiting Trade Agreement (ACTA) by Japan*, MINISTRY OF FOREIGN AFFAIRS OF JAPAN (Oct. 5, 2012), available at [http://mofa.go.jp/policy/economy/i\\_property/acta\\_conclusion\\_1210.html](http://mofa.go.jp/policy/economy/i_property/acta_conclusion_1210.html); see also EFF, *ACTA*, *supra* note 291.

<sup>298</sup> 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>.

<sup>299</sup> See, e.g., David Meyer, *ACTA Rejected by Europe, Leaving Copyright Treaty Near Dead*, ZDNet (July 4, 2013), <http://www.zdnet.com/acta-rejected-by-europe-leaving-copyright-treaty-near-dead-7000000255>.

<sup>300</sup> See U.S. TRADE REPRESENTATIVE, 2013 TRADE POLICY AGENDA AND 2012 ANNUAL REPORT (2013), <http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/2013-tpa-2012-ar>; see also EFF, *US Trade Office*, *supra* note 298.

negotiations. Current parties to negotiations include the United States, Australia, Canada, Japan, Mexico, Singapore, Malaysia, Vietnam, Brunei, Chile, Peru, and New Zealand.<sup>301</sup> The specifics of negotiations have been shrouded in secrecy, but a proposed draft text for the TPP Intellectual Property Rights Chapter was recently released by WikiLeaks.<sup>302</sup> The drafts indicate that negotiators, particularly from the U.S., are pushing for the adoption of IP minimum standards that are far more restrictive than currently required by TRIPS, and even move beyond the already controversial standards in the Anti-Counterfeiting Trade Agreement (ACTA).<sup>303</sup> For example, the draft text proposes expanding copyright terms for individual authors from life plus 50 years (the current TRIPS standard) to life plus 70 years, with even longer terms of 95 or 120 years for corporate works.<sup>304</sup> Scholars vigorously criticize the TPP's IP Chapter for its gross inconsistency with current laws in every TPP member country, including the U.S. itself; for abandoning many development-oriented flexibilities, particularly on access to medicine; and for the secrecy, lack of transparency, and unfairly exclusive nature of the negotiating process.<sup>305</sup> But if the innovation and resistance TRIPS has produced after twenty years is any indication, it will only be a matter of time before the TPP itself, if successful, may generate unintended welfare gains for global consumers.

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<sup>301</sup> See Electronic Frontier Foundation, *Trans-Pacific Partnership Agreement*, EFF.ORG, <https://www.eff.org/issues/tpp> (last visited Jan. 20, 2014); 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>.

<sup>302</sup> See *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, WIKILEAKS.ORG (Nov. 13, 2013), <http://wikileaks.org/tpp> [hereinafter WIKILEAKS].

<sup>303</sup> Sean Flynn, Margot E. Kaminski, Brook K. Baker & Jimmy H. Koo, *Public Interest Analysis of the US TPP Proposal for an IP Chapter 2–3* (Am. Univ. Wash. College of Law PIJIP Research Paper Series No. 21, 2011), available at <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1023&context=research>.

<sup>304</sup> WIKILEAKS, *supra* note **Error! Bookmark not defined.**; see also Carolina Rossini & Yana Welinder, *All Nations Lose with TPP's Expansion of Copyright Terms*, EFF.ORG (Aug. 8, 2012), <https://www.eff.org/deeplinks/2012/08/all-nations-lose-tpps-expansion-copyright-terms>.

<sup>305</sup> Flynn et. al, *supra* note **Error! Bookmark not defined.**, at 2–4.

*D. The Rise of Discrimination: Is the IP World Still Flat?*

As noted in Part I, the TRIPS agreement attempted to create a system of equality and non-discrimination among member states through two principles: national treatment and MFN (most-favored nation). Although these provisions may establish formal equality, in reality the TRIPS Agreement fails to create a system of substantive equality between developed and developing countries.<sup>306</sup> Rather, this one-size-fits-all model, which treats the IP world as flat, fails to account for critical distinctions between member countries including political and democratic limitations such as those seen in the U.S with regard to compliance with WTO dispute decisions, and in the EU with regard to ACTA's ratification. 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 actually 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.<sup>307</sup>

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, or form of "positive discrimination."<sup>308</sup> This approach will necessitate a reassessment of our current principles of formal non-discrimination and acknowledgment that legal innovation will respond, perhaps imperfectly, to any effort to enforce a flat national IP environment without regard to welfare interests. Scholars recognize that textual

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<sup>306</sup> See, e.g., Denis Borges Barbosa et al., *Slouching Towards Development in International Intellectual Property*, 2007 MICH. ST. L. REV. 71, 114–18; Margaret Chon, *A Substantive Equality Principle in International Intellectual Property Norm-Setting*, in TRADE, DEVELOPMENT AND INTELLECTUAL PROPERTY: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS PLUS ERA (Daniel Gervais ed., 2007).

<sup>307</sup> Barbosa et al., *supra* note 306, at 114–15.

<sup>308</sup> Tomer Brode, *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).

recognition of positive discrimination is an uphill battle that is probably infeasible; but some have suggested the development of exceptions or flexible interpretations of non-discrimination by legislative and judicial actors at both domestic and international levels.<sup>309</sup> In other words, a call for yet additional forms of legal innovation.

There is evidence of legal innovation in the copyright area fueled again by the numerous reform processes ongoing in developed and developing countries. For example, Brazil has been working on copyright reform through a series of proposed legislation bills.<sup>310</sup> In late November 2011, the third version of the draft bill was leaked.<sup>311</sup> According to a leaked letter from Brazil's Minister of Culture, Ana de Hollanda, addressed to President Rousseff:

Brazil's copyright reform focuses on three issues: i) to correct conceptual errors that are further sources of uncertainty and legal misinterpretations, ii) to implement new provisions, such as on orphan works, on works for hire, on the supervision and oversight of the collecting society, and on exceptions and limitations to copyrighted works, and iii) to clarify the Constitutional principles and objectives that apply to copyrighted works, and make sure that other principles and objectives of the Brazilian legal system found in the country's Civil Code are directly applied to copyright issues in order to strike a balance in the interests at stake.<sup>312</sup>

The leaked bill contains many new and modified provisions. These include the addition of works for hire with employer control limited to ten years, the exhaustion of copyrights after first authorized sale in a WTO member country, the ability of authors to put their works into the

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<sup>309</sup> See, e.g., Barbosa et al., *supra* note 306; Broude, *supra* note 308; Chon, *supra* note 306.

<sup>310</sup> See Pedro Paranaguá, *Inside Views: Brazil's Copyright Reform: Are We All Josef K?*, INTELL. PROP. WATCH (May 12, 2011, 7:45 PM), <http://www.ip-watch.org/2011/05/12/brazil%E2%80%99s-copyright-reform-are-we-all-josef-k>.

<sup>311</sup> 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>.

<sup>312</sup> *Id.*

public domain during their lifetime, and expanded compulsory licenses.<sup>313</sup> Exceptions to copyright infringement are expanded to include space-shifting, reproduction for persons with disabilities, reproduction of lectures, addresses and lessons by the person for whom they are intended, reproduction for conservation and preservation purposes, and musical performance in religious temples, while further restricting public performance exceptions.<sup>314</sup>

Another controversial bill at the House of Deputies is the Marco Civil bill.<sup>315</sup> 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. Under this proposed system, “content would be removed from the Internet only in response to court order, eschewing a notice-and-takedown system,”<sup>316</sup> as found in other countries such as the U.S. This court-order system empowered creators and sharers of online information and improved the power imbalance between users, service providers, and the entertainment industry. 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.<sup>317</sup> 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 take-down structure similar to that adopted by the U.S.<sup>318</sup>

Like the patent reform process in Brazil and the Draft IP policy in South Africa, the final landing strip for the Brazilian Copyright reform is not yet clear. But already, some of the bold

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<sup>313</sup> *Id.*

<sup>314</sup> 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 Feb. 15, 2014).

<sup>315</sup><sup>315</sup> See Pedro Mizukami, *Copyright Week: What Happened to the Brazilian Copyright Reform*, INFOJUSTICE.ORG (Jan. 20, 2014), <http://infojustice.org/archives/31993>.

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*

<sup>318</sup> See Paranaguá, *Leaked Draft*, *supra* note 311.

initiatives and the massive effort to engage the Brazilian polity reveal a deep understanding of the cultural impact of copyright policy on the people. Accordingly, the reform process has already committed normatively to access rhetoric that, even if not borne out in formal law, will undoubtedly shape the conceptual framework of the knowledge economy.

In the copyright realm, the Draft South African IP Policy recommends broad exemptions to copyright legislation for use by educators, researchers, and libraries,<sup>319</sup> as well as exceptions for reverse-engineering of software to accommodate local and educational needs,<sup>320</sup> as discussed above.<sup>321</sup> Like in the case of Brazil, these recommendations will exert some political and policy influence in the broader society, including with the courts and institutions that deal with social welfare. The access values so strongly imprinted in the Draft Policy will be difficult to excise from the DNA of any emerging copyright regime in South Africa.

Across the developed world, similar contests over the design of the information society are unfolding in the context of reform processes in the U.S., Australia, Spain, and the U.K. to name a few countries. In each instance, despite similar areas of study and focus for reform, it is clear that the TRIPS framework simply offers too little to assist in the construction of rights necessary to facilitate the flourishing of creative human expression, and in its production or use.

## CONCLUSION

It is clear that the connections between IP, foreign direct investment, and growth are far less plausible or predictable than once assumed.<sup>322</sup> Yet, any appeal of the multilateral IP system

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<sup>319</sup> *Id.* at 30.

<sup>320</sup> *Id.*

<sup>321</sup> See *supra* notes 265–266 (discussing the copyright section in the South Africa draft IP policy).

<sup>322</sup> 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* (2000) and Reichman, *Twenty-First*, *supra* note 52.

requires a link, no matter how tenuous, with development goals.<sup>323</sup> With regard to the development legacy of the TRIPS Agreement, the purported benefits of local creative industries has not yet materialized with the formal recognition of much of the South's wealth in genetic resources, folklore, and traditional knowledge. Moreover, much of the promised technical assistance and foreign direct investment (FDI) has also failed to meaningfully materialize in regard to the classic IP system.<sup>324</sup> This doesn't mean the international IP system can't support aspects of the technological and economic advancement of developing countries. But as the scholarly consensus suggests, the IP system and particularly its lead actor, WIPO, must allow for specific tailoring of IP laws to account for each country's local conditions and level of development, discard the unworkable one-size-fits-all model, and recognize the South's interests in integrating its knowledge systems with the IP regime on its own terms. Importantly, the multilateral IP system must accommodate and encourage the forms of emerging legal innovation in the developing countries.

The uncertain future of TRIPS and international IP is further compounded by the complex web of actors that interact to influence, negotiate, and control international IP standards. In addition to the traditional state actors and diplomats, 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 just 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

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<sup>323</sup> This may partly explain the tortured nature, structure and operational life of the WIPO development agenda.

<sup>324</sup> See *The 45 Adopted Recommendations under the WIPO Development Agenda*, WORLD INTELL. PROP. ORG., <http://www.wipo.int/ip-development/en/agenda/recommendations.html> (last visited Feb. 22, 2014). Most developed countries have not lived up to these obligations, and some describe the obligations as "purely aspirational." Peter K. Yu, *Enforcement, Enforcement, What Enforcement?*, 52 IDEA 239, 278 (2012). The assistance programs that have been developed are narrowly conceived and ignore local conditions in developing countries. *Id.*



commercial seed industry (\$21 billion).<sup>325</sup> With so much at stake, these industry players, continue to exert significant pressure and influence domestically, producing new ebbs of multilateral agreements, including the most recent and highly controversial, TPP. Their influence in national responses to legal innovation in various WTO member countries is certain to be part of the unfolding framework of global international IP relations.

The weaknesses of the TRIPS Agreement in accomplishing the greatest hopes of the developed countries could be, ultimately, also its greatest triumph. Developed countries may learn the lesson that bargaining towards the baseline of existing economic and institutional realities in their domestic markets is a short-term strategy at best. For the developing countries, there are prospects that downstream opportunities at the national level can emerge to dial back losses attributable to imbalanced capacity and resources for international negotiations, as clearly was the case during the Uruguay Round. For both sets of countries, the fast approaching twenty-first year of the Agreement is an opportunity to embrace various forms of resistance and innovation. Rather than unraveling the TRIPS Agreement, such innovation in particular may serve to strengthen those norms around which countries can dynamically respond to compliance and welfare costs of a forced convergence of global IP norms. At a minimum, twenty years of TRIPS should have taught the global community that national welfare considerations will inevitably challenge, and legal innovation will invariably emerge, to reflect the imprudence of a treaty that attempts to subvert the very territorial and self-seeking national ends for which IP law exists.

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<sup>325</sup> DEERE, *supra* note 145, at 9.