# INTELLECTUAL PROPERTY RULEMAKING IN THE GLOBAL CAPITALIST ECONOMY

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In the global capitalist economy, people, goods, services, capital, culture, and ideas flow through borders with ease, and countries interact with each other in a complex, interdependent economic relationship. As information and knowledge become increasingly commodified, hightechnology goods and services have become a staple of both domestic and crossborder trade. In many developed and middle-income developing countries, information- and entertainment-based industries now constitute some of the most highly important and fastest growing sectors in the national economy. The protection of intellectual property rights has therefore moved from a meager domestic or bilateral issue to the forefront of the international trade debate.

For many economic actors—whether they be wealthy developed countries or powerful transnational corporations—intellectual property provides the key ingredients for developing new forms of economic wealth and organization. At its core, intellectual property protection provides economic incentives for authors and investors to create.<sup>1</sup> Without these incentives, authors and inventors may be unable to recoup the time, effort, or resources they expended in the creative and inventive processes, and society would be worse off. From the macroeconomic standpoint, a well-functioning intellectual property system may also bring to a country its much-needed foreign investment, creating new jobs, facilitating technology transfer, promoting indigenous industries and technologies, and generating considerable tax revenues.<sup>2</sup>

Notwithstanding these benefits, economic incentives do not provide the primary motivation for *all* creative and inventive activities. For example, I do not need economic incentives to write an email to thank Birgitte Andersen for putting together this interesting volume, even though such an email is eligible for copyright protection if it is original, sufficiently creative, and satisfies other statutory requirements. Likewise, parents do not need economic incentives to take snapshots of their children, although those snapshots are also

<sup>&</sup>lt;sup>\*</sup> Copyright © 2008 Peter K. Yu. This Chapter was abridged and adapted from Peter K. Yu, *The International Enclosure Movement*, 82 Ind. L.J. 827 (2007).

<sup>&</sup>lt;sup>1</sup> William M. Landes & Richard A. Posner, An Economic Analysis of Copyright Law, 18 J. Legal Stud. 325 (1989).

<sup>&</sup>lt;sup>2</sup> Peter K. Yu, From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century, 50 Am. U. L. Rev. 131, 192–93 (2000).

eligible for copyright protection—and may sell for a large sum of money if these children turn out to be celebrities later in their lives. In fact, because intellectual property rights were not "invented" until a few centuries ago, many important inventions in humankind have been created without the economic incentives generated by the intellectual property system. The old adage, "necessity is the mother of all inventions," remains a valid explanation for the emergence of many historical inventions.

To complicate matters, economists have questioned the linkage between the strength of intellectual property protection and the volume of foreign direct investment, particularly in countries whose intellectual property system is underdeveloped or out of balance.<sup>3</sup> As they point out, by creating limited monopolies, the protection of intellectual property rights may incur considerable economic costs. If these costs are high enough, they eventually may offset the overall benefits derived from the intellectual property system. Among the documented costs are administrative and enforcement costs, adjustment costs due to labor displacement, social costs resulting from the abuse of intellectual property rights.<sup>4</sup>

Thus, if countries are to benefit from their intellectual property systems, they need to strike the right balance between proprietary interests and public access needs in their intellectual property system. To do so, they need wide policy space—or, in political terms, autonomy and sovereign discretion—to design their intellectual property system. Unfortunately, the growing push for high international intellectual property standards by developed countries has taken away the policy space needed by less developed countries. (Throughout this chapter, the term "less developed countries" will be used to cover both developing and least developed countries as referred to by the TRIPs Agreement.)

In recent years, commentators like James Boyle and Yochai Benkler, have extensively discussed a movement to "fence off" the public domain and turn freely-available raw materials into private property.<sup>5</sup> Professor Boyle termed this movement the "second enclosure movement," comparing it to the earlier enclosure movement in England. While this second enclosure movement is important and alarming, a different—and I would argue more important—movement is taking place at the global level. This movement is largely the result of rapid globalization, the increasing economic dependence on information- and knowledge-based goods and services, and the wide range of efforts to harmonize international rules and standards, especially in the intellectual property area.

For comparative purposes and rhetorical effectiveness, I will describe the latter phenomenon as the "international enclosure movement." <sup>6</sup> Unlike the second enclosure

<sup>&</sup>lt;sup>3</sup> Peter K. Yu, *Intellectual Property, Economic Development, and the China Puzzle, in* Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS Plus Era 173, 176–80 (Daniel J. Gervais ed., 2007).

<sup>&</sup>lt;sup>4</sup> Keith E. Maskus, Sean M. Dougherty & Andrew Mertha, *Intellectual Property Rights and Economic Development in China, in* Intellectual Property and Development: Lessons from Recent Economic Research 295, 302–306 (Carsten Fink & Keith E. Maskus eds., 2005).

<sup>&</sup>lt;sup>5</sup> Yochai Benkler, Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain, 74 N.Y.U. L. Rev. 354 (1999); James Boyle, Fencing off Ideas: Enclosure and the Disappearance of the Public Domain, Daedalus, Spring 2002, at 13; James Boyle, The Second Enclosure Movement and the Construction of the Public Domain, Law & Contemp. Probs., Winter/Spring 2003, at 33.

<sup>&</sup>lt;sup>6</sup> Peter K. Yu, The International Enclosure Movement, 82 Ind. L.J. 827 (2007).

movement, which fences off the public domain, this *international* enclosure movement fences off areas that provide attractive policy options for individual countries. As a result, less developed countries are increasingly forced to introduce intellectual property standards that do not sit well with their conditions, capabilities, interests, and priorities. They are unable to catch up with developed countries, and they have great difficulty in responding to problems within their borders—the massive HIV/AIDS crises being a very good but disturbing example.

The chapter begins by tracing the international enclosure movement from the creation of Berne and Paris Conventions to the establishment of the TRIPs Agreement and the recent bilateral and regional trade agreements. It explains how the one-size-fits-all standards required by the latter agreements have drastically reduced the policy space available to less developed countries. The chapter then examines the resistance efforts put up by less developed countries during the Doha Development Round of Trade Negotiations ("Doha Round"). It discusses, in particular, the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration"), the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement. The chapter concludes with a brief discussion of the root causes of the international enclosure movement and offers suggestions on how countries can reform the international intellectual property system—both to restore its balance and to reclaim their lost policy space.

# The Origin of the International Intellectual Property System

The cornerstones of the international intellectual property system are the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works. When these Conventions were created in the 1880s, they were primarily designed to patch up the divergent laws and customs of the participating countries.<sup>7</sup> Consider the Paris Convention, for example. When the Convention was being negotiated, countries disagreed significantly over such issues as compulsory licenses, parallel importation, working requirements, and filing systems.<sup>8</sup> Some countries, like the Netherlands and Switzerland, did not have a patent system,<sup>9</sup> while others, like Germany, remained heavily influenced by the anti-patent movement.<sup>10</sup>

To enable countries to coordinate this wide range of protections at the international level, the Convention struck a compromise by allowing each country to decide how intellectual property was protected within its borders. Thus, instead of creating a system with uniform rules and standards, the Convention embraced the anti-discrimination principle of national treatment and left considerable room for countries to experiment with different intellectual property systems. In the patent area, for example, countries could decide whether they wanted to include a local working requirement or a compulsory licensing provision. They could also explore whether the protection of patents in processes provided sufficient incentives or whether they

<sup>&</sup>lt;sup>7</sup> Paul Edward Geller, *From Patchwork to Network: Strategies for International Intellectual Property in Flux*, 9 Duke J. Comp. & Int'l L. 69, 70 (1998).

<sup>&</sup>lt;sup>8</sup> Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 Loy. L.A. L. Rev. 323, 349 (2004). <sup>9</sup> Eric Schiff, Industrialization Without National Patents (1971).

<sup>&</sup>lt;sup>10</sup> Heinrich Kronstein & Irene Till, *A Reevaluation of the International Patent Convention*, 12 Law & Contemp. Probs. 765 (1947); Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. Econ. Hist. 1 (1950).

needed to extend protection to products as well. Countries could even determine whether they wanted to protect patents in the first place.

While the early international intellectual property conventions worked well for developed countries, they failed to respond to the drastically different conditions in less developed countries. In fact, due to their status as colonies, the latter had no choice but to adopt these so-called international rules and standards despite their lack of participation in the drafting process. As Ruth Okediji explained:

Intellectual property law was not merely an incidental part of the colonial legal apparatus, but a central technique in the commercial superiority sought by European powers in their interactions with each other in regions beyond Europe. Granted, intellectual property systems in Europe prior to the seventeenth century were neither fully developed nor had intellectual property protection become a systematic policy designed primarily for encouraging domestic innovation. Whatever protections existed, however, would be exerted against other Europeans in colonial territories in the process of empire building. The [early period of European contact through trade with non-European peoples] thus was characterized predominantly by the extension of intellectual property laws to the colonies for purposes associated generally with the overarching colonial strategies of assimilation, incorporation and control. It was also characterized by efforts to secure national economic interests against other European countries in colonial territories.<sup>11</sup>

Even after these colonies became independent, many of the intellectual property laws that were originally transplanted from the former controlling powers remained on the books. These laws either survived state succession or had been retroactively adopted as part of the post-independence national law.<sup>12</sup> As Professor Okediji observed further:

It is well-known . . . that most developing countries retained the structure and form of laws and institutions established during the colonial period, including intellectual property laws. Until 1989, Lesotho operated under the Patents, Trade Marks and Designs Protection Proclamation of 1919, a United Kingdom instrument. Mauritius, a former French colony, continued to operate under its Trade Marks Act (1868) and Patents Act (1975) for over twenty years after obtaining independence in 1968. Swaziland also inherited its IP regime "as a colonial legacy." The same is true with respect to other laws and institutions. Indeed, prior to the compelled compliance with intellectual property rights imposed by the TRIPS Agreement, many developing and least developed countries still had as their own domestic laws the old Acts and Ordinances of the colonial era. While some developing countries had laws in place that attracted the ire of the developed countries by explicit refusals to grant patents to pharmaceutical products, or through compulsory licensing provisions, or by the failure to enforce recognized rights, many others simply had obsolete laws.<sup>13</sup>

In the 1960s, the decolonization effort and the emergence of less developed countries called into question the extent of protection in the international intellectual property system. During the Intellectual Property Conference of Stockholm in 1967, India and other less developed countries demanded special concessions in the international copyright system in light

<sup>&</sup>lt;sup>11</sup> Ruth L. Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System*, 7 Sing. J. Int'l & Comp. L. 315, 324–25 (2003).

 $<sup>^{12}</sup>$  Id. at 325–34.

 $<sup>^{13}</sup>$  Id. at 335–36 & n.73.

of their divergent economic, social, cultural, and technological conditions.<sup>14</sup> The conference eventually led to the creation of World Intellectual Property Organization (WIPO) as a specialized agency of the United Nations and the inclusion of the Protocol Regarding Developing Countries as an appendix to the Berne Convention.<sup>15</sup>

In the mid-1970s, less developed countries further demanded a revision of the Paris Convention to lower the minimum standards of intellectual property protection as applied to them and to expand compulsory licenses available under the Convention.<sup>16</sup> Through the efforts of the United Nations Conference on Trade and Development (UNCTAD), countries also worked together to develop a draft International Code of Conduct on the Transfer of Technology.<sup>17</sup> These demands, to which the United States objected vehemently, eventually precipitated the famous stalemate between developed and less developed countries in the 1981 Diplomatic Conference in Nairobi.

Led by the United States and heavily influenced by multinational corporations, developed countries responded to this stalemate by abandoning the intellectual property-based forum in favor of the General Agreement on Tariffs and Trade (GATT), a trade-based forum which eventually expanded into the World Trade Organization (WTO).<sup>18</sup> After close to a decade of negotiations, and some serious trade threats made by the United States, countries finally agreed to the Marrakesh Agreement Establishing the World Trade Organization, which included in its annex a multilateral agreement on intellectual property rights known as the TRIPs Agreement.

#### **Enclosure Through the TRIPs Agreement**

The TRIPs Agreement entered into effect in 1995. Based on models from developed countries, this Agreement remade the international intellectual property system by strengthening protection in at least four significant ways. First, it established minimum standards for intellectual property protection and achieved new international consensus on the protection of emerging technologies and subject matters. For example, article 10(2) of the Agreement states that "computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971)." Article 23 offers special protection to geographical indications for wines and spirits. Article 27(1) stipulates that "patents . . . be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." Article 27(3)(b) further requires each member state to "provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." Article 35 offers protection to integrated circuit topographies by reference to the Treaty on the Protection of Intellectual Property in Respect of Integrated Circuits.

<sup>&</sup>lt;sup>14</sup> Barbara A. Ringer, *The Role of the United States in International Copyright—Past, Present, and Future*, 56 Geo. L.J. 1050, 1065 (1968).

<sup>&</sup>lt;sup>15</sup> Yu, *Currents and Crosscurrents, supra* note 8, at 328.

<sup>&</sup>lt;sup>16</sup> *Id.* at 357.

<sup>&</sup>lt;sup>17</sup> International Technology Transfer: The Origins and Aftermath of the United Nations Negotiations on a Draft Code of Conduct (Surendra J. Patel, Pedro Roffe & Abdulqawi Yusuf eds., 2001).

<sup>&</sup>lt;sup>18</sup> Yu, *Currents and Crosscurrents, supra* note 8, at 357–58.

From the standpoint of the development of the international intellectual property system, these heightened standards are particularly important because they effectively transformed the system from an international framework to a global framework.<sup>19</sup> In the past, international intellectual property conventions were largely introduced to patch up the divergent protections in various national systems. In light of this patchwork effort, countries tended to focus only on the minimum standards, or the protection floor, when they negotiated international treaties. The TRIPs Agreement, however, altered that setup by imposing a "supranational code" on the weaker WTO member states despite their limited economic development.<sup>20</sup> Because the code now requires higher standards than are appropriate for these countries, the focus on minimum standards becomes misguided, and the lack of maximum international standards has made it difficult for countries to respond to massive domestic problems, such as the widely-reported public health crises concerning HIV/AIDS, tuberculosis, malaria, and other epidemics.<sup>21</sup>

Second, the TRIPs Agreement expanded the coverage of intellectual property protection to eight different areas. In addition to the three main branches of intellectual propertycopyrights, patents, and trademarks—the Agreement also covers geographical indications, industrial designs, plant variety protection, integrated circuit topographies, and protection of undisclosed information. Such coverage is remarkable because a number of these areas did not attain international consensus before the adoption of the TRIPs Agreement. As Javashree Watal, the former negotiator for India and a current WTO official, pointed out, "at least one [area], undisclosed information, has never been the subject of any multilateral agreement before, and another, protection for integrated circuit designs, had no effective international treaty, while others, like plant variety protection or performers' rights, were geographically limited."<sup>22</sup>

Third, through complex procedures and burdensome obligations, the TRIPs Agreement significantly curtailed the ability of less developed countries to design an intellectual property system that is tailored to local needs, interests, and goals. The three-step test in articles 13 and 30 and a similar test in article 17 have made it particularly difficult for countries to create new limitations or exceptions in their copyright, patent, and trademark systems. Article 31 also includes a set of complex procedural rules delineating the conditions under which a country can issue a compulsory license. Although these rules have been relaxed lately by the Doha Declaration and the August 30 Decision, it remains to be seen whether and when two-thirds of the WTO membership will ratify the protocol to formally amend the TRIPs Agreement by adding the proposed article 31bis.

Fourth, the TRIPs Agreement "married" intellectual property to international trade and established a dispute settlement process that is mandatory for disputes arising under the Agreement. As a result, this mandatory process has greatly improved the enforceability of the Berne and Paris Conventions, which hitherto have been virtually unenforceable.<sup>23</sup> The Agreement also provided developed countries with a process through which they can induce

<sup>&</sup>lt;sup>19</sup> Yu, The International Enclosure Movement, supra note 6, at 901–06.

<sup>&</sup>lt;sup>20</sup> Jane C. Ginsburg, International Copyright: From a "Bundle" of National Copyright Laws to a Supranational Code?, 47 J. Copyright Soc'y U.S.A. 265, 267–76 (2000); Yu, *Currents and Crosscurrents, supra* note 8, at 354–75. <sup>21</sup> Peter K. Yu, *TRIPS and Its Discontents*, 10 Marq. Intell. Prop. L. Rev. 369, 402 (2006).

<sup>&</sup>lt;sup>22</sup> Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries 4 (2001).

<sup>&</sup>lt;sup>23</sup> Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis 10 (2d ed. 2003); Yu, Currents and Crosscurrents, supra note 8, at 355.

their less developed trading partners to offer stronger intellectual property protection. This process includes such measures as consultation, good offices, conciliation, mediation, and finally, dispute settlement. To many commentators, the mandatory dispute settlement process was one of the crowning achievements, if not the crowning achievement, of the Uruguay Round of Multilateral Trade Negotiations that resulted in the establishment of the WTO.<sup>24</sup>

# The Limits of TRIPs Enclosure

Although the TRIPs Agreement increased considerably the protection of intellectual property rights at the international level, significant safeguards, flexibilities, and transitional measures exist in the Agreement to protect less developed countries. For example, article 7 states explicitly that

the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 recognizes the needs of WTO member states to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." Article 1 further states that member states are "free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." As Frederick Abbott highlighted, this freedom includes at least the following flexibilities:

The TRIPS Agreement . . . does not . . . restrict the authority of governments to regulate prices. It . . . permits [compulsory or government-use licenses] to be granted. It permits governments to authorize parallel importation. The TRIPS Agreement does not specify that new-use patents must be granted. It allows patents to be used for regulatory approval purposes, and it does not require the extension of patent terms to offset regulatory approval periods. The TRIPS Agreement provides a limited form of protection for submissions of regulatory data; but this protection does not prevent a generic producer from making use of publicly available information to generate bioequivalence test data. The TRIPS Agreement provides substantial discretion for the application of competition laws.<sup>25</sup>

In addition, through the efforts of negotiators, who were more astute than they were given credit for, the TRIPs Agreement includes many ambiguities that have been intentionally built into the instrument. As Carlos Correa pointed out, although developed countries would interpret the word "review" in article 27(3)(b) to mean "review of implementation," less developed countries are likely to interpret that same word to suggest the possibility for "revising" the

<sup>&</sup>lt;sup>24</sup> William J. Davey, The WTO Dispute Settlement System: The First Ten Years, 8 J. Int'l Econ. L. 17, 32 (2005); 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, 275 (1997); Ruth Okediji, Toward an International Fair Use Doctrine, 39 Colum. J. Transnat'l L. 75, 149–50 (2000). <sup>25</sup> Frederick M. Abbott, The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health, in Negotiating

Health: Intellectual Property and Access to Medicines 27, 30 (Pedro Roffe, Geoff Tansey & David Vivas-Eugui eds., 2006).

Agreement to meet their needs and interests.<sup>26</sup> Likewise, Sisule Musungu recently reminded us the different ways of conceptualizing the transitional periods built into the TRIPs Agreement:

While giving extra time due to administrative and financial constraints was one aim, the central objective of the LDCs [least developed countries] transition period under the TRIPS Agreement is different. Article 66.1 of TRIPS read together with the Preamble of the TRIPS Agreement and its objectives under Article 77 envisage the purpose and objectives of the LDCs transition period to be to respond and address: the special needs and requirements of these countries; and the need for maximum flexibility to help these countries create a sound and viable technological base.<sup>27</sup>

Thus, Jayashree Watal has described these ambiguous words and phrases as "constructive ambiguities." <sup>28</sup> These ambiguities are constructive, because they provide less developed countries with a bulwark against the continuous expansion of intellectual property rights. If carefully interpreted, they will enable countries to preserve the policy space appropriately reserved for them during the negotiation process. They may also allow less developed countries to "'claw[]' back much of what was lost in the negotiating battles in TRIPS."<sup>29</sup>

Finally, the Agreement recognized the inability of less developed countries to immediately increase their levels of protection. Article 65 provided developing and transition countries with a four-year transitional period, which has since expired. Likewise, article 66 provided least developed countries with an initial ten-year transitional period, which has now been extended to seventeen and a half years for most products as long as the country seeking an extension has not yet met the TRIPs requirements or has already offered protection in excess of those requirements. With respect to pharmaceuticals, the Doha Declaration extended to 2016 the deadline for least developed countries to offer protection. Article 66 further requires developed countries to provide incentives for their businesses and institutions to help create "a sound and viable technological base" in least developed countries by promoting and encouraging transfer of technology.

Thus, although the TRIPs Agreement has greatly strengthened intellectual property protection while significantly reducing the policy space of WTO member states, it includes certain safeguards, flexibilities, and transitional measures to help countries "buy time" to update their intellectual property systems. It also leaves little space for less developed countries to develop policies that respond to their needs, interests, and goals. Whether countries will be able to take advantage of these benefits will depend on their capacity to interpret the Agreement, insist on their interpretations, and resolve disputes before the WTO Dispute Settlement Body.<sup>30</sup>

<sup>&</sup>lt;sup>26</sup> Carlos M. Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options 211 (2000).

<sup>&</sup>lt;sup>27</sup> Sisule Musungu, A Conceptual Framework for Priority Identification and Delivery of IP Technical Assistance for LDCs During the Extended Transition Period Under the TRIPS Agreement 5 (2007), http://www.quno.org/geneva/pdf/economic/Issues/Priority-ID-English.pdf.

 $<sup>^{28}</sup>$  Watal, *supra* note 22, at 7.

<sup>&</sup>lt;sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, 7 J. Int'l Econ. L. 459, 473–76 (2004).

# **Further Enclosure Through TRIPs-Plus Agreements**

Unfortunately for less developed countries, recent years have seen further enclosure of their policy space. Whatever limited space the TRIPs Agreement retained, that space has been further enclosed by the aggressive push by developed countries for TRIPs-plus bilateral and regional agreements—free trade agreements with the United States, economic partnership agreements with the European Communities, and multilateral agreements like the Anti-Counterfeiting Trade Agreement proposed with members of the G8 and other OECD countries.<sup>31</sup>

There are generally three different types of provisions in the so-called TRIPs-plus agreements: TRIPs-plus provisions, TRIPs-extra provisions, and TRIPs-restrictive provisions. TRIPs-plus provisions increase the commitments of less developed countries by increasing the protection stated in the TRIPs Agreement. For example, although article 33 of the Agreement requires patent protection for only twenty years, some recent U.S. free trade agreements have required a limited extension of the patent term based on the period during which a product undergoes regulatory review.<sup>32</sup> Such an extension is similar to the extension provided by the United States' Hatch-Waxman Act of 1984.

TRIPs-extra provisions, by contrast, add new commitments that are not covered by the TRIPs Agreement. Examples of these provisions include those calling for the establishment of a data exclusivity regime to protect clinical trial data submitted during regulatory approval processes; the linkage of pharmaceutical product registration to patent status; the requirement that patents be granted for "new uses," or second indications, of known compounds; the ban on parallel importation of cheap, generic drugs; and the use of dispute settlement processes that are different from the one mandated by the WTO.<sup>33</sup> Although the WTO prohibits member states from taking retaliatory measures before exhausting all of the actions permissible under its rules, TRIPs-extra provisions are likely to rejuvenate the section 301 process and may lead to greater use of trade threats and unilateral sanctions, as the provisions cover issues outside of the TRIPs Agreement.<sup>34</sup>

Finally, TRIPs-restrictive provisions neither increase the protection under the TRIPs Agreement nor cover a new area of protection outside the Agreement. They nonetheless enclose the policy space of less developed countries by restricting how the Agreement is to be implemented. A textbook example of such provisions is one that requires less developed countries to protect plant varieties by introducing the 1991 Act of UPOV (International Union for the Protection of New Varieties of Plants), notwithstanding the fact that article 27(3)(b) of the TRIPs Agreement allows each member state to decide whether it wants to offer protection through patents, *sui generis* protection, or a combination of both.<sup>35</sup>

In sum, the recent bilateral and regional efforts have further enclosed the already very limited policy space available to less developed countries under the TRIPs Agreement. As these countries struggle to respond, they begin to explore new alternative fora in their effort to reclaim

<sup>&</sup>lt;sup>31</sup> Yu, *Currents and Crosscurrents, supra* note 8, at 392–400.

<sup>&</sup>lt;sup>32</sup> Yu, *The International Enclosure Movement, supra* note 6, at 868.

<sup>&</sup>lt;sup>33</sup> *Id.* at 868–69.

<sup>&</sup>lt;sup>34</sup> Panel Report, United States—Sections 301–310 of the Trade Act of 1974, WT/DS152/R (Dec. 22, 1999).

<sup>&</sup>lt;sup>35</sup> Yu, *The International Enclosure Movement, supra* note 6, at 869.

their lost policy space and to roll back the continuous expansion of intellectual property rights. They also have successfully pushed for the establishment of the WIPO Development Agenda to level the playing field and to establish countervailing principles, norms, and rules that they hope can be later incorporated into the international intellectual property system.<sup>36</sup>

# **Resistance to the International Enclosure Movement**

Since the introduction of the TRIPs Agreement, there has been growing resistance from less developed countries to the development and adoption of new international intellectual property standards. These efforts, which accelerated after the expiration of the transitional periods provided to developing countries by the TRIPs Agreement, eventually led to the launch of the Doha Round. This new round of trade negotiations underscored the need by less developed countries to have wide policy space to develop intellectual property policies that take into consideration the countries' social, economic, cultural, and developmental goals. As an illustration, this section focuses on the challenges and resistance efforts put up by less developed countries in the public health area. In particular, it discusses the development of the August 30 Decision and the proposed article 31*bis* of the TRIPs Agreement.

The Doha Declaration came at a time when developed countries were eager to move on to other issues in the international trade agenda, while the international community had been paying growing attention to the human rights implications of intellectual property protection.<sup>37</sup> As the United States' rhetoric was weakened following the "suggestion" of some of its government officials and politicians to use compulsory licenses as a response to high drug prices during the post-9/11 anthrax attacks, the political climate became very favorable to less developed countries.<sup>38</sup>

During the Fourth WTO Ministerial Conference in Doha, Qatar, less developed countries pushed for the adoption of the Doha Declaration, "sen[ding] a clear message that they would take steps to protect and advance their essential interests."<sup>39</sup> The first two paragraphs of the Declaration explicitly "recognize[d] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics . . . [and] the need for the [TRIPs Agreement] to be part of the wider national and international action to address these problems." In addition, the Declaration extended the deadline for least developed countries to protect pharmaceuticals to January 1, 2016. It also noted affirmatively that the TRIPs Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." Finally, paragraph 5 of the Declaration underscored the various "flexibilities" reserved for all WTO members under the TRIPs Agreement, which include the following:

<sup>&</sup>lt;sup>36</sup> Christopher May, The World Intellectual Property Organization: Resurgence and the Development Agenda (2007); Peter K. Yu, *A Tale of Two Development Agendas*, 35 Ohio N.U. L. Rev. (forthcoming 2008).

<sup>&</sup>lt;sup>37</sup> Yu, *The International Enclosure Movement, supra* note 6, at 865–66.

<sup>&</sup>lt;sup>38</sup> Debora Halbert, *Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*, 1 Seattle J. Soc. Just. 257, 280 (2002).

<sup>&</sup>lt;sup>39</sup> F.M. Abbott, Legal Options for Implementing Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health (2002).

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

The only unresolved issue concerning the lack of access to essential medicines in less developed countries was how to address the lack of an indigenous capacity to manufacture pharmaceuticals. Although paragraph 6 of the Doha Declaration "recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement," it merely instructed the TRIPs Council to devise an "expeditious solution." Thus, in August 2003, the TRIPs Council issued a decision granting interim waivers to member states that lack an indigenous manufacturing capacity, as well as those that have insufficient capacity to cope with unforeseen situations of national emergency. These waivers allowed the WTO member states to suspend article 31(f) of the TRIPs Agreement during the time when a permanent solution was being negotiated.

Although the August 30 decision, and the waivers granted in it, represented a promising first step in focusing attention on the public health crises in less developed countries, commentators have criticized the waivers for being "unduly cumbersome and complex."<sup>40</sup> Despite its existence for a few years, the waivers were not used until October 2007, when Canada notified the WTO of its authorization of the manufacture of a generic version of the patented AIDS therapy drug, TriAvir, for export to Rwanda.<sup>41</sup> Other oft-cited shortcomings include their lack of legal authority,<sup>42</sup> their failure to address the transfer of pharmaceutical technology to less developed countries,<sup>43</sup> and their inability to "prevent a private party from

<sup>&</sup>lt;sup>40</sup> Carlos M. Correa, Recent International Developments in the Area of Intellectual Property Rights 4 (2003), http://www.iprsonline.org/unctadictsd/bellagio/docs/CorreaBellagio2.pdf; K.M. Gopakumar, *The WTO Deal on Cheap Drugs: A Critique*, 7 J. World Intell. Prop. 99 (2004); Karin Timmermans, *Ensuring Access to Medicines in 2005 and Beyond, in* Negotiating Health, *supra* note 25, at 41, 45.

<sup>&</sup>lt;sup>41</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, Notification Under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health—Canada, IP/N/10/CAN/1 (Oct. 8, 2007); see also WTO, Canada Is First to Notify Compulsory Licence to Export Generic Drug, http://www.wto.org/english/news\_e/news07\_e/trips\_health\_notif\_oct07\_e.htm (Oct. 4, 2007).

<sup>&</sup>lt;sup>42</sup> Halbert, *supra* note 38, at 280.

<sup>&</sup>lt;sup>43</sup> M. Rafiqul Islam, *The General Drug Deal of the WTO from Doha to Cancun: A Peripheral Response to a Perennial Conundrum*, 7 J. World Intell. Prop. 675 (2004).

blocking the exportation or importation of drugs, if the national laws do not specifically permit such exports or imports under compulsory licenses."44

Notwithstanding these shortcomings, the August 30 Decision remains one of the most important steps that have sought to halt the growing international enclosure efforts at the intersection of intellectual property and public health. Since the decision, the TRIPs Council had actively explored a permanent replacement for the temporary waivers. As paragraph 11 of the Decision stated, "[t]his Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member." This paragraph therefore provided less developed countries an unprecedented opportunity to restore the balance of the international intellectual property system and to reclaim their lost policy space.

To take advantage of this opportunity, less developed countries and their supporting intergovernmental and nongovernmental organizations advanced a number of proposed templates for this "permanent solution." Meanwhile, developed countries responded with alternative templates that would protect the interests of their nationals and exporting industries. The pushes by both country groups eventually precipitated a "battle of templates," in which each group sought to impose its solution onto the others. Among the contentious issues in this battle were the scope of diseases, the members' eligibility for the benefits of the solution, and the choice of the TRIPs provision that would be used to implement the permanent solution. Other issues that were discussed and negotiated included the definition of the "pharmaceutical sector," protection against trade diversion and abuse, the ability to create economies of scale, the need for a moratorium on disputes over public health-related remedies in countries with no or insufficient manufacturing capacity, and the facilitation of technology transfer and technical assistance.<sup>45</sup>

Although the scope of diseases was not a major issue in the discussion leading to the adoption of the proposed article 31bis, it was one of the more contentious issues in the initial stage of this battle of templates.<sup>46</sup> At the outset, less developed countries considered it important to define the new provision "broadly [to] cover their present and future public health needs."<sup>47</sup> While their immediate concerns were HIV/AIDS, malaria, and tuberculosis, they sought recognition that the access-to-medicines problem extended beyond the list of diseases identified in paragraph 1 of the Doha Declaration. After all, from the standpoint of less developed countries, "[the] issue had been resolved at Doha by the adoption of a broadly framed declaration . . . [and any] attempts to limit the solution to particular diseases [would] amount[] to an effort to rewrite the Doha Declaration."48

Meanwhile, the United States feared that less developed countries with manufacturing capacity, like Brazil and India, might use the new provision to export drugs that were not intended to be covered by the Doha Declaration, such as lifestyle drugs like Rogaine and

<sup>&</sup>lt;sup>44</sup> Correa, Recent International Developments, *supra* note 40, at 3.

<sup>&</sup>lt;sup>45</sup> Yu. *The International Enclosure Movement, supra* note 6, at 877–78.

<sup>&</sup>lt;sup>46</sup> Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. Int'l L. 317, 327 (2005). <sup>47</sup> *Id.* at 328.

<sup>&</sup>lt;sup>48</sup> *Id*.

Viagra.<sup>49</sup> The United States, therefore, embraced a restrictive approach that sought to limit the list to only a few identified diseases. From the standpoint of developed countries, it is important to limit the number of diseases that are subject to a compulsory license, because that number will affect the amount of patented technologies that will be used without the patent holder's authorization while increasing the industry's risk of revenue loss.<sup>50</sup>

The second contentious issue concerned the eligibility of countries for the importation of pharmaceuticals under a compulsory license. Although all countries agreed to make the solution available to least developed countries, it was uncertain whether other WTO members would be eligible for the Paragraph 6 solution. The European Communities, for example, wanted to exclude developed countries, "focusing especially on least developed country Members and low income Members, with no or insufficient domestic manufacturing capacity, or, in case that product is patented in that Member, no or insufficient manufacturing capacity other than that of the patent holder of the product in that Member."<sup>51</sup> By contrast, the United States, in an effort to promote certainty and avoid disputes, pushed for the establishment of "a procedure to clarify which developing country Members can be considered to have insufficient or no manufacturing capacity in the pharmaceutical sector or at least the factors to be taken into consideration."52 Meanwhile, many less developed countries did not want any limitation at all,<sup>53</sup> while some developed countries favored the lack of distinction between developing and least developed countries.<sup>54</sup> The African Group went even further to propose that "where a request is properly made under the solution, there should be an obligation on the requested Member to take all measures necessary for the production and exportation to be speedily accomplished."<sup>55</sup>

Amidst the negotiation, tension developed among the less developed countries—between countries that had manufacturing capacity, like India and Brazil, and those that did not but were eager to increase local production capacity, like countries in the African group.<sup>56</sup> The latter "believe[d] that the ultimate solution to the paragraph 6 problem [wa]s to build domestic manufacturing capacity and that this should be explicitly agreed and mentioned in the solution."<sup>57</sup> Fortunately for the less developed world, the two groups of countries were able to set aside their differences and joined together to battle the developed countries—perhaps because the African Group realized that, for the foreseeable future, its members would continue to import new drugs from Brazil, China, and India even if they sought to develop their production capacity.<sup>58</sup>

<sup>&</sup>lt;sup>49</sup> Id.

<sup>&</sup>lt;sup>50</sup> *Id.* at 329.

 <sup>&</sup>lt;sup>51</sup> Communication from the European Communities and Their Member States, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, para. 12, IP/C/W/352 (June 20, 2002).
<sup>52</sup> Second Communication from the United States, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*,

<sup>&</sup>lt;sup>32</sup> Second Communication from the United States, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, para. 12, IP/C/W/358 (July 9, 2002). <sup>53</sup> Communication from the Permanent Mission of Brazil, *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and* 

<sup>&</sup>lt;sup>53</sup> Communication from the Permanent Mission of Brazil, *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health*, para. 4, IP/C/W/355 (June 24, 2002); Communication from Kenya, *Elements of a Paragraph 6 Solution*, para. 7, IP/C/W/389 (Nov. 14, 2002).

<sup>&</sup>lt;sup>54</sup> Communication from the United Arab Emirates, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, para. 11, IP/C/W/354 (June 24, 2002).

<sup>&</sup>lt;sup>55</sup> Kenya Proposal, *supra* note 53, para. 9.

<sup>&</sup>lt;sup>56</sup> Abbott, *WTO Medicines Decision, supra* note 46, at 334.

<sup>&</sup>lt;sup>57</sup> Kenya Proposal, *supra* note 53, para. 15(a).

<sup>&</sup>lt;sup>58</sup> Abbott, WTO Medicines Decision, supra note 46, at 334.

The last contentious issue concerned whether the WTO member states would amend article 30 or 31(f) of the TRIPs Agreement. During the TRIPs Council meeting in March 2002, four basic options were put on the table:

- (i) an authoritative interpretation based on Article 30;
- (ii) an amendment to Article 31 in order to overcome the restriction, under Article 31(f), to the possibility to export products manufactured and/or sold under a compulsory licence;
- (iii) a dispute settlement moratorium with regard to the non-respect of the restriction under Article 31(f); or
- (iv) a waiver with regard to Article 31(f).<sup>59</sup>

Initially, less developed countries, the World Health Organization, and nongovernmental organizations, favored a modification of article 30,<sup>60</sup> partly due to their concerns about potential bureaucratic delay caused by cumbersome compulsory licensing procedures. To provide "the most comprehensive approach to solving the problem," the African Group also proposed to modify article 31 in addition to article 30,<sup>61</sup> while the United Arab Emirates favored the modification of article 31 but proposed the interpretation of article 30 as "an alternative option."<sup>62</sup> Meanwhile, the United States preferred a modification of article 31 only, and the European Communities soon sided with the United States, realizing that "the United States would never accept an Article 30-based solution."<sup>63</sup> Less developed countries eventually yielded to their demands, perhaps because the United States was unlikely to change its position and other issues were far more important than the modification of article 30.

On December 6, 2005, shortly before the Sixth WTO Ministerial Conference in Hong Kong, WTO member states agreed to accept a protocol of amendment to the TRIPs Agreement, making permanent the interim waivers granted in the August 30 Decision. Embodied in the proposed article 31*bis*, the amendment lays out conditions under which countries can suspend article 31(f) of the TRIPs Agreement. If ratified before December 1, 2009 (a two-year extension from the earlier December 2007 deadline), the proposed provision will enter into effect.

Although the provision was designed to address problems of less developed countries, the amendment, in retrospect, is closer to a compromise between developed and less developed countries. Instead of allowing less developed countries to reclaim their lost policy space, or to roll back the recent expansion of intellectual property rights, the negotiation of the proposed amendment merely identified the policy space needed by less developed countries and facilitated the negotiation of the governing standards within that particular space. While less developed countries prevailed on the scope of diseases and country eligibility issues, the United States succeeded in limiting the amendment to article 31. Nevertheless, the Doha Round, the August 30 decision, and the proposed amendment did draw attention to the development needs of less

<sup>&</sup>lt;sup>59</sup> EC Proposal, *supra* note 51, para. 2.

<sup>&</sup>lt;sup>60</sup> Brazil Proposal, *supra* note 53, para. 8.

<sup>&</sup>lt;sup>61</sup> Abbott, WTO Medicines Decision, supra note 46, at 340.

<sup>&</sup>lt;sup>62</sup> UAE Proposal, *supra* note 54, para. 17.

<sup>&</sup>lt;sup>63</sup> Abbott, WTO Medicines Decision, supra note 46, at 340.

developed countries and "ma[d]e a start in some rebalancing of the asymmetry of the Uruguay Round."<sup>64</sup>

# Strategies to Reclaim the Lost Policy Space

Because the Doha Round only served as a starting point for the efforts by less developed countries to restore the balance of the international intellectual property system, new strategies are needed if less developed countries are to prevent the continuous expansion of intellectual property rights in the international intellectual property system. To help develop these strategies, this section identifies three possible explanations for the growing international enclosure efforts.

The first explanation concerns the significant disparity in power between developed and less developed countries. Such disparity forces less developed countries to adopt harmful transplants that ignore their local needs, national interests, technological capabilities, institutional capacities, and public health conditions. Consider the implementation of the TRIPs Agreement in less developed countries, for example. The changes required by the TRIPs Agreement were not only dramatic, but they also extend beyond intellectual property to affect other areas, such as agriculture, health, the environment, education, culture, competition, free speech, democracy, and the rule of law.<sup>65</sup> While the Agreement includes a mandatory dispute settlement process to prevent developed countries from introducing unilateral sanctions, the power asymmetry in the international system and the high economic and political costs of dispute resolution have greatly curtailed the ability by less developed countries to take advantage of this process. As a result, this sanction-laden process now has the perverse effect of forcing less developed countries to modify their intellectual property systems without giving them an equal opportunity to induce a similar modification from their more powerful trading partners.<sup>66</sup> If the inequities perpetuated by the TRIPs Agreement are not enough, the recent bilateral and regional trade agreements initiated by the European Communities and the United States have forced less developed countries to ratchet up intellectual property standards even further. These agreements largely ignore the fact that these countries have yet to successfully adjust to the heightened standards required by the TRIPs Agreement.

To be certain, the ideal solution to alleviate these problems is through the redesign of the international intellectual property system, including a wholesale revision of the TRIPs Agreement, based on the development and public health needs of less developed countries. Unfortunately, the power asymmetry in the international trading system virtually guarantees that such solution would never be adopted. In fact, the TRIPs Agreement is likely to stay, regardless of whether less developed countries can make successful adjustment to the heightened standards. Thus, if these poorer countries are to restore the balance of the international intellectual property system, they need to explore how to work the TRIPs Agreement to their advantage.

To help these countries, I have proposed elsewhere eight causes of action:

1. Develop a pro-development interpretation of the TRIPs Agreement.

<sup>65</sup> Yu, *Currents and Crosscurrents, supra* note 8, at 365.

<sup>&</sup>lt;sup>64</sup> Sylvia Ostry, *WTO Membership for China: To Be or Not to Be—Is That the Answer, in* China and the World Trading System: Entering the New Millennium 31, 38 (Deborah Z. Cass, Brett G. Williams & George Barker eds., 2003).

<sup>&</sup>lt;sup>66</sup> William J. Davey, *Dispute Settlement in GATT*, 11 Fordham Int'l L.J. 51, 90 (1987).

- 2. Explore the public interest safeguards in the TRIPs Agreement.
- 3. Take advantage of the WTO dispute settlement process.
- 4. Add explicit access rights to the TRIPs Agreement.
- 5. Explore the use of alternative international regimes.
- 6. Facilitate coalition building.
- 7. Understand the tension between the European Communities and the United States.
- 8. Assess the compatibility of the free trade agreements with the multilateral WTO system.<sup>67</sup>

These causes of action, which are intended to be nonexhaustive, do not seek to revise the TRIPs Agreement. Rather, they seek to utilize the TRIPs Agreement to introduce reforms to the current international intellectual property system. They also seek to caution less developed countries about the growing use of TRIPs-plus bilateral and regional agreements.

The second explanation concerns the linkage between trade and intellectual property and the growing emphasis on the protection of investment in the creative and inventive processes. This is what I have described as the "incentive-investment divide."<sup>68</sup> Today, policy makers in developed countries increasingly focus on the protection of trade interests, as compared to, say, the generation of economic incentives and the maximization of protection for foreign investment. When these policy makers negotiate, they tend to consider intellectual property protection a mere bargaining chip among the many other trade items in a package deal. In doing so, they often downplay the importance of harnessing local conditions to promote innovation. They also ignore the need for striking an appropriate balance in the intellectual property system in either the target country or the international community as a whole.<sup>69</sup>

The situation is equally problematic for policy makers in less developed countries. Although these poorer countries often have no or very limited foreign investments to protect, their policy makers are often blinded by their concern about international standing and therefore compliance with international obligations.<sup>70</sup> Their blindness also grows out of their fear of more powerful trading neighbors and their eagerness to use intellectual property reforms to attract foreign investment, technology transfer, inward trade flows, and human capital.<sup>71</sup> In the end, policy makers from these countries behave just like their counterparts from developed countries; they pay little attention to innovation and its needed incentives while ignoring the fact that intellectual property is "an integral part of national or regional systems of innovation."<sup>72</sup>

To bridge this investment-incentive divide, policy makers need to decouple intellectual property and trade in their policy assessment and carefully evaluate the need for new intellectual

<sup>&</sup>lt;sup>67</sup> Yu, *TRIPS and Its Discontents, supra* note 21, at 386–410.

<sup>&</sup>lt;sup>68</sup> Yu, *The International Enclosure Movement, supra* note 6, at 892–901.

<sup>&</sup>lt;sup>69</sup> Carlos M. Correa, Internationalization of the Patent System and New Technologies, 20 Wis. Int'l L.J. 523, 524 (2002); Carlos Maria Correa, Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals, 3 Chi. J. Int'l L. 69, 72 (2002); James Thuo Gathii, Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-end Consumers, 53 Fla. L. Rev. 727, 748 (2001); Ruth L. Okediji, Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection, 1 U. Ottawa L. & Tech. J. 125, 130 (2004).

<sup>&</sup>lt;sup>70</sup> Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods, in* International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime 3, 18 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

<sup>&</sup>lt;sup>71</sup> Yu, *The China Puzzle*, *supra* note 3, at 192–93.

<sup>&</sup>lt;sup>72</sup> Maskus & Reichman, *supra* note 70, at 18.

property standards outside the trade context. Here, I am not advocating the decoupling of intellectual property and trade in the international intellectual property system. Countries should be free to decide whether they want to link intellectual property with trade in the bargaining process, and such bargain linkage may indeed benefit countries if made under the right conditions. Instead, I am arguing for the decoupling of intellectual property and trade in an assessment of the need for heightened or new intellectual property standards. Because bargain linkage would likely distort the analysis by ignoring important concerns and side effects while inducing policy makers to ask questions in the wrong directions, the decoupling of intellectual property and trade would provide a more accurate assessment of the need for these new standards.

If additional incentives are found to be needed, policy makers then need to explore whether any alternative strategy that is *less restrictive* to the country's social, economic, cultural, and developmental goals exists. Examples of these goals are the enlargement of access to essential medicines, educational materials, computer software, and information technology; the protection of traditional knowledge and cultural expressions; the promotion of biological diversity; and the preservation of culture and free expression.

As a final step, policy makers need to conduct impact studies to ensure a holistic evaluation of the ramifications of the proposed new standards. These studies are important, because they not only will provide the needed information for all member states to consider, but also will ensure that nationals and policy makers of the *demandeur* countries be aware of the development-related impact of the policies for which they are pushing. The studies will also provide helpful information to enable policy makers to make informed judgment in the face of heavy lobbying by intellectual property rights holders. If the new policies fail, the studies may provide additional insight into potential mechanisms that can help correct the problem, or at least minimize its damage. It is therefore no surprise that impact studies have been widely endorsed in the areas of human rights, public health, and biological diversity as well as within the WIPO Development Agenda.<sup>73</sup>

The final explanation concerns the gradual transformation of the international intellectual property system from a patchwork coordination system to a supranational, harmonized code. As discussed above, when the Berne and Paris Conventions were established two centuries ago, they were designed to coordinate national protections so as to reduce commercial piracy and counterfeiting across borders. As a result, the participating members focused primarily on anti-discrimination tools, like the national treatment provision. Although the early acts of these conventions included minimum standards of protection, they reserved to each member state a considerable amount of autonomy to develop its own intellectual property policies based on local needs and conditions.

As protection became more uniform in the developed world, however, developed countries found it important to have greater harmonization of intellectual property standards. Led by the United States and members of the European Communities, developed countries pushed for a harmonization process that transformed the international intellectual property

<sup>&</sup>lt;sup>73</sup> Peter K. Yu, *The Political Economy of Data Protection*, 83 Chi.-Kent L. Rev. (forthcoming 2008).

system into a global code that imposes obligations on the different participating members. Because of power asymmetry, a potentially two-way harmonization process eventually became a one-way Westernization, or Northernization, process. Through this process, developed countries imposed one-size-fits-all standards on less developed countries, just like how the colonial powers used to transplant their rules and standards to their colonies.

To add to the plight of less developed countries, the TRIPs Agreement does not provide Although the Agreement includes a any safeguards against these one-way transplants. considerable number of *minimum* standards, it has very limited *maximum* standards.<sup>74</sup> In fact, article 1 of the TRIPs Agreement stipulated specifically that "[m]embers may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement." Thus, although the TRIPs Agreement does a fairly good job in harmonizing minimum standards, its lack of focus on the protection ceiling has taken away the checks and balances needed to prevent the international intellectual property system from going out of balance.

As a result of this built-in weakness, or one could say design defect, the post-TRIPs intellectual property system does not retain the type of balance commonly found in domestic intellectual property systems, in which limitations and exceptions are just as important as the grants of rights. To remedy this situation, countries need to start reexamining how international intellectual property norms are being developed. If the system, indeed, has been transformed from a patchwork system to a supranational one, there is a strong need to redesign the system by introducing structural constraints to recalibrate the balance between proprietary interests and public access needs.

These structural constraints can take two different forms: endogenous limits and exogenous limits. To create endogenous limits, commentators have advocated the establishment of access rights in the copyright system<sup>75</sup> and the introduction of early working and research exceptions in the patent system.  $^{76}$  They also have underscored the importance of using competition law as a counterbalancing measure.  $^{77}$  Articles 31(k) and 40 of the TRIPs Agreement specifically permit WTO member states to take appropriate measures to curb "an abuse of intellectual property rights having an adverse effect on competition in the relevant market."

Exogenous limits are equally important. In recent years, commentators have begun to locate limits outside the intellectual property regime, turning to such regimes as those governing public health, human rights, biological diversity, food and agriculture, and information and Consider human rights, for example. In Resolution 2000/7, the United communications.

 $<sup>^{74}</sup>$  Yu, *TRIPS and Its Discontents*, *supra* note 21, at 402.  $^{75}$  *Id*. at 396–401.

<sup>&</sup>lt;sup>76</sup> Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights 50 (2002), http://www.iprcommission.org/papers/pdfs/final report/CIPRfullfinal.pdf; Timmermans, supra note 40, at 52.

<sup>&</sup>lt;sup>77</sup> Jonathan Berger, Advancing Public Health by Other Means: Using Competition Policy, in Negotiating Health, supra note 25, at 181, 182; Carlos M. Correa, Intellectual Property and Competition Law Exploring Some Issues of Relevance to Developing Countries (ICTSD Programme on IPRs and Sustainable Development, Issue Paper No. 21, 2007); Ernst-Ulrich Petersmann, International Competition Rules for Governments and for Private Business: A "Trade Law Approach" for Linking Trade and Competition Rules in the WTO, 72 Chi.-Kent L. Rev. 545, 563 (1996); J.H. Reichman, From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement, 29 N.Y.U. J. Int'l L. & Pol. 11, 52-58 (1997).

Nations Sub-Commission on the Protection and Promotion of Human Rights reminded governments of "the primacy of human rights obligations over economic policies and agreements."<sup>78</sup> In a recent interpretative comment on the International Covenant on Economic, Social, and Cultural Rights, the Committee on Economic, Social, and Cultural Rights further underscored the obligation of states parties to "strike an adequate balance" between their obligation to protect the moral and material interests in intellectual creations and their other obligations under international human rights instruments,<sup>79</sup> such as the protection of the right to food, the right to health, the right to education, the right to self-determination, the right to freedom of expression, the right to cultural participation and development, and the right to the benefits of scientific progress.<sup>80</sup>

Taken together, these two forms of limits will provide the needed safeguards to ensure the development of appropriate international intellectual property standards that benefit less developed countries. These limits will also restore to the international intellectual property system those characteristics that are usually found in domestic intellectual property systems. Under this modified design, the international intellectual property system will include limitations and exceptions that are as important as the grant of rights itself.

## Conclusion

With the establishment of the TRIPs Agreement and the proliferation of bilateral and regional agreements, the policy space of less developed countries in the intellectual property area has been drastically reduced. While commentators and policy makers have expressed grave concerns about the enclosure of the public domain and the upward ratchet of intellectual property protection, they need to start paying attention to a different, and often complimentary, enclosure movement that has significantly eroded the policy space of less developed countries. By taking away their autonomy and sovereign discretion, this international movement has made it difficult for individual countries to design an appropriate intellectual property system. As a result, less developed countries not only fail to respond to problems within their borders, but also become ill-equipped to respond to the growing attempts by rights holders and their supporting developed countries to enclose the public domain. One therefore could make a strong argument that this "international enclosure movement" is at least as dangerous as, if not more so than, the other enclosure movement that is often discussed in intellectual property literature. While intellectual property remains highly valuable in the global capitalist economy, the growing enclosure of the policy space of less developed countries is alarming and deserves our full and urgent attention.

<sup>&</sup>lt;sup>78</sup> Intellectual Property Rights and Human Rights, Sub-Commission on Human Rights Resolution 2000/7, para. 3, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (Aug. 17. http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument.

<sup>&</sup>lt;sup>79</sup> Committee on Economic, Social & Cultural Rights, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He Is the Author (Article 15, Paragraph l(c), ofthe Covenant), para. 35, U.N. Doc. E/C.12/GC/17 (Jan. 12 2006). http://www.unhchr.ch/tbs/doc.nsf/898586b1dc7b4043c1256a450044f331/03902145edbbe797c125711500584ea8/\$ FILE/G0640060.pdf. <sup>9</sup> Peter K. Yu, Reconceptualizing Intellectual Property Interests in a Human Rights Framework, 40 U.C. Davis L. Rev. 1039, 1148 (2007); Peter K. Yu, Ten Common Questions About Intellectual Property and Human Rights, 23 Ga. St. U. L. Rev. 709, 719 (2007).