2016

International Intellectual Property Shelters

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90 Tul. L. Rev. 903

Tulane Law Review
March, 2016

Article

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INTERNATIONAL INTELLECTUAL PROPERTY SHELTERS

The battle over the reach and strength of international protections for intellectual property rights is one of the critical flashpoints between wealthy and low-income countries: those protections are perceived to obstruct access to essential medicines, thwart regulatory efforts to promote individual and population health, and undermine traditional forms of agriculture and food production. While scholars have thoroughly tracked the bilateral and multilateral trade and investment treaties responsible for the expansion of international intellectual property rights worldwide, they have paid significantly less attention to the strength and form that opposition to international intellectual property expansion has taken. This Article examines the proliferation of international legal agreements that carve out special areas of intellectual property for treatment that differs from protections extended under international trade and investment rules and argues that they should be reconceived as a unified body of international economic law. Responding to demands from low- and middle-income countries that benefits from intellectual property protections be more equitably shared, these "international intellectual property shelters" include the Doha Declaration on the TRIPS Agreement and Public Health, the World Health Organization's Pandemic Influenza Preparedness Standard Manual Transfer Agreements, the Framework Convention on Tobacco Control, the International Treaty on Plant Genetic Resources for Food and Agriculture, and the proposed Medical Research and Innovation Treaty. This Article analyzes the circumstances that give rise to international intellectual property shelters and the aspects of intellectual property rights they attempt to regulate. While these shelters are advocated as safeguards for areas of global public welfare, such as food security and population health, they tend to arise in areas in which a small number of knowledge-intensive firms dominate global markets. International intellectual property shelters should therefore be understood as forms of supranational regulation of those firms.

*905 I. INTRODUCTION

The transition of advanced modern economies from industrial production to knowledge creation and exploitation has placed the role of intellectual property at the center of fierce debates about economic development, human rights, and the historical and accelerating concentration of global wealth. As the world's wealthiest countries seek to expand intellectual property protections through their bilateral, regional, and multilateral trade and investment agreements, the tension between economic monopoly and access to knowledge embedded in intellectual property's conceptual core has become a geopolitical flashpoint. Proponents of strong intellectual property protections argue that those protections are necessary to encourage investment in research and development, which ultimately facilitates technology and knowledge transfer to low- and middle-income countries. In the face of an exploding HIV/AIDS crisis in South Africa, a representative of global pharmaceutical giant Bristol-Myers Squibb argued that "[p]atents are the lifeblood of our industry" and insisted that curtailing patent rights, even to facilitate access to HIV/AIDS medications, would jeopardize the long-term development of critical medicines: "There is a need not to fight the firefighters." [1] Critics responded that the protections afforded intellectual property proprietors, particularly patent and trademark holders, weigh disproportionately in favor of private rights over social welfare and magnify wealth disparities of all kinds. [2] Environmental activist Vandana Shiva declared of the international intellectual property regime:

> The seed wars, trade wars, patent protection, and intellectual property rights [[[at the World Trade Organization] are claims to ownership through separation and fragmentation. If the regime of rights being ***906** demanded . . . is implemented, the transfer of funds from poor to rich countries will exacerbate the Third World crisis 10 times over. [3]

Intellectual property protection has dominated international trade and investment negotiations for the last thirty years, playing a critical role in the success, delay, controversy, or termination of agreements like those overseen by the World Trade Organization (WTO), the Trans-Pacific Partnership Agreement (TPP), and the Anti-Counterfeiting Trade Agreement (ACTA), to name only the broadest multilateral treaties. [4] Industrialized states successfully tied the intellectual property protections they desired to the reductions in tariffs and other barriers to imports of foreign

agricultural, clothing, and textile goods sought by many developing countries, formalized in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). [5] Thousands of bilateral investment treaties, largely forged between developed states and developing states, include strong protections for intellectual property rights that frequently exceed those in existing international agreements, even TRIPS, and certainly those typically found in national legislative frameworks. [6] This network of agreements has generated a wide range of enforcement mechanisms that reach beyond the slow and relatively impotent diplomatic methods that characterized the earlier generation of international intellectual property protections. [7]

***907** Confrontations between the growing strength of international intellectual property protections and the development interests of low- and middle-income countries have correspondingly increased. [8] Strong intellectual property protections for products and processes relevant to agricultural production, access to medicines, and public health measures have generated disputes arising under both WTO rules and bilateral and regional trade and investment agreements. In 1998, pharmaceutical firms holding antiretroviral drug patents brought suit against the South African government for its efforts to use parallel imports and price controls to expand access to treatment for its exploding HIV/AIDS population. [9] Their suit was based in significant part on the failure of the government's legislative basis for the measures to comply with TRIPS. [10] Agriculture and seed companies based in the United States and Europe have regularly clashed with both farmers in developing countries and their governments over attempts to interrupt agricultural practices with patent infringement claims. [11] In 2007, Indonesia withheld samples of H5N1 avian influenza from the World Health Organization (WHO) on the basis that it was commonplace for developing countries to share their biological resources only to have them exploited, patented, and generated into commercial products priced out of the reach of consumers in the originating country--a particular problem in the context of medicines and vaccines. [12]

These confrontations have resulted in a kind of guerilla warfare against strong international intellectual property protections, using either loopholes in trade and investment agreements themselves or by developing parallel treaties and international agreements that cut away at the strength of intellectual property protections. Although there is in fact a specialized U.N. agency for intellectual property, [13] the World ***908** Intellectual Property Organization (WIPO), its membership is dominated by countries leading the opposition to strong international intellectual property protections and has thus never served as the central forum for the development of substantive international intellectual property law, focusing instead on coordination and harmonization. [14] The aforementioned agreements themselves do provide circumscribed limitations. TRIPS, for example, includes provisions encouraging technology transfer and protecting interests in "public health and nutrition." [15] Other agreements leave substantial flexibility for implementation, allowing a country, for example, to devote relatively fewer prosecutorial resources to intellectual property rights enforcement. [16]

In the class of approaches identified and analyzed in this Article, negotiators from developed and low- and middle-income countries target areas of overreach or defectiveness in existing intellectual property protections and draft entirely new agreements that aim to curtail expansive intellectual property rights or to impose more rigid regimes to force sharing of innovations and other benefits. I call the subject areas and provisions of these agreements "international intellectual property shelters," discrete areas of public concern like access to medicines, agricultural technology, and public health measures in which the strong intellectual property protections that now prevail under international economic law give way to realigned incentives for intellectual property rights holders or, in some cases, are jettisoned altogether.

This Article is the first to argue that these international intellectual property shelters--often couched within the language of biodiversity, public health, and food security--represent a body of international economic law that should be understood as a single, cohesive phenomenon that has emerged in response to intellectual property protections

expanding through trade and investment agreements. From the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) [17] to the WHO's Pandemic Influenza Preparedness Standard Material Transfer Agreements (Pandemic ***909** Influenza Preparedness Framework) [18] to the proposed Medical Research and Innovation Treaty, [19] international intellectual property shelters put at their core the fundamental distributive questions strong intellectual property rights raise. The Doha Declaration broke the monopoly patents gave pharmaceutical firms over price structure, at least for the diseases designated in the agreement. [20] The Pandemic Influenza Preparedness Framework conditioned pharmaceutical firms' access to influenza biological materials for research and development purposes on donation and discounted pricing of resulting vaccines and medical countermeasures. [21] The Framework Convention on Tobacco Control (FCTC) provided a legal basis for many jurisdictions to effectively eliminate tobacco trademarks. [22] These innovations fundamentally restructured the relationship between innovation, intellectual property, and access otherwise envisioned in international trade and investment agreements.

This Article also previews two related aspects of these shelters more extensively developed in subsequent work. [23] International intellectual property shelters have emerged not just where an issue of public or global welfare is at stake; if that were the case, there would be many more of them. Rather, these shelters have tended to emerge in economic sectors where a small number of global firms dominate. The first shelter, WHO's 1981 International Code of Marketing of Breast-Milk Substitutes, [24] was essentially created to regulate Nestlé and its 50% global infant formula market share, although Gerber, Bristol-Myers, and Abbott also maintained substantial global operations. [25] At the time the International Seed Treaty was formed, four agrochemical firms controlled 56% of the global seed market. [26] ***910** Similar concentrations prevailed in the tobacco and pharmaceutical sectors when relevant agreements were initiated or concluded. [27] Public health, biodiversity, and vaccine sharing treaties are, at least in part, efforts at supranational regulation of concentrated global industries.

Like domestic regulatory systems, international intellectual property shelters may adopt performance standards, command-and-control mechanisms, or incentive-based measures to affect firms' behavior. Similarly, international intellectual property shelters, as supranational regulation, may be captured, co-opted, or diluted in ways that ultimately undermine their welfare-enhancing or redistributive objectives. While there has been a relatively short time to observe their influence, some experiences already suggest that some aspects of regime design and participant inclusion may impart important lessons for future efforts.

Part II of this Article traces the history of international intellectual property protections from the relatively modest and weak 1883 Paris Convention for the Protection of Industrial Property (Paris Convention) to the contemporary wide network of bilateral, regional, and multilateral investment and trade treaties with significant enforcement mechanisms. [28] Part III illustrates the tensions generated by expanding international intellectual property protections through episodes in which strong patent and trademark protections appeared to threaten public health and food security in low- and middle-income countries. Part IV identifies and analyzes the emergence of international intellectual property shelters: agreements formed to curtail or eliminate strong intellectual property protections that would otherwise protect patents and trademarks in critical public health and agricultural sectors. Part V previews two aspects of international intellectual property shelters relevant not only for understanding why and how they have emerged, but also how they may achieve their objectives. The first is the relationship between those shelters and concentrated global industries; the second is the regulatory design each uses to change default international intellectual property protections. Part VI provides a brief conclusion.

*911 II. THE GROWING STRENGTH OF INTERNATIONAL INTELLECTUAL PROPERTY PROTECTIONS

The growth of intellectual property protections through international legal instruments and treaties has been sweeping and rapid.[29] Intellectual property protections have expanded not only in terms of their scope, but also in their enforceability.[30] While patents were protected as early as the 1883 Paris Convention, new international agreements assert protection over most, if not all, aspects of information submitted to national regulatory authorities in connection with marketing approvals.[31] Pharmaceutical intellectual property rights, for example, have in many agreements expanded to include all clinical and animal testing information used to support a patent or approval application. Many bilateral investment treaties include broadly worded protections for intellectual property (e.g., "know-how"), which grant parties the right to bring a government before international arbitrators if regulatory measures adversely affect that right as an "investment."[32] The end result is that international intellectual property protection is now much stronger than when it was envisioned toward the end of the nineteenth century.[33]

A. The 1883 Paris Convention for the Protection of Industrial Property

The origin of the world's first major intellectual property treaty is traced to an 1873 invitation by the Austro-Hungarian Empire to foreign governments to participate in an international exhibition of inventions in Vienna.[34] Inventors hesitated to attend out of fear that their creations would be stolen or copied, leading a small group of states to seek out a way to protect their citizens' industrial and intellectual property as they moved across borders.[35] The resulting ***912** Paris Convention created a legal union between participating states in which foreign industrial design, patent, and trademark applications received the same treatment as national applications, obtained priority in other participating states if first protected in one of the union jurisdictions, and enjoyed substantive protections codified in the treaty.[36] Membership in the Paris Convention grew from 11 parties in 1883 to 174 in 2013.[37]

The treaties created reasonable exemptions for covered intellectual properties. Compulsory patent licenses were always contemplated for public health and national security reasons, while the addition of article 6(B)(iii) in 1934 allowed the denial of registration or the invalidation of trademarks that could mislead consumers.[38] The WTO's TRIPS later incorporated the Paris Convention, although TRIPS substantially narrowed its exceptions.[39]

The Paris Convention's enforcement mechanisms were almost entirely reputational and diplomatic.[40] In 1967, the parties agreed to transfer administration of the intellectual property treaties to an international organization, WIPO, which began operating formally in 1970 and then as a specialized agency of the United Nations starting in ***913** 1974.[41] WIPO has largely overseen the growing body of intellectual property rights harmonization and coordination treaties like the Patent Cooperation Treaty and the Trademark Law Treaty.[42] Because WIPO became a specialized agency of the United Nations during the same period that developing and newly independent states were pressing for the New International Economic Order, WIPO never promoted strong international intellectual property protections.[43]

B. International Trade Law

International intellectual property law became decidedly more influential not only when it merged with the international free trade regime, but also when it became equipped with judicial enforcement requirements that gave intellectual property right holders the capability to enforce those rights in domestic courts and administrative tribunals. Because the

Paris Convention and other efforts at international intellectual property protection failed to satisfy the demands of states with strong intellectual property rights-holding constituencies, individual states often regulated intellectual property practices through domestic trade statutes.

For example, in the United States, section 301 of the Trade Act of 1974 grants the President the authority to take necessary action, including retaliation, to obtain the removal of any act, policy, or practice of a foreign government that burdens or restricts U.S. commerce and either violates an international trade agreement, discriminates against the United States, or "imposes unjustifiable or unreasonable barriers" to U.S. commerce. [44] In 1988, the United States Congress enhanced section 301 by requiring the Office of the U.S. Trade Representative (USTR) to compile "Special 301" Reports, identifying countries that do not provide "adequate and effective" protection of intellectual property rights or "fair and equitable market access to United States persons that rely upon intellectual property ***914** [rights]." [45] These reporting mechanisms are a robust source of pressure from knowledge-intensive industries like pharmaceutical firms that maintain active monitoring and reporting systems for purposes of filing Special 301 complaints. [46] Yet, even efforts like these confront diplomatic and political limits. Key allies of the United States often appear on the reports, but strong military ties, for example, are sufficient to deter serious pressure from the U.S. government. Because bilateral pressure was not sufficient, a broader, multilateral agreement on intellectual property appeared necessary to achieve global protection for strong intellectual property rights.

1. The WTO

After the failure of the Bretton Woods-envisioned International Trade Organization to materialize, the less centralized General Agreement on Tariffs and Trade (GATT) became the organizing treaty under which states reduced official or governmental barriers to trade. [47] Over eight rounds of negotiations lasting more than forty years, trading states lowered tariffs as well as "nontariff barriers" to trade like customs procedures, import licensing requirements, and export subsidies. [48] The so-called Uruguay Round of GATT negotiations commenced in 1986 and lasted through 1994, when the WTO was established. [49]

The "WTO" refers not only to the international facility based in Geneva, but also to about sixty agreements it oversees, several of which explicitly or implicitly advance strong protections for intellectual property rights. [50] The Agreement on Technical Barriers to Trade (TBT) governs potentially trade restrictive labeling regulations, while TRIPS requires that states pass laws providing intellectual ***915** property rights holders with a number of administrative and judicial protections. [51] The Agreement on Sanitary and Phytosanitary Measures (SPS) established the principles by which states may regulate food safety, but its standard-setting body, the Codex Alimentarius Commission (Codex), often passes guidelines and codes of conduct that affect intellectual property rights like trademarks. [52]

2. TRIPS

TRIPS is by far the most controversial of the WTO agreements with respect to tensions between wealthy and lower income states. [53] Unlike the general theory of *reducing* legal and tax barriers to trade that justified GATT, TRIPS was theoretically justified by the need to *increase* the legal protections of intellectual property right holders in order to facilitate expansion of products and processes (and their distinguishing symbols), as well as creative works, into new markets. [54]

TRIPS grants patent, copyright, and trademark holders rights to minimal statutory protections as well as the right to resort to administrative and judicial processes to enforce those rights. [55] Member states may pass protections greater than those detailed in TRIPS, [56] but additional protections must be extended to nationals of other member states. [57] In addition to substantive provisions, TRIPS also outlines a comprehensive framework for civil adjudication of intellectual property rights. [58] Member states must create private causes of action, [59] as well as remedies including injunctions, money damages, and the use of border restrictions. [60] States must also give intellectual ***916** property rights holders access to judicial review of all administrative decisions concerning their intellectual property laws. [61]

Prior to the Uruguay Round, the trade liberalization negotiation process had been driven by the trade priorities of developed states; the negotiation process largely excluded agriculture and the key bargains were achieved between industrialized countries. [62] The Uruguay Round, by contrast, encompassed a wider range of issues, many of which were long-standing priorities of low-and middle-income countries. [63] Their interests in lowering barriers to trade in agricultural goods, clothes, and textiles resulted in a "grand bargain," under which the parties agreed to adopt strong monopoly protections for copyrights, trademarks, and patents. [64]

Developing states negotiated some flexibilities with respect to implementation of TRIPS obligations, including articles 7 and 8, which declared the need for intellectual property law to allow for development, technology transfer, and measures necessary to protect public health and nutrition. [65] Those provisions did not provide a general exemption from TRIPS implementation, but rather conditioned those measures on TRIPS compliance. [66] Article 31 of TRIPS allows for the nonconsensual authorization of patents, but requires that those authorizations be accompanied by appellate access to national courts or "higher administrative authorities." [67]

These protections effectively installed a global regime of individually enforceable intellectual property rights. As Jerome Reichmann observed:

> ***917** [Developed countries] expect developing countries to implement [their] obligations concerning domestic judicial and administrative enforcement of foreigners' intellectual property rights, including detailed provisions governing the discovery of evidence, rights to counsel, injunctions, damages, and temporary restraining orders. These provisions mean business. [68]

States party to the agreement are not obliged to spend more resources on enforcement of intellectual property rights than "law in general," and thus many individual intellectual property rights holders may not see a sufficient payoff to invest resources in pursuing individual civil actions to vindicate property rights. But the economic sectors most closely tied to agriculture and human health--food, tobacco, alcohol, and pharmaceuticals--are precisely those in which intellectual property rights holders are likely to attempt to preserve substantial investments in advertising, research, and development and those that most significantly affect the interests of low- and middle-income states. [69]

3. ACTA and TPP

TRIPS effectively installed a floor for international intellectual property protections, a floor that subsequent bilateral and multilateral trade and investment negotiations have sought to surpass. ACTA [70] represents the codification of principles advanced in a number of initiatives undertaken by developed states to enhance protections for intellectual

property holders beyond what TRIPS achieved. [71] According to the USTR, "[T]he goal [of ACTA] is to set a new, higher benchmark for enforcement that countries can join on a voluntary basis. . . . ACTA will include commitments in three areas: (1) strengthening international cooperation, (2) improving enforcement practices, and (3) providing a strong legal framework for IPR ***918** [(intellectual property right)] enforcement." [72] After eleven rounds of negotiations, the final ACTA text was adopted in May 2011. [73]

ACTA requires parties to the agreement to increase criminal sanctions for intellectual property right infringement and to adopt stronger border measures [74] to target illegal trafficking in infringing goods through customs processes. [75] ACTA requires, under each parties' available laws, "enforcement procedures . . . to permit effective action against any act of infringement of intellectual property rights covered by [ACTA]." [76] Under ACTA, "Each Party shall make available to [intellectual property] right holders civil judicial procedures concerning the enforcement of any intellectual property right . . . ." [77] Among those procedures are injunctions, [78] damages, [79] other remedies, [80] and the collection and preservation of evidence. [81] These civil enforcement provisions are not limited to first-party infringers:

> ***919** Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities [shall] have the authority to issue an order against a party to desist from an infringement and, *inter alia*, an order to that party or, where appropriate, to a third party over whom the relevant judicial authority exercises jurisdiction, to prevent [infringing] goods . . . from entering into the channels of commerce. [82]

ACTA represents a new restructuring of civil enforcement to increase the rights of intellectual property holders, which could have potentially deleterious effects on access to medicines. [83] For example, because ACTA requires that judicial authorities have the power to issue injunctions against third parties, any intermediary provider of generic medicines to developing countries faces potential liability under the ACTA regime. [84] In the context of access to medicines, the concept of "intermediary services" may be quite ominous. Services are obviously provided by Intermediary Service Providers (ISPs), allowing suppliers to market medicines online and in the pharmaceutical context through shipping agents. Perhaps more ominously, many others who helped fund or facilitate purchases of generic drugs as they moved through the stream of international commerce from producer to consumer could face intermediary liability. For example, the Global Fund solicits and funds country-led proposals for funding priority disease prevention, treatment, and care. [85]

ACTA compliant laws may enable foreign rights holders to target local industries through threats or use of litigation. [86] The force of the agreement extends beyond its power to shape domestic law because ACTA will inevitably also form the template for future bilateral agreements between ACTA and non-ACTA states. [87]

TPP mimics many of ACTA's intellectual property provisions, although its conclusion is more distant. [88] Congress voted to give the President fast-track authority to negotiate the agreement, meaning that ***920** when TPP is finalized, Congress must either vote "yes" or "no" and cannot amend it. [89] The text of TPP states that patentability must be permitted for "new uses of a known product, new methods of using a known product, or new processes of a known product," suggesting it would include products that did not improve the known product and that could encompass, in part, evergreening strategies by pharmaceutical firms. [90] The United States and Japan also proposed a five-year data exclusivity period for the marketing approval of a new agricultural chemical product, leading to new insecticides, pesticides, and fungicides

enjoying high prices for at least five years before competitors may use safety and effectiveness data to introduce their own versions of those products. [91]

C. Bilateral and Regional Trade and Investment Treaties

More common than broad, multilateral trade instruments like TRIPS, ACTA, and TPP are bilateral and regional investment and trade agreements, which contain some of the strongest protections for intellectual property. [92] Bilateral investment treaties (BITs), for example, take a number of forms and include provisions authorizing intellectual property rights holders to vindicate claims in national or international courts or in other dispute resolution fora. Generally, BITs are negotiated between developed states and developing states. [93] BITs contain provisions guaranteeing investors from one state protections for their broadly defined "investments." These guarantees may include fair and equitable or nondiscriminatory treatment, [94] free transfer of ***921** profits and currency, and, in many cases, payment of compensation should a host state adopt measures having the effect of direct or indirect expropriation. [95] The origin and number of BITs in existence is well documented, although the reasons for their proliferation are disputed. [96] At the end of the 1980s, records at the U.N. Conference on Trade and Development showed 385 BITs, while a decade later, the number reached 1,857. [97] Current estimates show approximately 3,000 BITs in force. [98]

These treaties often give much stronger protection, with fewer standard exceptions, to intellectual property rights than international intellectual property agreements, TRIPS, or domestic law. For example, the standard Swiss BIT protects as investments "copyrights, industrial property rights (such as patents of inventions, utility models, industrial designs or models, trade or service marks, trade names, indications of source or appellation of origin), know-how and good-will" and requires the counterparty to compensate an investor for "tak[ing], either directly or indirectly, measures of expropriation, nationalization or any other measure having the same nature or the same effect." [99] Under the 2012 U.S. Model BIT, an "'investment' means every asset that an investor owns or controls, directly or indirectly . . . including intellectual property rights" that are accorded similar rights to arbitration. [100] For example, drafters of BITs often vaguely phrase public health exceptions in the preamble, which undermines their use as a defense to an investor claim. [101] BITs often provide investors access to one of the major international arbitral tribunals to vindicate rights under the agreement. [102]

*922 III. INCREASING CONFRONTATIONS BETWEEN STRONG INTELLECTUAL PROPERTY RIGHTS AND DEVELOPING COUNTRY INTERESTS

The strong substantive and enforcement rights that now prevail for intellectual property rights holders have predictably encouraged the aggressive policing of those rights. Indeed, large intellectual property rights-holding constituencies, or coalitions of them, may dedicate resources toward lobbying member governments to bring formal diplomatic action at the WTO or elsewhere and, if unsuccessful there, to bring arbitration or other enforcement actions under bilateral or regional trade and investment treaties. [103]

Complaints from developing countries take two principal forms. First, the aggressive policing of intellectual property rights disproportionately affects developing countries' ability to deal with human rights and public welfare obligations. [104] HIV/AIDS, for example, inflicts its most significant toll in eastern and southern Africa, uniquely implicating the pricing effect of pharmaceutical patents on relevant medications. [105] Similarly, images, brands, and trademarks that promote product consumption, while arguably benign in countries with educated, literate populations

with access to inexpensive consumer information, are more pernicious in countries with high rates of illiteracy. [106] Second, many of the human and natural ***923** resources used by innovators to create commercial, scientific, or other protectable works originate in low- and middle-income countries, yet these works are priced out of reach of the vast majority of consumers in those countries. [107]

These confrontations came to the fore in the wake of TRIPS's entry into force. It marked in fundamental ways the breadth and depth of the new reach of intellectual property protection. In critical product sectors that affect human health and nutrition, efforts in low- or middle-income countries (as well as some notable episodes in wealthier ones) to regulate industries with steep intellectual property investments--like brands, patents, and trademarks-- collided with the new strength of intellectual property protection driven by bilateral, regional, and multilateral international agreements.

A. Patents and Data Exclusivity

Both international trade law and international investment law have played critical roles in expanding intellectual property protections for pharmaceutical firms. Leading to the establishment of TRIPS, many low- and middle-income jurisdictions refused to allow any pharmaceutical patents, arguing that granting them would erect barriers to access to medicines for their often large and poor populations. [108] TRIPS introduced a twenty-year minimum floor for patents, including pharmaceuticals, and required that "undisclosed test or other data" be protected from "unfair commercial use." [109] Subsequent international agreements not only reinforced that floor, but also included protections for other aspects of drug development and approval, including marketing exclusion based on animal and clinical testing data used as part of a regulatory approval. [110] Similar protections were included for seed and other agrochemical products. [111]

***924** 1. Antiretrovirals

By the early 1990s, the population of people living with HIV/AIDS exploded in Sub-Saharan Africa, quickly comprising the large majority of the HIV/AIDS-afflicted population worldwide. [112] At the same time, populations living in Africa tended to have the least access to relatively rapidly developed (and patented) antiretroviral treatments. [113] By 2003, approximately twenty million people had died from AIDS, and another forty million people were infected with HIV. [114] Africa accounted for two-thirds of the people living with HIV/AIDS, despite holding a relatively small percentage of the global population. [115] Sometime between 1994 and 2001, South Africa became home to the world's largest population of people living with HIV/AIDS. [116] While antiretroviral drug treatments had been developed, patented, and approved as early as 1987, they cost approximately $1,000 per month when the true scope and severity of the HIV/AIDS problem in South Africa became clear. [117] The South African government regarded expanding access to patented medications as part of its responsibility under its constitution and announced that pharmaceutical firms' pricing strategies made it unable to do so. [118] South Africa adopted legislation amending its patent act to authorize parallel imports and to more steeply regulate available medicines, notwithstanding existing patent rights. [119]

The Pharmaceutical Manufacturers' Association of South Africa and the major global pharmaceutical firms individually sued the government, alleging that the law violated a number of constitutional provisions, including uncompensated property takings and constitutional commitments to honor obligations under international law generally and TRIPS specifically. [120] Under the pharmaceutical ***925** firms' theory, medicine patents relevant to HIV/AIDS drugs were no different than other pharmaceutical patents. The same intellectual property principles--exclusivity and monopoly rents

in exchange for investments in innovation--would lead to the same socially optimal outcomes for HIV/AIDS drugs as for other medicines. [121]

In 1996, Brazil adopted a "local working" requirement as part of its industrial property law, which enabled the Brazilian government to license patented medicines and technology to other firms for production if the patent was not "worked" in Brazil. [122] Pharmaceutical firms, which had exported patented medicines to Brazil but had not produced them locally, immediately protested the measure and, unlike in the dispute with South Africa, convinced the U.S. government to bring a formal dispute at the WTO for violating TRIPS. [123] Brazil requested consultations under the WTO Dispute Settlement Understanding (DSU), alleging that certain aspects of U.S. patent law, particularly those obtained with federal support, violated TRIPS. [124] The United States and Brazil terminated their dispute in 2001 in the wake of the Doha Declaration that they jointly drafted. [125] In 2007, Brazil granted a compulsory license for Merck's efavirenz after negotiations over price reductions failed. [126] Merck filed a motion for injunctive relief, which Brazilian courts rejected. [127]

Between 2006 and 2007, Thailand also issued compulsory licenses for Merck's efavirenz and Abbott's liponavir/ritonavir, noting that discussions with the firms over prices had lasted over two years. [128] After granting the compulsory licenses, the firms threatened to ***926** withdraw or not register other medicines in Thailand and complained to the USTR, but they ultimately agreed to lower their prices for the medications. [129]

In November 2008, Dutch customs agents seized a shipment of HIV/AIDS medications manufactured in India and destined for Nigeria. [130] GlaxoSmithKline had requested the seizure, claiming that the Indian drug, abacavir, violated its patent rights. [131] In 2008 and 2009, "Doctors Without Borders found at least 19 shipments of generic medicines from India to other countries were impounded while in transit in Europe." [132] The disputes between the parties led to formal action at the WTO both by European countries and by Brazil and India. [133]

2. Cancer, Diabetes, and Heart Disease Medicines

Trade and investment liberalization has promoted the availability of consumer goods that contribute to poor individual public health--like processed foods containing high levels of fat, salt, and sugar--without promoting the access to medicines and other healthcare infrastructure that wealthier countries maintain to address so-called "lifestyle" diseases like cancer, diabetes, and heart disease. [134] Even when these medicines are available in a given market, international agreements, including and influenced by TRIPS, push prices higher. [135] For example, the U.S.-Jordan Free Trade Agreement includes limitations on compulsory licenses and parallel imports. [136] The costliest TRIPS-plus terms are those that impose "data exclusivity" separate from patent protection. [137] Under data exclusivity regimes, a generic manufacturer is not allowed to use clinical and safety trial data used with the initial drug application, essentially requiring the generics applicant to undertake prohibitively expensive clinical trials and ***927** reimposing the cost to the government or end-user that generics theoretically exist to save. [138]

"[T]hese expenditures have required that both public health systems and individuals pay higher prices for many new medicines that are needed to treat [[[diseases] such as [cancer], hypertension, asthma, diabetes, and mental illness." [139] For example, new medicines to treat diabetes and heart disease cost anywhere from two to six times more in Jordan than in Egypt, where there are no agreements imposing additional intellectual property protections for pharmaceuticals. [140] Access to these medicines has generated conflicts with strong intellectual property agreements as have medicines

that prevent or treat infectious diseases that disproportionately affect low- and middle-income countries. Along with compulsory licenses for HIV/AIDS drugs in 2007, Thailand also issued a compulsory license for Plavix, one of the most prescribed heart disease drugs in industrialized countries. [141] It also announced compulsory licenses for four patented cancer medications. The Thai government noted that its decision was based on the relative burden each disease imposed on the Thai people; as many or more people in Thailand die from cancer as AIDS. [142] The Thai licenses prompted immediate retaliation from Abbott, which withdrew seven medications from the Thai market, and initiated a more concerted effort by the United States and from European countries to pressure the Thai government. [143]

3. Vaccines

The development of some vaccines, notably those that protect against influenza, depends on biological resources in low- and middle-income countries being made available to researchers, organizations, governments, and pharmaceutical firms in the major industrialized ***928** countries. Vaccines are one of the most important lines of defense against the emergence of pandemics. [144] Not only are vaccines typically patented, but so are components of vaccines that make them more effective. [145] Seasonal and pandemic influenza vaccines are possible in significant part because developing countries share influenza samples with the WHO's Global Influenza Surveillance and Response System, even though their populations have not historically received a proportionate benefit of resulting vaccines or other breakthroughs. [146]

The infrastructure and technology for vaccine development is overwhelmingly located in industrialized, wealthy states. [147] This concentration renders many developing states dependent on wealthier states to manufacture and distribute vaccines in sufficient quantities to address their needs in the case of disease outbreaks. [148] Yet influenza pandemics have typically originated in low- or middle-income states like Cambodia, Indonesia, Mexico, and Vietnam. [149] These states must therefore be willing to share disease samples and biological material relevant to risk assessment, risk management, disease research, and vaccine development. [150] When firms patent shared samples to produce unaffordable vaccines, the willingness to share them is undermined. [151]

***929** In 2006, Indonesia withheld H5N1 avian flu samples from the WHO system, compromising efforts to monitor and produce vaccines in response to an avian flu outbreak that had not only spread worldwide, but also threatened to become easily transmissible from birds to humans and then between humans. [152] Indonesia asserted that its decision was a response to an Australian company's development of a vaccine derived from a virus sample that Indonesia provided to the WHO. [153] The cycle demonstrated the inequities inherent in the global vaccine distribution system: developing countries provided informa-tion and virus samples to the WHO-operated system; pharmaceutical companies in industrialized countries then obtained free access to such samples, exploited them, and patented the resulting products, which the developing countries could not afford. [154] As David Fidler noted, "Without access to Indonesia's influenza strains, global surveillance was jeopardized, as was the refinement of diagnostic reagents and the development of intervention strategies, which depend on the information surveillance provides." [155]

In 2009, the outbreak of H1N1 influenza in Mexico demonstrated not only that the global surveillance system benefited pharmaceutical firms, but also that in the case of a real pandemic, those firms' sponsoring governments could not be relied upon to equitably share vaccines:

> Canada awarded its vaccine contract to a Canadian company because it feared that foreign governments might restrict exports to Canada because of vaccine shortages within their territories. The Australian

> government made it clear to the Australian manufacturer CSL that it must fulfill the government's domestic needs before exporting vaccine to the United States. The United States pledged on September 17, 2009, to donate 10% of its vaccine purchases to WHO, but on October 28, US Secretary of Health and Human Services Kathleen Sebelius stated that the United States would not donate H1N1 vaccine as promised until all at risk Americans had access, because production problems had created shortages in the United States. [156]

***930** Despite clear acknowledgment that the 2009 outbreak originated in Mexico and leveled its most significant toll there, Mexico "had a terrifically difficult time getting access to the pandemic vaccine." [157]

4. Seeds and Agrochemical Products

Just as spreading intellectual property protections stymied efforts by developing states to adopt measures against malnutrition and infectious disease, they also undermined those states' policies toward food self-sustainability and traditional processes for the preservation of biological and plant resources. [158] This confrontation was already well underway when TRIPS was negotiated, and it was essentially codified in article 27.3(b), which allows countries to exclude "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes" from patentable subject matter, [159] but requires protection for plant varieties either through patents or through a *sui generis* system like the International Union for the Protection of New Varieties of Plants (UPOV), leaving "micro-organisms" undefined. [160]

Patented seeds, tailored pesticides, insecticides, and fungicides, at a general level, interrupt or displace traditional forms of agriculture predominant in low- and middle-income countries. [161] Philippe Cullet described the change from traditional forms of agriculture, including seed exchange and crop rotation, to dependence on patented seeds and related products in Africa:

> The introduction of plant variety protection in African countries is a novelty for all but a few states. It constitutes a significant departure from previous practice which generally emphasized the free sharing of knowledge at all levels. The challenge is further compounded by the fact that plant variety protection has until now only been introduced in countries with relatively small but highly industrialized agricultural sectors. [162]

***931** From low- and middle-income countries' perspective, implementing intellectual property protected seeds and agricultural products in relatively undeveloped agricultural markets essentially redistributes wealth from farmers to the small number of global seed and agribusiness firms that dominate the global market. [163] Farmers pay high prices for seeds and products to treat the crops that grow from them, while prices for the resulting commodities are pressured lower by a small number of global food firms. [164] Indeed, as early as 1999--four years after TRIPS became international law--African countries sought to revisit the scope and reach of article 27: [165]

> The African Group seized the opportunity of the provision and prepared a strongly worded communication during the preparations for the WTO ministerial meeting in Seattle [in 1999], which vehemently questioned

> the overall provisions of Article 27.3(b). The Group suggested that the revision of the article should take into account the Convention on Biological Diversity as well as the FAO International Undertaking. Insinuating that a review of 27.3(b) could lead to changes in its substantive nature, the Group highlighted the artificial distinctions that it made "between biological and microbiological organisms and processes." [166]

B. Trademarks

While patents and data exclusivity have generated the widest controversies affecting food security, nutrition, and public health measures, trademarks have caused similar disputes between low- and middle-income countries and firms with steep investments in symbols, logos, and distinguishing marks that could mislead or deceive consumers in those states, many of which suffer high rates of illiteracy. [167] As a result of the conditions prevailing in many low-and middle-income countries, product appearance plays a different, arguably more important, role in consumption, and, therefore, product image and visuals around point of sale are critical for both commercial and regulatory objectives. [168]

***932** 1. Infant Formula

While maternal behavior with respect to breastfeeding varies in industrialized countries, little evidence suggests a significant effect on infant, maternal, or population health. In low- and middle-income countries, however, failure to breastfeed has relevant health effects on infants, mothers, and families. [169] In areas with low levels of education, people often fail to properly mix formula and, even when done correctly, infant formula may introduce contaminants from nearby water sources. [170] Senator Ted Kennedy phrased the problem this way: "Can a product which requires clean water, good sanitation, adequate family income, and a literate parent to follow printed instructions be properly and safely used in areas where water is contaminated, sewage runs in the streets, poverty is severe and illiteracy high?" [171] In one tragic episode, parents in Laos confused a red label Bear Brand coffee creamer (a Nestlé trademark), the logo of which features a mother bear holding her cub in the nursing position, for a breast-milk substitute, notwithstanding written warnings that the product was not intended for infants for any reason. [172] The confusion resulted in cases of both malnutrition and death. [173]

The WHO estimates that 13% of the 10.9 million deaths of children younger than five years could be prevented every year if universal protection, promotion, and support of breastfeeding were achieved. [174] Exclusive breast-feeding for the first six months of life is the number one intervention to save infants' lives. [175] Breastfeeding also plays a role in spacing pregnancies where contraception is unavailable or contraception failures are common. [176]

***933** Over the course of the 1970s and 1980s, breastfeeding rates in low- and middle-income countries declined, which the WHO and governments in those countries attributed to food firms' marketing of infant formula, other milk products, cereals for infants, vegetable mixes, and baby teas and juices. [177] Those firms' marketing practices explicitly asserted or implied nutritional and other health equivalencies with, or superiority to, breastfeeding. [178] Many low- and middle-income countries adopted national measures to control the marketing of breast-milk substitutes, including the use of images and brands to confuse the health-related attributes of breast-milk substitute products. [179]

In 1983, Guatemala adopted Law 66-83, Law on the Protection of Breastfeeding, which restricted the ability of breast milk substitute manufacturers to display images, brands, or trademarks that could lead its substantially illiterate population to believe that breast milk substitutes provided an adequate and effective alternative to breastfeeding during the first six months of infants' lives. [180] The Ministry of Health implemented the law through Governmental Order No. 847-87 in 1987. [181] Gerber--whose products carry one of the most recognizable trademarks worldwide, a healthy smiling baby--applied to introduce a new product line in Guatemala in 1992: [182]

> [Gerber] requested that the products be registered with the Food & Drugs Registration and Control Division [an equivalent of the United States FDA]. The FDRC required that Gerber remove its trademarked infant image, include a notice that "breastmilk is the best for baby" as required under the law and further specify the age of the child for which the products were intended. [183]

Gerber responded by pursuing a three-pronged strategy: Gerber asserted that its products were "complementary" foods under Guatemalan law and therefore not covered by Laws 66-83 and 841-87 and brought a statutory action under U.S. law to eliminate Guatemala's trading preferences for effectively "nationalizing" its trademark, threatening Guatemala's compliance with (still pending) TRIPS ***934** provisions. [184] Gerber argued that article 15 of TRIPS states, "The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark." [185] In addition, article 20 of the proposed agreement provides that "[t]he use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as . . . use in a special form or use in a manner detrimental to its capability to distinguish the goods." [186] The Guatemala Supreme Court of Justice, applying a strained interpretation of "complementary foods," determined that Laws 66-83 and 841-87 applied only to locally prepared foods, not to imported goods. [187] Without explicitly acknowledging the role that the trade-based agreements played in their construction of the law, the case "shows . . . that raising the spectre of the new WTO can be an effective pressure tool against small countries that want to implement strong health regulations that may also have negative impacts on commercial interests." [188]

The Pharmaceutical and Health Care Association of the Philippines successfully delayed and then earned relief from comprehensive breast milk labeling restrictions through similar arguments based in part on the trade-restrictive effect of warnings on formula containers. [189] Even in countries that have more successfully regulated the marketing of breast-milk substitutes, like India, food firms exploit ambiguities in statutory and regulatory language to continue practices that imply the superiority of substitutes over breast milk. [190]

***935** 2. Tobacco

The burden of smoking-related morbidity and mortality has shifted dramatically to low- and middle-income countries. Nearly 80% of the more than one billion smokers worldwide live in low- and middle-income countries, where the burden of tobacco-related illness and death is heaviest. [191] Tobacco consumption is, among other things, an economic and development issue. Tobacco users who die prematurely deprive their families of income, raise the cost of health care, and hinder economic development. [192]

For this reason, low- and middle-income countries led some of the earliest and strongest challenges to marketing efforts by tobacco firms, which relied heavily on investments in brands, images, and trademarks. [193] In 1994, South

Africa introduced "regulations relating to the Labelling, Advertising and Sale of Tobacco Products," which would have required 25% of advertisements and 50% of the front and back panels of cigarette packs to carry eleven different rotating warnings. [194] The then-president and CEO of Philip Morris International (PMI), William H. Webb, wrote a strongly worded letter implicitly threatening foreign investment in South Africa and detailing the violations the law would cause South Africa "under its internal laws and as a party to The Paris Convention for the Protection of International Property Rights [including trademark infringement] assurances to international consumer products companies that their trademark rights will be respected" and protected from outright expropriation. [195] RJR Nabisco focused its lobbying effort "on international trade aspects of the potential trademark infringement the new regulations would create." [196] The final implementing regulations ***936** halved the coverage of cigarette packs and reduced the number of rotating warnings. [197]

Between 2008 and 2010, Uruguay implemented a number of tobacco control measures, including two that addressed the manipulation of packaging and labeling to shape health perceptions of tobacco products. First, Uruguay required that pictorial warnings cover 80% of a cigarette pack's surface. Second, the Ministry of Health limited the sale of cigarettes to only one variety per brand, the so-called single presentation requirement. [198] This part of the law prevents a firm from selling multiple varieties of cigarettes under a single trademark. For example, PMI, whose most important asset is the Marlboro brand, could no longer sell Marlboro "Reds," Marlboro "Greens," and Marlboro "Blues," leaving "Marlboros" as its only authorized variety. [199] PMI first challenged the regulations in Uruguayan courts, seeking an injunction based in part on Uruguay's revised, TRIPS-compliant trademark law. [200] Unsuccessful in Uruguayan courts, PMI initiated, through entities it controlled, arbitration proceedings under Switzerland's BIT with Uruguay. [201] That treaty included not only broad definitions of "investor" and "investment," but also established narrow and toothless exceptions for public health regulation and even required laws passed with assurance ***937** of due process to compensate an investor for an "indirect" expropriation. [202]

Low- and middle-income countries were not the only ones facing international intellectual property challenges. Contesting Australia's 1992 effort to require tobacco manufacturers to sell cigarettes in plain packaging, British American Tobacco argued before the Australian Senate that such a law would violate both the Paris Convention and the Australian constitution. [203] Persuaded by the tobacco industry, the Australian government rejected the proposed regulations. [204] In 1994, PMI and RJR Reynolds undertook a similarly successful campaign in Canada, based in significant part on the intellectual property protection provisions of the North American Free Trade Agreement (NAFTA), and deputized the former USTR to send a letter on their behalf, suggesting that plain packaging of cigarettes would subject Canada to an arbitration proceeding for violating NAFTA's intellectual property chapter. [205]

Low- and middle-income countries have led efforts to regulate the reach of intellectual property protections for tobacco trademarks because the health burdens imposed by the consumption that trademarks promote fall disproportionately on their populations.

IV. INTERNATIONAL INTELLECTUAL PROPERTY SHELTERS

Scholars, as well as low- and middle-income countries, have advanced a number of measures to address the perceived imbalance rendered by the structure of existing agreements, some more practical than others. Kojo Yelpaala has written a searing indictment of the international intellectual property regime and has implicitly called for its ouster: [206]

> It is now widely acknowledged by most observers that TRIPS is a serious threat to human health security. . . . Before TRIPS, over forty ***938** countries offered no patent protection for pharmaceutical inventions. Such sovereign authority of states has been compromised by TRIPS as part of the WTO system of agreements. . . . This exploitation of the inequalities of bargaining power was undertaken at a time when many developing countries were ill equipped or unprepared to appreciate all the implications of TRIPS. [207]

On August 26, 2004, Argentina and Brazil sponsored a resolution at WIPO, calling for a "development agenda" to guide WIPO's activities, a moratorium on new international agreements that "expand and strengthen monopolies and further restrict access to knowledge," and the formation of a "Treaty on Access to Knowledge and Technology," which would essentially roll back expansive protections for copyrights, patents, and trademarks. [208]

While the more sweeping proposals have not gained much ground, movements across certain kinds of treaties, or mechanisms within certain treaties, reflect a consensus that international intellectual property law has overreached. Some states are revising or withdrawing from agreements with strong intellectual property protections. [209] Other solutions involve explicit limitations on the adjudicatory rights private parties enjoy under bilateral or multilateral instruments. [210]

Low- and middle-income states have also started to press for specific intellectual property regimes in discrete issue areas like seeds and agricultural technology, vaccines, and other medicines and product ***939** sectors like alcohol, infant formula, and tobacco. Within these issue areas, what this Article terms "international intellectual property shelters" are changing or eliminating strong intellectual property rights guaranteed under other international agreements. From access to medicines to the protection of biological resources (including seeds) to the protection of populations from tobacco advertising and other health threats, a set of international agreements has emerged that either have jettisoned intellectual property rights in specific issue areas or have reengineered the way intellectual property protection incentives function. [211]

A. The Doha Declaration on the TRIPS Agreement and Public Health

The 2001 Doha Declaration remains the most famous international intellectual property shelter. Formed to safeguard low- and middle-income countries' access to medicines for HIV/AIDS, tuberculosis, malaria, and "other epidemics," the Doha Declaration established that treatments for diseases affecting low- and middle-income countries deserve different treatment than the typical intellectual property-based exclusivity and price structure characteristic of the regime favored by TRIPS. [212] Instead, afflicted countries should, and ultimately do, enjoy greater flexibility to control monopoly prices that strong intellectual property rights cause. On the other hand, the Doha Declaration also implied that coercive mechanisms to acquire or discount non-HIV, -tuberculosis, or -malaria treatments would not be as favorably received. [213]

Between 1994, when TRIPS was finalized, and June 2001, when the TRIPS Council opened a special session to discuss access to medicines under the agreement, the disproportionate effect of HIV/AIDS on developing countries became clear, as did the contrast between global pharmaceutical firms' perspective on what TRIPS ***940** accomplished and what developing countries feared. [214] Many developing states considered the high prices that accompanied patented medicines and their production processes to frustrate their constitutional and international human rights obligations to provide

affordable health care to their citizens. The Doha Declaration essentially created a TRIPS-free zone for government policies aimed at assuring access to medicines for the three designated diseases and perhaps other "epidemics."

Paragraph 5 of the 2001 Doha Declaration provided:

> (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. [215]

Concurrently with the Doha Declaration, Japan introduced the idea of a global fund for the treatment of HIV/AIDS, tuberculosis, and malaria, which materialized in 2003. [216] The Doha Declaration by its terms carved out HIV/AIDS, tuberculosis, and malaria as diseases for which the rewards for medical research and innovation could be expected to function differently than the patent-and-reward system pharmaceutical firms envisioned when challenging Brazil's and South Africa's measures to reduce antiretroviral drug prices. [217] Together with the Global Fund and other international financing mechanisms, the Doha Declaration redistributed default monopoly rents that pharmaceutical patents previously directed to the major pharmaceutical firms to generics firms in middle-income countries that (1) possessed the manufacturing capacity to exploit the new market the Doha ***941** Declaration opened and (2) enjoyed sufficient influence internationally to exploit that capacity without alienating states that advocated for strong pharmaceutical patent rights. [218] Indeed, since 1995, Brazil, India, South Africa, and Thailand have led in using parallel imports, TRIPS flexibilities, and compulsory licenses to expand access to medicines for their own populations, as well as to obtain collective gains for developing countries. [219]

It was and is conceivable that the Doha Declaration may have energized more aggressive compulsory licensing activity outside of the diseases explicitly named in the agreement. In 2007, Thailand granted a compulsory license for the heart disease medication marketed as Plavix. [220] Thailand also issued compulsory licenses for four cancer drugs, the disease burden of which is heavier than HIV/AIDS. [221] From the Thai government's point of view, cancer "is no less serious than HIV/AIDS." [222] In 2012, India granted a compulsory license for kidney and liver cancer medications, but refused to grant several recent compulsory license applications. [223] Indeed, since 1995, "[m]ore than half the compulsory licensing episodes occurred in upper-middle-income countries (including Brazil and Thailand)." [224] Retaliatory measures by both governments and manufacturers have pushed innovators and governments to the bargaining table. Compulsory license activity has abated since the Doha Declaration, with the enhanced bargaining power of developing states leading to more

effective direct negotiations between manufacturers and governments. [225] No substantial wave of compulsory licensing activity has occurred. [226]

***942** So what did the Doha Declaration do? [227] It is difficult to answer the question without also analyzing the mushrooming of global medicines funding institutions that accompanied the Doha Declaration. The Doha Declaration certainly pushed patent-holding firms to the negotiating table with middle-income countries that possessed the manufacturing capacity to make compulsory licensing threats credible and gave those countries particular negotiating leverage in the discrete disease categories named by the Doha Declaration--HIV/AIDS, tuberculosis, and malaria. At the same time, however, the establishment of the Global Fund, Gavi (which has strongly suggested that it would finance an HIV vaccine should one be developed), [228] and the increase in health aid both to individual ministries of health and indirectly through the Global Fund, such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), [229] the rents pharmaceutical patent holders would have obtained under the old system have been partially replaced by the incentive to win opportunities through international funding mechanisms. Thus the major pharmaceutical firms have developed extensive relationships with ministries of health in less developed countries, and pharmaceutical pricing is more often undertaken collaboratively.

B. The Proposed Medical Research and Innovation Treaty

The controversies leading up to the Doha Declaration prompted a broader movement supporting an international agreement to restructure intellectual property incentives in the access-to-medicines context. To be sure, part of the larger problem was that monopoly rents supported by patents, trademarks, trade dress, and data ***943** exclusivity rendered medicines like antiretrovirals, cancer treatments, and diabetes-control drugs out of reach for low- and middle-income countries. But a similar, if not larger, part of the problem was that drug innovation and development did not occur for Type II and Type III diseases that primarily afflicted low- and middle-income countries. [230] The diseases for which the market would likely be paltry attracted little research and development funding. [231]

In 2005, Kenya submitted a resolution to the WHO's Executive Board requesting the creation of a group of member states to discuss a new global framework on medical research and development. [232] In January 2006, Brazil joined the resolution as a cosponsor, [233] requesting such a framework. [234] In May 2006, the World Health Assembly (WHA) adopted Resolution 59.24--Public Health, Innovation, Essential Health Research and Intellectual Property Rights--which called for an intergovernmental working group to study the relationship between intellectual property rights, other forms of financing, and the global problem of diseases unlikely to attract purely private-sector attention. [235] In 2012, the WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) published *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, which called for a binding framework treaty to address innovation and research capacity in developing ***944** countries and to design a system to promote development of treatments through incentive and other financing mechanisms. [236]

The CEWG's report extensively covered the obstacles strong intellectual property protections pose for addressing medical research and development needs in developing countries. [237] The report squarely addressed existing intellectual property instruments, viewing a medical research and innovation "convention not as a replacement for the existing intellectual property rights system but as a supplementary instrument where the current system does not function" and emphasizing

the need for research and development breakthroughs to be shared with other researchers, free from the constraints intellectual property protections normally impose. [238]

For example, for Type II and Type III diseases that dispropor-tionately affect populations in developing countries, the CEWG recommends a binding international treaty that provides for open innovation models in which (1) research and development costs are covered by public or philanthropic sources and research results are made available in the public domain; (2) funders or research organizations impose licensing conditions that permit nonexclusive licensing or prescribe a low target price for a product; (3) advance market commitments or prize funds that involve separate payments compensate for the costs of research and development, prescribing either predetermined product prices at a low level or permitting competitive manufacture of developed products; and (4) more comprehensive schemes envisage wholesale replacement of the intellectual property innovation and exclusivity system. [239]

Deep divides still stand in the way of the formation of the agreement. Brazil, Kenya, and the many low- and middle-income countries that stand to gain from a treaty allocating more resources to research into neglected diseases and diluting intellectual property rights in general support the proposed treaty. European countries, especially those with large pharmaceutical firms, have ***945** overwhelmingly opposed it. [240] In 2013, the United States proposed a series of demonstration projects that might bridge the current, deep divides between member states over the treaty's terms. [241]

C. The WHO's Pandemic Influenza Preparedness Framework

Indeed, the kind of regime envisioned by the medical research and innovation treaty exists to some degree in the limited context of pandemic influenza. Indonesia's refusal to share avian flu samples on the basis of inequities in the global vaccine development and distribution system, along with the catastrophic potential of the 2009 H1N1 episode, encouraged pharmaceutical firms, the WHO, wealthy countries, and poor ones to address the balance between intellectual property rights in shared biological resources and the products resulting from that sharing system. [242]

In 2007, the WHA commenced a series of negotiations over "sharing of influenza viruses and access to vaccines and other benefits," in light of Indonesia's refusal to share critical virus samples. [243] Disagreements over the extent to which vaccine manufacturers' intellectual property rights should be diluted or eliminated erected critical barriers to early negotiations. [244] The failure of H5N1 to become a pandemic influenza episode reduced the significance of Indonesia's refusal to participate in sample sharing. In 2009, however, the emergence of H1N1 in Mexico and the United States [245] rendered the negotiations more urgent.

As a result of these episodes, developing countries, led by Indonesia, pressed both the WHO and developed states to conclude an agreement on equitable access to pandemic vaccines. In 2011, the WHO Open-Ended Working Group of Member States on Pandemic Influenza Preparedness (PIP) finalized an agreement in which developing countries agreed to routinely share mutating flu virus ***946** samples in exchange for a series of measures taken under the auspices of the newly formed Pandemic Influenza Preparedness Framework. [246]

Under the Framework, major pharmaceutical manufacturers retain their ability to access samples shared through the WHO's Global Influenza Surveillance and Response System, but now firms using the system must contribute towards half the cost of its maintenance (approximately $30 million annually) and must promise to share either intellectual property, products developed through use of the system, or other medical countermeasures critical to pandemic

response.[247] For manufacturers of vaccines and/or antivirals, the recipient shall commit to at least two of the following options:

> A1. Donate at least 10% of real time pandemic vaccine production to WHO.
>
> A2. Reserve at least 10% of real time pandemic vaccine production at affordable prices to WHO.
>
> A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO.
>
> A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices.
>
> A5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.
>
> A6. Grant royalty-free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.[248]

Because a subsequent pandemic influenza episode has yet to emerge to test the system, it is too early to know whether the Framework will achieve its objectives. Key terms like "pandemic," "real-time," and ***947** "affordable" are left undefined, at least in the core agreements, and those terms caused substantial problems during the WHO's negotiation, procurement, and deployment of pandemic vaccine in 2010.[249] Nevertheless, the Framework can be plausibly understood to be the result of low- and middle-income countries changing the international intellectual property regime both ex ante (through access to materials for research and development) and ex post (through sharing of intellectual property-generated products).

D. The Convention on Biological Diversity

While often tied to its sibling treaty, the U.N. Framework Convention on Climate Change (and less so the U.N. Convention To Combat Desertification) as an outcome of the 1992 Earth Summit in Rio de Janeiro, the Convention on Biological Diversity not only endeavored to create worldwide agreement on the conservation of biodiversity and sustainable practices for plant genetic resources, but it also established a general regime for "access and benefit sharing" of a kind arguably at odds with its other two objectives; however, it proved fruitful for finding legal bases to shape or

curtail intellectual property rights. [250] Indeed, in its dispute with the WHO and wealthy countries in 2007, Indonesia cited the Convention on Biological Diversity as one of its legal justifications for withholding H5N1 virus samples. [251] After the Convention went into force, it has served as a primary focal point for low- and middle-income countries to revisit and advocate for amendment of TRIPS, as well as to develop subsequent treaties that target intellectual property protections in a range of ways. [252] The Convention's goal of "access and benefit sharing" includes both plant genetic resources as well as the relevant technology associated with their development, [253] and it specifically ties terms of access to intellectual property rights, providing that "patents and other ***948** intellectual property rights may have an influence on the implementation of [the Convention, and thus parties] shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives." [254]

The Convention asks parties to take legislative, administrative, or policy measures "as appropriate" to implement the Convention's goals. [255] This has led to broad diversity in implementation strategies between nations, [256] with many seeking to protect their resources, rather than facilitating access and benefit sharing, and others essentially using the Convention to obtain favorable terms for commercial exploitation, arguably in tension with the Convention's conservation objective. [257] This latter phenomenon puts signatory governments and farmers at odds in several different ways because while the biological resources belong to the sovereign government, farmers' rights are not addressed in the text of the Convention. [258]

The Convention relies on bilateral contracts between parties and the linear movement of plant genetic resources from the field to commercial development, using negotiation with the sovereign state to facilitate access and sharing of benefits. [259] This method treats plant genetic resources as if they are private goods and opens possibilities for arrangements that modify intellectual property rights. [260] In addition, the Convention encourages parties to disclose the country of origin of plant genetic resources in their applications for intellectual property rights. [261]

***949** 1. International Treaty on Plant Genetic Resources for Food and Agriculture (International Seed Treaty)

The International Treaty on Plant Genetic Resources for Food and Agriculture (International Seed Treaty) in many ways embodies a disagreement between North American, European, and Japanese governments and low- and middle-income countries that begins with article 27 of TRIPS. Low- and middle-income countries always maintained that article 27 was inconsistent with the Convention on Biological Diversity. The Treaty was adopted on November 3, 2001, after a seven-year negotiation process [262] and entered into force in 2004. [263] The International Seed Treaty is a protocol adopted pursuant to the International Undertaking on Plant Genetic Resources (Undertaking) and the Convention on Biological Diversity, intended to update the Undertaking and make it legally binding. [264]

The Undertaking, adopted in 1983, [265] is an international instru-ment aimed at encouraging international cooperation in the conservation and sustainable use of plant genetic resources. [266] It originally advocated the view that plant genetic resources are a common heritage of humanity and should be freely available without restriction. [267] This view was later qualified by several resolutions which amended the Undertaking. Resolution 4/89 recognized plant breeders' and farmers' rights, subjecting free availability to property rights. [268] However, these "rights" are merely recognition without force--no individual rights are enumerated in the resolution. [269] Resolution 3/91 went a step further by recognizing the sovereign rights of nations over plant genetic resources within their territories. [270]

In an effort to update the goals of the Undertaking and the Convention on Biological Diversity and to make them legally binding, negotiations on the International Seed Treaty began in 1994.[271] These ***950** included matters of extensive debate, such as access and benefit sharing, farmers' rights, and financial resources, but an informal meeting of negotiators in Switzerland overcame these differences in 1999.[272] The parties agreed on which crops to include on the Treaty's Annex 1 list and compromised on intellectual property rights in April 2001.[273] The International Seed Treaty does not include plant genetic resources not on the Annex 1 list, which remain under the legal framework of the Convention on Biological Diversity, as do resources accessed for nonagricultural purposes.[274] In June 2001, parties agreed to a multilateral system for access and benefit sharing.[275]

Two major provisions of the International Seed Treaty affect intellectual property rights. First, the Treaty recognizes farmers' rights.[276] Second, the Treaty creates a multilateral system for access and benefit sharing.[277] Article 9 of the Treaty enumerates three elements of farmers' rights: (1) the protection of relevant traditional knowledge, (2) the right of farmers to participate equitably in sharing benefits arising from the utilization of plant genetic resources, and (3) the right of farmers to participate in decision making at national levels.[278] Article 9 also states, "Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate."[279] Article 15 of the Treaty recognizes that states hold sovereign authority over their own natural resources.[280] As with the Undertaking, these provisions essentially create intellectual property rights held by farmers and nations over plant genetic resources that previously did not exist.[281]

The Treaty's multilateral system for access and benefit sharing also affects intellectual property rights. The multilateral system is ***951** primarily composed of two parts: the Annex 1 list of plant genetic resources[282] and the Material Transfer Agreement (Agreement).[283] Annex 1 lists thirty-five specific crops to which the Treaty applies.[284] Access to these resources is limited to those under the management and control of the public domain or in the gene banks of international institutions.[285] However, the Treaty does require parties to take measures to encourage natural and legal persons in their jurisdictions to grant access to privately held plant genetic resources.[286]

The Agreement provides for facilitated access to plant genetic resources, benefit sharing mechanisms of the Treaty, and any associated intellectual property rights.[287] Facilitated access is subject to both intellectual property rights and plant breeders' rights, and access to material under development remains under the discretion of the developer.[288] In exchange for facilitated access, recipients are prohibited from seeking intellectual property rights on plant genetic resources in the form received from the multilateral system, including parts and components of such resources.[289]

Facilitated access itself is a benefit under the International Seed Treaty, but the Treaty and the Agreement also provide for the sharing of monetary benefits,[290] improved plant genetic resources,[291] and technology and information.[292] Annex 2 of the Agreement triggers monetary benefits when a recipient commercializes a product from the plant genetic resources received and when that product is not available without restriction to others for further research and breeding purposes.[293] This provision effectively discourages the use of patents, other intellectual property rights, or other contractual or technological methods that achieve the same effect.[294]

After the expiration of any intellectual property rights, recipients are encouraged to place a sample of their products into a collection ***952** that is part of the multilateral system.[295] In addition, they are also required to share all nonconfidential

information about the improved plant genetic resources that result from the recipient's research and development processes. [296] Recipients who commercialize a product are also encouraged to make monetary contributions, although they are not presently required to do so. [297] These measures are intended to establish and strengthen conservation and scientific research in developing countries. [298]

In response to the Treaty, some nations have proposed or adopted liberal legislation to protect the rights of farmers. [299] African Model Legislation suggests that countries recognize and protect farmers' varieties and breeds that do not meet the criteria of distinction, uniformity, and stability [300] traditionally required for intellectual property protections, such as plant breeders' rights. [301] It also provides farmers with the right to participate in decision making on matters related to conservation and sustainable use of plant genetic resources; the right to save, use, exchange, and sell farm-saved seeds both individually and collectively; and the right to use protected breeders' varieties to develop new farmers' varieties. [302] Under this model legislation, farmers still may not sell farm-saved seeds of a breeders' protected variety at commercial sales. [303]

India has likewise developed liberal legislation protecting farmers' rights. [304] India adopted the Protection of Plant Varieties and Farmers' Rights Act in 2001. [305] This Act permits farmers to protect and recognize farmers' varieties, which are defined broadly as "ha[ving] been traditionally cultivated and evolved by the farmers in their fields; or [are] wild relative[[[s] or land race[s] of a variety about which farmers possess common knowledge." [306] As with the African Model Legislation, farmers are permitted to save, use, sow, resow, exchange, ***953** share, or sell farm produce and protected varieties of seeds as long as the seeds are not sold commercially. [307] These provisions allow countries like India and Zambia to protect farmers commercially by granting them intellectual property rights, promote conservation and stewardship by the farming community, and limit the power of intellectual property rights held by third parties. [308]

Other countries have failed to implement legislation that adequately protects farmers [309] or implements the Treaty. [310] This is largely due to the fact that the International Seed Treaty does not actually require parties to legally recognize farmers' rights to freely exchange and use harvested seeds. [311] The fact that several of the world's largest holders of plant genetic resources, such as the United States, China, Russia, and Japan, have not ratified the Treaty limits the overall effectiveness of the Treaty. [312] As a result, they have not passed legislation to effectively share and receive benefits through the multilateral system. [313]

Aside from the failure of key states to ratify and others to implement legislation, the International Seed Treaty's text itself includes weaknesses that open its access and benefit provisions to vulnerabilities against international intellectual property agreements. [314] The provision prohibiting recipients from taking out intellectual property rights on plant genetic resources in the form received from the multilateral system fails to define what "in the form they are received" means or what degree of alteration or change is required to allow recipients to seek intellectual property rights. [315] Some countries interpret the language to mean that the Treaty will not impinge on national intellectual property rights, laws, or policies. [316] The EU understands that parts and components that are subject to innovation can be protected by intellectual property rights. [317] Developing ***954** countries, on the other hand, interpret this provision as per se disfavoring applications for intellectual property rights that could restrict access to plant genetic resources. [318]

The International Seed Treaty is new, and therefore no consensus exists as to whether it has been effective in achieving its objectives or limiting the assertion of intellectual property rights over plant genetic resources. [319] However, at least in the arena of advancing farmers' rights, it does seem to have been somewhat successful in countries, such as India and Zambia, that have enacted legislation granting farmers broad rights to use, save, exchange, and sell seeds. [320]

2. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) aimed to encompass the broader universe of drugs, medical therapies, agrochemical products, vaccines, and other products derived from genetic resources not regulated by other international instruments (although its relationship with the WHO Pandemic Influenza Preparedness Framework is disputed). [321] In short, the Nagoya Protocol, another agreement formed subsequent to the Convention on Biological Diversity, regulates access to genetic resources in party states and establishes mechanisms for "fair and equitable sharing of benefits arising from the utilisation of genetic resources." [322]

Countries adopting legislation or regulation pursuant to the Nagoya Protocol ensure that access to any genetic resources within the territory of that country is conditioned on prior informed consent not only of the country of origin, but also on access being "[i]n accordance with domestic law" and on the consent of indigenous and local communities. [323] Moreover, once access to genetic resources results in a commercially viable product:

> ***955** [B]enefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. [324]

The precise nature of benefit sharing, both monetary and nonmonetary, is left to the states themselves to negotiate with those who generate commercialized products.

South Africa's Regulations on Bio-Prospecting, Access and Benefit-Sharing, for example, require firms to obtain a permit from the government if they intend to use South African genetic resources for research or patenting. [325] These permits can only be obtained with a benefit-sharing agreement with relevant stakeholders. [326] South Africa integrates this system with its patent application system as well, such that patent applications must identify indigenous biological resources or forms of traditional knowledge leading to the patentable subject matter. [327] As of 2016, only nineteen countries and the EU submitted legislative, administrative, or policy measures in furtherance of the Nagoya Protocol, but its potential to shape the scope of intellectual property rights, especially patents, is clear. [328]

Indeed, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (Bonn Guidelines), a set of voluntary guidelines issued subsequent to the Convention on Biological Diversity, but before the Nagoya Protocol, recommended the following provisions for contracts between sovereign states and commercial entities:

> (a) Regulating the use of resources in order to take into account ethical concerns of the particular Parties and stakeholders, in particular indigenous and local communities concerned;
>
> (b) Making provision to ensure the continued customary use of genetic resources and related knowledge;
>
> ***956** (c) Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent;
>
> (d) The possibility of joint ownership of intellectual property rights according to the degree of contribution. [329]

The Bonn Guidelines similarly suggest that parties might condition transfer of material on a promise not to seek intellectual property rights at all. [330]

Countries like India and Peru have used the Convention on Biological Diversity and the Nagoya Protocol to aggressively police both access based on informed consent and benefit sharing with parties and indigenous communities and to share its policies internationally. The Indian government has created a Traditional Knowledge Digital Library, which stores Indian traditional medicine treatments and is accessible to patent offices around the world. [331] Peru's National Commission Against Biopiracy has used its database records to oppose the grant of patents containing Peruvian traditional knowledge. [332]

Like the International Seed Treaty, the world's major economic powers (with substantial intellectual property right-holding constituencies) are not parties to the Nagoya Protocol. Early experience suggests that the Nagoya Protocol shares weaknesses and lacunae with the International Seed Treaty. For example, in 2010, a subsidiary of Nestlé filed international patent applications for therapeutic derivatives of rooibos and honeybush, plants indigenous to South Africa, and obtained them without the required permits under the legislation implementing the Nagoya Protocol in South Africa. [333]

Nestlé claimed that it had neither sourced the plants in South Africa nor researched them there (claiming instead that they were provided by South African suppliers of other goods), it had not yet ***957** commercialized any products (although that was not relevant under South African law), and it would comply with the law when, or if, it became necessary. [334] The case highlights the ambiguities in the Nagoya Protocol, not only over what constitutes covered material and conduct regulated by the Protocol, but also what relationship third parties may play in evading the Protocol's reach.

E. The International Code of Marketing of Breast-Milk Substitutes

The International Code of Marketing of Breast-Milk Substitutes (International Code), like the WHO's Pandemic Influenza Preparedness Framework, is, legally speaking, only a recommendation adopted under article 23 of the WHO

Constitution, rather than a more formally binding treaty or international agreement. [335] However, the recommendation is an evidence-based standard adopted by international food safety bodies and is independently influential as a human rights norm. [336]

The International Code seeks to prevent companies from advertising; implement strict labeling requirements, including a proscription on infant images or other pictures that idealize breast-milk substitutes; limit influence on health care workers; and prohibit distribution of free samples of breast-milk substitutes. [337] Eighty-four states have enacted legislation enacting all or some aspects of the International Code, while another fourteen have legislation pending. [338]

While the text of the International Code does not address trademarks as explicitly as the WHO's FCTC, the Code prohibits "pictures of infants [and] other pictures or text which may idealize the use of infant formula." [339] Major infant formula markets like Brazil, China, and India have banned the use of images on infant formula ***958** containers, while a growing number of developing and wealthy countries are considering stronger measures to limit the appearance or use of trademarks in connection with infant formula. [340]

Codex, the joint international organization run by the U.N. Food and Agriculture Organization and the WHO, has adopted the relevant trademark restricting provisions of the International Code into its Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, which allows states to require that infant formula "label[s] . . . have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula." [341] As the standard-setting body for the WTO's Agreement on Sanitary and Phytosanitary Measures, [342] the adoption of the standard means that parties to the WTO may ban images of infants and women without concern that it may inappropriately burden trade. While the Codex standard operates separately from measures sanctioned by TRIPS, the standard effectively creates a safe harbor for banning trademarks on infant formula products. Indeed, despite industry protest against states and other political entities, like Hong Kong, that have restricted or banned trademarks on infant formula, no state has brought a challenge to those restrictions at the WTO, nor has any of the major food firms used the strong enforcement mechanisms available through BITs to protest prohibitions on infant images. [343]

F. The Framework Convention on Tobacco Control

Because tobacco consumption has declined in Europe and North America as a result of strong public health measures and taxation policies, [344] the global tobacco industry has focused on low- and middle-income countries as key targets to sustain demand for ***959** conventional cigarettes. [345] In developing and wealthy markets, tobacco trademarks play a critical role in the broader advertising, promotion, and marketing efforts that persuade young men and women to commit to, and identify with, a specific brand of cigarette.

Trademarks must not only appeal to this target demographic, but must also frame and shape the act of consuming cigarettes as less dangerous. Framing includes minimizing or obfuscating mandatory health warnings, using descriptors like "mild," "light," and "ultra-light," and shaping cigarette containers--for example, to mimic famous perfume packaging--to appeal to target populations. [346] Cigarette manufacturers also use package colors and images to shape health perceptions. Two aspects of trademarks magnify these public health problems in low- and middle-income countries. First, low- and middle-income countries have larger populations who lack the functional literacy necessary for written warnings that communicate product risks. Therefore, regulation of pictures and images is necessary for effective regulation. Second, trademarks in the cigarette context are explicitly tied to the rise of middle-income classes in wealthier

countries. Indeed, the global morbidity and mortality burden associated with tobacco consumption now falls heaviest on low- and middle-income countries. [347]

Motivated by the public health burden imposed by tobacco products and the success of the industry in thwarting regulation, frequently on intellectual property grounds, Canada, Finland, Mexico, and Tanzania sponsored the idea for an international agreement [348] to regulate tobacco at the WHA in 1995. [349] In 1998, member states established a WHO FCTC Working Group to draft core treaty elements and an intergovernmental negotiating body to develop the text of the treaty. [350] Member states adopted the treaty in 2003, and it ***960** entered into force on February 27, 2005. [351] One hundred and seventy-seven parties have ratified or acceded to the FCTC as of September 2013. [352]

While the FCTC covers a wide range of supply and demand factors affecting tobacco consumption, core aspects of its nonprice provisions are aimed at eliminating or limiting trademark protection in the tobacco context. Article 11 (packaging and labeling) and article 13 (promotion) include provisions curtailing trademark rights. [353] The governing body of the treaty has included additional guidelines that further erode international protections for tobacco trademarks. [354]

Section 1(a) of article 11 regulating packaging and labeling provides that each party will take measures to ensure that

> tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about the product's characteristics, health effects, hazards or emissions, including any term, descriptor, trademark or figurative or other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than others. [355]

In addition, section 1(b) of article 11 requires that packages carry health warnings describing the harmful effects of tobacco use that must cover no less than 30% of the principal display area, but recommends coverage of 50% or more of the display area. [356]

The guidelines for the implementation of article 11 state that countries should consider regulatory measures that effectively eliminate the use or effectiveness of trademarks. [357] Paragraph 7 recommends large, graphic health warnings because they are more noticeable, better communicate health risks, provoke a greater emotional response, and increase motivation to quit or decrease tobacco consumption. [358] Paragraph 8 provides that health warnings should be located on both the front and back of the package, at the top ***961** of all principal display areas. [359] Paragraph 9 suggests that health warnings should also be located on all sides of the package, inserts, and onserts. [360] Referencing article 11.1(b)(v), paragraph 12 of the guidelines encourages parties to require health warnings that cover more than 50% of the principal display areas, [361] and paragraph 16 recommends that these warnings should be pictorial because they will "disrupt the impact of brand imagery" and the overall attractiveness of the package. [362]

Paragraph 43 affects words and phrases that would normally be subject to trademark protection. It provides a nonexhaustive list of terms, as mentioned in article 11.1(a), which "creates the false impression that a particular tobacco product is less harmful than others." [363] Paragraphs 8, 10, and 54 address obstruction of warnings by other elements of

packaging or trade dress. [364] Paragraph 8 states that health warnings should not be damaged or concealed by the normal opening of the package. [365] Paragraph 10 reiterates the need for warnings to remain unobstructed by other elements of the packaging, such as labelling markings, inserts, and onserts. [366] Finally, paragraph 54 indicates that warnings should not be obscured, obliterated, or undermined by extraneous adhesive labels, stickers, cases, covers, sleeves, and wrappings. [367] Paragraph 46 addresses plain packaging:

> Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others. [368]

Article 13 on advertising, promotion, and sponsorship also affects trademark rights. [369] Sections 2 and 3 of article 13 require a party, subject to its constitutional principles, either to ban or to apply ***962** restrictions on tobacco advertising, promotion, and sponsorship. [370] Section 4 sets minimum standards, subject to the national constitution, for restrictions on tobacco advertising. [371] It requires a prohibition on all forms of advertising, promotion, and sponsorship that promote tobacco by means that are false, misleading, deceptive, or likely to create an erroneous impression about its characteristics, health effects, hazards, or emissions; [372] that health warnings accompany all tobacco advertising; [373] a ban or restrictions on tobacco advertising, promotion, or sponsorship on radio, television, print media, and other media as appropriate; [374] and a prohibition or restriction on tobacco sponsorship of international events, activities, or participants. [375]

Several countries, including Uruguay, [376] Thailand, [377] and India, [378] have implemented or introduced legislation to implement plain packaging or similar restrictions on tobacco products. Uruguay became the first country to introduce substantial (80%) trademark restrictions and pictorial warnings in 2009. [379] Uruguay's primary tobacco packaging provisions require that packs be covered by graphic warnings, with images such as rotting teeth and premature babies, to discourage smoking. [380] In addition, a firm may not sell different brand variants, which means tobacco firms may not use variants on words like "light" to shape health perceptions of its products. [381]

***963** Following Uruguay, Australia introduced plain packaging in December 2013. [382] Under Australia's legislation, packs must be a standard, dark brown color [383] and comply with the following structural aspects: they must have no decorative ridges, embossing, bulges, or irregularities in shape or texture; [384] the edges must be ridged, straight, and not beveled or otherwise shaped or embellished in any way; [385] packs may not make a noise or produce a scent that could be construed as advertising or promotion; [386] they may not include features intended to change after sale, such as heat-activated inks or inks that are visible only in certain light; [387] and they may not include inserts or onserts. [388] Packs may only state the brand and variant name in a font, size, and color that is uniform across all brands [389] and may not display any trademarks or other identifying marks. [390] In addition, packs are required to display large health warnings with graphics and explanatory messages over at least 75% of the front surface of tobacco packaging and 75-90% of the

back surface. [391] The paper casings of cigarettes are also regulated; they must either be white or white with an imitation cork tip. [392]

The FCTC has so far proved effective at creating a safe regulatory space for the modification or elimination of tobacco trademarks. Plain packaging has survived in Australia due in part to its adoption pursuant to the FCTC. [393] While there is as yet no arbitration decision based on expropriation of tobacco trademarks, the FCTC has provided an important legal basis for Australia and Uruguay to claim that no award is appropriate in light of a binding multilateral ***964** agreement that modifies trademark protections otherwise available in their BITs. [394]

There are weaknesses, although ostensibly fewer of them, with the FCTC as well. Much of the language in the FCTC, and nearly all that used in the guidelines, is precatory, and there have been wide variations in implementation. [395] A subsequent protocol to the FCTC on illicit trade in tobacco products allowed countries to effectively use TRIPS as an alternative to other protocol measures. [396] Separately, tobacco firms have become involved in drafting international trade agreements to strengthen intellectual property protections in light of trends in FCTC implementation. PMI, for example, has lobbied the USTR to include strong investment protections for tobacco trademarks in the proposed TPP. [397]

V. THE DESIGN AND OBJECTIVE OF INTERNATIONAL INTELLECTUAL PROPERTY SHELTERS

Taken together, the aforementioned international agreements regulate intellectual property by creating conditions for access to patentable subject matter, eliminating or substantially modifying trademarks at their core level (i.e., by source identification), and redistributing the benefits of intellectual property that either draw from the resources of low- and middle-income countries or dispropor-tionately affect their welfare, or both. Heretofore, these agreements have been understood to represent advances of one sort or another in their respective contexts: environmental law, indigenous peoples' law, public health law, or the law of biological diversity. More are coming. In 2010, Thailand introduced large graphic warning labels for alcohol containers some years after public health advocates argued that the WHO should develop a Framework Convention on Alcohol Control ***965** modeled on the FCTC. [398] Argentina and Brazil have called for a reorientation of WIPO, which may include a so-called "access to knowledge" treaty. [399]

There are at least two key implications for understanding biodiversity and public health treaties as part of a wider trend of resistance to expansive intellectual property protections asserted through bilateral and multilateral investment and trade treaties. First, forming parallel agreements that curtail or modify intellectual property rights may be just as or more effective than leveraging flexibilities under current investment and trade instruments or using hard-nosed negotiation over intellectual property protections in new treaties. Current scholars tend to emphasize the use of intellectual property framing as part of wider mobilization of social movements contesting the expansion of intellectual property rights through international agreements. [400] In her thoughtful study of "the new politics of intellectual property," for example, Amy Kapczynski notes widespread protests against TRIPS in India, the failure of the Clinton Administration to effect a range of digital copyright treaties, and the efforts to reorient WIPO toward a "development agenda" are part of the success that counter-intellectual-property mobilization forces have enjoyed by framing many development and human rights issues as fundamentally about "intellectual property." [401] But of the international agreements that have experienced the most success in curtailing intellectual property rights (with the possible exception of the Doha Declaration), the 1981 International Code and the FCTC effectively used individual and public health threats as subtle means by which to circumvent strong trademark protections in specific contexts.

Second, understanding the growing network of intellectual property that explicitly curtails intellectual property rights in areas like agriculture and public health as a discrete corpus of international economic law opens new possibilities for understanding the ***966** circumstances under which international intellectual property shelters form, as well as under what conditions they may achieve their objectives. There are at least two of these factors worth exploring further: the nature of the global market in which shelters form and the process by which firms within that market are allowed to participate in the establishment and processes of the shelters. The purpose of this discussion is simply to provide an overview of the value of understanding the agreements discussed in Part IV as a cohesive whole, not to provide an exhaustive evaluation of the factors affecting international intellectual property shelters' targets and designs, which are elaborated elsewhere.

A. Global Concentration of Knowledge-Intensive Industries

The emergence of international intellectual property shelters coincides almost precisely with the global concentration of the industries that have most aggressively asserted their intellectual property rights. For example, the 1981 International Code is effectively a Nestle-specific agreement, which, even in 1981, controlled 50% of the global infant formula market. [402] When Canada, Finland, Tanzania, and Mexico introduced the idea of a global tobacco control treaty at the WHO, four corporations controlled 75% of the global tobacco market and already demonstrated a strong ability to shape health perceptions of their products through the use of their trademarks. [403] Of the forty-two members of the Pharmaceutical Research Manufacturers Association that existed in 1988, only eleven remained as of 2012. [404]

Similar consolidation occurred in the proprietary seed and agrochemical markets, in which four firms control 56% of the global market. [405] Indeed, until recently, the division between pharmaceutical and agrochemical corporations was not so clear. The Swiss pharmaceutical giant Novartis formed after a merger between Ciba-Geigy and Sandoz and consolidated massive pharmaceutical and ***967** agrochemical units. [406] In 2000, Novartis spun off its agrochemical unit into Syngenta, the world's third largest seed and agrochemical company, which draws more than half its sales from emerging markets. [407] Syngenta is now in merger negotiations with Monsanto, which holds the world's largest share of the global commercial seed market. [408] Bayer, which controls more of the global market of seeds and agrochemicals than any other firm except Monsanto, maintains a substantial share of the global pharmaceutical market, although much less than Johnson & Johnson, GlaxoSmithKline, and Pfizer. [409] Crosslicensing between these firms in specific product sectors means even tighter concentration than market share alone suggests. [410]

The corresponding capacity of those firms to control and/or influence forms of knowledge, or otherwise use their market positions to influence population health outcomes (e.g., relating to tobacco), prompted the development of treaties to constrain their behavior. Indeed, it was the formation of the large network of international investment and trade treaties that had allowed global consolidation to occur in the medicines, seeds, and tobacco contexts.

That international intellectual property shelters are in fact efforts at supranational regulation of global firms is supported by the perceptions of the firms themselves. When momentum picked up for the establishment of an international agreement regulating the use of infant images and other visuals to promote breast-milk substitutes, Nestlé established a central office under the control of its chief operating officer to coordinate the responses of each global market. [411] The global tobacco industry put the conceptual notion of supranational regulation at the core of its fierce resistance to the FCTC. In one of its many communications regarding the treaty, British American Tobacco argued that supranational regulation was warranted "'only if and insofar as the objectives of the proposed action cannot be sufficiently achieved' by individual countries," a line echoed in submissions by ***968** Brown & Williamson to the U.S. Department of Health

and Human Services.[412] Because tobacco control measures could be adopted at the national level, the argument went, there was no need for an international instrument.[413] PMI endeavored to discredit the WHO as a tobacco regulatory body and sought to weaken the treaty through its influence on the U.S. delegation.[414]

The global pharmaceutical industry similarly tended to discuss broad access-to-medicines agreements and frameworks in terms of their regulatory nature. Reacting to the ways in which the Doha Declaration altered the global landscape of pharmaceutical patents, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the global pharmaceutical trade group, argued that compulsory licenses "are certainly not a solution to access problems" and that "frequent use of them could discourage the introduction of new medicines . . . and . . . undermine[s] the system that underpins the ability of the private sector to undertake essential R&D [[[(research and development)]."[415] The negotiations over the establishment of the WHO Pandemic Influenza Preparedness Framework were viewed, at least by the IFPMA, as fundamentally about what level of supranational regulation would be imposed for them to participate in the Global Influenza Surveillance and Response network for virus samples with pandemic potential.[416]

B. The Design of International Intellectual Property Shelters

If international intellectual property shelters are effectively low- and middle-income country-led efforts to regulate knowledge- ***969** intensive firms at the international level, then it is also plausible that those regulatory regimes may be captured, restrained, or effectively structured to secure important public interests like health protection and food security. It is far too early to assess the relative strength of the shelters identified above in facilitating their stated objectives like protecting individuals from the health perceptions trademarks shape, ensuring that patents and data exclusivity do not erect insuperable barriers to access to medicines, or preserving traditional forms of agriculture and seed exchange. However, it is possible to identify different aspects of how international intellectual property shelters are constructed and at least preliminary reasons to believe that some regulatory designs may better promote welfare-enhancing objectives than others.

Within the shelters identified above, some entirely barred participation by regulated firms, while others included them as integral parts of the negotiation process. The WHO allowed participation by "representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the U.N. system, of intergovernmental organizations with which WHO has established effective relations, and of nongovernmental organizations in official relations with WHO," effectively cutting global tobacco firms out of the official treaty drafting process (although they could and did participate as part of national delegations).[417] The FCTC codified this norm in article 5.3, which required parties to protect their health policies from tobacco industry interests, made even stronger in guidelines issued by the Conference of the Parties, which declared a "fundamental and irreconcilable conflict between the tobacco industry's interests and public health" and set forth recommendations that, at their strongest, quashed tobacco company participation in the policy-making process altogether.[418]

The International Code, by contrast, involved regulated firms from its first draft. Not only were infant formula company representatives from nine countries consulted by WHO drafters, but also by the global trade group, the International Council of Infant Food Industries.[419] Similarly, the WHO's Pandemic Influenza Preparedness Framework could not have materialized, at least in its present form, without the participation of the major global pharmaceutical firms because they not only promise to share benefits of participation in the ***970** Global Influenza Surveillance and Response System, but they also fund its operation.[420]

Between full participation and prohibition of formal participation exist a number of possibilities, including participation as part of national delegations, the forms of influence firms may exercise through each channel, and what role, if any, direct financial support for negotiations or shelter mechanisms may play. Each of these factors may influence the extent to which a given international intellectual property shelter effectively reorients intellectual property rights from private wealth accumulation to redistribution or furtherance of global population health and nutrition outcomes.

International intellectual property shelters similarly may void an entire class or category of intellectual property, alter the ways in which intellectual property protection affects prices, or condition access to promising sources of intellectual property on redistribution of benefits thereby derived. The FCTC, for example, explicitly calls for states to adopt measures that ensure that "trademark[s do not] directly or indirectly create[] [a] false impression that a particular tobacco product is less harmful than other tobacco products." [421] It implicitly regulates trademarks by recommending large, graphic warnings as part of tobacco product labeling. [422] The International Code similarly urges prohibitions on "pictures of infants, [and] other pictures or text which may idealize the use of infant formula." [423]

The WHO's expert report calling for an international treaty to address the development of drugs and products that focus on the needs of low- and middle-income countries urges the delinking of innovation costs and product prices to condition coverage of research costs on open knowledge research and development and open innovation models in which research costs are covered by public or philanthropic sources and research results are made available in the public domain, licensing conditions imposed by funders or research organizations permit nonexclusive licensing or prescribe a low target price for a product, and prize funds involve separate payments to compensate for the costs of research and development and prescribe either predetermined product prices at a low level or permit competitive ***971** manufacture of developed products; "more comprehensive schemes . . . envisage wholesale replacement of the intellectual property system by government-funded payments for R&D." [424]

The WHO Pandemic Influenza Preparedness Framework conditions access to biological materials collected through the Global Influenza Surveillance and Response System (GISRS) on promises to provide pandemic vaccines, share intellectual property, or share doses of antiviral medicines, as well as requiring pharmaceutical, medical device, and diagnostic firms to pay for half of the GISRS system. [425]

Whatever the context, international intellectual property shelters are at least in part a result of globalization at its core. The emergence of a small number of global firms that dominate knowledge-intensive markets was made possible through the expanding network of trade and investment treaties. The dependence of those firms on legal protections for intangible assets has encouraged them to persistently press for stronger intellectual property laws even in contexts in which substantial public interests may require more flexibility. In those contexts, international intellectual property shelters mediate the creation, flow, and concentration of global wealth between wealthy and low- or middle-income countries. Each of these aspects of the development of international intellectual property shelters demands treatment far more extensive than what is allowed here. This Article has endeavored only to argue that these phenomena should be understood as a cohesive body of international economic law, studied as part of the response to growing international intellectual property protections and evaluated for their purposes and designs.

VI. CONCLUSION

Confrontations between expanding intellectual property rights and the development interests of low- and middle-income states are now poised to increase as international agreements addressing both proliferate. [426] This Article argues that agreements to preserve access to medicines, protect population health, and ensure food security should be seen not

only as responses to the overreach of international intellectual property agreements, but also as forms of supranational regulation over highly concentrated global industries that benefit most ***972** from the privatization of knowledge creation. That assertion necessarily entails study of the structure of global businesses working in these areas, as well as the governments with which those businesses are affiliated or look to for support and promotion. As forms of regulation, international intellectual property shelters' designs will ultimately determine how well they achieve their objectives, whether those are protections of global public welfare or merely efforts to redistribute wealth from rich to poor or vice versa, and in which contexts additional shelters are likely to emerge. This Article has endeavored to take the first of these steps by identifying a heretofore unrecognized phenomenon at work in international economic law.

Footnotes

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79 *Id.* ch. 2, § 2, art. 9, ¶ 2. Each party must provide its "judicial authorities [the power] to order the infringer ... to compensate for the injury the [intellectual property] right holder has suffered as a result of the infringement." *Id.*

80 *Id.* ch. 2, § 2, art. 10, ¶¶ 1-2. The "other remedies" provision can be summed up as relating to the counterfeit goods, and all materials used in the production of such goods can be destroyed at the intellectual property right holder's request. Additionally, ACTA authorizes the party to carry out the disposal or destruction of the goods at the infringer's expense. *Seeid.*

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144 Eileen M. Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1146 (2009).

145 *Id.* at 1158 ("For example, the use of nonviral chemicals that augment the immunogenicity of a vaccine--known as adjuvants--is critical. Such compounds allow a vaccine to include less actual antigen or virus, and thus allow for dose-sparing clinical approaches that maximize the utility of the available viral components. These compounds can be patented in isolation and can also appear in patents that claim a vaccine as a specific combination of antigen and adjuvant.").

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150 *Id.*

151 Kane, *supra* note 144, at 1153-55 ("In an effort to document the patent landscape of the field, the WHO has undertaken a project to map where patents have been sought on any of the relevant H5N1 viral materials. This research demonstrates that a small cluster of patent applications have been filed on various sequences and proteins of H5N1 and several patents have been issued, but the report further notes that patent landscaping must continue as the field matures. The sequence of the H5N1 and novel H1N1 influenza viruses have been determined. The WHO provided notice that genetic sequences from one novel H1N1 virus isolate were available on the GISAID database within several days of the first reports of the outbreak.... Three separate groups of international researchers filed U.S. patent applications on the DNA sequences of the virus.").

152 Fidler, *supra* note 12, at 88.

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175 *See* Barennes et al., *supra* note 172, at 4.

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178 *Id.* at 4 n.2; *see* World Health Assembly Res. WHA31.47 (May 24, 1978), http://www.who.int/nutrition/topics/WHA31.47_nut_en.pdf.

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186 *Id.* art. 20; Letter from Mario Permuth to Gustavo Hérnandez Polanco, Minister of Pub. Health, Republic of Guat. (Feb. 16, 1994) (on file with author) ("The Gerber Executive explained that they will fight with all their strength for the application and enforcement of their industrial property rights in Guatemala and that, at this moment, the major damages affecting them derive from the fact that they have not been able to sell the [infant image-labeled] product in Guatemala.").

187 *See* Fienieg, *supra* note 170, at 4.

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As of 31 December 2009, Article 3 of Ordinance 514 has resulted in an approximately 15 per cent decrease in Abal's sales. The hardest hit brand has been "Marlboro," of which the discontinued "Marlboro Gold," "Marlboro Blue" and "Marlboro Green (Fresh Mint)" varieties represented 40.5 per cent of total sales in 2008.... It should be noted that Philip Morris affiliates worldwide have invested significant amounts of time and money in developing a revision of the three sub-brands of the

Marlboro family. As a result of Ordinance 514, Philip Morris has been prevented from introducing these innovations in Uruguay and accordingly has been deprived of the use of its intellectual property.
Id.

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212 *See* TRIPS, *supra* note 5.

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